As submitted confidentially with the Securities and Exchange Commission on January 27, 2020. This draft registration statement has not been publicly filed with the Securities and Exchange Commission and all information herein remains strictly confidential.

Registration No. 333-

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

FORM F-1
REGISTRATION STATEMENT
UNDER
THE SECURITIES ACT OF 1933

BioNTech SE

(Exact Name of Registrant as Specified in Its Charter)

Not Applicable
(Translation of Registrant's name into English)

Federal Republic of Germany	**2836**	**NOT APPLICABLE**
(State or Other Jurisdiction of Incorporation or Organization)	**(Primary Standard Industrial Classification Code Number)**	**(I.R.S. Employer Identification Number)**

Prof. Ugur Sahin, M.D.
An der Goldgrube 12
D-55131 Mainz
Germany
Tel: +49 6131-9084-0
(Address, Including Zip Code, and Telephone Number, Including Area Code, of Registrant's Principal Executive Offices)

BioNTech USA Holding, LLC
228 E 45th Street, Suite 9e
New York, NY 10017
+1 (347) 694-5321
(Name, Address, Including Zip Code, and Telephone Number, Including Area Code, of Agent For Service)

Copies to:

Paul Claydon **Eric W. Blanchard** **Matthew T. Gehl** **Covington & Burling LLP** **265 Strand** **London WC2R 1BH** **United Kingdom** **+44 20 7067 2000**	**Jochen Dieselhorst** **Peter Versteegen** **Freshfields Bruckhaus Deringer LLP** **Hohe Bleichen 7** **20354 Hamburg** **Germany** **+49 40 36 90 60**	**Stephan Hutter** **Skadden, Arps, Slate, Meagher & Flom LLP** **TaunusTurm** **Taunustor 1** **60310 Frankfurt am Main** **Germany** **+49 69 74 22 00**	**Deanna Kirkpatrick** **Yasin Keshvargar** **Davis Polk & Wardwell LLP** **450 Lexington Avenue** **New York,** **New York 10017** **+1 (212) 450-4000**

Approximate date of commencement of proposed sale to the public: As soon as practicable after the effective date of this Registration Statement.

If any of the securities being registered on this form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, check the following box. ☐

If this form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

If this form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

If this form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933.

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 7(a)(2)(B) of the Securities Act. ☐

† The term "new or revised financial accounting standard" refers to any update issued by the Financial Accounting Standards Board to its Accounting Standards Codification after April 5, 2012.

CALCULATION OF REGISTRATION FEE

Title of Each Class of Securities To Be Registered(1)	Amount to be Registered(2)	Proposed Maximum Offering Price Per Share(3)	Proposed Maximum Aggregate Offering Price(3)	Amount Of Registration Fee
Ordinary shares, no par value per share		$	$	$

(1) All ordinary shares will be represented by American Depositary Shares, or ADSs, with each ADS representing one ordinary share. ADSs issuable upon deposit of the ordinary shares registered hereby are registered pursuant to a separate Registration Statement on Form F-6 (File No. 333-233898).

(2) Includes additional ordinary shares represented by ADSs that may be sold upon exercise of an option to purchase additional ordinary shares to be granted to the underwriters.

(3) Estimated solely for the purpose of calculating the amount of the registration fee pursuant to Rule 457(a) of the Securities Act of 1933, as amended.

The Registrant hereby amends this Registration Statement on such date or dates as may be necessary to delay its effective date until the Registrant shall file a further amendment which specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933, as amended, or until the Registration Statement shall become effective on such date as the Commission, acting pursuant to such Section 8(a), may determine.

Table of Contents

The information contained in this preliminary prospectus is not complete and may be changed. We may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective.

PRELIMINARY PROSPECTUS SUBJECT TO COMPLETION, DATED , 2020

American Depositary Shares

BIONTECH

Representing Ordinary Shares

We are offering American Depositary Shares, or the ADSs, with each ADS representing one ordinary share. The public offering price is $ per ADS. ADSs representing our ordinary shares are listed on the Nasdaq Global Select Market under the symbol "BNTX." On , 2020, the last reported sale price of the ADSs on the Nasdaq Global Select Market was $ per ADS.

Investing in the ADSs involves a high degree of risk. See "Risk Factors" beginning on page 17 of this prospectus.

We are an "emerging growth company" and a "foreign private issuer" as defined under the U.S. federal securities laws and, as such, are eligible for reduced public company disclosure requirements. See "Prospectus Summary—Implications of Being an Emerging Growth Company and a Foreign Private Issuer" for additional information.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

	PER ADS	TOTAL
Public offering price	$	$
Underwriting discounts and commissions(1)	$	$
Proceeds to us before expenses	$	$

(1) We have agreed to reimburse the underwriters for certain expenses incurred in this offering. See "Underwriting" for details.

We have granted the underwriters an option for a period of 30 days from the date of this prospectus to purchase an additional ADSs. If the underwriters exercise the option in full, the total underwriting discounts and commissions payable by us will be $, and the total proceeds to us, before expenses, will be $.

Delivery of the ADSs is expected to be made on or about , 2020.

J.P. Morgan **BofA Securities**

Prospectus dated , 2020

TABLE OF CONTENTS

ABOUT THIS PROSPECTUS

Unless otherwise indicated or the context otherwise requires, all references in this prospectus to the terms "BioNTech," the "Company," "we," "us" and "our" refer to BioNTech SE and our wholly owned subsidiaries.

PRESENTATION OF FINANCIAL INFORMATION

This prospectus includes our audited consolidated financial statements as of and for the years ended December 31, 2018 and 2017, which have been prepared in accordance with International Financial Reporting Standards, or IFRS, as issued by the International Accounting Standards Board, or IASB, which differ in certain significant respects from U.S. generally accepted accounting principles, or U.S. GAAP.

Our financial information is presented in Euros. For the convenience of the reader, we have translated some of our financial information into U.S. dollars. Unless otherwise indicated, these translations were made at the rate of €1.00 to $, the noon buying rate of the Federal Reserve Bank of New York on , 2020. Such U.S. dollar amounts are not necessarily indicative of the amounts of U.S. dollars that could actually have been purchased upon exchange of Euros at the dates indicated. All references in this prospectus to "$" mean U.S. dollars and all references to "€" mean Euros.

We have made rounding adjustments to some of the figures contained in this prospectus. Accordingly, numerical figures shown as totals in some tables may not be exact arithmetic aggregations of the figures that preceded them.

TRADEMARKS, SERVICE MARKS AND TRADE NAMES

The BioNTech SE logo, FixVac®, RiboMab®, RiboCytokine®, MammaTyper® and other trademarks or service marks of BioNTech appearing in this prospectus are the property of the Company. Solely for convenience, some of the trademarks, service marks, logos and trade names referred to in this prospectus are presented without the ® and ™ symbols, but such references are not intended to indicate, in any way, that we will not assert, to the fullest extent under applicable law, our rights or the rights of the applicable licensors to these trademarks, service marks and trade names. This prospectus contains additional trademarks, service marks and trade names of others. All trademarks, service marks and trade names appearing in this prospectus are, to our knowledge, the property of their respective owners. We do not intend our use or display of other companies' trademarks, service marks, copyrights or trade names to imply a relationship with, or endorsement or sponsorship of us by, any other companies.

MARKET AND INDUSTRY DATA

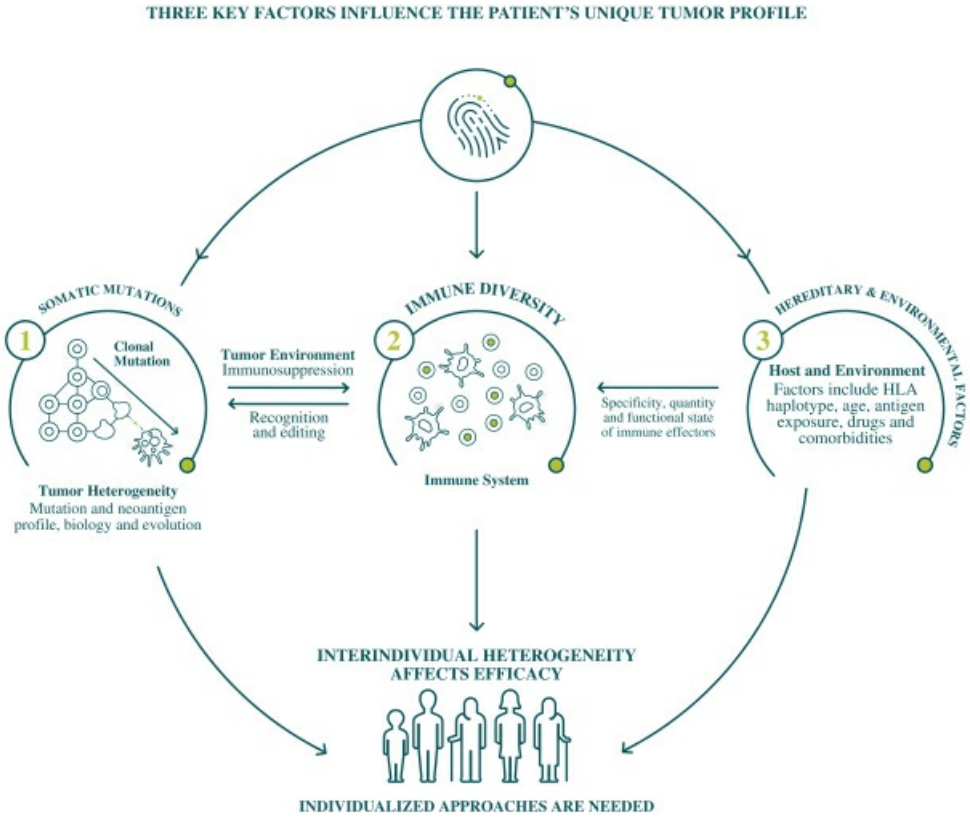
This prospectus contains industry, market and competitive position data that are based on industry publications and studies conducted by third parties as well as our own internal estimates and research. These industry publications and third-party studies generally state that the information they contain has been obtained from sources believed to be reliable, although they do not guarantee the accuracy or completeness of such information. While we believe that each of these publications and third-party studies is reliable, we have not independently verified the market and industry data obtained from these third-party sources. Forecasts and other forward-looking information obtained from these sources are subject to the same qualifications and uncertainties as the other forward-looking statements contained in this prospectus. These forecasts and forward-looking information are subject to uncertainty and risk due to a variety of factors, including those described in "Risk Factors." These and other factors could cause results to differ materially from those expressed in our forecasts or estimates or those of independent third parties. While we believe our internal research is reliable and the definitions of our market and industry are appropriate, neither such research nor these definitions have been verified by any independent source.

PROSPECTUS SUMMARY

Overview

BioNTech was founded in 2008 on the understanding that every cancer patient's tumor is unique and that in order to effectively address this challenge, we must create individualized treatments for each patient. To realize this vision, we combine decades of groundbreaking research in immunology, cutting-edge therapeutic platforms and a suite of patient profiling and bioinformatic tools to develop individualized immunotherapies for cancer as well as other diseases. We leverage powerful new therapeutic mechanisms and exploit a diverse array of biological targets to harness the power of each patient's immune system to address the unique molecular signature of each patient's underlying disease. We believe we are uniquely positioned to develop and commercialize the next generation of immunotherapies with the potential to significantly improve clinical outcomes for patients and usher in a new era of individualized medicine.

The interconnected dimensions of cancer heterogeneity on which we focus are illustrated below. The interaction between cancer and the immune system is shaped by various host, tumor and environmental factors. The complex interplay of these sources of interpatient heterogeneity both affects the course of disease and determines the most appropriate choice of treatment.



Leveraging our expertise in these factors, we and our collaborators have advanced a development pipeline of over 20 product candidates, of which 10 have entered into 11 ongoing clinical trials. While we believe our approach is broadly applicable across a number of therapeutic areas, our most advanced programs are focused on oncology, where we have treated over 400 patients across 17 tumor types to date. In our Phase 1 trials, we have observed single-agent antigen-specific immune responses in over 90% of advanced melanoma patients treated with BNT111, our wholly owned lead off-the-shelf immunotherapy product candidate from our FixVac platform. In addition, we have observed single-agent antigen-specific immune responses in patients treated with BNT121, the precursor to RO7198457 (BNT122), our lead individualized neoantigen specific immunotherapy product candidate from our iNeST platform, which we are co-developing with Genentech, Inc., or Genentech. For both product candidates, we have also observed durable reduction in tumor volume in both the monotherapy and checkpoint-combination settings.

Our potentially first-in-class product candidates are the result of our pioneering development of numerous immunotherapeutic platforms across four drug classes:

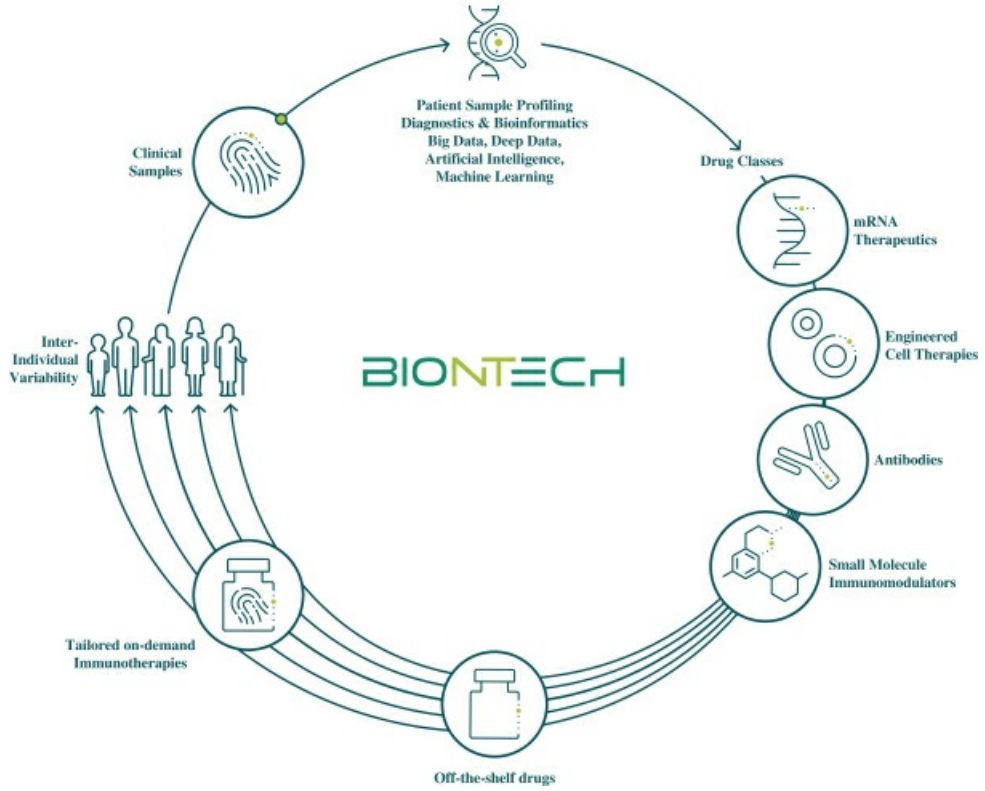
- **mRNA Therapeutics.** We have developed multiple proprietary formats and formulations of messenger ribonucleic acid, or mRNA, to deliver genetic information to cells, where it is used to express proteins for therapeutic effect.
- **Engineered Cell Therapies.** We are developing a range of cell therapies, including CAR-T cells, in which the patient's T cells are modified to target cancer-specific antigens.
- **Antibodies.** We are developing next-generation antibodies, including bispecifics, that are designed to target immune checkpoints and novel cancer antigens.
- **Small Molecule Immunomodulators.** We use small molecules to augment the activity of other drug classes by inducing specific and discrete patterns of immunomodulation.

Our Approach

We are focused on delivering on the promise of individualized immunotherapy for cancer patients. We believe that we can accomplish this by applying the following principles:

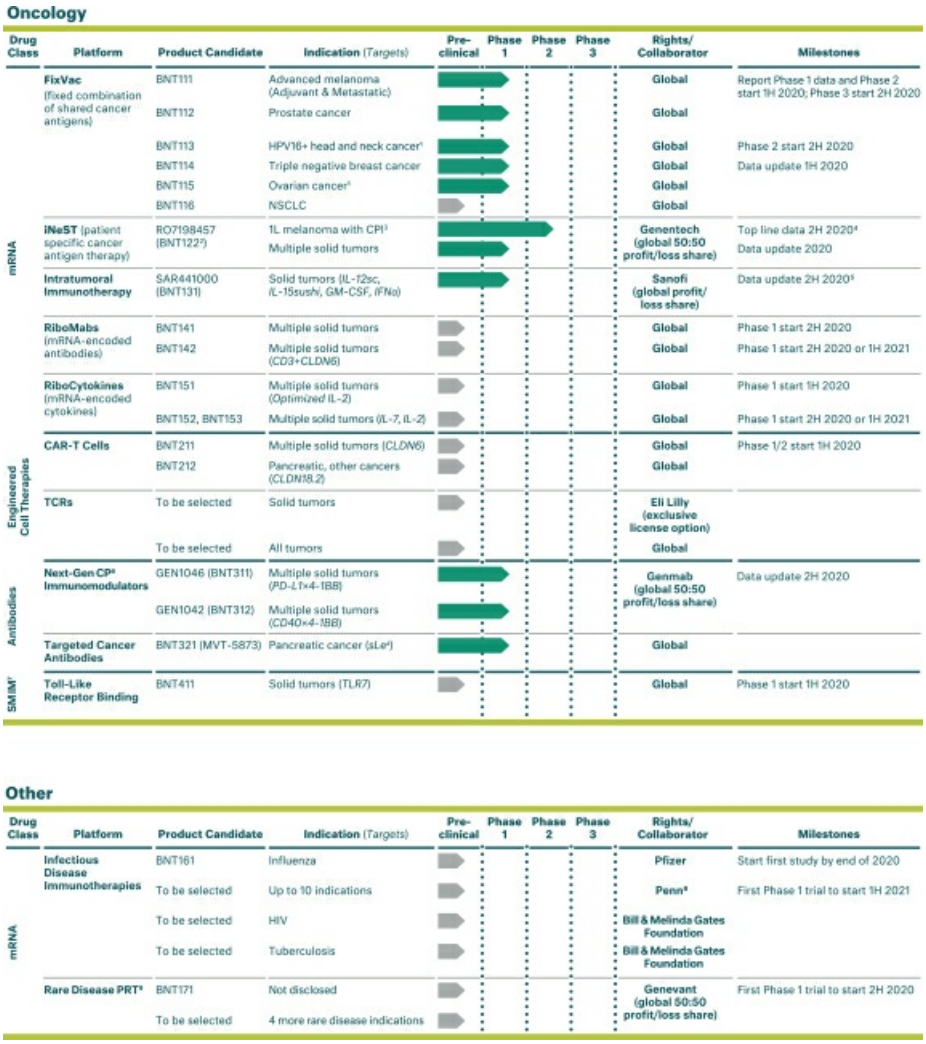
- Harnessing the full potential of the immune system by exploiting multiple drug classes and addressing multiple complementary immune pathways.
- Broadening the universe of patients benefiting from cancer immunotherapy.
- Improving the success rate of treatment by developing and engineering highly potent, precise and target-specific drug candidates either as off-the-shelf or individualized immunotherapies.
- Focusing on curative approaches by addressing interindividual variability and cancer heterogeneity.

Our patient-centric model starts with profiling and diagnostics by utilizing a target identification engine. This engine combines next generation sequencing, genomics, bioinformatics, machine learning and artificial intelligence to (a) identify gene targets of interest, (b) characterize the functional relevance of these targets (i.e., the ability to raise an immune response to or through a target) and (c) demonstrate their drugability. From our founding onwards, we have been developing the novel technologies needed to match the identified targets to the optimal individualized treatment approach. Our patient-centric model is illustrated below.



Our Pipeline

We are advancing a deep and broad portfolio of product candidates derived from our four drug classes.



1 BNT113 and BNT115 are currently being studied in investigator-initiated phase 1 trials
2 BNT122 (iNeST) is investigated in arm 2 (N=15) of the 3 arm TNBC-MERIT trial, with BNT114 as an optional treatment; BNT114 is investigated in arm 1 (N=12) and arm 3 (N=15) of the TNBC-MERIT trial (total patients in study: N=42)
3 Checkpoint Inhibitor
4 Update on the ongoing study including patient enrollment number, efficacy and safety data for an interim update expected in the second half of 2021
5 As the trial is sponsored and conducted by Sanofi, the timing of data updates is not under our control and is subject to change by Sanofi

6 Checkpoint
7 Small Molecule Immunomodulators
8 We are eligible to receive worldwide licenses
9 Protein Replacement Therapy

We believe the breadth of our technology is greater than the sum of its parts as it positions us to combine modes of action in a coordinated, potentially synergistic way to treat cancer in a more efficacious manner than current existing therapies. For example, we have capitalized on synergies in our portfolio by combining our CAR-T cell development with a CARVac primer based on our FixVac platform. We further believe that our patient-centric approach and our broad, potentially synergistic portfolio of drug platforms place us at the forefront of a paradigm shift toward individualized immunotherapies and allow us to potentially address a larger share of cancer patients, as illustrated below:

Cancer segment	Patient Population	Challenge	Our Therapeutic Strategy
High mutational burden/ adjuvant stage cancers	Significant portion of cancer patients	Poor risk-benefit profile of checkpoint inhibitors	• ***mRNA Neoantigen Immunotherapy*** *(iNeST)*
Low mutational burden cancers	>60% of cancers	Poor response to checkpoint inhibitors	• ***Shared Antigens*** *(FixVac, CAR-T cells, Antibodies)*
"Immune desert" cancers	>40% of high-mutational cancers	Poor infiltration and activation of T-cells in tumor microenvironment	• ***mRNA Immunotherapy*** • ***Immunostimulatory Compounds*** *(intratumoral, RiboCytokines)*
Cancers with MHC / B2M loss	20-30% of CPI-experienced advanced cancers	Failure of immune system to recognize tumor cells	• ***Antibodies*** • ***CAR-Ts***
Refractory tumors	Patients with large tumors and multiple resistance mechanisms	Few treatment options	• ***Engineered Cell Therapies*** • ***Combination Therapies***

We have established relationships with seven pharmaceutical collaborators, which comprise Genentech, Sanofi S.A., or Sanofi, Genmab A/S, or Genmab, Genevant Sciences GmbH, or Genevant, Eli Lilly and Company, or Eli Lilly, Bayer AG, or Bayer, and Pfizer Inc., or Pfizer, in order to advance our science and development capabilities and provide non-dilutive capital. In addition, we have established research collaborations with the University of Pennsylvania and Translational Oncology at the University Medical Center of the Johannes Gutenberg University Mainz (Translationale Onkologie an der Universitätsmedizin der Johannes Gutenberg Universität Mainz gemeinnützige GmbH), or TRON. 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.

Our ability to develop, control and optimize the manufacturing of our product candidates is a core strategic pillar and competitive advantage, especially for our individualized mRNA product candidates. We operate three Good Manufacturing Practice, or GMP, certified manufacturing facilities in Germany, where we manufacture mRNA therapeutics and engineered cell therapies for our own pipeline and for external customers. We operate a fourth manufacturing facility in Germany where we manufacture custom peptides to support our extensive immunomonitoring activities, which are critical to our development programs. Additionally, we have collaborated with Siemens AG to develop efficient, semi-automated processes to produce our individualized mRNA immunotherapies on demand.

Our team is comprised of first-movers and entrepreneurs in the fields of immunology and oncology, with experience in pioneering cutting-edge technologies for new, forward-looking therapeutic applications in order to capture new opportunities. Our scientific founders each have over 25 years of experience characterizing the molecular signatures of cancer and discovering potent high-precision immunotherapies. They are translating this combined

knowledge into the development of highly individualized treatments to target patients' specific cancers and other diseases. Our co-founders, Chief Executive Officer Prof. Ugur Sahin, M.D., and Supervisory Board member Prof. Christoph Huber, M.D., along with our Chief Medical Officer Özlem Türeci, M.D., have been published widely in the field of immunology and oncology and are recognized as thought leaders in their disciplines.

We were founded in 2008, and to date we have raised approximately $1.4 billion of capital in private placements of our shares, our initial public offering, or our IPO, and from our collaborators. Our investors currently include the Strüngmann family office, which is our majority shareholder, MIG Fonds, Salvia GmbH, Fidelity Management & Research Company, Redmile Group, Janus Henderson Investors, the Invus Group, LLC and the Bill & Melinda Gates Foundation.

Our Strengths

Our key strengths include:

- We are a next-generation immunotherapy powerhouse pioneering individualized immunotherapies to address the shortcomings of existing treatments for cancer and other indications with significant unmet need.
- We are developing product candidates addressing highly specific immuno-oncology targets, employing a technology-agnostic approach.
- We have tested our lead mRNA product candidates in over 250 patients and have already demonstrated signs of single-agent clinical activity in our two lead programs.
- We have developed a very broad and advanced mRNA therapeutic portfolio for the treatment of cancer.
- We have a deep, diversified pipeline and expect data updates for up to five oncology programs by the end of 2020.
- We have formed multiple collaborations with leading pharmaceutical companies and have retained significant development, commercial and financial rights across our portfolio.
- We have created a vertically integrated business with comprehensive in-house manufacturing capabilities.
- Our scientific DNA, which is the foundation of the BioNTech approach, has attracted a talented team from nearly 50 countries around the world.

Our Strategy

To deliver our vision of truly individualized immunotherapies, we plan to:

- Rapidly advance our potential first-in-class product candidates derived from our FixVac and iNeST platforms toward market approvals in oncology, either on our own or with our collaborators.
- Progress additional product candidates through clinical development, leveraging our multiple drug classes and the synergies between them in order to expand our oncology pipeline.
- Maximize the potential and leverage the broad applicability of our mRNA drug class in additional therapeutic areas beyond cancer, including through selective collaborations.
- Strengthen our position as a leader in the highly automated,on-demand manufacture of individualized therapies with the goal of delivering our therapies globally.
- Establish a commercial organization to bring our portfolio of cancer immunotherapies to patients.
- Expand our current technology suite by continuing to develop existing and new drug classes and platforms, and selectively in-licensing technologies that are complementary to our existing pipeline.
- Maintain our culture of scientific excellence to continue to drive future innovation.

Recent Developments

Acquisition of Neon Therapeutics, Inc.

On January 16, 2020, we announced that we entered into a definitive merger agreement with Neon Therapeutics, Inc. (listed on the Nasdaq Global Select Market under the symbol "NTGN"), or Neon, under which we will acquire Neon in an all-stock transaction valued at approximately $67.0 million, which we refer to as the Merger. At closing, we will issue, and Neon shareholders will receive, 0.063 of our American Depositary Shares, or ADSs, in exchange for each of their shares of Neon. The exchange ratio implies a deal value of $2.18 per share of Neon, based on the $34.55 closing price of our ADSs on January 15, 2020.

Neon is a biotechnology company developing novel neoantigen-based T cell therapies. The transaction will combine two organizations with a common culture of pioneering translational science and a shared vision for the future of cancer immunotherapy. Neon has deep expertise in the development of neoantigen therapies, with both vaccine and T-cell capabilities. Neon's most advanced program is NEO-PTC-01, a personalized neoantigen-targeted T cell therapy candidate consisting of multiple T cell populations targeting the most therapeutically relevant neoantigens from each patient's tumor. Neon is also advancing a precision T cell therapy program targeting shared neoantigens in genetically defined patient populations. The lead program from this approach, NEO-STC-01, is a T cell therapy candidate targeting shared RAS neoantigens. In addition, Neon has assembled libraries of high-quality TCRs against various shared neoantigens across common HLAs. Neon's pipeline is underpinned by its platform technologies including RECON®, its machine-learning bioinformatics platform, and NEO-STIM™, its proprietary process to directly prime, activate and expand neoantigen-targeting T cells ex vivo.

Merger Agreement

On January 15, 2020, we entered into an Agreement and Plan of Merger, or the Merger Agreement, with Neon and Endor Lights, Inc., or Endor Lights, our direct, wholly owned subsidiary, pursuant to which, subject to the satisfaction or waiver of the conditions therein, Endor Lights will merge with and into Neon, with Neon surviving as our wholly owned subsidiary. Subject to the terms of the Merger Agreement, at the effective time of the Merger, or the Effective Time, each share of Neon common stock issued and outstanding immediately prior to the Effective Time shall automatically be cancelled and converted into the right to receive 0.063 of our ADSs.

At the Effective Time, (i) each Neon stock option, whether or not then vested or exercisable, that is outstanding immediately prior to the Effective Time will be cancelled and converted automatically into the right to receive, as soon as reasonably practicable after the Effective Time (but no later than ten business days thereafter), a cash payment in an amount as set forth in the Merger Agreement; (ii) each share of Neon restricted stock that is outstanding as of immediately prior to the Effective Time will vest in full and each such share of Neon restricted stock shall be cancelled and converted automatically into the right to receive our ADSs in the same manner as the other outstanding Neon shares; and (iii) each Neon restricted stock unit that is held by any current Neon employee and is outstanding as of immediately prior to the Effective Time will vest in full and each such restricted stock unit will be cancelled and converted automatically into the right to receive our ADSs in respect of each Neon share underlying the unsettled portion of the restricted stock unit.

The Merger Agreement contains customary representations, warranties and covenants of Neon and us, including, among others, covenants by Neon to conduct its business in the ordinary course of business during the period between execution of the Merger Agreement and consummation of the Merger, or the Closing, and prohibiting Neon from engaging in certain kinds of activities during such period without our consent. The Merger Agreement also contains customary termination provisions for both Neon and us. The Merger is conditioned upon, among other things, the approval of the Merger Agreement by the shareholders of Neon and other customary closing conditions.

The Merger Agreement contains a customary "no-shop" provision. Neon is also subject to a "force the vote" provision, which requires Neon to hold a meeting of its shareholders even if its board of directors changes its recommendation. The Merger Agreement contains certain termination rights for both Neon and us, and provides that, upon termination of the Merger Agreement under specified circumstances, Neon will be required to pay to us a termination fee of approximately $3.2 million.

Voting Agreements

In connection with the execution and delivery of the Merger Agreement, certain Neon shareholders, including directors, executive officers and Third Rock Ventures entered into voting agreements with us, or the Voting Agreements, pursuant to which such directors, executive officers and Third Rock Ventures agreed to vote their respective Neon shares for the approval and adoption of the Merger Agreement, the approval of the Merger and the other transactions contemplated by the Merger Agreement. The shareholders signing Voting Agreements currently own an aggregate of approximately 36% of Neon's outstanding shares.

Risks Associated with Our Business

Our business is subject to a number of risks of which you should be aware before making an investment decision. These risks are discussed more fully in the section of this prospectus titled "Risk Factors" immediately following this prospectus summary. These risks include, but are not limited to, the following:

- We are a clinical-stage biopharmaceutical company with no pharmaceutical products approved for commercial sale.
- We have incurred significant losses since our inception and we anticipate that we will continue to incur significant losses for the foreseeable future.
- We will require substantial additional financing to achieve our goals.
- We will need to develop and expand our company, and we may encounter difficulties in managing this development and expansion, which could disrupt our operations.
- Pharmaceutical product development is inherently uncertain, and there is no guarantee that any of our product candidates will receive marketing approval.
- No mRNA immunotherapy has been approved, and none may ever be approved, in this new potential category of therapeutics. mRNA drug development has substantial clinical development and regulatory risks due to the novel and unprecedented nature of this new category of therapeutics.
- Some of our product candidates are classified as gene therapies by the U.S. Food and Drug Administration and the European Medicines Agency. 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.
- Our product candidates may not work as intended, may cause undesirable side 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.
- We may be unable to obtain regulatory approval for our product candidates under applicable international regulatory requirements.
- We face significant competition in an environment of rapid technological and scientific change, and our failure to effectively compete would prevent us from achieving significant market penetration.
- Even if we receive regulatory approval for our product candidates, the products may not gain market acceptance and we and our collaborators may not be able to effectively commercialize them.

- If we are not successful in developing and commercializing our product candidates, our ability to expand our business and achieve our strategic objectives will be impaired.
- We are dependent on our collaborators for advancing the development and commercialization of certain of our product candidates. These collaborations may not be successful, which could significantly limit the likelihood of receiving the potential economic benefits of such collaborations and adversely affect our ability to develop and commercialize our product candidates.
- We have entered into several arrangements with a related party for the performance of nonclinical research programs, and these arrangements present potential conflicts of interest.
- 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 may encounter difficulties in manufacturing, product release, shelf life, testing, storage, supply chain management or shipping.
- 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 our efforts to obtain, maintain, protect, defend and/or enforce the intellectual property related to our product candidates and technologies are not adequate, we may not be able to compete effectively in our market.
- We may be involved in lawsuits 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.
- Our ability to satisfy the conditions to the Merger, including the ability to obtain the approval of Neon's shareholders, on the proposed terms and timeframe.
- Our ability to realize the anticipated benefits of transactions related to the Merger and other acquisitions, restructuring activities, including in connection with the Merger, or other initiatives in a timely manner or at all.

Corporate Information

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

Our principal executive offices are located at An der Goldgrube 12, D-55131 Mainz, Germany. Our telephone number is +49 6131-9084-0. Our website address is http://www.biontech.de. The information contained on, or that can be accessed through, our website is not incorporated by reference into this prospectus. We have included our website address as an inactive textual reference only.

Implications of Being an Emerging Growth Company and a Foreign Private Issuer

Emerging Growth Company

As a company with less than $1.07 billion in revenue during our last fiscal year, we are an "emerging growth company" as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. As such, we

may take advantage of certain exemptions from various reporting requirements that are applicable to publicly traded entities that are not emerging growth companies. These exemptions include:

- the ability to include only two years of audited financial statements and only two years of related Management's Discussion and Analysis of Financial Condition and Results of Operations disclosure;
- an exemption from the auditor attestation requirement in the assessment of our internal control over financial reporting pursuant to the Sarbanes-Oxley Act of 2002, as amended;
- to the extent that we no longer qualify as a foreign private issuer, (i) reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements and (ii) exemptions from the requirement to hold a non-binding advisory vote on executive compensation, including golden parachute compensation; and
- an exemption from compliance with the requirement that the Public Company Accounting Oversight Board has adopted regarding a supplement to the auditor's report providing additional information about the audit and the financial statements.

As a result, the information contained in this prospectus may be different from the information you receive from other public companies in which you hold shares.

Section 107 of the JOBS Act also provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards applicable to public companies. This provision allows an emerging growth company to delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. This transition period is only applicable under U.S. GAAP. As a result, we will adopt new or revised accounting standards on the relevant dates on which adoption of such standards is required or permitted by the IASB.

We may take advantage of these provisions for up to five years from the completion of our initial public offering or until such earlier time that we are no longer an emerging growth company. We would cease to be an emerging growth company upon the earliest to occur of: (i) the last day of the first fiscal year in which our annual gross revenues exceed $1.07 billion, (ii) the date on which we have issued more than $1 billion in non-convertible debt securities during the previous three years and (iii) the first day of the year following the first year in which, as of the last business day of our most recently completed second fiscal quarter, the market value of our common equity held by non-affiliates exceeds $700 million.

Foreign Private Issuer

We report under the Securities Exchange Act of 1934, as amended, or the Exchange Act, as anon-U.S. company with foreign private issuer status. Even after we no longer qualify as an emerging growth company, as long as we continue to qualify as a foreign private issuer under the Exchange Act, we are exempt from certain provisions of the Exchange Act that are applicable to U.S. domestic public companies, including:

- the rules under the Exchange Act requiring domestic filers to issue financial statements prepared under U.S. GAAP;
- the sections of the Exchange Act regulating the solicitation of proxies, consents or authorizations in respect of a security registered under the Exchange Act;
- the sections of the Exchange Act requiring insiders to file public reports of their share ownership and trading activities and liability for insiders who profit from trades made in a short period of time; and
- the rules under the Exchange Act requiring the filing with the Securities and Exchange Commission, or the SEC, of quarterly reports on Form 10-Q containing unaudited financial statements and other specified information, and current reports on Form8-K upon the occurrence of specified significant events.

Notwithstanding these exemptions, we will file with the SEC, within four months after the end of each fiscal year, or such applicable time as required by the SEC, an annual report on Form 20-F containing financial statements audited by an independent registered public accounting firm.

We may take advantage of these exemptions until such time as we are no longer a foreign private issuer. We would cease to be a foreign private issuer at such time as more than 50% of our outstanding voting securities are held by U.S. residents and any of the following three circumstances applies: (i) the majority of our executive officers or directors are U.S. citizens or residents, (ii) more than 50% of our assets are located in the United States or (iii) our business is administered principally in the United States.

Both foreign private issuers and emerging growth companies also are exempt from certain more stringent executive compensation disclosure rules. Thus, even if we no longer qualify as an emerging growth company, but remain a foreign private issuer, we continue to be exempt from the more stringent compensation disclosures required of companies that are neither an emerging growth company nor a foreign private issuer.

THE OFFERING

ADSs offered by us	ADSs, each representing one ordinary share
ADSs to be outstanding immediately following this offering	ADSs
Ordinary shares to be outstanding immediately after the offering	ordinary shares
Option to purchase additional ADSs	We have granted to the underwriters an option, exercisable for a period of 30 days after the date of this prospectus, to purchase an aggregate of up to an additional ADSs.
American Depositary Shares	The underwriters will deliver American Depositary Shares, or the ADSs. Each ADS represents one of our ordinary shares, no par value per share. As an ADS holder, you will not be treated as one of our shareholders and you will not have shareholder rights. The depositary, The Bank of New York Mellon, will be the holder of the ordinary shares underlying the ADSs. You will have the rights of an ADS holder or beneficial owner (as applicable) as provided in the deposit agreement among us, the depositary and holders and beneficial owners of ADSs from time to time. To better understand the terms of the ADSs, see "Description of American Depositary Shares." We also encourage you to read the deposit agreement, the form of which is incorporated by reference as an exhibit to the registration statement of which this prospectus forms a part.
Depositary	The Bank of New York Mellon
Use of proceeds	We estimate that the net proceeds to us from this offering will be approximately $ million (€ million) (or approximately $ million (€ million) if the underwriters exercise in full their option to purchase an additional ADSs), based on an assumed public offering price of $ per ADS, which was the last reported sale price of our ADSs on the Nasdaq Global Select Market on , 2020, and after deducting underwriting discounts and commissions and estimated offering expenses payable by us. We intend to use the net proceeds from this offering as follows: • approximately $ million to complete our ongoing and currently planned clinical trials for our FixVac product candidates BNT111, BNT112, BNT113, BNT114 and BNT115 and our targeted cancer antibody, MVT-5873 (BNT321), as well as to fund our portion of the research and development expenses for each of the following: RO7198457 (BNT122), which is being developed in collaboration with Genentech, SAR441000 (BNT131), which is

	being developed in collaboration with Sanofi, and GEN1046 (BNT311) and GEN1042 (BNT312), which are being developed in collaboration with Genmab; • approximately $ million to advance additional product candidates through Phase 1 clinical trials, including product candidates from CAR T, RiboMabs, RiboCytokines and TCR platforms in oncology, and our infectious disease immunotherapy and rare disease protein replacement therapy platforms outside oncology; • approximately $ million to advance additional preclinical product candidates, develop additional product candidates leveraging our current therapeutic platforms and fund the further development of our core technologies; and • approximately $ million to fund the further expansion of our manufacturing and laboratory capacity and the continued development of our infrastructure. We expect to use the remainder of any net proceeds from this offering, as well as our existing cash and cash equivalents, for general corporate purposes. We may also use a portion of the net proceeds to in-license or acquire or invest in complementary technologies, products, businesses or assets, either alone or together with a collaborator. However, we have no current plans, commitments or obligations to do so. See "Use of Proceeds" for a more complete description of the intended use of proceeds from this offering.
Risk factors	See "Risk Factors" beginning on page 17 and the other information contained in this prospectus for a discussion of factors you should consider before deciding to invest in the ADSs.
Nasdaq Global Select Market symbol	ADSs representing our ordinary shares are listed on the Nasdaq Global Select Market under the symbol "BNTX."

Unless otherwise indicated, the number of our ordinary shares to be outstanding after this offering is based on 216,262,336 ordinary shares outstanding as of September 30, 2019 and additionally includes 10,517,408 ordinary shares issued in connection with our initial public offering after September 30, 2019 and excludes:

- 11,852,784 ordinary shares issuable upon the exercise of options outstanding as of September 30, 2019;
- 10,022,022 ordinary shares available for future issuance under our Employee Stock Ownership Plan or any future share option plan; and
- 5,524,506 ordinary shares held in treasury.

Unless otherwise indicated, all information contained in this prospectus:

- reflects an 18-for-1 stock split of our ordinary shares, which became effective on September 18, 2019, upon registration with the commercial register (*Handelsregister*);
- assumes no exercise of the outstanding options described above;

- assumes a public offering price of $ per ADS, which was the last reported sale price of the ADSs on the Nasdaq Global Select Market on , 2020;
- assumes no exercise of the option granted to the underwriters to purchase up to additional ADSs in this offering; and
- excludes the anticipated effects of the Merger, see "Unaudited Pro Forma Condensed Combined Financial Information."

SUMMARY CONSOLIDATED FINANCIAL DATA

The following tables set forth a summary of our historical consolidated financial data as of and for the years ended December 31, 2018 and 2017, and as of September 30, 2019 and for the nine months ended September 30, 2019 and 2018. We derived the summary of our results for the years ended December 31, 2018 and 2017 from our audited consolidated financial statements included elsewhere in this prospectus. The summary consolidated financial data as of September 30, 2019 and for the nine months ended September 30, 2019 and 2018 have been derived from our unaudited interim condensed consolidated financial statements included elsewhere in this prospectus and have been prepared on the same basis as the audited financial statements. In the opinion of management, the unaudited interim data reflects all adjustments necessary for a fair presentation of the financial information in those statements. We present our consolidated financial statements in Euros and in accordance with IFRS as issued by the IASB.

The summary consolidated financial data below should be read together with our consolidated financial statements and related notes, and our unaudited interim condensed consolidated financial statements included elsewhere in this prospectus, as well as the sections of this prospectus titled "Selected Consolidated Financial Data" and "Management's Discussion and Analysis of Financial Condition and Results of Operations." Our historical results for any prior period are not necessarily indicative of results to be expected in any future period, and the results for the nine months ended September 30, 2019 are not necessarily indicative of the results to be expected for the full year ended December 31, 2019.

	For the Nine Months Ended September 30,		For the Years Ended December 31,	
	2019	2018	2018	2017
(in thousands except per share data)	(unaudited)			
Consolidated statements of operations:				
Revenues from contracts with customers	€ 80,601	€ 63,796	€ 127,575	€ 61,598
Cost of sales	(12,925)	(9,215)	(13,690)	(9,318)
Gross profit	67,676	54,581	113,885	52,280
Research and development expenses	(161,039)	(91,244)	(143,040)	(85,496)
Sales and marketing expenses	(1,908)	(1,984)	(3,041)	(6,603)
General and administrative expenses	(34,481)	(16,222)	(26,334)	(23,520)
Other operating income	1,340	4,043	5,396	2,349
Other operating expenses	(163)	(631)	(720)	(288)
Operating loss	(128,575)	(51,457)	(53,854)	(61,277)
Finance income	9,170	6,644	8,046	2,133
Finance expense	(233)	(12)	(48)	(26,007)
Interest expense related to lease liability	(1,283)	(1,297)	(1,721)	(676)
Share of loss of equity method investees	—	(84)	(84)	(78)
Loss before tax	(120,921)	(46,206)	(47,662)	(85,905)
Income taxes	(28)	(583)	(600)	(45)
Loss for the period	€ (120,949)	€ (46,789)	€ (48,262)	€(85,950)
Loss attributable to equity holders of the parent	€ (120,833)	€ (46,667)	€ (48,019)	€(85,653)
Loss attributable to non-controlling interests	(116)	(122)	(243)	(297)
Basic and diluted loss per share	€ (0.59)	€ (0.25)	€ (0.25)	€ (0.51)

The following table presents our summary consolidated statement of financial position as of September 30, 2019 (i) on an actual basis, (ii) on a pro forma basis to give effect to the issuance of 10,517,408 of our ordinary shares for net proceeds of €135.4 million ($149.1 million)(1) in connection with our initial public offering and (iii) on a pro forma as adjusted basis to give further effect to the sale of ADSs representing ordinary shares by us in the offering at the assumed public offering price of $ per ADS, which was the last reported sale price of the ADSs on the Nasdaq Global Select Market on , 2020, and after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

	As of September 30, 2019		
(in thousands)	Actual	Pro Forma(3) (unaudited)	Pro Forma As adjusted(2) (3)
Consolidated statements of financial position:			
Cash and cash equivalents	€ 463,308	€ 598,688	€
Total assets	738,408	873,788	
Total liabilities	322,003	322,003	
Share capital	221,787	232,304	
Accumulated losses	(366,604)	(366,604)	
Total equity	416,405	551,785	

(1) These proceeds were received in a combination of Euros and U.S. dollars. We have presented this information in Euros, reflecting the conversion of the U.S. dollar amount into a Euro amount using the exchange rates in effect at the times we transferred these proceeds to our Euro-denominated bank account.

(2) Each $1.00 increase (decrease) in the assumed public offering price of $ per ADS, which was the last reported sale price of the ADSs on the Nasdaq Global Select Market on , 2020, would increase (decrease) each of cash and cash equivalents, total assets and total equity by € million, assuming the number of ADSs offered by us, as set forth on the cover page of this prospectus, remains the same, and after deducting underwriting discounts and commissions and estimated offering expenses payable by us. We may also increase or decrease the number of ADSs we are offering. An increase (decrease) of 1,000,000 in the number of ADSs offered by us would increase (decrease) each of cash and cash equivalents, total assets, and total equity by approximately € million, assuming no change in the assumed public offering price and after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

(3) Excludes the anticipated effects of the Merger. See “Unaudited Pro Forma Condensed Combined Financial Information.”

RISK FACTORS

Risks Related to our Financial Condition and Capital Requirements

We are a clinical-stage biopharmaceutical company with no pharmaceutical products approved for commercial sale. We have incurred significant losses since our inception and we anticipate that we will continue to incur significant losses for the foreseeable future, which makes it difficult to assess our future viability.

We have incurred net losses in each year since our inception in 2008, including net losses of €48.3 million and €86.0 million for the years ended December 31, 2018 and 2017, respectively, and €120.9 million for the nine months ended September 30, 2019. As of September 30, 2019, we had accumulated losses of €366.6 million.

We have devoted most of our financial resources to research and development, including our clinical and preclinical development activities and the development of our platforms. To date, we have financed our operations primarily through the sale of equity securities and proceeds from collaborations and, to a lesser extent, through revenue from manufacturing operations and grants from governmental and private organizations. The amount of our future net losses will depend, in part, on the rate of our future expenditures and our ability to obtain funding through equity or debt financings, sales of assets, collaborations or grants. We have not commenced or completed pivotal clinical trials for our programs and it will be several years, if ever, before we or our collaborators have a product candidate ready for commercialization. Even if we obtain regulatory approval to market a product candidate, our future revenues will depend upon the size of any markets in which our product candidates have received approval, and our ability to achieve sufficient market acceptance, reimbursement from third-party payors, and adequate market share in those markets. We may never achieve profitability.

We expect to continue to incur significant expenses and increasing operating losses 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 add to internal 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 we progress our product candidates toward commercialization;
- attract and retain skilled personnel;
- create additional infrastructure to support our operations as a public company and our product development and planned future commercialization efforts, including expansion of sites in Germany and new sites in the United States;
- seek marketing approvals and reimbursement for our product candidates;
- establish a sales, marketing, and distribution infrastructure to commercialize any products for which we may obtain marketing approval;
- seek to identify and validate additional product candidates;
- acquire or in-license other product candidates and technologies;
- 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.

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 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 prospectus:

- delays or failures in advancement of existing or future product candidates into the clinic or in clinical trials;
- our ability to develop, manufacture and commercialize our programs;
- our ability to manage our growth;
- 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;
- our operation in a net loss position for the foreseeable future;
- risks associated with the international aspects of our business outside Germany, including the conduct of clinical trials in multiple locations and potential commercialization in such locations;
- our ability to consistently manufacture our product candidates;
- our ability to accurately report our financial results in a timely manner;
- our dependence on, and the need to attract and retain, key management and other personnel;
- our ability to obtain, protect, maintain, defend and enforce our intellectual property rights;
- our ability to prevent the theft or infringement, misappropriation or other violation of our intellectual property, trade secrets,know-how or technologies;
- 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 additional capital that may be necessary to develop and commercialize products under our collaboration agreements;
- business interruptions such as power outages, strikes, acts of terrorism or natural disasters; and
- our ability to use our net operating loss carryforwards to offset future taxable income.

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.

The net losses we incur may fluctuate significantly from one reporting period to the next, such that aperiod-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 overall valuation. The price of the ADSs may decline as a result of unexpected clinical trial results in one or more of our programs, including adverse safety events reported for any of our programs.

We have only generated limited revenue and may never be profitable.

Our ability to generate revenue and achieve 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 limited revenue from sales of products by our external services business unit, we do not anticipate generating revenues from pharmaceutical product sales in the near term. 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;
- 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 product candidates, if approved;
- obtaining market acceptance of our product candidates as a treatment option;
- launching and commercializing product candidates 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;
- 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.

If one or more of the product candidates that we develop is approved for commercial sale, we anticipate incurring significant costs associated with commercializing any approved product candidate. Our expenses could increase beyond our expectations if we are required by the U.S. Food and Drug Administration, or the FDA, the European Medicines Agency, or the 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. Even if we are able to generate revenues from the sale of any approved products, we may not become profitable and may need to obtain additional funding to continue operations.

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 Germany, we have unused tax loss carryforwards for corporate taxes, though we have not recognized deferred tax assets related to such loss carryforwards for International Financial Reporting Standards, or IFRS, reporting purposes. In general, net operating loss, or NOL, carryforwards in Germany do not expire. They are,

however, subject to review and possible adjustment by the German tax authorities. 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. In addition, we may in the future have U.S. federal and state NOL carryforwards due to our subsidiary in the United States.

We may not be able to utilize a material portion of our NOLs or credits in either Germany or the United States. 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 our recognition could be subject to challenge by taxing authorities. 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. Furthermore, our ability to use our NOLs or credits is conditioned upon our attaining profitability and generating taxable income. As described above, we have incurred significant net losses since our inception and anticipate that we will continue to incur significant losses for the foreseeable future. We do not know whether or when we will generate the taxable income necessary to utilize our NOL or credit carryforwards.

Under German tax laws, we are obligated to withhold a percentage of royalty payments we make to third party licensors of intellectual property rights and remit those withholdings to German tax authorities, and late withholding tax payments may subject us to penalties and fees.

Under German tax laws, we are obligated to withhold a percentage of royalty payments we make to third parties in consideration of the grant of rights under their intellectual property, and remit those withholdings to German tax authorities. As a result of an internal review, we have discovered that in the 11 year period before April 2019 we and certain of our subsidiaries did not withhold, report and remit certain withholding taxes in connection with the in-licensing of intellectual property as required to be withheld under German tax laws, and have not made the requisite recordings in our and their financial books and records in relation thereto. We have notified the tax authorities of the late payments. We may be subject to penalties and further fees as a result of late withholding tax payments.

It is possible to seek the refund of these withholding taxes from the German Federal Central Tax office after filing exemption and refund applications, and we intend to do so. However there is a possibility that the relevant claims against the licensors and/or the authority, may in some instances, not be enforceable as a result of a licensor no longer existing, the lapse of time or any other facts preventing the enforcement of such claims.

We will 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.

As of September 30, 2019, we had €463.3 million in cash and cash equivalents. We estimate that the net proceeds from this offering will be approximately $ million, based on the assumed public offering price of $ per ADS, which was the last reported sale price of our ADSs on the Nasdaq Global Select Market on , 2020, and after deducting underwriting discounts and commissions and estimated offering expenses payable by us. We expect that the net proceeds from this offering and our existing cash and cash equivalents will be sufficient to fund our operating expenses and capital expenditure requirements through at least the next months. However, our operating plan 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. In any event, we will require additional capital to obtain regulatory approval for, and to commercialize, our 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 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 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;
- the number and characteristics of product candidates that we develop or mayin-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; 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 and revenue from collaborations and we cannot be certain that additional funding will be available on favorable terms, or at all. Until we can generate sufficient product sales or royalty revenue to finance our operations, which we may never do, we expect to finance our future cash needs through a combination of public or private equity offerings, debt financings, collaborations, sales of assets, 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.

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 our shares to decline. If we raise additional funds through public or private equity offerings, the terms of these securities may include liquidation or other preferences that may adversely affect our shareholders' rights.

Further, to the extent that we raise additional capital through the sale of ADSs, ordinary shares or securities convertible or exchangeable into ordinary shares, your ownership interest will be diluted. We have entered into three secured credit facilities with an aggregate drawing capacity of €70 million. In addition, we may enter into additional credit facilities from time to time, which may be secured, to fund certain of our operations. 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 or other 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 develop and expand our company, and we may encounter difficulties in managing this development and expansion, which could disrupt our operations.

As of December 31, 2019, we had more than 1,300 full-time employees and, in connection with the growth and advancement of our pipeline and becoming a public company, we expect to increase the number of employees and the scope of 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. Also, 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, 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 implement our business strategy. Our future financial performance and our ability to compete effectively and commercialize our product candidates, if approved, will depend in part on our ability to effectively manage the future development and expansion of our company.

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. If we obtain marketing approval for any product candidates that we or our collaborators may develop, we intend to acquire insurance coverage to include the sale of commercial products, but we may be unable to obtain such insurance on commercially reasonable terms or in adequate amounts. We currently maintain insurance coverage for losses relating to an interruption of our development, manufacturing or commercialization efforts caused by contamination in an amount of €50,000,000

per claim up to an aggregate cap of €160,000,000 in any two-year period, and the coverage or coverage limits of our insurance policies may not be adequate. If our losses exceed our insurance coverage, our financial condition would be adversely affected. In the event of contamination or injury, we could be held liable for damages or be penalized with fines in an amount exceeding our resources. Clinical trials or regulatory approvals for any of our product candidates could be suspended, which could adversely affect our results of operations and business, including by preventing or limiting the development and commercialization of any product candidates that we or our collaborators may develop. We also expect that operating as a public company will make it more expensive for us to obtain director and officer liability insurance, and we may be required to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. As a result, it may be more difficult for us to attract and retain qualified individuals to serve on our Supervisory Board, our board committees or our Management Board.

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 any product candidates we may develop. Any immunotherapy 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. We have not received approval to market any biopharmaceutical product candidates from regulatory authorities in any jurisdiction, and it is possible that none of our 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 contract research organizations, or CROs, regulatory consultants or collaborators to assist us in this process. To our knowledge, there is no current precedent for an mRNA-based immunotherapy such as the type we are developing being approved for sale by the FDA, European Commission or any other regulatory agency elsewhere in the world. Although we expect to submit BLAs for our mRNA-based product candidates in the United States, and in the European Union, mRNA therapies have been classified as gene therapy medicinal products, other jurisdictions may consider our mRNA-based product candidates to be new drugs, not biologics or gene therapy medicinal products, and require different marketing applications. Securing regulatory approval requires the submission of extensive 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. 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 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 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 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 an immunotherapy for fewer or more limited indications 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.

No mRNA immunotherapy has been approved, and none may ever be approved. mRNA drug development has substantial clinical development and regulatory risks due to the novel and unprecedented nature of this new category of therapeutics.

As a potential new category of therapeutics, to our knowledge, no mRNA immunotherapies have been approved to date by the FDA, EMA or other regulatory agency. 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. To date, there has never been a Phase 3 trial for an mRNA-based product or a commercialized mRNA-based product. 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 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.

Currently, mRNA is considered a gene therapy product by the FDA. Unlike certain gene therapies that irreversibly alter cell DNA and may cause certain side effects, mRNA-based medicines are designed not to 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, because no mRNA-based product has been approved, the regulatory pathway in the United States and may other jurisdictions for approval is uncertain. The pathway for an individualized therapy, such as our iNeST mRNA-based immunotherapy where each patient receives a different combination of mRNAs, remains particularly unsettled. 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 gene 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 side 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 side 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 compromised immune and other systems and 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 European Union 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 potential 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 with and are expected to continue to contract with academic medical centers and hospitals experienced in the assessment and management of toxicities arising during clinical trials. Nonetheless, these centers and hospitals may have difficulty observing patients and treating toxicities, which may be more challenging due to personnel changes, inexperience, shift changes, house staff coverage or related issues. This could lead to more severe or prolonged toxicities or even patient deaths, which could result in us or the FDA, EMA or other comparable regulatory authority delaying, suspending or terminating one or more of our clinical trials, and which could jeopardize regulatory approval. We also expect the centers using our product candidates, if approved, on a commercial basis could have similar difficulty in managing adverse events. Medicines used at centers to help manage adverse side effects of our product candidates may not adequately control the side effects and may have a detrimental impact on the efficacy of the treatment. Use of these medicines may increase with new physicians and centers administering our product candidates.

In addition, even if we successfully advance one of our product candidates into and through clinical trials, such trials will likely only include a limited number of subjects 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 effect 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 side effects caused by such products, a number of potentially significant negative consequences could result, including:

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

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

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

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

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 side 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 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;
- 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;
- the cost of preclinical or nonclinical testing and studies and clinical trials of any product candidates may be greater than we anticipate;
- the supply or quality of our product candidates or other materials necessary to conduct clinical trials may be insufficient or inadequate;
- safety or efficacy concerns regarding our product candidates may result from any concerns arising from nonclinical or clinical testing of other therapies targeting a similar disease state or other therapies, such as gene therapy, that are perceived as similar to ours; and
- the FDA or other regulatory authorities may require us to submit additional data, such as long-term toxicology studies, or impose other requirements before permitting us to initiate a clinical trial.

We could also encounter delays if a clinical trial is suspended or terminated by us, the FDA or other regulatory authorities, ethics committees, or the IRBs of the institutions in which such trials are being conducted,

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

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

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

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

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

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

patient populations, the timeline for recruiting trial participants, conducting studies, and obtaining regulatory approval of potential products may be delayed. These delays could result in increased costs, delays in advancing our product development, delays in testing the effectiveness of our product, or termination of the clinical studies altogether.

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

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

In addition, our clinical trials will 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 departure from more traditional methods for disease treatment and prevention, potential trial participants and their doctors may be inclined to use conventional therapies or other new therapies rather than enroll trial participants in any future clinical trial involving individualized 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.

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 numerous countries, including Germany, Austria, Belgium, Czechia, France, Italy, the Netherlands, Poland, Spain, Sweden, the United Kingdom, Israel, Australia, Canada and the United States, 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 patientself-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 do 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.

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 interimtop-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 publicly disclose regarding a particular study or clinical trial is based on what is typically extensive information, and you or others 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 you 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 reveal significant adverse events not seen in our preclinical or nonclinical studies and may result in a safety profile that could delay or terminate clinical trials, or delay or prevent regulatory approval or market acceptance of any of our product candidates.

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

Some of our product candidates are being developed or are intended to beco-administered with other developmental therapies or approved medicines. For example, RO198457 (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 applicable 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.

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

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

For our individualized immunotherapy candidates, the FDA and similar 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, EMA or other regulatory authorities may not consider the endpoints of our clinical trials to provide clinically meaningful results.

There may not be pharmacologic therapies approved to treat the underlying causes of many diseases that we may address in the future. For instance, we and our collaborators are applying our technology to develop

therapeutics in indications such as certain rare diseases, including some for which no or few clinical trials have been attempted. As a result, any future design and conduct of clinical trials of product candidates for the treatment of certain rare diseases may take longer, be more costly, or be less effective as part of the novelty of development in these diseases. Even if we decide to conduct clinical trials and the FDA does find our success criteria to be sufficiently validated and clinically meaningful, we may not achieve the pre-specified endpoint to a degree of statistical significance in any pivotal or other clinical trials we or our collaborators may conduct for our programs. Further, even if we do achieve the pre-specified criteria, our trials may produce results that are unpredictable or inconsistent with the results of the more traditional efficacy endpoints in the trial. The FDA also could give overriding weight to other efficacy endpoints over a primary endpoint, even if we achieve statistically significant results on that endpoint, if we do not do so on our secondary efficacy endpoints. The FDA also weighs the benefits of a product against its risks and the FDA may view the efficacy results in the context of safety as not being supportive of licensure. Other regulatory authorities in Europe and other countries may make similar findings with respect to these endpoints.

The FDA, 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 submission of a BLA 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, EMA or other regulatory agencies may grant accelerated approval for our product candidates and, as a condition for accelerated approval, the FDA, 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, 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, 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; 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 European Union member states 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 competent authorities of European Union member states or similar application with other comparable regulatory authorities will result in the FDA, the competent authorities of European Union member states or any comparable regulatory authority allowing testing and clinical trials to begin, or that, once begun, issues will not arise that result in the suspension or termination of such clinical trials. Additionally, even if such regulatory authorities agree with the design and implementation of the clinical trials set forth in an IND, clinical trial application or similar applications, we cannot guarantee that such regulatory authorities will not change their requirements in the future.

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

Our strategy includes filing for orphan drug designation where available for our product candidates. Under the 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 effectively protect the product from competition because different drugs with different active moieties may receive and be approved for the same condition, and only the first applicant to receive approval will receive the benefits of marketing exclusivity. Even after an orphan-designated product is approved, the FDA can subsequently approve a later drug with the same active moiety for the same condition if the FDA concludes that the later drug is clinically superior if it is shown to be safer, more effective, or makes a major contribution to patient care. Similar considerations apply in the European Union with respect to drugs or biologics designated as orphan medicinal products. Orphan drug designation neither shortens the development time or regulatory review time of a drug, nor gives the drug any advantage in the regulatory review or approval process. In addition, while we may seek orphan drug designation for our product candidates, we may never receive such designations.

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

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

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

We may also seek Fast Track Designation in the United States for some of our product candidates. If a therapy is intended for the treatment of a serious or life-threatening condition and the therapy demonstrates the potential to address significant unmet medical needs for this condition, the drug sponsor may apply for Fast Track Designation. The FDA has broad discretion whether or not to grant this designation, and even if we believe a particular product candidate is eligible for this designation, we cannot assure you 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 Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or the ACA, includes a subtitle called the Biologics Price Competition and Innovation Act of 2009, or the BPCIA, which created an abbreviated approval pathway for biological products that are biosimilar to or interchangeable with an FDA-approved reference biological product. Under the BPCIA, an application for a biosimilar product may not be submitted to the FDA until four years following the date that the reference product was first approved by the FDA. In addition, the approval of a biosimilar product may not be made effective by the FDA until 12 years from the date on which the reference product was first approved. During this 12-year period of exclusivity, another company may still market a competing version of the reference product if the FDA approves a BLA for the competing product containing the sponsor's own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity and potency of the other company's product. The law is complex and is still being interpreted and implemented by the FDA. As a result, its ultimate impact, implementation and meaning are subject to uncertainty.

We believe that any of our product candidates approved as a biological product under a BLA should qualify for a12-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 counties 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.

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 eventually market any of 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 countries, and regulatory approval in one country does not guarantee regulatory approval in any other country. Approval processes vary among countries and can involve additional product testing and validation and additional administrative review periods.

Seeking regulatory approval in other jurisdictions could result in difficulties and costs for us and require additional preclinical studies or clinical trials which could be costly and time-consuming. Regulatory requirements can vary widely from country to country and could delay or prevent the introduction of our products in those countries. The European Union and other jurisdictions' regulatory approval processes involve all of the risks associated with FDA approval. We do not have any product candidates approved for sale in any jurisdiction, including international markets, and we do not have experience in obtaining regulatory approval in international markets. 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 similar 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 similar 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 similar 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 similar regulatory authority approval.

If the FDA, the EMA or similar 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.

Even if we receive regulatory approval of our product candidates, 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.

Even if we obtain regulatory approval in a jurisdiction, the applicable regulatory authority may still impose significant restrictions on the indicated uses or marketing of our product, or impose ongoing requirements for potentially costly post-approval studies or post-market surveillance. For example, the holder of an approved BLA is obligated to monitor and report adverse events and any failure of a product to meet the specifications in the BLA. The holder of an approved BLA must also submit new or supplemental applications and obtain FDA approval for certain changes to the approved product, product labeling or manufacturing process. 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.

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 supplements to a BLA 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 such product candidates 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, if we successfully obtain regulatory approval for 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 impact 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. 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.

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 successfully develop and commercialize such products 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.

Risks Related to the Manufacturing of our Product Candidates and Future Pipeline

Our mRNA product candidates are based on novel technologies and any product candidates we develop 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 product candidates are novel and complex. There are no immunotherapies commercialized to date or manufactured at such scale. Due to the novel nature of this technology and limited 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 in the past resulted in and may in the future result in our having to resupply batches for preclinical or clinical 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 or clinical supply.

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 product candidates is complex and, if not developed and manufactured under well-controlled conditions, can adversely impact pharmacological activity. Furthermore, we have not manufactured immunotherapies at commercial scale. 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 manufacturing process may in turn impact 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 trial. Our mRNA product candidates may prove to have a stability profile that leads to a lower than desired shelf life of the final approved immunotherapy. 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 have cross contamination of products inside of our factories, CROs, 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 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 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.

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.

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 quantities of our product candidates, or our failure to comply with applicable regulatory requirements, would 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. All internal manufacturing is performed under GMP guidelines. We do not rely on any external CMOs for the manufacture of our product candidates and at this time, 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 manufacturing facilities experiences 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 can resume operations. We may also be required to incur significant expenditures to resolve such difficulties.

Our facilities are subject to various regulatory requirements and may be subject to the inspection of the FDA or other regulatory authorities. If we cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA, EMA or comparable regulatory authorities in other jurisdictions, we may not be able to rely on our manufacturing facilities for the manufacture of our product candidates. If the FDA, EMA or another comparable regulatory authority finds our facilities inadequate for the manufacture of 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 product candidates.

Additionally, we may experience manufacturing difficulties due to resource constraints or as a result of labor disputes or unstable political environments. If we were to encounter any of these difficulties, our ability to provide our product candidate to patients in clinical trials, or to provide product 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.

While the design of our facilities is based on current standards for biotechnology facilities, it has not been reviewed orpre-approved by any regulatory agency, nor have our facilities been inspected by any regulatory agency such as the FDA. 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 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.

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, those suppliers normally support blood-based hospital businesses and generally do not have the capacity to support commercial products manufactured under GMP by biopharmaceutical firms. These suppliers may be ill-equipped to support our needs, especially innon-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.

Our product candidates are inherently sensitive to shipping and storage conditions and could be subject to risk of loss or damage.

Our product candidates are sensitive to temperature, storage and handling conditions. Loss in 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 is not fully quantified and is expected to be variable, and it is

possible that 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 otherwise.

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 clinical trials. Poor control of the GMP production processes can lead to product quality failures that can impact our ability to supply product, resulting in cost overruns and delays to clinical timelines, 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 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 we may develop 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 produce product candidates 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 commercialize 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, 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 contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. Furthermore, all of our contract manufacturers are engaged with other companies to supply or manufacture materials or products for such companies, which exposes our contract manufacturers 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 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, 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 third-party 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 or product launches, 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 will 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 the Commercialization of our Pipeline

The successful commercialization of our product candidates will depend in part on the extent to which governmental authorities, private health insurers and other third-party payors provide coverage and adequate reimbursement levels and implement pricing policies favorable for our product candidates. Failure to obtain or maintain coverage and adequate reimbursement for our product candidates, if approved, 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 expensive treatments such as the medicines that we hope to develop and sell. In addition, because several of our product candidates represent new approaches to the treatment of cancer, we

cannot accurately estimate how these products 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 a sufficient return on our investment in any of our products.

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

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

Moreover, increasing efforts by governmental and third-party payors, in the United States and abroad, to cap or reduce healthcare costs may cause such organizations to limit both coverage and level of reimbursement for new products approved and, as a result, they may not cover or provide adequate payment for our product candidates. For example, the U.S. government recently 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 the state level, legislatures are increasingly passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access, and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation 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 and 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.

We face significant competition 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 in 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. 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 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 may therefore 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 noncompetitive before we can recover the expenses of developing and commercializing our products, if approved.

The market opportunities for certain of our product candidates may be limited due to the rarity of the disease, or limited to those patients who are ineligible for or have failed prior treatments, and may be small. As the target patient populations for some of our programs are small, we must be able to successfully identify trial participants and achieve a significant market share to maintain profitability and growth.

The FDA often approves new therapies initially only for use by patients with relapsed or refractory advanced cancer. We expect to initially seek approval of certain of our product candidates in this context. Subsequently, for those products that prove to be sufficiently beneficial, if any, 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 are small, we may never achieve profitability without obtaining regulatory approval for additional indications.

We currently have no marketing and sales organization and as a company, we have no experience in marketing pharmaceutical products. If we are unable to establish 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.

Given our stage of development, we have no sales, distribution or marketing capabilities, and we have not designed our preclinical studies and clinical trials with specific commercialization or marketing considerations in mind. To successfully commercialize any products that may result from our development programs, we will need to develop 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 future collaborators do not commit sufficient resources to commercialize 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 will be competing with many companies that currently have extensive and well-funded marketing and sales operations. Without a significant internal team or the support of a third party to perform marketing and sales functions, we may be unable to compete successfully against these more established companies.

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

Our future profitability, if any, 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 in particular 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;
- 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, cancer 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 become profitable. 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 side effects, including any limitations or warnings contained in a product's approved labeling;
- the prevalence and severity of any side effects resulting from checkpoint inhibitors or other drugs or therapies with which our products are administered;
- relative convenience and ease of 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 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.

Commercial success of any approved products will also depend in large part on the availability of coverage and adequate reimbursement from third-party payors, including government payors such as the Medicare and Medicaid programs and entry into managed care organizations, which may be affected by existing and future healthcare reform measures designed to reduce the cost of healthcare. 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. If government and other healthcare payors do not provide adequate coverage and reimbursement levels for any of our products once approved, whether due to healthcare reform legislation or otherwise, market acceptance and commercial success would be reduced.

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 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, 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 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. 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 health care 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 ACA was passed, which substantially changes the way health care is financed by both governmental and private insurers, and significantly impacts the U.S. pharmaceutical industry. The ACA, among other things, increased the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program and extended the rebate program to individuals enrolled in Medicaid managed care organizations, established annual fees and taxes on manufacturers of certain branded prescription drugs, and promoted a new Medicare Part D coverage gap discount program. Considerable uncertainty remains regarding the implementation and impact of the ACA.

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 has recently 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, defer, 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, tax, penalty or regulatory burden on individuals, healthcare providers, health insurers, 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.

In addition, other legislative changes have been proposed and adopted in the United States since the ACA was enacted. The Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions of Medicare payments to providers up to 2% per fiscal year. These reductions will remain in effect through 2025 unless additional congressional action is taken.

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 health care and the pricing and reimbursement of products in that context. In general, however, the healthcare budgetary constraints in most European Union 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 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 products 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 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 European Union member states.

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 European Union 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 Reliance on Third Parties

We have entered into several arrangements with a related party for the performance of nonclinical research programs, and these arrangements present potential conflicts of interest.

We have had a longstanding relationship with Translational Oncology at the University Medical Center of the Johannes Gutenberg University Mainz (Translationale Onkologie an der Universitätsmedizin der Johannes Gutenberg Universität Mainz gemeinnützige GmbH), or TRON, a non-profit limited liability company engaged in biopharmaceutical research. During 2018 and the nine months ended September 30, 2019, we incurred €11.2 million and €6.3 million, respectively, to TRON, and TRON's research has historically constituted a significant portion of our discovery pipeline and target discovery engine. Prof. Ugur Sahin, M.D., our co-founder and Chief Executive Officer, co-founded TRON and served as Managing Director at TRON until 2019 and currently serves as a Professor of Medicine at the University of Mainz. Prof. Sahin resigned from this position with TRON, effective September 10, 2019. Additionally, Prof. Christoph Huber, M.D., a member of our Supervisory Board, served on TRON's supervisory board until his resignation in April 2019. We and TRON also share certain intellectual property.

The existence or appearance of a conflict of interest could depress the price of the ADSs or attract scrutiny from shareholders, regulators or other stakeholders. Additionally, any conflicts of interest would create the risk that our officers may favor their personal interests over those of our shareholders.

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.

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 competent authorities of the 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 assure you 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 development programs may be materially and irreversibly harmed. If we are unable to rely on preclinical and clinical data collected by our CROs, we could be required to repeat, extend the duration of, or increase the size of any clinical trials we conduct and this could significantly delay commercialization and require significantly greater expenditures.

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

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 potentially 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, or external factors, such as an acquisition, that divert resources or create competing priorities;
- collaborators may delay clinical trials, provide insufficient funding for clinical trials, stop a clinical trial, abandon a product candidate, repeat or conduct new clinical trials, or require a new formulation of a product candidate for clinical testing;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our product candidates if the collaborators believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours;
- product candidates developed in collaborations with us may be viewed by our collaborators as competitive with their own product candidates or products, which may cause collaborators to cease to devote resources to the development or commercialization of our product candidates;
- a collaborator with marketing and distribution rights to one or more of our product candidates that achieve regulatory approval may not commit sufficient resources to the marketing and distribution of any such product;
- disagreements with collaborators, including disagreements over proprietary rights, contract interpretation, or the preferred course of development of any product candidates, may cause delays or termination of the research, development or commercialization of such product candidates, may lead to additional responsibilities for us with respect to such product candidates, or may result in litigation or arbitration, any of which would be time-consuming and expensive;
- collaborators may not properly maintain, protect, defend or enforce our intellectual property rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential litigation;
- disputes may arise with respect to the ownership of intellectual property developed pursuant to our collaborations;
- collaborators may infringe, misappropriate or otherwise violate the intellectual property rights of third parties, which may expose us to litigation and potential liability;
- collaborations may be terminated for the convenience of the collaborator and, if terminated, the development of our product candidates may be delayed, and we could be required to raise additional capital to pursue further development or commercialization of the applicable product candidates;
- future relationships may require us to incur non-recurring and other charges, increase our near- and long-term expenditures, issue securities that dilute our existing shareholders, or disrupt our management and business;

- we could face significant competition in seeking appropriate collaborators, and the negotiation process is time-consuming and complex; and
- our international operations through any future collaborations, acquisitions or joint ventures may expose us to certain operating, legal and other risks not encountered in 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 under the collaborations. If we do not receive the funding we expect under these agreements, our development of product candidates could be delayed and we may need additional resources to develop 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 prospectus 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 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 similar 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 CellScript LLC and its affiliate, mRNA RiboTherapeutics, Inc., to patent rights claiming certain uses of modified RNA, as well as licenses from certain other parties for intellectual property useful in pharmaceutical formulations. We may enter into additional licenses to third-party intellectual property in the future.

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

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

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

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.

If we commit certain material breaches and fail to cure them (if such breach is curable), we are required to repurchase shares held by the Bill & Melinda Gates Foundation.

If we commit a specified material breach under the letter agreement with the Bill & Melinda Gates Foundation, or BMGF, and such breach remains uncured after a specified period of time (if curable), we are required to either (i) repurchase the shares held by BMGF or locate a third party to purchase the shares from BMGF, in either case at a price that is the greater of the original purchase price or the fair market value of the shares at the time of repurchase, or (ii) if we cannot meet the requirements under (i) (e.g., because we do not have sufficient cash reserves), then we must use our best efforts to effect BMGF's withdrawal right as soon as practicable, which may mean acquiring the shares in tranches over time. If we are required to repurchase BMGF's shares, our financial position could be materially and adversely affected.

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 may need to rely on outside vendors to manufacture supplies and process our product candidates. We have not yet caused our product candidates to be manufactured or processed on a commercial scale and may not be able to achieve commercial-scale manufacturing and processing and may be unable to create an inventory of mass-produced, off-the-shelf product to satisfy demands for our product candidates.

We do not yet have sufficient information to reliably estimate the cost of the commercial manufacturing and processing of our product candidates, and the actual cost to manufacture and process our product candidates could materially and adversely affect the commercial viability of our product candidates. As a result, we may never be able to develop a commercially viable product.

In addition, our reliance on a limited number of third-party manufacturers 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 third-party manufacturers 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 third-party manufacturers' compliance with these regulations and standards;
- we may not own, or may have to share, the intellectual property rights to any improvements made by our third-party manufacturers in the manufacturing process for our products;
- our third-party manufacturers 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 product candidates by the FDA or regulatory authorities in other jurisdictions or the commercialization of our 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 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 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 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 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 products, 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 product candidates.

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

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

- delays to the development timelines for our product candidates;
- interruption of supply resulting from modifications to or discontinuation of a supplier's operations;
- delays in product shipments resulting from uncorrected defects, reliability issues, or a supplier's variation in a component;
- a lack of long-term supply arrangements for key components with our suppliers;
- inability to obtain adequate supply in a timely manner, or to obtain adequate supply on commercially reasonable terms;
- difficulty and cost associated with locating and qualifying alternative suppliers for our components in a timely manner;
- production delays related to the evaluation and testing of components from alternative suppliers, and corresponding regulatory qualifications;

- delay in delivery due to our suppliers' prioritizing other customer orders over ours;
- damage to our reputation caused by defective components produced by our suppliers; and
- fluctuation in delivery by our suppliers due to changes in demand from us or their other customers.

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

Risks Related to Our Intellectual Property

If our efforts to obtain, maintain, protect, defend and/or enforce the intellectual property related to our 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 product candidates, proprietary technologies and their uses, as well as our ability to operate, develop, manufacture and commercialize 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 the claims 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 product candidates or otherwise afford sufficient protection against competitors with similar technology, nor can there be any assurance that the patents issued 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 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 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 erode or negate any competitive advantage we may have, which could have a material adverse effect on our financial condition and results of operations.

The patent application process is subject to numerous risks and uncertainties, and there can be no assurance that we or any of our current or future licensors or collaborators will be successful in prosecuting, obtaining, protecting, maintaining, enforcing or defending patents and patent applications necessary or useful to protect our 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 patent 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;
- issued patents that we own (solely or jointly) or havein-licensed may be challenged, invalidated, modified, revoked, circumvented, found to be unenforceable or otherwise may not provide any competitive advantage;
- our competitors, many of whom have substantially greater resources than we do and many of whom have made significant investments in competing technologies, may seek or may have already obtained patents that will limit, interfere with or eliminate our ability to make, use, sell, import or otherwise exploit our product candidates or other technologies;
- other parties may have designed around our patent claims or developed technologies that may be related or competitive 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 or devices or by claiming subject matter that could dominate one or more of our patent claims;
- any successful opposition to any patents owned by or in-licensed to us could deprive us of rights necessary for the development and exploitation of 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; 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 Congress of the United States 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 also 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, contract manufacturers, consultants, advisors and other third parties, any of these parties may breach such agreements and disclose such output before a patent application is filed, thereby jeopardizing our ability to seek patent protection. We also rely to a certain extent on trade secrets, know-how, and technology, which are not protected by patents, to maintain our competitive position. If any trade secret, know-how or other technology not protected by a patent were to be disclosed to or independently developed by a competitor, our business and financial condition could be materially adversely affected.

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

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

In addition, proceedings to enforce or defend our owned or in-licensed patents could put our patents at risk of being invalidated, held unenforceable or interpreted narrowly. Such proceedings could also provoke third parties to assert claims against us, including that some or all of the claims in one or more of our patents are invalid or otherwise unenforceable. Such challenges may result in loss of patent rights, loss of exclusivity, or in patent claims being narrowed, invalidated or held unenforceable, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and product candidates. If any of our owned or in-licensed patents covering our

product candidates or other technologies are narrowed, invalidated or found unenforceable, or if a court found that valid, enforceable patents held by third parties covered one or more of our product candidates or other technologies, our competitive position could be harmed or we could be required to incur significant expenses to protect, enforce or defend our rights. If we initiate lawsuits to protect, defend or enforce our patents, or litigate against third-party claims, such proceedings would be expensive and would divert the attention of our management and technical personnel, 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 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 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 patents we own or license and, if challenged, a court would hold that such patents 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 business;
- our competitors do not conduct research and development 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 or product candidates that are separately patentable; or
- our development and commercialization activities, including our manufacturing processes, or products will not infringe upon the 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 may assert intellectual property rights that prevent us from developing and commercializing 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 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, manufacture and commercialization of therapeutic modalities and our delivery technologies, including 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 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 have filed, and will continue to file, patent applications claiming inventions in the field in the United States and abroad. 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 or our licensors may in the future become a party to patent proceedings or priority disputes in the United States, Europe or other jurisdictions. The Leahy-Smith America Invents Act, or the America Invents Act, enacted in September 2011, included a number of significant changes that affect the way patent applications will be 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. We expect that we will 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 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. In addition, third parties may attempt to invalidate our intellectual property rights. Even if our rights are not directly challenged, disputes could lead to the weakening of our intellectual property rights. Our defense against any attempt by third parties to circumvent or invalidate our intellectual property rights could be costly to us, could require significant time and attention of our management 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 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, there may be 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 and commercialization 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 or a court rules 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 and commercialization of one or more of the product candidates we may develop. Any of the foregoing could result in a material adverse effect on our business, financial condition, results of operations or prospects.

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

We currently have rights to certain intellectual property, through our owned andin-licensed patents and other intellectual property rights, relating to identification and development 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.

For example, we sometimes collaborate with academic institutions in certain aspects of our preclinical research or development under written agreements with these institutions. Typically, these institutions provide us with an option to negotiate a license to any of the institution's rights in technology resulting from the collaboration. However, these institutions may not honor our option and right of first negotiation for intellectual property rights or we may otherwise be unable to negotiate a license within the specified time frame or under terms that are acceptable to us. If we are unable to do so, the institution may offer the intellectual property rights to other parties, potentially blocking our ability to pursue our program or otherwise continue to develop certain product candidates or other technologies.

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

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

The lifespans of our patents may not be sufficient to effectively protect our 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. 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 Action 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. 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. Moreover, the applicable time period or the scope of patent protection afforded could be less than we request. If we are unable to obtain patent term extension or the term of any such extension is less than we request, our competitors may obtain approval of competing products following our patent expiration, and our business, financial condition, results of operations and prospects could be materially harmed.

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

We are heavily reliant upon licenses to certain intellectual property and other proprietary rights from third parties that are important or necessary to the development and commercialization of our technology and product 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 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 third parties, or such activities, if controlled by us, may require the input of such third parties. In some cases, patent prosecution of our in-licensed intellectual property is controlled solely by the licensor. We may also require the cooperation of our licensors and collaborators to enforce or defend any in-licensed patent rights, and such 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. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations and prospects.

Moreover, any failure to satisfy obligations or any material breach under any of our licenses to third-party intellectual property could give the licensor the right to terminate the license. 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, or we are subject to a bankruptcy, the licensor may have the right to terminate the license agreement, in which event we would not be able to develop, market and commercialize product 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 and commercialize the 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, market and commercialize our 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, market and commercialize the affected 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 and the Louisiana State University, 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 include a non-exclusive, non-transferable, irrevocable worldwide license to use inventions for any governmental purpose. In addition, the U.S. government has 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 also has 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 orin-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 comply with these manufacturing requirements, we may experience a material adverse effect on our competitive position, business, financial conditions, results of operations and prospects.

Our current proprietary position for certain product candidates depends upon our owned or in-licensed patent filings covering components of such product candidates, 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 obtained patent protection covering components of certain product candidates, manufacturing-related methods, formulations and/or methods of use, we do not currently have any claims in our owned or in-licensed issued U.S. patents that cover, for example, the overall construct used in our iNeST product candidates, and we 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 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, 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 candidates, and we might be required to litigate or obtain licenses from third parties in order to develop or market our product candidates.

Because our product candidates are still in early developmental stages, and one or more features of the product candidates or related technologies such as their manufacture, formulation 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. 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 is submitted. 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 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 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 or use at the time that we seek to commercialize them. In such cases, we may not be in a position to develop 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 prohibitively expensive or impossible.

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

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

There is a substantial amount of litigation, both within and outside the United States, involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries, including patent infringement lawsuits, interferences, oppositions, *ex parte* reexaminations, post-grant review, and *inter partes* review proceedings before the USPTO and corresponding European and othernon-U.S. patent offices. Competitors and other third parties may infringe, misappropriate or otherwise violate our intellectual property rights or those of our licensors. To prevent infringement, misappropriation or other unauthorized use, we may be required to file claims, which can be expensive and time-consuming. In certain instances, we have instituted and may in the future institute *inter partes* review proceedings against issued U.S. patents and opposition proceedings against European patents owned by third parties in the field of immunotherapy. We have a number of these opposition proceedings ongoing at the European Patent Office against third-party patents related to mRNA technologies. 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 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 lack of novelty, obviousness or non-enablement. 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 would lose at least part, and perhaps all, of the patent protection on such 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, ranging from 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, methods of manufacture or methods for treatment related to the use, development, manufacture or commercialization of our product candidates. 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 candidates may infringe. In addition, third parties may obtain patents in the future and claim that our technologies infringe upon these patents. If any third-party patents were held by a court of competent jurisdiction to cover the manufacturing process of any of our product candidates, any molecules formed during the manufacturing process 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 and commercialize such 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 manufacture or methods of use, including combination therapy, the holders of any such patents may be able to block our ability to develop and commercialize the applicable 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 and other employees. In addition, the uncertainties associated with litigation could have a material adverse effect on our ability to raise the funds necessary to continue our clinical trials, continue our research programs, license necessary technology from third parties or enter into development or manufacturing collaborations that would help us bring our 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 technical and management personnel 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 financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could compromise our ability to compete in the marketplace.

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

Such licenses are likely to be non-exclusive and, therefore, our competitors may have access to the same intellectual property and technology licensed to us. If we fail to obtain a required license and are unable to design around a patent, we may be unable to effectively market some of our technology and product candidates, which could limit our ability to generate revenues or achieve 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 firm and rely on our outside counsel to pay these fees due to non-U.S. patent agencies; however, we cannot guarantee that we will successfully pay these fees. The USPTO and various non-U.S. governmental patent agencies require compliance with a number of procedural, documentary, fee payment, and other similar provisions during the patent application process. We employ reputable law firms and other professionals to help us comply, and in many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. However, there are situations in which non-compliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. We are also dependent on our licensors to take the necessary action to comply with these requirements with respect to our in-licensed intellectual property, and we cannot guarantee that they will do so. In such an event, our competitors might be able to enter the market with similar or identical products or technology, and this would have a material adverse impact on our business, financial condition, results of operations and prospects.

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

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

In addition, 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 and the USPTO, 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 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 and development 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, contract manufacturers, 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. Despite our best efforts, any of these parties may breach the agreements and 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. 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. 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 will not be able to establish or maintain a competitive advantage in our market, which could materially adversely affect our business, operating results, financial condition and prospects.

We may be subject to claims that we have wrongfully hired an employee from a competitor, or that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of third parties or that our employees have wrongfully used or disclosed 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 and 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.

We may in the future 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. The assignment of intellectual property rights may not be self-executing, or the assignment agreements may be breached. For example, we may have inventorship disputes arise from conflicting obligations of employees, consultants, independent contractors, collaborators or other third parties who are involved in developing and commercializing our product candidates. Litigation may be necessary to defend against these and other claims challenging inventorship. 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 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 laws of the United States. 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 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 candidates and 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, 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 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 foreign jurisdictions. 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, marketing and commercialization of competing products in violation of our 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, then 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, 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, then 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. Though these license agreements may provide guidelines for how our trademarks and trade names may be used, a breach of these agreements or misuse of our trademarks and trade names by our licensees may jeopardize our rights in or diminish the goodwill associated with our trademarks and trade names. Our efforts to enforce or protect our proprietary rights related to trademarks, trade names, trade secrets, know-how, domain names, copyrights or other intellectual property may be ineffective and could result in substantial costs and diversion of resources and could adversely affect our business, financial condition, results of operations and prospects.

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

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

- others may be able to make personalized cancer immunotherapies that are similar to 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 orin-license in the future will not lead to issued patents;
- issued patents that we own or have exclusivelyin-licensed may be held invalid or unenforceable, including as a result of legal challenges by our competitors;
- our competitors might conduct research and development 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 orknow-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 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.
- 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

Securities and Exchange Commission, or 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 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, 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 European Union 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 European Union member states. These requirements are provided in the national laws, industry codes, or professional codes of conduct, applicable in the European Union 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 health data in the European Union had previously been governed by the provisions of the Data Protection Directive, which has been replaced by the European Union General Data Protection Regulation, or GDPR. 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 provides goods or services to residents 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 data subjects 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 European Union 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. 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, especially with regard to clinical trial conduct. 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. 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 European Union member states, or if regulators assert we have failed to comply with these laws, it may lead to regulatory enforcement actions, which can result in monetary penalties of up to €20,000,000 or up to 4% of the total worldwide annual turnover of the preceding financial year, whichever is higher, and other administrative penalties. If any of these events were to occur, our business and financial results could be significantly disrupted and adversely affected.

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

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

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

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

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

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

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

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

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

General Risks Related to our Business

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. The loss of any of these persons' services may adversely impact the achievement of our research, development, financing and commercialization objectives. We currently do not have "key person" insurance on any of our employees.

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

Recruiting and retaining other qualified employees, consultants and advisors for our business, including scientific and technical personnel, also will be critical to our success. Competition for skilled personnel, including in mRNA research, 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 our results of operations.

We are exposed to the risk of fraud or other misconduct by our employees, principal investigators and consultants. 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.

Our employees may, from time to time, 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.

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 GDPR and relevant member state law in the European Union, and 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. We have since 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.

Our business continuity and disaster recovery plans may not adequately protect us from a serious disaster.

We recognize the need for, and are in the early stages of, developing disaster recovery, business continuity and document retention plans that would allow us to be operational despite casualties or unforeseen events impacting our corporate headquarters or distribution center. Without disaster recovery, business continuity and document retention plans, if we encounter difficulties or disasters with our manufacturing facilities or at our corporate headquarters, our critical systems, operations and information may not be restored in a timely manner, or at all, and this could have an adverse effect on our business.

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 we may face an even greater risk if we commercialize any product candidate that we may develop. 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;
- the inability to commercialize any product candidates that we may develop; and
- injury to our reputation and significant negative media attention.

We carry clinical trial insurance, including product liability insurance, which we believe to be sufficient in light of our current clinical programs; however, we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses due to liability. If and when we obtain marketing approval for product candidates, we intend to expand our insurance coverage to include the sale of commercial products; however, we may be unable to obtain product liability insurance on commercially reasonable terms or in adequate amounts. 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 of 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.

If we engage in future acquisitions, joint ventures or collaborations, this 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.

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.

Risks Related to the Merger

Our agreement with Neon Therapeutics, Inc., or Neon, under which we will acquire Neon in an all-stock transaction, which we refer to as the Merger, is subject to a number of conditions, some of which are outside of the parties' control, and, if these conditions are not satisfied, the Merger Agreement may be terminated and the Merger may not be completed.

The Agreement and Plan of Merger, by and among us, Neon and our wholly owned subsidiary, Endor Lights, dated as of January 15, 2020, or the Merger Agreement, contains a number of conditions that must be fulfilled to complete the Merger. These conditions include, among other customary conditions, (i) the approval and adoption of the Merger Agreement by the shareholders of Neon, (ii) the absence of an enacted or promulgated law by any federal or state governmental entity of competent jurisdiction that precludes, restrains, enjoins or prohibits the consummation of the Merger, (iii) the absence of any temporary restraining order, preliminary or permanent injunction or any other order preventing the consummation of the Merger and any law that makes illegal the consummation of the Merger, (iv) the SEC having declared effective a registration statement on Form F-4 to be filed with the SEC and the absence of a stop order suspending such effectiveness and the absence of any proceeding initiated for that purpose by the SEC, (v) the approval for listing on Nasdaq, subject to official notice of issuance, of our ADSs to be issued in the Merger, (vi) subject to certain materiality exceptions, the accuracy of certain representations and warranties of each of the parties contained in the Merger Agreement and the compliance by each party with the covenants contained in the Merger Agreement, and (vii) the absence of a material adverse effect with respect to each of the parties thereto.

The required satisfaction of the foregoing conditions could delay the completion of the Merger for a significant period of time or prevent it from occurring. Any delay in completing the Merger could cause the

combined company not to realize some or all of the benefits that the parties expect the combined company to achieve. Further, there can be no assurance that the conditions to the closing of the Merger will be satisfied or waived or that the Merger will be completed.

In addition, if the Merger is not completed by October 15, 2020 (subject to potential extensions), either we or Neon may choose to terminate the Merger Agreement. Either party may also elect to terminate the Merger Agreement in certain other circumstances, and the parties can mutually decide to terminate the Merger Agreement at any time prior to the closing of the Merger, before or after shareholder approval, as applicable.

Failure to complete the Merger could negatively affect our or Neon's share prices, future business and financial results.

If the Merger is not completed, the ongoing businesses of either or both parties may be adversely affected. Additionally, if the Merger is not completed and the Merger Agreement is terminated, in certain circumstances Neon may be required to pay us a termination fee. In addition, we and Neon have incurred and will continue to incur significant transaction expenses in connection with the Merger regardless of whether the Merger is completed. Furthermore, we or Neon may experience negative reactions from the financial markets, including negative impacts on our or their stock prices, or negative reactions from suppliers or other business partners, should the Merger not be completed.

The foregoing risks, or other risks arising in connection with the failure to consummate the Merger, including the diversion of management attention from conducting the business of the respective companies and pursuing other opportunities during the pendency of the Merger, may have a material adverse effect on our or Neon's business, operations, financial results and share and stock prices. Either party could also be subject to litigation related to any failure to consummate the Merger or any related action that could be brought to enforce a party's obligations under the Merger Agreement.

The exchange ratio is fixed and will not be adjusted in the event of any changes in either party's stock price.

Upon completion of the Merger, each share of Neon common stock outstanding immediately prior to the completion of the Merger will be converted into the right to receive 0.063 of an ADS of BioNTech without interest. This exchange ratio will not be adjusted for changes in the market price of either our ADSs or Neon common stock between the date the Merger Agreement was signed and completion of the Merger. As a result, changes in the price of our ADSs prior to the completion of the Merger will affect the value of our ADSs delivered upon completion of the Merger. An increase in the price of our ADSs will increase the value of the consideration we deliver. Similarly, a decrease in the price of Neon's shares will increase the premium that we pay per Neon share.

Stock price changes may result from a variety of factors, including, among others, general market and economic conditions, changes in our and Neon's respective businesses, operations and prospects, risks inherent in their respective businesses, changes in market assessments of the likelihood that the Merger will be completed and/or the value that may be generated by the Merger, and changes with respect to expectations regarding the timing of the Merger and regulatory considerations.

Litigation against us and/or Neon, or the members of the Neon Board of Directors, could prevent or delay the completion of the Merger or result in the payment of damages following completion of the Merger.

It is a condition to the Merger that no temporary restraining order, preliminary or permanent injunction or other order preventing the consummation of the Merger Agreement or the transactions contemplated thereby shall have been issued by any court of competent jurisdiction or other governmental authority of competent jurisdiction and remain in effect. No party to the Merger Agreement is aware of any lawsuit or proceeding specific to the Merger having been filed to date. If such a lawsuit or other proceeding is commenced and if in any such litigation or proceeding a plaintiff is successful in obtaining a restraining order or injunction prohibiting the consummation of the Merger Agreement or the transactions contemplated thereby, then the closing of the Merger

may be delayed or may never occur. Even if the Merger is permitted to occur, the parties may be required to pay damages, fees or expenses in respect of claims related to the Merger or the transactions contemplated thereby.

Uncertainty about the Merger may adversely affect the relationships of the parties with their respective suppliers and employees, whether or not the Merger is completed.

In response to the announcement of the Merger, existing or prospective suppliers of either party may:

- delay, defer or cease providing goods or services to us, Neon or the consolidated company;
- delay or defer other decisions concerning us, Neon or the consolidated company, or refuse to extend credit to us, Neon or the consolidated company; or
- otherwise seek to change the terms on which they do business with us, Neon or the consolidated company.

Any such delays or changes to terms could harm the business of each company or, if the Merger is completed, the consolidated company.

In addition, as a result of the Merger, current and prospective employees could experience uncertainty about their future with the consolidated company. These uncertainties may impair the consolidated company's ability to retain, recruit or motivate key management, technical and other personnel.

Until the completion of the Merger or the termination of the Merger Agreement in accordance with its terms, in consideration of the agreements made by the parties in the Merger Agreement, the parties are each prohibited from entering into certain transactions and taking certain actions that might otherwise be beneficial to the parties and their respective shareholders.

Until the Merger is completed, the Merger Agreement restricts us and Neon from taking specified actions without the consent of the other party, and requires Neon to operate in the ordinary course of business consistent with past practices. These restrictions may prevent Neon or us from making appropriate business changes or pursuing attractive business opportunities that may arise prior to the completion of the Merger.

Risks Related to the Consolidated Company

The consolidated company may not fully realize the anticipated benefits of the Merger or realize such benefits within the timing anticipated.

The parties entered into the Merger Agreement because each company believes that the Merger will be beneficial to each company and its respective shareholders. The consolidated company may not be able to achieve the anticipated long-term strategic benefits of the Merger within the timing anticipated or at all. For example, the benefits from the Merger will be partially offset by the costs incurred in completing the transaction. Any delays and challenges that may be encountered in completing the Merger or in the post-Merger process of consolidation could have an adverse effect on the business and results of operations of the consolidated company, and may affect the value of our ordinary shares and the ADSs representing our ordinary shares after the completion of the Merger.

The consolidated company will incur significant transaction-related costs in connection with the Merger.

We and Neon expect to incur significant costs associated with the Merger. The amount of these costs may not be determined as of the Effective Time and may be material to the financial position and results of operations of the consolidated company. We expect that the substantial majority of expenses resulting from the Merger will be comprised of transaction costs related to the Merger and employee-related costs. We and Neon will also incur fees and costs related to integration and systems consolidation. The elimination of duplicative costs may not offset incremental transaction-related and other integration costs in the near term.

We may have failed to discover undisclosed liabilities of Neon.

Our investigations and due diligence review of Neon may have failed to discover undisclosed liabilities of Neon. If Neon has undisclosed liabilities, we as a successor owner may be responsible for such undisclosed liabilities. We have tried to minimize our exposure to undisclosed liabilities, for example by obtaining certain protections under the Merger Agreement, including representations and warranties from Neon regarding undisclosed liabilities, which expire by their terms on the completion of the Merger. There can be no assurance that such provisions in the Merger Agreement will protect us against any undisclosed liabilities being discovered or provide an adequate remedy for any undisclosed liabilities that are discovered. Such undisclosed liabilities could have an adverse effect on our business and results of operations and our subsidiaries and may adversely affect the value of our ordinary shares and the ADSs representing our ordinary shares after the consummation of the Merger.

The consolidated company's goodwill or other intangible assets may become impaired, which could result in material non-cash charges to its results of operations.

The consolidated company will have a substantial amount of goodwill and other intangible assets resulting from the Merger. At least annually, or whenever events or changes in circumstances indicate a potential impairment in the carrying value as defined by IFRS, the consolidated company will evaluate this goodwill for impairment based on the recoverable value, being the higher of fair value less costs to sell and value in use, of the cash generating units to which goodwill has been allocated. Estimated fair values could change if there are changes in the consolidated company's capital structure, cost of debt, interest rates, capital expenditure levels, operating cash flows or market capitalization. Impairments of goodwill or other intangible assets could require material non-cash charges to the consolidated company's results of operations.

Future results of the consolidated company may differ materially from the unaudited pro forma financial information included in this prospectus.

The consolidated company's future results may be materially different from those shown in the unaudited pro forma financial information presented in this prospectus that show only a combination of our and Neon's historical results. We expect to incur significant costs associated with completing the Merger and combining the operations of the two companies, and the exact magnitude of these costs is not yet known. Furthermore, these costs may decrease capital that could be used by us for future income-earning investments.

The financial analyses and forecasts considered by us, Neon and our respective financial advisors may not be realized.

While the financial projections utilized by us, Neon and our respective advisors in connection with the Merger were prepared in good faith based on information available at the time of preparation, no assurances can be made regarding future events or that the assumptions made in preparing such projections will accurately reflect future conditions. In preparing such projections, our management and the management of and Neon made assumptions regarding, among other things, future economic, competitive, regulatory and financial market conditions and future business decisions that may not be realized and that are inherently subject to significant uncertainties and contingencies, including, among others, risks and uncertainties described or incorporated by reference in this section and in "Cautionary Statement Regarding Forward-Looking Statements," all of which are difficult to predict and many of which are beyond the control of us and Neon and will be beyond the control of the consolidated company. There can be no assurance that the underlying assumptions or projected results will be realized, and actual results will likely differ, and may differ materially, from such projections, which could result in a material adverse effect on the consolidated company's business, financial condition, results of operations and prospects.

Risks Related to Ownership of the ADSs and this Offering

The price of the ADSs may be volatile and fluctuate substantially, which could result in substantial losses for purchasers of the ADSs in this offering.

The market price of the ADSs is likely to be volatile. The stock market in general, and the market for biopharmaceutical companies in particular, has experienced extreme volatility that has often been unrelated to the operating performance of particular companies. As a result of this volatility, you may not be able to sell the ADSs at or above the public offering price. The market price for the ADSs may be influenced by many factors, including:

- results of clinical trials of our product candidates or those of our competitors;
- the success of competitive products or technologies;
- commencement or termination of collaborations;
- regulatory or legal developments in the United States and other countries;
- developments or disputes concerning patent applications, issued patents, or other intellectual property or proprietary rights;
- the recruitment or departure of key personnel;
- the level of expenses related to any of our product candidates or clinical development programs;
- the results of our efforts to discover, develop, acquire orin-license additional product candidates;
- actual or anticipated changes in estimates as to financial results, development timelines or recommendations by securities analysts;
- variations in our financial results or those of companies that are perceived to be similar to us;
- changes in the structure of healthcare payment systems;
- market conditions in the pharmaceutical and biotechnology sectors;
- general economic, industry and market conditions; and
- the numerous programs in our pipeline, the development of which could each generate news or significant adverse events that could impact financial results or recommendations by securities analysts.

If our quarterly or annual results fall below the expectations of investors or securities analysts, the price of the ADSs could decline substantially. Furthermore, any quarterly or annual fluctuations in our results may, in turn, cause the price of the ADSs to fluctuate substantially. We believe that period-to-period comparisons of our results are not necessarily meaningful and should not be relied upon as an indication of our future performance.

In the past, following periods of volatility in the market price of a company's securities, securities class-action litigation often has been instituted against that company. Such litigation, if instituted against us, could cause us to incur substantial costs to defend such claims and divert management's attention and resources, which could seriously harm our business, financial condition, results of operations and prospects.

We have incurred increased costs as a result of operating as a public company, and our management has been required to devote substantial time to new 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, and particularly after we are no longer an "emerging growth company" as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act, we incur significant legal, accounting and other expenses that we did not incur as a private company. In addition, the 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 have increased our legal and financial compliance costs and have made some activities more 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, concurrent with our second annual report on Form 20-F we are required to furnish a report by our management on our internal control over financial reporting, including the attestation report on internal control over financial reporting issued by our independent registered public accounting firm. However, while we remain an emerging growth company, we will not be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm in our annual filings with the SEC. To achieve compliance with Section 404 within the prescribed period, we have initiated the process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we will need to continue to dedicate internal resources, have engaged outside consultants, and are adopting 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 neither we nor our independent registered public accounting firm (once we are no longer an emerging growth company) will be able to conclude within the prescribed timeframe that our internal control over financial reporting is effective as required by Section 404. This could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our financial statements.

In July 2010, the Dodd-Frank Wall Street Reform and Consumer Protection Act, or the Dodd-Frank Act, was enacted. There are significant corporate governance and executive compensation related provisions in the Dodd-Frank Act that require the SEC to adopt additional rules and regulations in these areas such as "say on pay" and proxy access. Recent legislation permits emerging growth companies to implement many of these requirements over a longer period and up to five years from the pricing of this offering. We intend to take advantage of this new legislation but cannot guarantee that we will not be required to implement these requirements sooner than budgeted or planned and thereby incur unexpected expenses. 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.

We have identified a material weakness in our internal control over financial reporting and may identify additional material weaknesses in the future that may cause us to fail to meet our reporting obligations or result in material misstatements in our financial statements. If we fail to remediate our material weakness, 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 operated as a private company that was not required to comply with the obligations of a public company with respect to internal control over financial reporting. We have historically operated with limited accounting personnel and other resources with which to address our internal control over financial reporting.

In connection with the audit of our 2018 and 2017 financial statements in preparation for our initial public offering, we and our auditors identified a material weakness primarily related to (i) a lack of sufficient accounting and supervisory personnel who have the appropriate level of technical accounting experience and training, (ii) a lack of supervision over external consultants and (iii) a lack of consistent application of accounting processes and procedures by our accounting personnel. These deficiencies constitute a material weakness in our internal control over financial reporting in both design and operation. As a result of the material weakness, management failed to identify audit adjustments in various areas, including but not limited to revenue, capitalization of tangible and intangible assets, and share-based compensation. We have relied on the assistance of outside advisors with expertise in these matters to assist us in the preparation of our financial statements and in our compliance with SEC reporting obligations related to this offering, and we expect to continue to do so while we remediate this material weakness.

We are in the process of developing a remediation plan to address the material weakness; however, our overall control environment is still immature and may expose us to errors, losses or fraud. Our remediation plan includes the hiring of additional staff. Additionally, we intend to document and implement consistent accounting policies and procedures and provide additional training to our accounting and finance staff. While we are working to remediate the material weakness as quickly and efficiently as possible, we cannot at this time provide an estimate of the costs we expect to incur or the expected timeline in connection with implementing our remediation plan. These remediation measures may be time-consuming and costly, and might place significant demands on our financial and operational resources. If we are unable to successfully remediate this material weakness 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 that, when discovered in the future, could cause us to fail to meet our future reporting obligations and cause the price of our ADSs to decline.

We are an "emerging growth company" and the reduced disclosure requirements applicable to emerging growth companies may make our ordinary shares and the ADSs less attractive to investors.

We are an "emerging growth company" under the JOBS Act, and we will remain an emerging growth company until the earlier of:

- the last day of the first fiscal year in which our annual gross revenues exceed $1.07 billion;
- the date on which we have issued more than $1 billion in nonconvertible debt securities during the previous three years;

- the date on which we are deemed to be a large accelerated filer under the rules of the SEC, which means the first day of the year following the first year in which, as of the last business day of our most recently completed second fiscal quarter, the market value of our common equity held by non-affiliates exceeds $700 million; and
- the last day of the fiscal year following the fifth anniversary of the date of the completion of our initial public offering.

For so long as we remain an emerging growth company, we are permitted and intend to rely on exemptions from certain disclosure requirements that are applicable to public companies that are not emerging growth companies. These exemptions include:

- not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act;
- not being required to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements;
- reduced disclosure obligations regarding executive compensation; and
- exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and shareholder approval of any golden parachute payments not previously approved.

We may choose to take advantage of some, but not all, of the available exemptions. We have taken advantage of reduced reporting burdens in this prospectus. In particular, we have not included all of the executive compensation information that would be required if we were not an emerging growth company. We cannot predict whether investors will find the ADSs less attractive if we rely on certain or all of these exemptions. If some investors find the ADSs less attractive as a result, there may be a less active trading market for the ADSs and the price per ADS may be more volatile.

In addition, the JOBS Act provides that an emerging growth company may take advantage of an extended transition period for complying with new or revised accounting standards. This allows an emerging growth company to delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. Such provisions are only applicable under U.S. GAAP. As a result, we will adopt new or revised accounting standards on the relevant dates on which adoption of such standards is required or permitted by the IASB.

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 are 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 will file an annual report on Form20-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 and 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, 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 the Nasdaq applicable to listed U.S. companies, including an affirmative determination that all members of the audit committee are "independent," using more stringent criteria than those applicable to us as a foreign private issuer.

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

A significant portion of our total outstanding ordinary shares after this offering will be restricted from immediate resale but may be sold in the near future. 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.

Sales of a substantial number of ordinary shares or the ADSs could occur at any time, subject to certain restrictions described below. These sales, or the perception in the market that holders of a large number of shares

intend to sell shares, could reduce the market price of the ADSs. Based on the number of our ordinary shares outstanding as of September 30, 2019, we will have ordinary shares outstanding after this offering (or ordinary shares if the underwriters exercise their option to purchase additional ADSs in full).

In connection with our initial public offering, we, all of our directors and officers, and substantially all of our shareholders entered intolock-up agreements with the underwriters and/or are subject to market standoff agreements or other agreements with us under which we and they agreed, subject to specific exceptions, not to sell any of our shares for at least 180 days following the date of our initial public offering. In connection with this offering, we, all of our directors and officers and certain significant shareholders have entered into additional lock-up agreements with the underwriters under which we and they agreed, subject to specific exceptions, not to sell any of our shares for at least 90 days following the date of this prospectus. The remaining ordinary shares will be available for sale after this offering since they are not subject to contractual and legal restrictions on resale. Any or all of the shares subject to lock-up agreements may be released prior to the expiration of thelock-up period at the discretion of the lead underwriters for this offering. To the extent shares are released before the expiration of the lock-up period and these shares are sold into the market, the market price of the ADSs could decline.

We intend to file one or more registration statements on FormS-8 under the Securities Act of 1933, as amended, or the Securities Act, to register all ordinary shares issued or issuable under our equity plans. Any such Form S-8 registration statements will automatically become effective upon filing. Accordingly, shares registered under such registration statements will be available for sale in the open market following the expiration of the applicable lock-up period. See “Shares and ADSs Eligible for Future Sale” appearing elsewhere in this prospectus for a more detailed description of the restrictions on selling shares.

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 for you to sell the ADSs.

If you purchase ADSs in this offering, you will incur immediate and substantial dilution in the book value of your investment.

You will suffer immediate and substantial dilution in the net tangible book value of the ADSs if you purchase ADSs in this offering. Based on an assumed public offering price of $ per ADS, which was the last reported sale price of our ADSs on the Nasdaq Global Select Market on , 2020, after giving effect to this offering, purchasers of ADSs in this offering will experience immediate dilution in net tangible book value of $ per ADS. In addition, after giving effect to this offering, investors purchasing ADSs in this offering will contribute % of the total amount invested by shareholders since inception but will only own % of the ordinary shares outstanding. See “Dilution” for a more detailed description of the dilution to new investors in the offering.

Holders of the ADSs are not treated as shareholders of our company and will not have the same voting rights as our shareholders, which may affect the value of the ADSs.

By participating in this offering, you will become a holder of ADSs with underlying ordinary shares in a European stock corporation (*Societas Europaea*). Holders of ADSs are not treated as our shareholders unless they cancel the ADSs and withdraw the ordinary shares underlying the ADSs from the depositary, which is the holder of the ordinary shares underlying the ADSs. Holders of ADSs, therefore, do not have any rights as shareholders of our company, other than the rights that they have pursuant to the deposit agreement. As such, holders of ADSs will not be able to directly vote underlying ordinary shares. Holders of ADSs may instruct the depositary how to vote the ordinary shares underlying their ADSs. If we ask it to, the depositary will send out information about shareholder meetings and solicit voting instructions and will try to carry out voting

instructions it receives. However, we are not required to instruct the depositary to take action with respect to shareholder meetings. If we do not do so, holders of the ADSs can still send voting instructions to the depositary, and the depositary may try to carry out those instructions, but it is not required to do so. Holders of the ADSs may not become aware of shareholder meetings if the depositary does not send out information. Even if the depositary does solicit voting instructions, holders of ADSs may not receive the information in time. As a result of these factors, holders of ADSs may not be able to effectively exercise voting rights that they would have if they held our ordinary shares directly.

If we sell our ordinary shares or the ADSs in future financings, holders of ADSs may experience immediate dilution and, as a result, the price of the ADSs may decline.

We may from time to time issue additional ordinary shares or sell ADSs at a discount from the current trading price of our ordinary shares or the ADSs. As a result, holders of ADSs would experience further immediate dilution upon the purchase of any ordinary shares or ADSs sold at such discount. In addition, as opportunities present themselves, we may enter into financing or similar arrangements in the future, including the issuance of debt securities, ordinary shares or ADSs. If we issue ordinary shares or securities convertible or exchangeable into ordinary shares, such as ADSs, holders of the ADSs would experience additional dilution and, as a result, the price of the ADSs may decline.

Raising additional capital may cause dilution to our existing shareholders, restrict our operations, or require us to relinquish rights to our technologies or product candidates.

We may seek additional capital through a combination of public and private equity offerings, debt financings, collaborations and licensing arrangements. To the extent that we raise additional capital through the sale of equity securities, including securities convertible or exchangeable into ordinary shares, your ownership interest will be diluted and the terms may include liquidation or other preferences that adversely affect your rights as a holder of ADSs. The incurrence of indebtedness would result in increased fixed payment obligations and could involve restrictive covenants, such as limitations on our ability to incur additional debt, limitations on our ability to acquire or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. If we raise additional funds through collaborations and licensing arrangements with third parties or through asset sales, we may have to relinquish valuable rights to our technologies or product candidates, or grant licenses on terms unfavorable to us.

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, 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.

ADS holders will not be entitled to exercise or sell such rights unless we register the rights and the securities to which the rights relate under the Securities Act or an exemption from the registration requirements is available. In addition, the deposit agreement provides that the depositary need not make rights available to you unless the distribution to ADS holders of both the rights and any related securities are either registered under the Securities Act or exempted from registration under the Securities Act. We are under no obligation to file a registration statement with respect to any such rights or securities or to endeavor to cause such a registration statement to be declared effective. Moreover, we may not be able to establish an exemption from registration under the Securities Act. Accordingly, ADS holders may be unable to participate in our rights offerings and may experience dilution in their holdings. 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.

U.S. holders of ADSs may suffer adverse tax consequences if we are characterized as a passive foreign investment company.

A non-U.S. corporation will be classified as a passive foreign investment company, or PFIC, for U.S. federal income tax purposes for any taxable year, if either (i) 75% or more of its gross income for such year consists of certain types of "passive" income or (ii) 50% or more of the value of its assets (determined on the basis of a quarterly average) during such year produce or are held for the production of passive income. Passive income generally includes dividends, interest, royalties, rents, annuities, net gains from the sale or exchange of property producing such income and net foreign currency gains. In addition, a non-U.S. corporation will be treated as owning its proportionate share of the assets and earning its proportionate share of the income of any other corporation in which it owns, directly or indirectly, more than 25% (by value) of the stock. Based on the current composition of our income and assets and the value of our assets, including goodwill, which is based on the current market price of the ADSs, we do not expect to be treated as a PFIC for our current taxable year or in any future taxable year. However, because PFIC status is based on our income, assets and activities for the entire taxable year, which we expect may vary substantially over time, it is not possible to determine whether we will be characterized as a PFIC for any taxable year until after the close of the taxable year. Moreover, we must determine our PFIC status annually based on tests that are factual in nature, and our status in future years will depend on our income, assets and activities in each of those years. There can be no assurance that we will not be considered a PFIC for any taxable year. If we were to be or become a PFIC for any taxable year during which a U.S. holder (defined below in "Taxation—Material United States Federal Income Tax Considerations") holds ADSs, certain adverse U.S. federal income tax consequences could apply to such U.S. holder. See "Taxation—Material United States Federal Income Tax Considerations—Passive Foreign Investment Company Considerations."

The interpretation of the treatment of ADSs by the German tax authorities is subject to change.

The specific treatment of ADSs under German tax law is based on administrative provisions by the fiscal authorities, which are not codified law and are subject to change. Tax authorities may modify their interpretation and the current treatment of ADSs may change. According to the circular issued by the German Federal Ministry of Finance (*BMF-Schreiben*), dated May 21, 2019, (reference number IV C 1 – S 1980-1/16/10010 :001, ADSs are not treated as capital participation (*Kapitalbeteiligung*) within the meaning of Section 2 Para. 8 of the Investment Tax Code (*Investmentsteuergesetz*). Such interpretation by the fiscal authorities may have adverse effects on the taxation of investors.

U.S. investors may have difficulty enforcing civil liabilities against our company and members of our Supervisory Board and Management Board and the experts named in this prospectus.

We are incorporated under the laws of Germany as a European stock corporation (*Societas Europaea*) pursuant to the SE Regulation. The majority of our assets are located outside the United States and all of the members of our Management Board and Supervisory Board reside outside of the United States. As a result, it may not be possible for investors to effect service of process within the United States upon such persons or to enforce against them or us in U.S. courts' judgments predicated upon the civil liability provisions of the federal securities laws of the United States. In addition, awards of punitive damages in actions brought in the United States or elsewhere may be unenforceable in Germany. An award for monetary damages under the U.S. securities laws would be considered punitive if it does not seek to compensate the claimant for loss or damage suffered and is intended to punish the defendant. The enforceability of any judgment in Germany will depend on the particular facts of the case as well as the laws and treaties in effect at the time. There is currently no treaty between the United States and Germany providing for reciprocal recognition and enforceability of judgments rendered in connection with civil and commercial disputes and, accordingly, a final judgment rendered by a U.S. court based

on civil liability would, except where explicitly ruled enforceable by a competent German court, not be enforceable in Germany as such. However, a U.S. court's judgment may carry evidentiary value in any proceedings for civil liability brought in the German courts. Litigation in Germany is also subject to rules of procedure that differ from the U.S. rules, including with respect to the taking and admissibility of evidence, the conduct of the proceedings and the allocation of costs. Proceedings in Germany would have to be conducted in the German language, and all documents submitted to the court would, in principle, have to be translated into German. For these reasons, it may be difficult for a U.S. investor to bring an original action in a German court predicated upon the civil liability provisions of the U.S. federal securities laws against us or any members of our Management or Supervisory Boards.

German and other non-U.S. courts may refuse to hear a U.S. securities law claim because such courts may not be the most appropriate forums in which to bring such a claim. Even if a non-U.S. court agrees to hear a claim, it may determine that the law of the jurisdiction in which the court resides, and not U.S. law, is applicable to the claim. Further, if U.S. law is found to be applicable, the content of applicable U.S. law must be proved as fact, which can be a time-consuming and costly process, and certain matters of procedure would still be governed by the law of the jurisdiction in which the foreign court resides.

The rights of shareholders in a stock corporation subject to German law differ in material respects from the rights of shareholders of corporations incorporated in the United States.

We are a European stock corporation (*Societas Europaea*) with our registered office in Germany. Our corporate affairs are governed by the laws governing stock corporations and European stock corporations incorporated in Germany, the SE Regulation and our articles of association. The rights of shareholders may be different from the rights and obligations of shareholders in companies governed by the laws of U.S. jurisdictions. Among other differences in shareholder rights, under German law, certain important resolutions, including, for example, capital decreases, measures under the German Transformation Act (*Umwandlungsgesetz*), such as mergers, conversions and spin-offs and the dissolution of the German stock corporation apart from insolvency and certain other proceedings, require the vote of a 75% majority of the capital present or represented at the relevant shareholders' meeting. Therefore, the holder or holders of a blocking minority of more than 25% or, depending on the attendance level at the shareholders' meeting, the holder or holders of a smaller percentage of the shares in a German stock corporation may be able to block any such votes, possibly to our detriment or the detriment of other shareholders.

As a general rule under German law, in the case of atwo-tier European stock corporation a shareholder has no direct recourse against the members of the management board and the supervisory board, in the event that it is alleged that they have breached their duty of loyalty or duty of care to the corporation. Apart from insolvency or other special circumstances, only the European stock corporation itself has the right to claim damages from members of the management and supervisory boards. A European stock corporation may waive or settle these damages claims only if at least three years have passed and the shareholders approve the waiver or settlement at the shareholders' meeting with a simple majority of the votes cast, provided that a minority holding, in the aggregate, 10% or more of the European stock corporation's share capital does not have its opposition formally noted in the minutes.

In addition, the responsibilities of members of our Management Board and Supervisory Board may differ from the duties of directors of U.S. corporations. For example, in the performance of their duties, our Management Board and Supervisory Board may take into account a broad range of considerations, including our interests, the interests of our shareholders, employees, creditors and, to a limited extent, the general public. It is possible that some of these parties will have interests that are different from, or in addition to, your interests as a holder of ADSs.

For more information, we have provided summaries of relevant German corporation law and of our articles of association under "Management" and "Description of Share Capital and Articles of Association (*Satzung*)."

An active trading market for the ADSs may not develop.

Prior to our initial public offering in October 2019, there was no public market for ADSs representing our ordinary shares. Although the ADSs are listed on the Nasdaq Global Select Market, an active trading market for the ADSs may never develop or be sustained. If an active market for the ADSs does not develop, it may be difficult for you to sell ADSs you purchase in this offering without depressing the market price for the ADSs, or at all.

If securities analysts publish negative evaluations of us, the price of the ADSs could decline.

The trading market for the ADSs will rely, in part, on the research and reports that industry or financial analysts publish about us or our business. If one or more of the analysts covering our business downgrade their evaluations of us, the price of the ADSs could decline. If one or more of these analysts cease to cover the ADSs, we could lose visibility in the market for the ADSs, which in turn could cause price of the ADSs to decline.

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 approximately 83.40% of our ordinary shares and, upon closing of this offering, assuming no exercise of the underwriters' option to purchase additional ADSs from us, that same group will beneficially own approximately % of our outstanding ordinary shares. Therefore, even after this offering, these shareholders will have the ability to influence us through their ownership positions. For example, these shareholders, acting together, may be able to exert significant influence over matters such as elections of directors, amendments of our organizational documents, or approval of any merger, sale of assets or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our ordinary shares that you may believe are in your best interest as one of our shareholders.

We have broad discretion in the use of our cash, cash equivalents and investments, including the net proceeds from this offering, and we may not use them effectively.

Our management will have broad discretion in the application of our cash, cash equivalents and investments, including the net proceeds from this offering, and could spend the proceeds in ways that do not improve our results of operations or enhance the value of our ordinary shares. The failure by our management to apply these funds effectively could result in financial losses that could have a material adverse impact on our business, cause the price of the ADSs to decline, and delay the development of our product candidates. Pending their use, we may invest our cash, cash equivalents and investments, including the net proceeds from this offering, in a manner that does not produce income or that loses value. See "Use of Proceeds" for more information.

Because we do not currently pay cash dividends on our ordinary shares and do not anticipate doing so in the foreseeable future, capital appreciation, if any, will be the sole source of gain on investments in the ADSs.

There is no plan to declare or pay cash dividends on our ordinary shares. The intention is to retain all future earnings, if any, to finance the growth and development of the business. Additionally, the terms of any future debt agreements may preclude dividend payments. Our ability to pay dividends is also limited under the terms of the investment agreement we have entered into with BMGF. As a result, capital appreciation, if any, on the ADSs will be the sole source of gain for the foreseeable future.

If we were to pay dividends, holders of the ADSs may be unable to claim tax credits with respect to, or tax refunds to reduce German withholding tax applicable to, the payment of such dividends, or such dividends may effectively be taxed twice.

As a German tax resident company, if we were to pay dividends, such dividends will be subject to German withholding tax. Currently, the applicable German withholding tax rate is 26.375% of the gross dividend. This

German tax can be reduced to the applicable U.S.-Germany income tax treaty, or Treaty, rate, which is generally 15%, if the applicable taxpayer is eligible for such Treaty rate and files an application containing a specific German tax certificate with the German Federal Central Tax Office (*Bundeszentralamt für Steuern*). If such a tax certificate cannot be delivered to the ADS holder due to applicable settlement mechanics or lack of information regarding the ADS holder, holders of the ADSs may be unable to benefit from the double tax treaty relief (including "Eligible U.S. Holders" as defined under the Treaty) and may be unable to file for a credit of such withholding tax in its jurisdiction of residence. Further, the payment made to the ADS holder equal to the net dividend may, under the tax law applicable to the ADS holder, qualify as taxable income that is in turn subject to withholding, which could mean that a dividend is effectively taxed twice. There can be no guarantee that the information delivery requirement can be satisfied in all cases, which could result in adverse tax consequences for affected ADS holders. ADS holders should note that the applicable interpretation circular (*Besteuerung von American Depositary Receipts (ADR) auf inländische Aktien*) issued by the German Federal Ministry of Finance *(Bundesministerium der Finanzen*), dated May 24, 2013 (reference number IV C 1-S2204/12/10003), as amended by the circular dated December 18, 2018 (reference number IV C 1-S2204/12/10003), or the ADR Tax Circular, is not binding on German courts, and there is no certainty as to whether a German tax court will follow the ADR Tax Circular in determining the German tax treatment of the ADSs. In addition, the ADR Tax Circular does not include details on how an ADR program should be designed. If the ADSs were determined not to fall within the scope of application of the ADR Tax Circular, or a German tax court did not follow the ADR Tax Circular, and profit distributions made with respect to the ADSs were not treated as a dividend for German tax purposes, a holder of the ADSs would not be entitled to a refund of any taxes withheld on the dividends under German tax law and profit distributions made with respect to the ADSs may be effectively taxed twice.

We could be subject to securities class action litigation.

In the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because biopharmaceutical companies have experienced significant price volatility in recent years. If we face such litigation, it could result in substantial costs and a diversion of management's attention and resources, which could harm our business.

ADS holders may not be entitled to a jury trial with respect to claims arising under the deposit agreement, which could result in less favorable outcomes to the plaintiffs in an action of that kind.

The deposit agreement governing the ADSs representing our ordinary shares provides that, to the fullest 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 ordinary shares, the ADSs or the deposit agreement, including any claim under 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 based on the facts and circumstances of that case in accordance with the applicable state and federal law. To our knowledge, the enforceability of a contractual pre-dispute jury trial waiver in connection with claims arising under the federal securities laws has not been finally adjudicated by the United States Supreme Court. However, we believe that a contractual pre-dispute jury trial waiver provision is generally enforceable, including under the laws of the State of New York, which govern the deposit agreement, by a federal or state court in the City of New York, which has non-exclusive jurisdiction over matters arising under the deposit agreement. In determining whether to enforce a contractual pre-dispute jury trial waiver provision, courts will generally consider whether a party knowingly, intelligently and voluntarily waived the right to a jury trial. We believe that this is the case with respect to the deposit agreement and the ADSs. It is advisable that you consult legal counsel regarding the jury waiver provision before entering into the deposit agreement.

If you or any other ADS holders bring a claim against us or the depositary in connection with matters arising under the deposit agreement or relating to the ADSs, including claims under federal securities laws, you may not be entitled to a jury trial with respect to such claims, which may have the effect of limiting and discouraging

lawsuits against us or the depositary. If a lawsuit is brought against us or the depositary under the deposit agreement, it may be heard only by a judge or justice of the applicable trial court, which would be conducted according to different civil procedures and may result in different outcomes than a trial by jury would have had, including results that could be less favorable to the plaintiffs in that action.

Nevertheless, if this jury trial waiver provision is not permitted by applicable law, an action could proceed under the terms of the deposit agreement with a jury trial.

No condition, stipulation or provision of the deposit agreement or the ADSs serves as a waiver by any ADS holder or by us or the depositary of compliance with any substantive provision of the U.S. federal securities laws and the rules and regulations promulgated thereunder.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus 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. Many of the forward-looking statements contained in this prospectus can be identified by the use of forward-looking words such as "anticipate," "believe," "could," "estimate," "expect," "intend," "may," "might," "plan," "potential," "should," "target," "would" and other similar expressions that are predictions of or indicate future events and future trends, although not all forward-looking statements contain these identifying words.

Forward-looking statements are based on our management's beliefs and assumptions and on information currently available to our management. Such statements are subject to risks and uncertainties, and actual results may differ materially from those expressed or implied in the forward-looking statements due to a variety of factors, including, but not limited to, those identified in the section titled "Risk Factors" in this prospectus. These risks and uncertainties include factors relating to:

- 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;
- the timing of and our ability to obtain and maintain regulatory approval for our product candidates;
- our ability to identify research opportunities and discover and develop investigational medicines;
- the ability and willingness of our third-party collaborators to continue research and development activities relating to our development candidates and investigational medicines;
- our expectations regarding the size of the patient populations for our product candidates, if approved for commercial use;
- our estimates of our expenses, ongoing losses, 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, and the scope of such protection;
- the development of and projections relating to our competitors or our industry;
- our ability to commercialize our product candidates, if approved;
- the pricing and reimbursement of our investigational medicines, if approved;
- the rate and degree of market acceptance of our investigational medicines;
- the amount of and our ability to use net operating losses and research and development credits to offset future taxable income;
- our ability to manage our development and expansion;
- regulatory developments in the United States and foreign countries;
- our ability to manufacture our product candidates with advantages in turnaround times or manufacturing cost;
- our ability to implement, maintain and improve effective internal controls;
- the ability to satisfy the conditions to the merger of Endor Lights, Inc., our wholly owned subsidiary, with Neon Therapeutics, Inc., in an all-stock transaction, or the Merger, including the ability to obtain the shareholder approval, on the proposed terms and timeframe;

- the ability to realize the anticipated benefits of transactions related to the Merger and other acquisitions, restructuring activities, including in connection with the Merger, or other initiatives in a timely manner or at all;
- the risk of unanticipated costs, liabilities or delays relating to the Merger, including the outcome of any legal proceedings relating to the Merger;
- risks relating to expectations regarding the capitalization, resources and ownership of the consolidated company;
- our use of the proceeds from this offering; and
- our expectations regarding the time during which we will be an emerging growth company under the JOBS Act and a foreign private issuer.

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 prospectus speak only as of the date of this prospectus, 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.

USE OF PROCEEDS

We estimate that the net proceeds to us from this offering will be approximately $ million (€ million) (or approximately $ million (€ million) if the underwriters exercise in full their options to purchase an additional ADSs), assuming a public offering price of $ per ADS, which was the last reported sale price of the ADSs on the Nasdaq Global Select Market on , 2020, and after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

Each $1.00 increase (decrease) in the assumed public offering price of $ per ADS, which was the last reported sale price of our ADSs on the Nasdaq Global Select Market on , 2020, would increase (decrease) the net proceeds to us from this offering by approximately $ million (€ million), assuming the number of ADSs offered by us, as set forth on the cover page of this prospectus, remains the same, and after deducting underwriting discounts and commissions and estimated offering expenses payable by us. We may also increase or decrease the number of ADSs we are offering. An increase (decrease) of 1,000,000 in the number of ADSs offered by us would increase (decrease) the net proceeds to us from this offering by approximately $ million (€ million), assuming no change in the assumed public offering price and after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

We currently intend to use the net proceeds from this offering as follows:

- approximately $ million to complete our ongoing and currently planned clinical trials for our FixVac product candidates BNT111, BNT112, BNT113, BNT114, BNT115 and our targeted cancer antibody, MVT-5873 (BNT321), as well as to fund our portion of the research and development expenses for each of the following: RO7198457 (BNT122), which is being developed in collaboration with Genentech, SAR441000 (BNT131), which is being developed in collaboration with Sanofi, and GEN1046 (BNT311) and GEN1042 (BNT312), which are being developed in collaboration with Genmab;
- approximately $ million to advance additional product candidates through Phase 1 clinical trials, including product candidates from our CAR T, RiboMabs, RiboCytokines and TCR platforms in oncology, and our infectious disease immunotherapy and rare disease protein replacement therapy platforms outside oncology;
- approximately $ million to advance additional preclinical product candidates, develop additional product candidates leveraging our current therapeutic platforms and fund the further development of our core technologies; and
- approximately $ million to fund the further expansion of our manufacturing and laboratory capacity and the continued development of our infrastructure.

We expect to use the remainder of any net proceeds from this offering, as well as our existing cash and cash equivalents, for general corporate purposes. We may also use a portion of the net proceeds to in-license or acquire or invest in complementary technologies, products, businesses or assets, either alone or together with a collaborator. However, we have no current plans, commitments or obligations to do so.

Our expected use of net proceeds from this offering represents our current intentions based on our present plans and business condition, which could change as our plans and business conditions evolve. The amounts and timing of our actual use of net proceeds will vary depending on numerous factors, including the progress of our clinical development of our product candidates, including our ongoing clinical trials. As a result, we cannot predict with certainty all of the particular uses for the net proceeds to be received upon the closing of this offering or the amounts that we will actually spend on the uses set forth above. Our management will have broad discretion in the application of the net proceeds from this offering.

We expect that we will need to raise significant additional funds beyond this offering in order to continue to advance our pipeline. In particular, we will need additional funds in order to advance our product candidates

through Phase 3 clinical trials and to potential commercialization. We may seek to raise capital through public or private equity or debt financing, government or other third-party grants or funding, sales of assets, marketing and distribution arrangements, other collaborations or a combination of these approaches.

Based on our planned use of the net proceeds of this offering and our existing cash and cash equivalents, we estimate that such funds will be sufficient to enable us to fund our operating expenses and capital expenditure requirements through at least the next months. We have based this estimate on assumptions that may prove to be incorrect, and we could use our available capital resources sooner than we currently expect.

Pending our use of the net proceeds from this offering, we plan to invest the net proceeds in short- and intermediate-term interest-bearing financial instruments.

DIVIDEND POLICY

We have never paid or declared any cash dividends on our ordinary shares, and we do not anticipate paying any cash dividends on our ordinary shares in the foreseeable future. We intend to retain all available funds and any future earnings to fund the development and expansion of our business. In addition, our ability to pay cash dividends is also limited in certain circumstances under the terms of an agreement we have entered into with BMGF. All of the shares represented by the ADSs offered by this prospectus will generally have the same dividend rights as all of our other outstanding shares.

Under German law, we may pay dividends only from the distributable profit (*Bilanzgewinn*) reflected in our unconsolidated financial statements (as opposed to the consolidated financial statements for us and our subsidiaries) prepared in accordance with the principles set forth in the German Commercial Code (*Handelsgesetzbuch*) and adopted by our management board (*Vorstand*) and the supervisory board (*Aufsichtsrat*), or, as the case may be, by our shareholders in a shareholders' meeting. See "Description of Share Capital and Articles of Association (*Satzung*)," which explains in more detail the procedures we must follow and the German law provisions that determine whether we are entitled to declare a dividend.

CAPITALIZATION

The table below sets forth our cash and cash equivalents and our total capitalization as of September 30, 2019:

- on an actual basis;
- on a pro forma basis to give effect to the issuance of 10,517,408 of our ordinary shares for net proceeds of €135.4 million ($149.1 million)(1) in connection with our initial public offering; and
- on a pro forma as adjusted basis to give effect to our issuance and the sale of ADSs by us in this offering, assuming a public offering price of $ per ADS, which was the last reported sale price of our ADSs on the Nasdaq Global Select Market on , 2020, and after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

Our capitalization following the offering will be adjusted based on the actual offering price and other terms of the offering determined at pricing, including the amount by which actual offering expenses are higher or lower than estimated. You should read this table in conjunction with our consolidated financial statements and related notes included in this prospectus as well as the sections titled "Use of Proceeds," "Selected Consolidated Financial Data" and "Management's Discussion and Analysis of Financial Condition and Results of Operations."

	As of September 30, 2019		
	Actual	Pro Forma	Pro Forma As Adjusted(2)(3)
		(unaudited)	
(in thousands except share and per share data)			
Cash and cash equivalents	€ 463,308	€ 598,688	€
Total debt	13,600	13,600	
Equity			
Ordinary shares, no par value per share: 216,262,336 shares, actual; 226,779,744 shares, pro forma; shares, pro forma as adjusted share capital	221,787	232,304	
Capital reserve	569,751	694,614	
Treasury shares	(5,525)	(5,525)	
Accumulated losses	(366,604)	(366,604)	
Other reserves	(3,004)	(3,004)	
Total equity	416,405	551,785	
Total capitalization	€ 430,005	€ 565,385	

(1) These proceeds were received in a combination of Euros and U.S. dollars. We have presented this information in Euros, reflecting the conversion of the U.S. dollar amount into a Euro amount using the exchange rates in effect at the times we transferred these proceeds to our Euro-denominated bank account.

(2) Each $1.00 increase (decrease) in the assumed public offering price of $ per ADS, which was the last reported sale price of the ADSs on the Nasdaq Global Select Market on , 2020, would increase (decrease) each of cash and cash equivalents, capital reserve, total equity and total capitalization by approximately € million, assuming the number of ADSs offered by us, as set forth on the cover page of this prospectus, remains the same, and after deducting underwriting discounts and commissions and estimated offering expenses payable by us. We may also increase or decrease the number of ADSs we are offering. An increase (decrease) of 1,000,000 in the number of ADSs offered by us would increase (decrease) each of cash and cash equivalents, total equity and total capitalization by approximately € million, assuming no change in the assumed public offering price and after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

(3) Excludes the anticipated effects of the Merger. See "Unaudited Pro Forma Condensed Combined Financial Information."

The number of our ordinary shares issued and outstanding actual, pro forma and pro forma as-adjusted is based on 216,262,336 ordinary shares outstanding as of September 30, 2019 and excludes:

- the anticipated effects of the Merger, see "Unaudited Pro Forma Condensed Combined Financial Information";
- 11,852,784 ordinary shares issuable upon the exercise of options outstanding as of September 30, 2019; and
- 10,022,022 ordinary shares available for future issuance under our Employee Stock Ownership Plan or any future share option plan.

DILUTION

If you invest in the ADSs in this offering, your interest will be diluted immediately to the extent of the difference between the public offering price per ADS and our as adjusted net tangible book value per ADS after completion of the offering.

Net tangible book value per ADS represents the amount of our total assets less our total liabilities, excluding intangible assets, divided by the number of our ordinary shares outstanding as of September 30, 2019, (one ADS represents one ordinary share). As of September 30, 2019, we had a historical net tangible book value of €321.9 million ($ million), corresponding to a net tangible book value per ordinary share of €1.49 ($) (equivalent to $ per ADS). Our pro forma net tangible book value as of September 30, 2019 was €457.3 million ($ million), corresponding to a pro forma net tangible book value per ordinary share of €2.02 ($) (equivalent to $ per ADS), based on the total number of shares of our common stock outstanding as of September 30, 2019, and after giving effect to the issuance of 10,517,408 of our ordinary shares for net proceeds of €135.4 million ($149.1 million)(1) in connection with our initial public offering.

After giving effect to the issuance and sale of ADSs in this offering at an assumed offering price of $ per ADS, which was the last reported sale price of our ADSs on the Nasdaq Global Select Market on , 2020, and after deducting underwriting discounts and commissions and estimated offering expenses payable by us, our pro forma as adjusted net tangible book value as of September 30, 2019 would have been € million ($ million), corresponding to a net tangible book value per ordinary share of € ($) (equivalent to $ per ADS). This represents an immediate increase in net tangible book value of € ($) per ordinary share (equivalent to $ per ADS) to existing shareholders and immediate dilution of $ per ADS to new investors purchasing ADSs in this offering. Dilution per ADS to new investors is determined by subtracting our pro forma as adjusted net tangible book value per ADS from the assumed public offering price per ADS paid by new investors.

The following table illustrates this dilution on a per-ADS basis:

Assumed public offering price per ADS		$
Historical net tangible book value per ADS as of September 30, 2019	$	
Pro forma net tangible book value per ADS as of September 30, 2019	$	
Increase in net tangible book value per ADS attributable to new investors participating in this offering	$	
Pro forma as adjusted net tangible book value per ADS after this offering		$
Dilution per ADS to new investors participating in this offering		$

(1) These proceeds were received in a combination of Euros and U.S. dollars. We have presented this information in Euros, reflecting the conversion of the U.S. dollar amount into a Euro amount using the exchange rates in effect at the times we transferred these proceeds to our Euro-denominated bank account.

Each $1.00 increase (decrease) in the assumed offering price of $ per ADS, which was the last reported sale price of our ADSs on the Nasdaq Global Select Market on , 2020, would increase (decrease) our pro forma as adjusted net tangible book value as of September 30, 2019 by $ ($) per ADS, and would increase (decrease) dilution to new investors in this offering by $ ($) per ADS, assuming that the number of ADSs offered by us, as set forth on the cover page of this prospectus, remains the same, and after deducting underwriting discounts and commissions and estimated offering expenses payable by us. An increase (decrease) of 1,000,000 in the number of ADSs offered by us would increase (decrease) our pro forma as adjusted net tangible book value after this offering by $ ($) per ADS, and would decrease (increase) dilution to investors in this offering by approximately $ ($) per ADS, assuming no change in the assumed public offering price per ADS and after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

If the underwriters exercise in full their option to purchase additional ADSs, our pro forma as adjusted net tangible book value per ADS would be $, representing an immediate increase in pro forma as adjusted net tangible book value to existing shareholders of $ per ADS and immediate dilution of $ per ADS to new investors, assuming no change in the assumed public offering price per ADS and after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

The as adjusted information is illustrative only, and we will adjust this information based on the actual public offering price and other terms of this offering determined at pricing.

The following table sets forth, on a pro forma as adjusted basis as of September 30, 2019, after giving effect the issuance of 10,517,408 of our ordinary shares for net proceeds of €135.4 million ($149.1 million)(1) in connection with our initial public offering, the number of ordinary shares owned by existing shareholders and to be owned by new investors purchasing ADSs in this offering, the total consideration paid to us, the average price per ordinary share paid by our existing shareholders and the average price per ADS to be paid by new investors purchasing ADSs in this offering. The calculation below is based on an assumed public offering price of $ per ADS, which was the last reported sale price of the ADSs on the Nasdaq Global Select Market on , 2020, before deducting underwriting discounts and commissions and estimated offering expenses payable by us:

	Ordinary Shares Purchased		Total Consideration		Average Price Per Share	Average Price Per ADS
	Number	Percent	Amount	Percent		
Existing shareholders		%	$	%	$	$
New investors						
Total		100%		100%	$	$

(1) These proceeds were received in a combination of Euros and U.S. dollars. We have presented this information in Euros, reflecting the conversion of the U.S. dollar amount into a Euro amount using the exchange rates in effect at the times we transferred these proceeds to our Euro-denominated bank account.

Each $1.00 increase (decrease) in the assumed public offering price of $ per ADS, which was the last reported sale price of our ADSs on the Nasdaq Global Select Market on , 2020, would increase (decrease) the total consideration paid by new investors by $ million and increase (decrease) the percentage of total consideration paid by new investors by approximately %, assuming that the number of ADSs offered by us, as set forth on the cover page of this prospectus, remains the same, and before deducting underwriting discounts and commissions and estimated offering expenses payable by us. An increase (decrease) of 1,000,000 in the number of ADSs offered by us would increase (decrease) the total consideration paid by investors participating in this offering approximately $ million, and increase (decrease) the percentage of total consideration paid by new investors by approximately %, assuming no change in the assumed public offering price and before deducting underwriting discounts and commissions and estimated offering expenses payable by us.

The number of our ordinary shares issued and outstanding actual, pro forma and pro forma as-adjusted is based on 216,262,336 ordinary shares outstanding as of September 30, 2019 and excludes:

- the anticipated effects of the Merger, see “Unaudited Pro Forma Condensed Combined Financial Information”.
- 11,852,784 ordinary shares issuable upon the exercise of options outstanding as of September 30, 2019; and
- 10,022,022 ordinary shares available for future issuance under our Employee Stock Ownership Plan or any future share option plan.

We may choose to raise additional capital due to market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans. To the extent that additional capital is raised through the sale of equity or convertible debt securities, the issuance of such securities may result in further dilution to our shareholders.

SELECTED CONSOLIDATED FINANCIAL DATA

The following tables present selected consolidated financial data as of and for the years ended December 31, 2018 and 2017, as of September 30, 2019 and for the nine months ended September 30, 2019 and 2018. We derived the selected consolidated statements of operations for the years ended December 31, 2018 and 2017 and the selected consolidated statement of financial position data as of December 31, 2018 from our audited consolidated financial statements included elsewhere in this prospectus. The selected consolidated statements of operations data for the nine months ended September 30, 2019 and 2018 and the selected consolidated statement of financial position data as of September 30, 2019 have been derived from our unaudited interim condensed consolidated financial statements included elsewhere in this prospectus and have been prepared on the same basis as the audited financial statements. In the opinion of management, the unaudited interim data reflects all adjustments necessary for a fair presentation of the financial information in those statements. We present our consolidated financial statements in Euros and in accordance with IFRS as issued by the IASB.

The selected consolidated financial data below should be read together with our consolidated financial statements and related notes, and our unaudited interim condensed consolidated financial statements included elsewhere in this prospectus, as well as the sections of this prospectus titled "Capitalization" and "Management's Discussion and Analysis of Financial Condition and Results of Operations." Our historical results for any prior period are not necessarily indicative of results to be expected in any future period, and the results for the nine months ended September 30, 2019 are not necessarily indicative of the results to be expected for the full year ended December 31, 2019.

	For the Nine Months Ended September 30,		For the Years Ended December 31,	
	2019	2018	2018	2017
(in thousands except per share data)	(unaudited)			
Consolidated statement of operations:				
Revenues from contracts with customers	€ 80,601	€ 63,796	€ 127,575	€ 61,598
Cost of sales	(12,925)	(9,215)	(13,690)	(9,318)
Gross profit	67,676	54,581	113,885	52,280
Research and development expenses	(161,039)	(91,244)	(143,040)	(85,496)
Sales and marketing expenses	(1,908)	(1,984)	(3,041)	(6,603)
General and administrative expenses	(34,481)	(16,222)	(26,334)	(23,520)
Other operating income	1,340	4,043	5,396	2,349
Other operating expenses	(163)	(631)	(720)	(288)
Operating loss	(128,575)	(51,457)	(53,854)	(61,277)
Finance income	9,170	6,644	8,046	2,133
Finance expense	(233)	(12)	(48)	(26,007)
Interest expense related to lease liability	(1,283)	(1,297)	(1,721)	(676)
Share of loss of equity method investees	—	(84)	(84)	(78)
Loss before tax	(120,921)	(46,206)	(47,662)	(85,905)
Income taxes	(28)	(583)	(600)	(45)
Loss for the period	€ (120,949)	€ (46,789)	€ (48,262)	€(85,950)
Loss attributable to non-controlling interests	(116)	(122)	(243)	(297)
Loss attributable to equity holders of the parent	€ (120,833)	€ (46,667)	€ (48,019)	€(85,653)
Basic and diluted loss per share	€ (0.59)	€ (0.25)	€ (0.25)	€ (0.51)

(in thousands)	As of September 30, 2019 (unaudited)	As of December 31, 2018
Consolidated statement of financial position:		
Cash and cash equivalents	€ 463,308	€ 411,495
Total assets	738,408	652,986
Total liabilities	322,003	385,986
Share capital	221,787	193,296
Treasury shares	(5,525)	—
Accumulated losses	(366,604)	(245,771)
Total equity	416,405	267,000

UNAUDITED PRO FORMA CONDENSED COMBINED FINANCIAL INFORMATION

On January 15, 2020, BioNTech SE, or the Company, entered into an agreement to acquire Neon Therapeutics, Inc., or Neon, for total consideration of 0.063 American Depositary Shares, or ADSs, representing the Company's ordinary shares, per share of Neon. The relevant 30-day volume weighted average price on January 14, 2020, the day prior to when the transaction was signed, equaled $34.89 per ADS. The Company plans to finance the acquisition by issuing new ordinary shares.

The following unaudited pro forma condensed combined financial statements are based on the Company's historical consolidated financial statements prepared in accordance with International Financial Reporting Standards as issued by the IASB, or IFRS, and Neon's historical consolidated financial statements as adjusted to give effect to the Company's pending acquisition of Neon. Additionally, as Neon prepared its financial statements in accordance with U.S. generally accepted accounting principles, or U.S. GAAP, and applied U.S. dollars as its reporting currency, adjustments have been made to convert Neon's financial statements to IFRS and its reporting currency to Euros. Please see "Unaudited Pro Forma Condensed Combined Financial Information—2 Accounting policy conformity changes" and "—3 Foreign currency adjustments" below for a discussion of the adjustments made to convert Neon's financial information from U.S. GAAP to IFRS.

The unaudited pro forma condensed combined statements of operations for the nine months ended September 30, 2019 and the year ended December 31, 2018 give effect to this transaction as if it had occurred on January 1, 2018. The unaudited pro forma condensed combined statement of financial position as of September 30, 2019 gives effect to this transaction as if it had occurred on September 30, 2019.

As of the date of this filing, the Company has not performed the detailed valuation studies necessary to derive the required estimates of the fair value of Neon's assets to be acquired and liabilities to be assumed and the related allocations of the purchase price, and the Company has performed a high-level assessment of the adjustments necessary to conform Neon's U.S. GAAP accounting policies to the IFRS accounting policies of the Company.

As indicated in Note 5 to the unaudited pro forma condensed consolidated financial information, the Company has made certain adjustments to adjust the historical book values of the assets and liabilities of Neon to reflect preliminary estimates of the fair values necessary to prepare the unaudited pro forma condensed consolidated financial information, with the excess of the estimated purchase price over the net assets of Neon, as adjusted to reflect estimated fair values, recorded as intangible assets and goodwill.

Additionally, as indicated in Note 2 to the unaudited pro forma condensed consolidated financial information, estimated effects related to the application of IFRS have been based on high-level, preliminary assessments and as indicated in Note 3 to the unaudited pro forma condensed consolidated financial information, the reporting currency has been applied based on a simplified method. Actual results are expected to differ from these unaudited pro forma condensed combined financial information once the Company has determined the final purchase price for Neon, completed the valuation studies necessary to finalize the required purchase price allocation and finalized conforming accounting changes for Neon. Such differences may be material.

The assumptions and estimates underlying the unaudited adjustments to the pro forma condensed combined financial statements are described in the accompanying notes, which should be read together with the pro forma condensed combined financial information.

The unaudited pro forma condensed combined financial statements should be read together with:

- the Company's audited consolidated financial statements and related notes included in this Registration Statement for the years ended December 31, 2018 and 2017;
- the Company's unaudited financial statements and notes included in this Registration Statement for the nine months ended September 30, 2019 and 2018;

- Neon's audited consolidated financial statements and related notes included in this Registration Statement for the year ended December 31, 2018; and
- Neon's unaudited financial statements and notes included in this Registration Statement for the nine months ended September 30, 2019 and 2018.

The unaudited pro forma condensed consolidated financial information do not include the realization of any future cost savings or restructuring or integration charges that are expected to result from the Merger.

The unaudited pro forma condensed combined financial information is not intended to represent or to be indicative of the consolidated results of operations and financial condition of the consolidated company that would have been reported had the acquisition been completed as of the dates presented, and should not be taken as being representative of the future consolidated results of operations or financial condition of the consolidated company.

Unaudited Pro Forma Condensed Combined Balance Sheet
as of September 30, 2019
(in thousands)

	BioNTech SE Historical IFRS EUR	NEON THERAPEUTICS Inc. Historical USGAAP USD	NEON THERAPEUTICS Inc. Historical USGAAP EUR(1)	NEON THERAPEUTICS Inc. IFRS Adjustments EUR(1)	Pro Forma Adjustments EUR(1)	Notes	Pro Forma Combined EUR(1)
Intangible assets	94,482	—	—	—	19,901	5 a), 5 e)	114,383
Property, plant and equipment	142,631	15,518(2)	14,250	97	(551)	2 a), 5 e)	156,427
Other non-current assets	—	485	445	—	—		445
Total non-current assets	237,113	16,003	14,695	97	19,350		271,255
Inventories	10,869	—	—	—	—		10,869
Trade receivables	8,931	—	—	—	—		8,931
Deferred expenses and other current assets	18,187	2,036	1,870	—	—		20,057
Cash and cash equivalents	463,308	44,278	40,663	—	—		503,971
Total assets	738,408	62,317	57,228	97	19,350		815,083
Total shareholders equity	416,405	45,334	41,632	83	15,491	5 c)	473,611
Contract liabilities	126,067	—	—	—	—		126,067
Deferred tax liabilities	—	—	—	—	3,859	5 b)	3,859
Other non-current liabilities	67,813	6,884(3)	6,322	—	—		74,135
Total non-current liabilities	193,880	6,884	6,322	—	3,859		204,062
Trade payables	21,813	1,935	1,777	—	—		23,590
Contract liabilities	82,585	—	—	—	—		82,585
Other current liabilities	23,725	8,164(4)	7,497	14	—	2 a)	31,236
Total liabilities	322,003	16,983	15,596	14	3,859		341,473
Total liabilities and equity	738,408	62,317	57,228	97	19,350		815,083

(1) Please see “3 Foreign currency adjustments.”
(2) Consists of property, plant and equipment of $7,670 and operating lease right of use asset of $7,848.
(3) Consists of operating lease liabilities of $6,875 and other liabilities of $9.
(4) Consists of accrued expenses of $6,968 and operating lease liabilities of $1,196.

Unaudited Pro Forma Condensed Statement of Operations
For the period ended September 30, 2019
(in thousands, except for per share information)

	BioNTech SE Historical IFRS EUR	NEON THERAPEUTICS Inc. Historical USGAAP USD	NEON THERAPEUTICS Inc. Historical USGAAP EUR(1)	NEON THERAPEUTICS Inc. IFRS Adjustments EUR(1)	Pro Forma Adjustments EUR(1)	Notes	Pro Forma Income Statement EUR(1)
Revenue	80,601	—	—	—	—		80,601
Cost of sales	(12,925)	—	—	—	—		(12,925)
Research and development expenses	(161,039)	(47,027)	(42,297)	(2,055)	—	2 a), 2 b)	(205,391)
Sales and marketing expenses	(1,908)	—	—	—	—		(1,908)
General and administrative expense	(34,481)	(16,122)	(14,501)	(2,181)	—	2 a), 2 b)	(51,163)
Other operating income	1,340	—	—	—	—		1,340
Other operating expenses	(163)	—	—	—	—		(163)
Operating loss	(128,575)	(63,149)	(56,798)	(4,236)	—		(189,609)
Finance income, net	7,654	1,252	1,126	(551)	—	2 a)	8,229
Other expenses	—	(39)	(35)	—	—		(35)
Loss before tax	(120,921)	(61,936)	(55,707)	(4,787)	—		(181,415)
Income taxes	(28)	—	—	—	—		(28)
Loss for the period	(120,949)	(61,936)	(55,707)	(4,787)	—		(181,443)
Net loss attributable to non-controlling interests	(116)	—	—	—	—		(116)
Net loss attributable to common stockholders	(120,833)	(61,936)	(55,707)	(4,787)	—		(181,327)
Basic and diluted loss per share	(0.59)				—		(0.87)
Weighted-average shares (in thousands)	206,406				1,785		208,191

(1) Please see “3 Foreign currency adjustments.”

Unaudited Pro Forma Condensed Statement of Operations
For the year ended December 31, 2018 (in thousands, except for per share information)

	BioNTech SE Historical IFRS EUR	NEON THERAPEUTICS Inc. Historical USGAAP USD	NEON THERAPEUTICS Inc. Historical USGAAP EUR(1)	NEON THERAPEUTICS Inc. IFRS Adjustments EUR(1)	Pro Forma Adjustments EUR(1)	Notes	Pro Forma Income Statement EUR(1)
Revenue	127,575	—	—	—	—		127,575
Cost of sales	(13,690)	—	—	—	—		(13,690)
Research and development expenses	(143,040)	(60,425)	(51,143)	1,461	—	2 a), 2 b)	(192,722)
Sales and marketing expenses	(3,041)	—	—	—	—		(3,041)
General and administrative expense	(26,334)	(18,276)	(15,469)	841	—	2 a), 2 b)	(40,961)
Other operating income	5,396	—	—	—	—		5,396
Other operating expenses	(720)	—	—	—	—		(720)
Operating loss	(53,854)	(78,701)	(66,612)	2,303	—		(118,163)
Finance income, net	6,192	1,792	1,517	(695)	—	2 a)	7,013
Other expenses	—	(25)	(21)	—	—		(21)
Loss before tax	(47,662)	(76,934)	(65,116)	1,607	—		(111,171)
Income taxes	(600)	—	—	—	—		(600)
Loss for the year	(48,262)	(76,934)	(65,116)	1,607	—		(111,771)
Accretion of redeemable convertible preferred stock to redemption value	—	(6,371)	(5,392)	—	5,392	5 d)	—
Net loss attributable to non-controlling interests.	(243)	—	—	—	—		(243)
Net loss attributable to common stockholders	(48,019)	(83,305)	(70,508)	1,607	5,392		(111,528)
Basic and diluted loss per share	(0.25)				—		(0.58)
Weighted-average shares (in thousands)	190,710				1,785		192,495

(1) Please see “3 Foreign currency adjustments.”

Notes to Unaudited Pro Forma Condensed Combined Financial Information

1 Basis of preparation

The historical consolidated financial statements of the Company and Neon have been adjusted in the pro forma condensed combined financial information to give effect to pro forma events that are (1) directly attributable to the business combination, (2) factually supportable and (3) with respect to the pro forma condensed combined statements of operations, expected to have a continuing impact on the combined results following the business combination.

The business combination was accounted for under the acquisition method of accounting in accordance with IFRS 3, Business Combinations. As the acquirer for accounting purposes, the Company has performed preliminary estimates of the fair value of Neon's assets acquired and liabilities assumed and performed a high-level, preliminary conversion to conform the U.S. GAAP accounting policies of Neon to its own accounting policies under IFRS.

2 Accounting policy conformity changes

The historical financial information of Neon was prepared in accordance with U.S. GAAP. The following high-level, preliminary adjustments convert Neon's financial information from U.S. GAAP to IFRS and align Neon's accounting policies to those applied by the Company.

a) This adjustment for pro formas reflects the impact as if Neon adopted IFRS 16 Leases as of January 1, 2018. In its historical U.S. GAAP financial statements, Neon applied ASC 840 in 2018 and adopted ASC 842 as of January 1, 2019. Neon has one building lease arrangement that is classified as operating lease under U.S. GAAP and several leases for office and laboratory equipment. Under IFRS, unless a recognition exemption is elected, all leases from the lessee's perspective are treated under a single model that is similar to the treatment of finance leases under U.S. GAAP. IFRS does not provide for an equivalent to operating lease classification from the lessee's perspective. Considering the IFRS adjustments for the pro forma income statement in 2018 the Company recognizes the difference between depreciation and operating lease expense of k€170 as research and development expenses, k€38 as general and administrative expense and reclassifies interest expense k€(695). As Neon adopts ASC 842 as of January 1, 2019, lease accounting under U.S. GAAP do not result in a difference compared to IFRS, except the subsequent measurement of the right-of-use asset and the presentation of interest expense. Thus, the Company made adjustments to the subsequent measurement of right-of-use asset of k€97 in the pro forma balance sheet and presents interest expense of k€(551), research and development expenses of k€230 and general and administrative expenses of k€51 in the pro forma income statement as of September 30, 2019. In respect of the office and laboratory equipment, amounts classified as short-term or low-value leases and the lease payments were expensed as they occured.

b) Neon has various stock-based compensation plans in place that vest in installments over up to four years. Neon recognized compensation cost for an employee award according to ASC 718 on a straight-line basis over the requisite period for the entire award. The IFRS adjustment (for year ended December 31, 2018: research and development expenses: k€1,292 and general and administrative expenses k€804; for 9 months ended September 30, 2019: research and development expenses: k€(2,286) and general and administrative expenses: k€(2,233)) reflects the requirement to recognize the awards on a straight-line basis over the requisite service period for each separately vesting portion of the award as if the award was, in substance, multiple awards (i.e. accelerated method).

3 Foreign currency adjustments

The historical financial statements of Neon were presented in U.S. dollars. The historical financial information was translated from U.S. dollars to Euros using the following historical exchange rates:

	$ / €
Average exchange rate for the nine months ended September 30, 2019	1.11
Period end exchange rate as of September 30, 2019	1.09
Average exchange rate for year ended December 31, 2018	1.18

4 Financing transactions

The Company expects to complete the acquisition of Neon for 0.063 ADSs representing ordinary shares of the Company for each outstanding share of Neon common stock. The Company intends to finance the acquisition by issuing new ordinary shares.

Preliminary purchase price allocation

The Company has performed a preliminary valuation analysis of the fair market value of Neon's assets and liabilities. The following table summarizes the preliminary purchase price allocation as of the acquisition date (in thousands). The total consideration was calculated based on the outstanding shares of Neon as of September 30, 2019.

Total consideration	57,206
Intangible assets	551
Property, plant and equipment	13,796
In-process research and development	14,102
Prepaid expenses and other assets	2,315
Cash and cash equivalents	40,663
Long-term liabilities	(6,322)
Accounts payable	(1,777)
Other liabilities	(7,511)
Deferred tax liabilities, net	(3,859)
Goodwill	**5,248**

This preliminary purchase price allocation has been used to prepare pro forma adjustments in the pro forma balance sheet and income statement. The final purchase price allocation will be determined when the Company has completed the detailed valuations and necessary calculations. The final allocation could differ materially from the preliminary allocation used in the pro forma adjustments. The final allocation may include material changes in allocations to intangible assets such as licenses, technology and customer relationships as well as goodwill and other changes to assets and liabilities.

5 Pro forma adjustments

The pro forma adjustments are based on the Company's preliminary estimates and assumptions that are subject to change. The following adjustments have been reflected in the unaudited pro forma condensed combined financial information:

a) Reflects the adjustment of intangible assets acquired by the Company to their estimated fair values. As part of the preliminary valuation analysis, the Company identified intangible assets in form of in-process research and development projects. The fair value of identifiable intangible assets is determined primarily using the benchmark approach. Since all information required to perform a detailed valuation analysis of Neon's intangible assets could not be obtained as of the date of this filing, for purposes of these unaudited pro forma condensed combined financial information, the

Company used certain assumptions based on publicly available transaction data for the industry. Amortization for the in-process research and development projects has not been reflected as the assets are not yet ready for use. These preliminary estimates of fair value will likely differ from final amounts the Company will calculate after completing a detailed valuation analysis, and the difference could have a material impact on the accompanying unaudited pro forma condensed combined financial information. A change in the valuation of intangible assets would correspond to an increase or decrease in the balance of goodwill.

b) Adjusts the deferred tax liabilities resulting from the acquisition. The estimated increase in deferred tax liabilities to €3.9 million stems primarily from the fair value adjustments for non-deductible intangible assets based on an estimated tax rate of 27.32%. This estimate of deferred income tax balances is preliminary and subject to change based on management's final determination of the fair value of assets acquired and liabilities assumed by jurisdiction.

c) Represents the elimination of the historical equity of Neon and the issuance of common shares to finance the acquisition, as follows (in thousands):

Net equity proceeds from issuance of 0.063 American Depositary Shares of the Company per share of Neon	57,206
Less: historical Neon shareholders' equity in EUR, IFRS adjusted as of 30 September 2019	(41,715)
Pro forma adjustment to shareholder's equity	**15,491**

d) Reflects the elimination of accretion expense of Neon redeemable convertible preferred stock to redemption value and expense of accrued dividends.

e) The adjustment reclassifies software assets of €551 thousand from property, plant and equipment to intangibles to conform the presentation of the balance of the Company's presentation.

MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

You should read the following discussion and analysis of our financial condition and results of operations together with the information in "Selected Consolidated Financial Data" and our financial statements and related notes included elsewhere in this prospectus. 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 prospectus. Please also see "Cautionary Note Regarding Forward-Looking Statements."

BioNTech was founded in 2008 on the understanding that every cancer patient's tumor is unique and that in order to effectively address this challenge, we must create individualized treatments for each patient. To realize this vision, we combine decades of groundbreaking research in immunology, cutting-edge therapeutic platforms, and a suite of patient profiling and bioinformatic tools to develop individualized immunotherapies for cancer as well as other diseases. We leverage powerful new therapeutic mechanisms and exploit a diverse array of biological targets to harness the power of each patient's immune system to address the unique molecular signature of each patient's underlying disease. We believe we are uniquely positioned to develop and commercialize the next generation of immunotherapies with the potential to significantly improve clinical outcomes for patients and usher in a new era of individualized medicine.

Our clinical stage pipeline includes ten product candidates in eleven ongoing clinical trials. Our immunotherapy drug classes consist of mRNA therapeutics, engineered cell therapies, antibodies and small molecule immunomodulators, and our product candidates span oncology, infectious diseases and rare diseases.

We have assembled an exceptional team of over 1,300 employees and have established relationships with seven pharmaceutical collaborators, which comprise Genentech, Inc., or Genentech, Sanofi S.A., or Sanofi, Genmab A/S, or Genmab, Genevant Sciences GmbH, or Genevant, Eli Lilly and Company, or Eli Lilly, Bayer AG, or Bayer, and Pfizer Inc., or Pfizer. We have built out comprehensive in-house manufacturing capabilities and aim to strengthen our position as a leader in the highly automated, on-demand manufacturing of individualized therapies.

We have raised $1.4 billion of capital in private placements of our shares, our initial public offering and from our collaborators. We use the capital we have raised to fund operations and investing activities across research for technology creation, drug discovery and clinical development programs, infrastructure (including digital infrastructure), creation of our portfolio of intellectual property, and administrative support.

Since we were founded we have incurred significant operating losses. Our net losses were €120.9 million and €46.8 million for the nine months ended September 30, 2019 and 2018, respectively, and €48.3 million and €86.0 million for the years ended December 31, 2018 and 2017, respectively. As of September 30, 2019 our accumulated losses were €366.6 million and as of December 31, 2018 and 2017, they were €245.8 million and €197.8 million, respectively. We expect to continue to incur significant expenses and operating losses for the foreseeable future. In addition, we anticipate that our expenses will increase significantly in connection with our ongoing activities as we:

- 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 studies or 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 add to internal 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 we progress our product candidates toward commercialization;
- attract and retain skilled personnel;
- create additional infrastructure to support our operations as a public company and our product development and planned future commercialization efforts, including expansion of sites in Germany and new sites in the United States;
- seek marketing approvals and reimbursement for our product candidates;
- establish a sales, marketing and distribution infrastructure to commercialize any products for which we may obtain marketing approval;
- seek to identify and validate additional product candidates;
- acquire or in-license other product candidates and technologies;
- 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 do not expect to generate revenue from the sale of our product candidates unless and until we successfully complete clinical development and obtain regulatory approval for such product candidates. If we seek to obtain regulatory approval for any of our product candidates, we expect to incur significant commercialization expenses.

As a result, we will need substantial additional funding to support our continued operations and pursue our growth strategy. Until we can generate significant revenue from pharmaceutical product sales, if ever, we expect to finance our operations through a combination of public or private equity offerings and debt financings, government funding arrangements, collaborations and marketing, distribution and licensing arrangements. We may be unable to raise additional funds or enter into such other arrangements on favorable terms, or at all. If we fail to raise capital or enter into such arrangements as, and when, needed, we may have to significantly delay, scale back or discontinue the development and commercialization of one or more of our programs.

Because of the numerous risks and uncertainties associated with pharmaceutical development, we are unable to predict the timing or amount of increased expenses or when or if we will be able to achieve or maintain profitability. Even if we are able to generate revenues from the sale of our products, we may not become profitable. If we fail to become profitable or are unable to sustain profitability on a continuing basis, then we may be unable to continue our operations at planned levels and may be forced to reduce our operations.

Information About Our Business Units and Operating Segments

Our business is managed in two business units: our biotech business unit and our external services business unit. Our biotech business unit is comprised of the following three operating segments:

- The **Clinical** segment contains all development activities relating to clinical programs. Clinical trials include testing the product candidates on humans. Clinical trials are an essential part of the development and licensing of the pharmaceutical products and are performed before the respective product can be placed on the market. We are actively engaged in many collaborations and licensing deals with leading pharmaceutical companies and academic collaborators.

- The **Technology Platform** segment contains all development activities relating to preclinical programs. Preclinical development is the stage of research that begins before clinical trials. It is performed to determine the desired pharmacological effects and to identify any unwanted effects that may cause adverse reactions during human exposure.
- The **Manufacturing** segment is an essential part of the research and development process as it includes the manufacturing unit of mRNA and engineered cell therapies. All of the medical substances and tools that form the basis for the research studies performed by BioNTech are manufactured in this segment (*i.e.*, the Manufacturing segment contains only internally produced substances and tools).

Our biotech business unit also includes our business services operations. Our business services operations comprise our central administrative functions, such as finance, procurement, human resources, legal and intellectual property. Revenue and expenses relating to a program are attributed to the Technology Platform segment until the program commences late-stage preclinical studies, including IND-enabling studies, at which time the program revenues and expenses are attributed to the Clinical segment. In addition, the majority of our Manufacturing segment revenue and expenses are related to the development of our clinical product candidates.

Our external services business unit comprises the external services segment, which includes activities related to the sales of diagnostic products, peptides, retroviral vectors for clinical supply, and development and manufacturing services that are sold to third-party customers.

Financial Operations Overview

The following table summarizes our consolidated statements of operations for each period presented (in thousands):

	Nine Months Ended September 30,		Year Ended December 31,	
	2019	2018	2018	2017
	(unaudited)			
Revenue	€ 80,601	€ 63,796	€ 127,575	€ 61,598
Cost of sales	(12,925)	(9,215)	(13,690)	(9,318)
Gross profit	**67,676**	**54,581**	**113,885**	**52,280**
Research and development expenses	(161,039)	(91,244)	(143,040)	(85,496)
Sales and marketing expenses	(1,908)	(1,984)	(3,041)	(6,603)
General and administrative expenses	(34,481)	(16,222)	(26,334)	(23,520)
Other operating income	1,340	4,043	5,396	2,349
Other operating expenses	(163)	(631)	(720)	(288)
Operating loss	**(128,575)**	**(51,457)**	**(53,854)**	**(61,277)**
Finance income	9,170	6,644	8,046	2,133
Finance expense	(233)	(12)	(48)	(26,007)
Interest expense related to lease liability	(1,283)	(1,297)	(1,721)	(676)
Share of loss of equity method investees	—	(84)	(84)	(78)
Loss before tax	**(120,921)**	**(46,206)**	**(47,662)**	**(85,905)**
Income taxes	(28)	(583)	(600)	(45)
Loss for the period	**€(120,949)**	**€(46,789)**	**€ (48,262)**	**€(85,950)**

Revenue

To date, we have not generated any revenue from the sale of pharmaceutical products. Our revenue has been primarily derived from our collaborations and the sale of diagnostic products, peptides, retroviral vectors for clinical supply, and development and manufacturing services that are sold to third-party customers.

The following is a summary of revenue recognized for the periods indicated (in thousands):

	Nine Months Ended September 30,		Year Ended December 31,	
	2019	2018	2018	2017
	(unaudited)			
Revenue:				
Collaboration revenue	€64,260	€45,482	€ 101,837	€ 42,333
Other sales transactions	16,341	18,314	25,738	19,265
Total revenue	€80,601	€63,796	€ 127,575	€ 61,598

The following table summarizes our collaboration revenue for the periods indicated (in thousands):

	Nine Months Ended September 30,		Year Ended December 31,	
	2019	2018	2018	2017
	(unaudited)			
Collaboration revenue:				
Genentech	€47,620	€34,528	€ 49,536	€ 27,829
Pfizer	10,761	3,587	7,174	—
Sanofi	4,058	3,951	41,712	5,665
Genmab	—	2,740	2,740	6,765
Eli Lilly	1,821	676	676	2,074
Total collaboration revenue	€64,260	€45,482	€ 101,837	€ 42,333

Our collaboration revenue consists of milestone payments, upfront licensing payments and reimbursement of development expenses. Certain of these payments are initially recorded on our statement of financial position and are subsequently recognized as revenue in accordance with our accounting policy as described further in "—Critical Accounting Policies and Use of Estimates" and Note 2.3.4 to our consolidated financial statements included elsewhere in this prospectus. Our collaborations with Bayer and Genevant did not result in any revenue in the nine months ended September 30, 2019 and 2018 or in the years ended December 31, 2018 and 2017. The increase in collaboration revenue from our Sanofi collaboration in 2018 was due primarily to a reimbursement of 50% of CellScript sublicense costs pursuant to a separate sub-sublicense agreement dated December 22, 2018.

Our revenue from other sales transactions consists of sales of diagnostic products, peptides, retroviral vectors for clinical supply, and development and manufacturing services sold to third-party customers.

Our ability to generate revenue from sales of pharmaceutical products and become profitable depends upon our and our collaborators' ability to successfully commercialize our product candidates. For the foreseeable future, we do not expect revenue from pharmaceutical product sales. To the extent that existing or potential future collaborations generate revenue, our revenue may vary due to many uncertainties in the development of our product candidates and other factors.

For further information on our revenue recognition policies, see "—Critical Accounting Policies and Use of Estimates—Revenue Recognition."

Cost of Sales

Our cost of sales includes personnel-related expenses, social security expenses, laboratory supplies, purchased services, depreciation and other expenses incurred in connection with the manufacturing of our external products.

The following table summarizes our cost of sales for the nine months ended September 30, 2019 and 2018 and the years ended December 31, 2018 and 2017 (in thousands):

	Nine Months Ended September 30,		Year Ended December 31,	
	2019	2018	2018	2017
	(unaudited)			
Cost of sales:				
Wages	€ 5,306	€3,791	€ 5,582	€5,115
Social security expenses	922	797	1,144	990
Laboratory supplies	2,417	1,127	1,368	2,849
Purchased services	1,543	1,551	2,514	—
Depreciation	1,066	902	1,367	—
Other	1,671	1,047	1,715	364
Total cost of sales	€12,925	€9,215	€13,690	€9,318

Research and Development Expenses

The nature of our business and primary focus of our activities generate a significant amount of research and development expenses. All research and development expenses are expensed as incurred. Research and development expenses include our share of expenses payable by us under the terms of our collaboration agreements and 100% of the expenses for our wholly owned product candidates. Research and development expenses represent costs incurred by us for the following:

- cost to develop our platforms;
- discovery efforts leading to product candidates;
- clinical development expenses for our programs;
- cost to develop our manufacturing technology and infrastructure; and
- digital infrastructure costs.

The costs above comprise the following categories:

- personnel-related expenses, including salaries, benefits, share-based compensation expense and social security expense;
- expenses incurred under agreements with third parties, such as consultants, investigative sites, contract research organizations, or CROs, that conduct our preclinical studies and clinical trials, and in-licensing arrangements;
- costs of acquiring, developing and manufacturing materials for preclinical studies and clinical trials, including both internal manufacturing and third-party contract manufacturing organizations, or CMOs;
- expenses incurred for the procurement of materials, laboratory supplies and non-capital equipment used in the research and development process; and
- facilities, depreciation and amortization, and other direct and allocated expenses incurred as a result of research and development activities.

The following table summarizes our research and development expenses for the nine months ended September 30, 2019 and 2018 and the years ended December 31, 2018 and 2017 (in thousands):

	Nine Months Ended September 30,		Year Ended December 31,	
	2019	2018	2018	2017
	(unaudited)			
Research and development expenses:				
Wages and social security expenses (excluding share-based compensation)	€ 43,620	€27,142	€ 38,882	€ 26,403
Share-based compensation	17,249	—	6,786	5,567
Purchased services	45,434	26,112	42,079	22,686
Laboratory supplies	27,701	16,336	22,921	15,762
Depreciation	19,150	11,743	18,312	9,859
Other	7,885	9,911	14,060	5,219
Total research and development expenses	€161,039	€91,244	€ 143,040	€ 85,496

Our "other" research and development expenses comprise expenses in relation to clinical studies, travel costs, incidental rental costs, and lease and lease-related costs.

The largest component of our total operating expenses has historically been our investment in research and development activities, including development of our platforms and manufacturing technologies. We cannot reasonably estimate the nature, timing and amount of research and development expenses required to complete the development of the product candidates we are currently developing or may develop in the future. There are numerous risks and uncertainties associated with the research and development of such product candidates, including, but not limited to:

- scope, progress and expense of developing ongoing and future product candidates;
- entry in and completion of related preclinical studies;
- enrollment in and completion of subsequent clinical trials;
- safety and efficacy of product candidates resulting from these clinical trials;
- changes in laws or regulations relevant to the investigational medicines in development;
- receipt of the required regulatory approvals; and
- commercialization, including establishing manufacturing and marketing capabilities.

A change in expectations or outcomes of any of the known or unknown risks and uncertainties may materially impact our expected research and development expenditures. Continued research and development is central to the ongoing activities of our business. Product candidates in later stages of clinical development generally have higher development expenses than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials. We expect these costs to continue to increase in the future as our product candidates progress through the development phases and as we identify and develop additional programs. However, we do not believe that it is possible at this time to accurately project total program-specific expenses through commercialization. There are numerous factors associated with the successful commercialization of any of our product candidates, including future trial design and various regulatory requirements, many of which cannot be determined with accuracy at this time based on our stage of development. Additionally, future commercial and regulatory factors beyond our control will impact our clinical development programs and plans.

Sales and Marketing Expenses

Our sales and marketing expenses consist of personnel-related costs, purchased services, travel costs, social security, transport costs and depreciation. If we obtain regulatory approval for any of our product candidates and do not enter into any third-party commercialization collaborations, we expect to incur significant expenses related to building a sales and marketing team to support sales, marketing and distribution activities.

For the nine months ended September 30, 2019, our sales and marketing expenses amounted to €1.9 million, €0.2 million of which constituted expenses for purchased services. For the nine months ended September 30, 2018, our sales and marketing expenses amounted to €2.0 million, €0.7 million of which constituted expenses for purchased services.

Our sales and marketing expenses amounted to €3.0 million in the fiscal year 2018, €0.8 million of which constituted expenses for purchased services. Our sales and marketing expenses amounted to €6.6 million in the fiscal year 2017, €2.8 million of which constituted expenses for purchased services.

General and Administrative Expenses

General and administrative expenses consist primarily of personnel-related costs (including share-based compensation) for finance, legal, human resources, business development and other administrative and operational functions, professional fees, accounting and legal services, information technology and facility-related costs. These costs relate to the operation of the business, unrelated to the research and development function or any individual program.

The following table summarizes our general and administrative expenses for the nine months ended September 30, 2019 and 2018 and years ended December 31, 2018 and 2017 (in thousands):

	Nine Months Ended September 30,		Year Ended December 31,	
	2019	2018	2018	2017
	(unaudited)			
General and administrative expenses:				
Wages and social security expenses (excluding share-based compensation)	€ 9,485	€ 4,981	€ 7,854	€ 6,363
Share-based compensation	4,472	—	728	3,498
IT and office equipment	3,219	2,488	3,774	2,706
Purchased services	4,593	3,238	5,177	3,544
Office costs	988	607	608	1,611
Depreciation	3,841	1,104	2,284	630
Other	7,883	3,804	5,908	5,167
Total general and administrative expenses	€34,481	€16,222	€26,334	€23,520

Our "other" general and administrative expenses are mainly comprised of travel costs, job advertisement expenses, contract staffing expenses, training expenses and incidental rental costs. For the period ended September 30, 2019, "other" general and administrative expenses also included a charge of €2.6 million in connection with certain withholding tax payments for intellectual property licenses related to prior years.

We anticipate general and administrative expenses will increase as research and development expands. These increases will likely relate to additional personnel and increased costs related in part to finance, legal and intellectual property-related matters along with increased expenses related to operating as a publicly traded company, such as fees related to audit, legal and tax services, regulatory compliance programs and investor relations.

Other Operating Income (Expenses)

Our other operating income consists primarily of government grants. For the nine months ended September 30, 2019, our other operating income amounted to €1.3 million, €0.6 million of which constituted government grants. For the nine months ended September 30, 2018, our other operating income amounted to €4.0 million, €3.5 million of which constituted government grants.

In the fiscal year 2018, our other operating income amounted to €5.4 million, €4.2 million of which constituted government grants. In the fiscal year 2017, our other operating income amounted to €2.4 million, €2.3 million of which constituted government grants.

In the fiscal year 2018, no impairment loss was recognized. In the fiscal year 2017, we suffered an impairment loss of €281 thousand as a result of a write-down of a software program which was no longer usable.

Finance Income (Expenses)

Our finance income consists of interest income on cash and foreign exchange gains. For the nine months ended September 30, 2019, our finance income amounted to €9.2 million, €8.1 million of which were attributable to unrealized foreign exchange gains. For the nine months ended September 30, 2018, our finance income amounted to €6.6 million, €5.1 million of which were attributable to unrealized foreign exchange gains.

In the fiscal year 2018, finance income amounted to €8.0 million, €6.1 million of which were attributable to unrealized foreign exchange gains. In the fiscal year 2017, no foreign exchange gains were reported under finance income and our finance income amounted to €2.1 million.

Our finance expense consists of the amortized cost of financial instruments and foreign exchange losses. For the nine months ended September 30, 2019, our finance expense amounted to €233 thousand. For the nine months ended September 30, 2018, our finance expense amounted to €12 thousand.

In the fiscal year 2018, no foreign exchange losses were reported under finance expense and our finance expense amounted to €48 thousand. In the fiscal year 2017, our finance expense amounted to €26.0 million, almost all of which was attributable to unrealized foreign exchange losses resulting from unhedged U.S. dollar cash accounts.

Tax Losses

We have accumulated tax losses with respect to corporate tax and trade tax. As at September 30, 2019, our accumulated tax losses amounted to €290.9 million with respect to corporate tax and €287.9 million with respect to trade tax.

We had accumulated tax losses of €179.3 million with respect to corporate tax and €176.4 million with respect to trade tax as at December 31, 2018. We had accumulated tax losses of €178.5 million with respect to corporate tax and €176.0 million with respect to trade tax as at December 31, 2017.

Biotech Business Unit

The following table summarizes the statements of operations of our biotech business unit, consisting of the Clinical, Technology Platform and Manufacturing segments and the associated business services operations for each period presented (in thousands):

	Nine Months Ended September 30,		Year Ended December 31,	
	2019	2018	2018	2017
	(unaudited)			
Revenue	€ 64,875	€ 51,312	€ 108,662	€ 42,657
Cost of sales	—	(40)	(40)	—
Gross profit	64,875	51,272	108,622	42,657
Research and development expenses	(160,774)	(90,842)	(142,448)	(83,583)
Sales and marketing expenses	(924)	(983)	(2,106)	(4,904)
General and administrative expenses	(32,139)	(14,537)	(23,791)	(21,094)
Other result	799	3,117	4,065	1,598
Operating loss	€(128,163)	€(51,973)	€ (55,659)	€(65,326)

Comparison of the Nine Months Ended September 30, 2019 and 2018

Revenue

The following table summarizes the revenue of our biotech business unit by segment for each period presented (in thousands):

	Nine Months Ended September 30,		Change	
	2019	2018	€	%
	(unaudited)			
Clinical	€25,605	€22,986	2,619	11
Technology Platform	2,577	10,413	(7,836)	(75)
Manufacturing	36,685	17,871	18,814	105
Business Services	8	42	(34)	(80)
Total unit revenue	€64,875	€51,312	13,563	26

The total revenue of our biotech business unit increased by €13.6 million, or 26%, to €64.9 million as at September 30, 2019 from €51.3 million as at September 30, 2018. This increase was driven by increases in revenue in our Clinical and Manufacturing segments, offset by a decrease in revenue in our Technology Platform segment.

The increase in revenue in our Clinical segment of €2.6 million, from €23 million for the nine months ended September 30, 2018 to €25.6 million for the nine months ended September 30, 2019, was predominantly due to the progress of our collaboration agreement with Pfizer into the clinical stage from the research stage.

The decrease in revenue in our Technology Platform segment of €7.8 million, from €10.4 million for the nine months ended September 30, 2018 to €2.6 million for the nine months ended September 30, 2019, is due to the progress of our collaboration agreement with Sanofi from the research stage into the clinical stage as described above, because revenue from such collaboration agreement was recorded in our Technology Platform segment for the nine months ended September 30, 2018. The decrease was also due to the occurrence of the Transfer and License Agreement with Ganymed for Bispecific Antibodies in the nine months ended September 30, 2018, which did not reoccur in the nine months ended September 30, 2019.

The increase in revenue in our Manufacturing segment of €18.8 million, from €17.9 million for the nine months ended September 30, 2018 to €36.7 million for the nine months ended September 30, 2019, was primarily due to progress in our collaboration agreement with Genentech.

Research and Development Expenses

The following table summarizes the research and development expenses of our biotech business unit by segment for each period presented (in thousands):

	Nine Months Ended September 30,		Change	
	2019	2018	€	%
	(unaudited)			
Clinical	€ 65,634	€ 27,777	37,857	136
Technology Platform	52,503	42,295	10,208	24
Manufacturing	38,905	19,340	19,565	101
Business Services	3,732	1,430	2,302	161
Total unit research and development expenses	€ 160,774	€ 90,842	69,932	77

The research and development expenses of our biotech business unit increased by €69.9 million, or 77%, to €160.8 million as at September 30, 2019 from €90.8 million as at September 30, 2018. This increase was due to an increase in headcount, the introduction of the ESOP program and higher expenses regarding our collaboration agreements.

The following table summarizes our clinical research and development expenses, by drug class and selected platforms, for the nine months ended September 30, 2019 and 2018 (in thousands):

	Nine Months Ended September 30,	
	2019	2018
	(unaudited)	
Clinical:		
mRNA		
FixVac	€ 7,849	€ 1,503
iNeST	15,420	12,167
Other mRNA	18,425	2,213
Total mRNA	41,694	15,882
Engineered Cell Therapies	677	32
Antibodies	9,771	11,148
Small Molecule Immunomodulators	1,889	666
Other	11,602	49
Total clinical research and development expenses	€ 65,634	€ 27,777

The €16.2 million increase in other mRNA clinical research and development expenses mainly relates to new collaboration agreements and license programs with existing partners that were initiated in the fourth quarter of 2018 and therefore only affected the nine months ended September 30, 2019. Other mRNA expenses for the nine months ended September 30, 2019 is primarily comprised of €6.2 million of RiboCytokines project costs, €3.7 million of Intratumoral Immunotherapy costs, €3.2 million of Infectious Disease Vaccines costs and €2.6 million of RiboMabs platforms costs. Other mRNA expenses for the nine months ended September 30, 2018 is primarily comprised of €1.2 million of RiboMabs platforms costs.

Other clinical research and development expenses primarily consist of share-based compensation, which is not directly related to individual drug classes and platforms.

Sales and Marketing Expenses

The sales and marketing expenses of our biotech business unit consist of sales and marketing expenses which are not directly attributable to one of our operating segments and are allocated to business services.

The sales and marketing expenses of our biotech business unit increased by €59 thousand, or 6%, to €924 thousand as at September 30, 2019 from €983 thousand as at September 30, 2018.

General and Administrative Expenses

The general and administrative expenses of our biotech business unit are attributable to the Manufacturing segment and business services.

The general and administrative expenses of our biotech business unit increased by €17.6 million, or 121%, to €32.1 million as at September 30, 2019 from €14.5 million as at September 30, 2018. This increase was due to an increase in headcount, the expense recognized from the granting of options under the ESOP program an expense for withholding tax related to prior years, expenses related to the Series B financing round and expenses for an additional office building.

Other Result

The other result of our biotech business unit mostly relates to a decrease in government grants. This income decreased by €2.3 million, or 75%, to €799 thousand as at September 30, 2019 from €3.1 million as at September 30, 2018.

Comparison of the Years Ended December 31, 2018 and 2017

Revenue

The following table summarizes the revenue of our biotech business unit by segment for each period presented (in thousands):

	Year Ended December 31,		Change	
	2018	2017	€	%
Clinical	€ 36,750	€ 25,721	11,029	43
Technology Platform	46,235	14,828	31,407	212
Manufacturing	25,635	2,108	23,527	1,116
Business Services	42	—	42	—
Total unit revenue	€ 108,662	€ 42,657	66,005	155

The total revenue of our biotech business unit increased by €66.0 million, or 155% from €42.7 million to €108.7 million, due to a significant increase in the revenue recognition of our collaboration revenue, particularly with respect to our collaborations with Genentech (in the Clinical and Manufacturing segments) and Sanofi, as well as revenue from our collaboration with Pfizer, which was entered into in 2018. In the Technology Platform segment, 2018 revenue included €3.9 million for outlicensing patents and know-how to a third party. No further payments are due.

Research and Development Expenses

The following table summarizes the research and development expenses of our biotech business unit by segment for each period presented (in thousands):

	Year Ended December 31,		Change	
	2018	2017	€	%
Clinical	€ 48,641	€ 25,099	23,542	94
Technology Platform	60,320	37,019	23,301	63
Manufacturing	31,508	14,764	16,744	113
Business Services	1,979	6,701	(4,722)	(70)
Total unit research and development expenses	€ 142,448	€ 83,583	58,865	70

The research and development expenses of our biotech business unit increased by €58.9 million, or 70%, to €142.4 million in 2018 from €83.6 million in 2017. This increase was primarily due to increase in clinical development activities, manufacturing for the iNeST clinical study supply and increased headcount.

The following table summarizes our clinical research and development expenses, broken down by drug class and selected platforms, for the years ended December 31, 2018 and 2017 (in thousands):

	Year Ended December 31,	
	2018	2017
Clinical:		
mRNA FixVac	€ 3,018	€ 2,539
iNeST	13,335	17,223
Other mRNA	9,441	3,124
Total mRNA	25,794	22,886
Engineered Cell Therapies	653	2,213
Antibodies	14,353	—
Small Molecule Immunomodulators	1,497	—
Other	6,344	—
Total clinical research and development expenses	€ 48,641	€ 25,099

Other clinical research and development expenses primarily consist of share-based compensation, which is not directly related to individual drug classes and platforms.

Sales and Marketing Expenses

The sales and marketing expenses of our biotech business unit decreased by €2.8 million, or 57%, to €2.1 million in 2018 from €4.9 million in 2017. This decrease was primarily due to a reduction of purchased sales and marketing services.

General and Administrative Expenses

The general and administrative expenses of our biotech business unit increased by €2.7 million, or 13%, to €23.8 million in 2018 from €21.1 million in 2017. This increase was primarily due to increased purchased administrative services, information technology and office equipment as well as increased depreciation.

Other Result

The other result of our biotech business unit increased by €2.5 million, or 154%, to income of €4.1 million in fiscal year 2018 from income of €1.6 million in fiscal year 2017. This increase was primarily attributable to an increase in government grants.

External Services Business Unit

The following table summarizes the statements of operations of our external services business unit for each period presented (in thousands):

	Nine Months Ended September 30,		Year Ended December 31,	
	2019	2018	2018	2017
	(unaudited)			
Revenue	€ 15,726	€12,484	€ 18,914	€18,941
Cost of sales	(12,770)	(9,024)	(13,358)	(9,318)
Gross profit	2,956	3,460	5,556	9,623
Research and development expenses	(420)	(553)	(884)	(1,912)
Sales and marketing expenses	(984)	(1,001)	(935)	(1,698)
General and administrative expenses	(2,204)	(1,685)	(2,542)	(2,427)
Other result	378	272	559	463
Operating profit (loss)	€ (274)	€ 493	€ 1,753	€ 4,049

Our external services business unit's operating profit decreased by €767 thousand to an operating loss of €274 thousand as at September 30, 2019 from an operating profit of €493 thousand as at September 30, 2018. This decrease was mainly due to an increase in cost of sales and an increase in general and administrative expenses.

Our external services business unit's operating profit decreased by €2.3 million, or 57%, during the year ended December 31, 2018, compared to the prior year. The decrease was primarily attributable to an increase in cost of sales by €4.0 million, or 43%, partially offset by a decrease in research and development and sales and marketing expenses in 2018 by €1.8 million, or 50%.

Liquidity and Capital Expenditures

We have historically funded our operations primarily from private placements of our ordinary shares, proceeds from collaborators and services and proceeds from secured bank loans. As of September 30, 2019, we had cash and cash equivalents of €463.3 million. Cash and cash equivalents are invested in accordance with our investment policy, primarily with a view to liquidity and capital preservation, and consist primarily of cash in banks and on hand and short-term deposits with an original maturity of three months or less, which are stated at fair value.

We maintain two secured credit facilities with Deutsche Bank AG, or Deutsche Bank, to finance the buildout of our JPT Peptide Technologies GmbH facility and Innovative Manufacturing Services GmbH (IMFS) facility. Our €10.0 million secured credit facility, entered into with Deutsche Bank by our subsidiary BioNTech Innovative Manufacturing Services GmbH, bears interest at a rate of 2.15% and matures on December 30, 2027. We have drawn €9.0 million under this facility as of September 30, 2019. The loan is repayable in equal quarterly installments of €312.5 thousand commencing on March 31, 2020. Our €9.45 million secured credit facility, entered into with Deutsche Bank by our subsidiary JPT Peptide Technologies GmbH, bears interest at a rate of 2.08% and matures on September 30, 2028. We have drawn €4.6 million as of September 30, 2019. The loan is repayable by quarterly installments of €286.4 thousand commencing on September 30, 2020. The loan is

drawn as construction costs are incurred, and we expect the loan to be fully drawn at January 15, 2020. Each of these facilities is secured by liens over our property.

We maintain a financing arrangement with The European Investment Bank, or the EIB, to partially support the implementation of certain technical aspects of our investment in the development of patient-tailored therapeutic vaccines for cancer in Germany, or the Investment. Under this arrangement, the EIB has agreed to provide BioNTech with a credit in an amount of up to €50,000,000 to partially finance the Investment, provided that the amount of credit does not exceed 50% of the cost of the Investment. The credit consists of (i) a term loan in the amount of €25,000,000 that may be drawn in a single tranche upon the achievement of certain milestone events, not all of which have been achieved (Credit A), and (ii) a term loan in the amount of €25,000,000 that may be drawn in a maximum of four tranches each of which must be for a minimum of €5,000,000 or the balance of the remaining facility (Credit B). Tranches under Credit B may only be drawn after Credit A has been drawn down and upon the achievement of certain milestone events. Each tranche under Credit A and Credit B must be repaid within six years from the date on which the tranche is disbursed to us. Interest is payable on the outstanding balance of Credit A at the cash interest fixed rate of 1% per annum quarterly in arrears, plus deferred interest at fixed rate of 5% per annum. We pay interest on the outstanding balance of Credit B at the cash interest fixed rate of 2% per annum quarterly in arrears. In addition, we are obligated to pay the EIB a tiered proportion of drug product revenues received by us ranging from less than single-digit to low single-digit percentages. The profit participation right will end at the end of a six-year period beginning in 2023 or when the EIB has received €15,000,000 in profit participation payments, whichever occurs first. The financing arrangement is to be secured by way of liens over certain of our property.

Cash Flow

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

	Nine Months Ended September 30,		Year Ended December 31,	
	2019	2018	2018	2017
	(unaudited)			
Net cash flows from (used in):				
Operating activities	€ (134,910)	€ (55,412)	€ (58,180)	€ (52,562)
Investing activities	(67,046)	(46,137)	(67,148)	(52,549)
Financing activities	253,723	282,609	365,177	(1,643)
Exchange rate differences	46	10	(459)	(24,820)
Total cash inflow (outflow)	€ 51,813	€ 181,070	€ 239,389	€ (131,573)

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 our use of cash for operating expenses and working capital to support the business. We have historically experienced negative cash flows from operating activities as we have invested in the development of our technologies and manufacturing capabilities, as well as for clinical and preclinical development of our product candidates.

Net cash used in operating activities for the nine months ended September 30, 2019 was €134.9 million, comprising a loss before tax of €120.9 million, non-cash adjustments of €46.8 million, and a net negative change in assets and liabilities of €60.8 million.Non-cash items primarily included depreciation and share-based compensation 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.

Net cash used in operating activities for the nine months ended September 30, 2018 was €55.4 million, comprising a loss before tax of €46.2 million, non-cash adjustments of €13.6 million, and a net negative change in assets and liabilities of €22.8 million.Non-cash items primarily included depreciation. The net negative change in assets and liabilities was primarily due to a decrease in trade receivables and in payables and liabilities.

Net cash used in operating activities for the year ended December 31, 2018 was €58.2 million, comprising a loss before tax of €47.7 millionnon-cash adjustments of €30.5 million, and a net negative change in assets and liabilities of €41.0 million. Non-cash items primarily included depreciation and share-based compensation expenses. The net negative change in assets and liabilities was primarily due to an increase in trade receivables and in payables and liabilities.

Net cash used in operating activities for the year ended December 31, 2017 was €52.6 million, comprising a loss before tax of €85.9 millionnon-cash adjustments of €43.1 million, and a net negative change in assets and liabilities of €9.8 million. Non-cash items primarily included depreciation and share-based compensation expenses and exchange rate differences. The net negative change in assets and liabilities was primarily due to a decrease in payables and liabilities.

Investing Activities

Net cash used in investing activities for the nine months ended September 30, 2019 was €67.0 million, of which €32.9 million was attributable to the purchase of intangible assets, including the final installment payment for the license agreement for the CellScript patent, and €28.6 million was attributable to the purchase of property, plant and equipment, partially offset by proceeds from the sale of property, plant and equipment amounting to €568 thousand.

Net cash used in investing activities for the nine months ended September 30, 2018 was €46.1 million, of which €29.3 million was attributable to the purchase of intangible assets, including payment for the license agreement for the CellScript patent, and €17.4 million was attributable to the purchase of property, plant and equipment, partially offset by proceeds from the sale of property, plant and equipment amounting to €565 thousand.

Net cash used in investing activities for the year ended December 31, 2018 was €67.1 million, of which €37.3 million was attributable to the purchase of intangible assets, including payment for the license agreement for the CellScript patent, and €30.6 million was attributable to the purchase of property, plant and equipment, partially offset by proceeds from the sale of property, plant and equipment amounting to €705 thousand.

Net cash used in investing activities for the year ended December 31, 2017 was €52.5 million, of which €33.4 million was attributable to the purchase of intangible assets, including payment for the license agreement for the CellScript patent, and €24.3 million was attributable to the purchase of property, plant and equipment, partially offset by proceeds from the sale of property, plant and equipment amounting to €5.2 million.

Financing Activities

Our primary financing activities consist of issuances of share capital, proceeds from bank loans and payments of finance lease liabilities.

During the nine months ended September 30, 2019, we generated cash from financing activities of €253.7 million, primarily from proceeds from the issuance of shares in the amount of €247.9 million, partially offset by the payment of finance lease liabilities in the amount of €2.2 million.

During the nine months ended September 30, 2018, we generated cash from financing activities of €282.6 million, primarily from proceeds from the issuance of shares in the amount of €281.7 million, partially offset by the payment of finance lease liabilities in the amount of €1.6 million.

During the year ended December 31, 2018, we generated cash from financing activities of €365.2 million, primarily from proceeds from the issuance of shares in the amount of €361.7 million and proceeds from loans and borrowings in the amount of €5.6 million, partially offset by the payment of finance lease liabilities in the amount of €2.1 million.

We had insignificant financing activities in 2017.

Operation and Funding Requirements

Since our inception, we have incurred significant losses and negative cash flows from operations due to our significant research and development expenses and our investment in our manufacturing capabilities. We have accumulated losses of €366.6 million as of September 30, 2019 and €245.8 million as of December 31, 2018. We expect to continue to incur significant losses in the foreseeable future and expect our expenses to increase in connection with our ongoing activities, particularly as we continue research and development and clinical activities for our product candidates. In addition, upon the closing of this offering, we expect to incur additional costs associated with operating as a public company. Our expenses will also increase if, and as, we:

- 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 studies or 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 add to internal 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 we progress our product candidates toward commercialization;
- attract and retain skilled personnel;
- create additional infrastructure to support our operations as a public company and our product development and planned future commercialization efforts, including expansion of sites in Germany and new sites in the United States;
- seek marketing approvals and reimbursement for our product candidates;
- establish a sales, marketing and distribution infrastructure to commercialize any products for which we may obtain marketing approval;
- seek to identify and validate additional product candidates;
- acquire or in-license other product candidates and technologies;
- 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 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 forecast of the period of time through which our financial resources will be adequate to support our operations is a forward-looking statement and involves risks and uncertainties, and actual results could vary as a result of a number of factors. We have based this estimate on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we

currently expect. We believe that our existing cash and cash equivalents, together with the proceeds of this offering, will be sufficient to enable us to fund our operating expenses and capital expenditure requirements through at least the next 24 months.

Our future funding requirements 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 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;
- the number and characteristics of product candidates that we develop or mayin-license;
- the outcome, timing and cost of meeting regulatory requirements established by the FDA, 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; 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.

Off-Balance Sheet Arrangements

We did not have during the periods presented, and we do not currently have, any off-balance sheet arrangements that have or are reasonably likely to have a current or future effect on our financial condition, revenues or expenses, results of operations, liquidity, capital expenditures or capital resources.

Contractual Obligations and Commitments

The following table summarizes our contractual obligations as of December 31, 2018 and the effects that such obligations are expected to have on our liquidity and cash flows in future periods (in thousands):

	Payments Due by Period				
	Total	Less than 1 year	1–3 years	3–5 years	More than 5 years
Leases	€ 73,669	3,813	6,999	6,333	56,524
Loans	5,600	—	5,350	250	—
Total contractual cash obligations	€ 79,269	3,813	12,349	6,583	56,524

We have lease agreements for land and buildings in all of our locations, which will expire from 2020 to 2027. In addition, we have various leases for equipment and cars which will expire in 2020. The amounts in the table above represent our fixed contractual lease obligations and do not include the optional extensions.

In addition to the above obligations, we enter into a variety of agreements and financial commitments in the normal course of business. The terms generally allow us the option to cancel, reschedule and adjust our requirements based on our business needs, prior to the delivery of goods or performance of services. It is not possible to predict the maximum potential amount of future payments under these agreements due to the conditional nature of our obligations and the unique facts and circumstances involved in each particular agreement.

Critical Accounting Policies and Use of Estimates

Our consolidated financial statements for the nine months ended September 30, 2019 and September 30, 2018, respectively, and the fiscal years ending December 31, 2018 and 2017, respectively have been prepared in accordance with IFRS, as issued by the IASB.

The preparation of the consolidated financial statements in accordance with IFRS required the use of estimates and assumptions by the management that affect the value of assets and liabilities—as well as contingent assets and liabilities—as reported on the balance sheet date, and revenues and expenses arising during the fiscal year. The main areas in which assumptions, estimates and the exercising of a degree of discretion are appropriate relate to the determination of the useful lives of non-current assets and the formation of provisions, as well as income taxes. 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 our control. Hence, our estimates may vary from the actual values.

We believe that the following accounting policies are critical to the process of making significant judgments and estimates in the preparation of our consolidated financial statements. We have reviewed these critical accounting policies and estimates with the audit committee of our Supervisory Board.

Revenue Recognition

We recognize revenue through collaboration and license agreements, rendering of services and sales of products.

Under our collaboration and license agreements, described in more detail in "Business—XIV. Third-Party Strategic Collaborations," we receive milestone payments, up-front licensing payments and reimbursement of development expenses, for committing to collaborate with the respective collaborator to research and develop certain pharmaceutical products. Such collaboration agreements also include licenses of certain of our intellectual property to the respective collaborators. As these agreements comprise several promises, it must be assessed whether these promises are capable of being distinct within the context of the contract. For some agreements, this results in us accounting for all goods and services promised in a collaboration and license agreement as a single performance obligation with a single measure of progress. We determined that the grant of the license is the predominant promise within the (combined) performance obligation and the promise to grant a license is accounted for as a performance obligation satisfied over time as our customer simultaneously receives and consumes the benefits from our performance. Up-front licensing payments and reimbursement for development expenses are initially deferred on our statement of financial position and subsequently recognized as revenue over time, either as costs are incurred or over the length of the agreement, as above. Milestone payments are included in the transaction price at the amount stipulated in the respective agreement and recognized as revenue if the occurrence of reaching the future milestone is highly probable.

The collaboration and license agreements may also provide for additional profit-sharing or royalty income, to the extent a pharmaceutical product is successfully commercialized. To date, no such income has been recognized.

We provide development and manufacturing services to customers and recognize revenue over time using an input-based method to measure progress toward complete satisfaction of the service because the customer simultaneously receives and consumes the benefits provided. We recognize such revenue based on a fixed agreed amount and therefore it is not subject to estimation.

We recognize revenue from the sale of medical products (*e.g.*, peptides and retroviral vectors for clinical supply) when control has been transferred. The transaction price is quoted in the relevant price lists in force at the date of the customer placing the respective order for such products, and is not subject to significant discounts or rebates.

For further information regarding our revenue recognition policy, please refer to Note 2.3.4 of our consolidated financial statements included elsewhere in this prospectus.

Research and Development Expenses

Research and development expenses are expensed as incurred.

Share-Based Compensation

Employees (and others providing similar services) receive remuneration in the form of share-based payments which are settled in equity instruments (equity-settled transactions). In addition, in the past, employees and others providing similar services were granted share appreciation rights which were settled in equity instruments (equity-settled transactions).

The cost of equity-settled transactions is determined by the fair value at the grant date. These costs are recognized in research and development expenses, sales and marketing expenses or general and administrative expenses, together with a corresponding increase in equity (other capital reserves), over the period in which the service is provided (the vesting period). The cumulative expense recognized for equity-settled transactions at each reporting date until the vesting date reflects the extent to which the vesting period has expired and our best estimate of the number of equity instruments that will ultimately vest. The expenses or credits in the statement of profit or loss for a period represent the movement in cumulative expense recognized as at the beginning and end of that period.

Fair Value of Share-Based Awards

2018 Employee Stock Ownership Plan

On November 15, 2018, we established a share option program that grants selected employees options to receive shares in the Company. The program is designed as an Employee Stock Ownership Plan and option grants are classified as share-based equity-settled remuneration. As at September 30, 2019, we had options outstanding representing 11,852,784 ordinary shares with a weighted-average exercise price of €10.14.

The following share options have been issued to the management board:

Name	Share Options Outstanding	Number of Ordinary Shares Underlying Options	Option Exercise Price (€) Per Share
Prof. Ugur Sahin, M.D.	101,686	1,830,348	10.14
Sean Marett	33,895	610,110	10.14
Dr. Sierk Poetting	33,895	610,110	10.14
Dr. Özlem Türeci	108,463	1,952,334	10.14
Ryan Richardson	8,306	149,508	10.14

The fair value of the employee share options has been measured using a binomial model. Service conditions were not taken into account in measuring the fair value.

The option rights generally fully vest after four years (except that Dr. Türeci's option vested on March 16, 2019 and except for one similar arrangement in the case of Ryan Richardson) 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 in the 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. The option rights will be forfeited without compensation if not exercised within eight years after the allocation date. Both of these conditions have been incorporated into the fair value at grant date.

The inputs used in the measurement of the fair values at grant date of the 2018 Employee Stock Ownership Plan were as follows:

	Grant Date November 15, 2018	Grant Dates Between February 21 and April 3, 2019	Grant Dates Between April 29 and May 31, 2019
(Weighted average) fair value	€ 7.41	€ 6.93	€ 7.04
(Weighted average) share price	€ 14.40	€ 15.72	€ 16.03
Exercise price	€ 10.14	€ 15.03	€ 15.39
Expected volatility (%)	46.0%	46.0%	46.0%
Expected life (years)	5.84	6	6
Risk-free interest rate (%)	0.05%	0.05%	0.05%

The share price at grant date was determined by reference to an observable transaction. We involved an independent third-party appraiser to confirm that the transaction selected was appropriate for the purposes of determining fair value. Expected volatility was 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 was based on general optionholder behavior for employee options.

2019 Employee Stock Ownership Plan

In September 2019, we agreed to grant 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' per share exercise price is Euro translation of the public offering price from our initial public offering, €13.60. The option will vest annually in equal installments after four years commencing on the first anniversary of our initial public offering and will be exercisable four years after our initial public offering. The option will be subject to the terms, conditions, definitions and provisions of our ESOP and the applicable option agreement thereunder.

The vested option rights can only be exercised if and to the extent that each of the following performance criteria has been achieved: (i) at the time of exercise, the current price is equal to or greater than the threshold amount (that is, the exercise price, provided that such amount increases by seven percentage points on each anniversary of the allocation date); (ii) at the time of exercise, the current price is at least equal to the target price (that is, (a) for the twelve-month period starting on the fourth anniversary of the allocation date, $8.5 billion divided by the total number of the shares outstanding immediately following the initial public offering (other than shares owned by us), and (b) for each twelve-month period starting on the fifth or subsequent anniversary of the allocation date, 107% of the target share price applicable for the prior twelve-month period); and (iii) the

closing price for the fifth trading day prior to the start of the relevant exercise window is higher than the exercise price by at least the same percentage by which the Nasdaq Biotechnology Index or a comparable successor index as of such time is higher than such index was as of the last trading day before the allocation date.

A Monte-Carlo simulation model has been used to measure the fair value at grant date of the 2019 Employee Stock Ownership Plan. 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 date. The inputs used in the measurement of the fair value at grant date of the 2019 Employee Stock Ownership Plan were as follows:

(Weighted average) fair value	€ 5.04
(Weighted average) share price	€ 13.60
Exercise price	€ 13.60
Expected volatility (%)	41.42%
Expected life (years)	5.81
Risk-free interest rate BioNTech (%)	(0.47)%

The share price at grant date was the offering price of our initial public offering on October 10, 2019. 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 optionholder behavior for employee options.

Income Taxes

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 we operate and generate taxable income. 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 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. As long as taxable profit is not probable, no tax assets are recognized.

Deferred tax assets and liabilities are measured at the tax rates that are expected to apply in the year when 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. Deferred tax items are recognized in correlation with the underlying transaction either in other comprehensive income or directly in equity.

We offset deferred tax assets and deferred tax liabilities if and only if 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 the same taxable entity or 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.

Recently Issued Accounting Pronouncements

The standards applied for the first time as of January 1, 2019, as disclosed in note 2.5 to the consolidated financial statements as of December 31, 2018, had no impact on our interim condensed consolidated financial statements as of September 30, 2019.

Standards/Interpretation		Date of Application
IFRIC 23	Uncertainty over income tax treatment	January 1, 2019
Amendments to IFRS 9	Prepayment features with negative compensation	January 1, 2019
Amendments to IAS 19	Plan amendment, curtailment or settlement	January 1, 2019
Amendments to IAS 28	Long-term interests in associates and joint ventures	January 1, 2019
Annual improvements 2015—2017 Cycle	Annual improvement cycle to IFRS 2015 -2017	January 1, 2019

Quantitative and Qualitative Disclosures About Market Risk

We are exposed to various risks in relation to financial instruments, including liquidity risk and currency risk. Our risk management is coordinated by our executive 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.

Currency Risk

We are subject to currency risk, 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. We aim to match U.S. dollar cash inflows with U.S. dollar cash outflows where possible, and we do not hedge this exposure. If we increase sales of our products in the United States, we would expect to have significant increases in cash balances, revenues and sales and marketing expenses denominated in U.S. dollars, while we would expect the majority of our development and operating expenses to remain denominated in Euro.

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. 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 10% against the Euro, cash and cash equivalents as of December 31, 2018 would decrease by €16.0 million, or 4%, and as of September 30, 2019 would decrease by €8.8 million, or 2%.

Material Weakness

Historically, we have been a private company and did not maintain the internal accounting and financial reporting resources necessary to comply with the obligations of a public reporting company, including maintaining effective internal control over financial reporting. We identified a material weakness primarily related to (i) our lack of sufficient accounting and supervisory personnel with the appropriate level of technical accounting experience/training and (ii) our lack of consistent application of its accounting processes and procedures, particularly in the areas of share-based compensation, revenue from collaborators and capitalization of tangible and intangible assets. As of consequence of point (i) above, management relies on the assistance of outside advisors with expertise in these matters to assist in the preparation of IFRS financial statements and compliance with SEC reporting obligations in relation to our anticipated U.S. public offering. However, our lack of sufficient accounting and supervisory personnel also means there has also been a lack of supervision over external consultants. We identified several other audit adjustments including leasing, inventory and accruals, which indicate difficulties in properly applying accounting policies and processes consistently throughout the organization and omission of assessment of critical accounting guidance for complex areas or areas requiring judgments indicating inadequate supervision of its external consultants.

We have begun to develop a remediation plan to address this material weakness. Our remediation plan includes the hiring of additional staff, documenting and implementing consistent accounting policies and procedures and providing additional training to our accounting and finance staff. While we are working to remediate the material weakness as quickly and efficiently as possible, we cannot at this time provide a timeline on such remediation. See our risk factor on this material weakness in "Risk Factors—Risks Related to Ownership of the ADSs and this Offering."

JOBS Act and Emerging Growth Company Status

In April 2012, the JOBS Act was enacted. The exemptions and reduced reporting requirements under the JOBS Act for emerging growth companies include presentation of only two years of audited financial statements in a registration statement for an initial public offering, an exemption from the requirement to provide an auditor's report on internal control over financial reporting pursuant to Section 404(b) of the Sarbanes-Oxley Act, an exemption from any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation, and less extensive disclosure about our executive compensation arrangements. Additionally, the JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. Such provisions are only applicable under U.S. GAAP. As a result, we will adopt new or revised accounting standards on the relevant dates on which adoption of such standards is required or permitted by the IASB.

We will remain classified as an emerging growth company until the earlier of (i) the last day of the fiscal year following the fifth anniversary of the date of the completion of our initial public offering, (ii) the last day of the first fiscal year in which our annual gross revenues exceed $1.07 billion, (iii) the date on which we have issued more than $1 billion of non-convertible debt securities during the previous three years, or (iv) the date on which we are deemed a large accelerated filer under the rules of the SEC, which means the first day of the year following the first year in which, as of the last business day of our most recently completed second fiscal quarter, the market value of our common equity that is held by non-affiliates exceeds $700 million.

BUSINESS

I. Overview

BioNTech was founded in 2008 on the understanding that every cancer patient's tumor is unique and that in order to effectively address this challenge, we must create individualized treatments for each patient. To realize this vision, we combine decades of groundbreaking research in immunology, cutting-edge therapeutic platforms, and a variety of patient profiling and bioinformatic tools to develop individualized immunotherapies for cancer as well as other diseases. We leverage powerful new therapeutic mechanisms and exploit a diverse array of biological targets to harness the power of each patient's immune system to address the unique molecular signature of each patient's underlying disease. We believe we are uniquely positioned to develop and commercialize the next generation of immunotherapies with the potential to significantly improve clinical outcomes for patients and usher in a new era of individualized medicine.

We and our collaborators have advanced a development pipeline of over 20 product candidates, of which 10 have entered into 11 ongoing clinical trials. While we believe our approach is broadly applicable across a number of therapeutic areas, our most advanced programs are focused on oncology, where we have treated over 400 patients across 17 tumor types to date. Our immunotherapy drug classes consist of messenger ribonucleic acid, or mRNA, therapeutics, engineered cell therapies, antibodies and small molecule immunomodulators. Our product candidates span oncology, infectious diseases and rare diseases.

We have assembled an exceptional team of over 1,300 employees and have established relationships with seven pharmaceutical collaborators, including Genentech, Inc., or Genentech, Sanofi S.A., or Sanofi, Genmab A/S, or Genmab, Genevant Sciences GmbH, or Genevant, Eli Lilly and Company, or Eli Lilly, Bayer AG, or Bayer, and Pfizer Inc., or Pfizer. We have built out comprehensive highly automated, on-demand in-house manufacturing capabilities that complement the development of our individualized immunotherapies.

Our programs are based on our pioneering development of numerous immunotherapeutic platforms, designed to provide patients with highly tailored treatment options. Our platforms leverage the following four drug classes:

- **mRNA Therapeutics.** We are utilizing messenger ribonucleic acid, or mRNA, to deliver genetic information to cells, where it is used to express proteins for therapeutic effect. We are developing a portfolio of immunotherapies that utilize four different mRNA formats and three different formulations to derive five distinct platforms for the treatment of cancer. Three of these platforms are currently in human testing: (i) our off-the-shelf shared antigen immunotherapy, or FixVac; (ii) our individualized neoantigen specific immunotherapy, or iNeST, in collaboration with Genentech; and (iii) our intratumoral immunotherapy, in collaboration with Sanofi. In addition, we are developing two platforms in which we use mRNA to express directly in the patient either (a) particular antibodies, or RiboMabs, or (b) specific cytokines, or RiboCytokines. In collaboration with Pfizer and Genevant, we are also leveraging our mRNA technology beyond oncology to treat influenza and rare diseases.
- **Engineered Cell Therapies.** We are developing a range of novel cell therapies in which the patient's T cells are modified to target cancer-specific antigens. These include two platforms for the treatment of solid tumors: chimeric antigen receptor, or CAR, T cells and T cell receptor, or TCR, programs. We are also combining our mRNA FixVac platform with our first CAR T product candidates, using "CARVac" immune boosters to enhance the persistence of CAR-T cells *in vivo*.
- **Antibodies.** We are developing, in collaboration with Genmab, next-generation bispecific antibodies that are designed to target immune checkpoints that modulate the patient's immune response to cancer. We are also exploring additional targeted cancer antibody approaches utilizing our in-house and recently acquired antibody capabilities.
- **Small Molecule Immunomodulators.** We use small molecules to augment the activity of other drug classes by inducing specific and discrete patterns of immunomodulation. We are developing a small molecule toll-like receptor 7, or TLR7, immunomodulator for the treatment of solid tumors.

We have leveraged these four drug classes to build a robust pipeline of product candidates. Our pipeline includes 10 product candidates in 11 ongoing clinical trials. Our most advanced programs are focused on oncology, where we have to-date treated over 400 patients across 17 solid tumor types. We also are developing more than 10 additional preclinical programs and expect to initiate clinical testing with several of them in the near future. We are targeting the advancement of up to five product candidates into the clinic in 2020, with clinical data updates for up to five programs expected by the end of 2020. In our Phase 1 trials, we have observed antigen-specific immune responses in over 90% of advanced melanoma patients treated with BNT111, our lead FixVac off-the-shelf product candidate, as a single agent. In addition, we have observed single-agent antigen-specific immune responses in patients treated with BNT121, the precursor to RO7198457 (BNT122), our lead iNeST product candidate. In both trials, we have observed durable objective responses (reduction in tumor volume) in both the monotherapy and checkpoint-combination settings.

We have established multiple collaborations to advance our science and development capabilities and providenon-dilutive capital. We have entered into selective collaborations with leading pharmaceutical companies where a collaborator may bring incremental expertise or resources that we currently do not possess in-house. To date, we have formed relationships with seven pharmaceutical companies, which comprise Genentech, Sanofi, Genmab, Genevant, Eli Lilly, Bayer and Pfizer. We have entered into some of these collaborations in order to advance our technologies and business outside of our initial focus on cancer. We are collaborating with Pfizer to develop an influenza vaccine through our mRNA-based immunotherapy technology and have a collaboration with Genevant to develop protein replacement therapies in up to five rare disease indications. We have also collaborated with the University of Pennsylvania, or Penn, to develop mRNA-based vaccines in up to 10 additional infectious disease indications. In addition, we have a relationship with Translational Oncology at the University Medical Center of the Johannes Gutenberg University Mainz (Translationale Onkologie an der Universitätsmedizin der Johannes Gutenberg Universität Mainz gemeinnützige GmbH), or TRON, to further our immunotherapy research. 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.

Our ability to develop, control and optimize the manufacturing process is a core strategic pillar and competitive advantage across our portfolio, in particular for our individualized product candidates. We operate three Good Manufacturing Practice, or GMP, certified manufacturing facilities in Germany, where we manufacture mRNA therapeutics and engineered cell therapies for our own pipeline and for external customers. We operate a fourth manufacturing facility in Germany where we manufacture custom peptides to support our extensive immunomonitoring activities within our development programs. We have collaborated with Siemens AG, or Siemens, to develop efficient, semi-automated processes to produce our individualized mRNA immunotherapies on demand.

We were founded in 2008, and to date we have raised $1.4 billion of capital in private placements of our shares, our initial public offering and from our collaborators. Our investors include the Strüngmann family office, which is our majority shareholder, MIG Fonds, Fidelity Management & Research Company, Redmile Group, Janus Henderson Investors, the Invus Group, LLC and the Bill & Melinda Gates Foundation.

Our Team

Our team combines proven biotechnology entrepreneurs, world-renowned immunologists and sophisticated biopharma investors. We were founded in 2008 by our scientific founders, Prof. Ugur Sahin, M.D., Prof. Christoph Huber, M.D. and Özlem Türeci, M.D., with a seed investment of €150 million from the Strüngmann family, through its investment vehicle AT Impf, and MIG Fonds, or MIG. Andreas and Thomas Strüngmann are serial entrepreneurs, having co-founded Hexal AG, a German pharmaceutical firm, which they built and sold to Novartis, along with their majority stake in Eon Labs, Inc., a U.S. public pharmaceutical firm, for a combined €5.6 billion (at the time, $8.3 billion). After selling Hexal, they founded a family office focused on healthcare. The Strüngmann family office and MIG have invested in, helped build and sold, either on their own or together, a

number of biotechnology and healthcare companies, such as SuppreMol, Ganymed AG, or Ganymed, CorImmun, Sivantos (former Siemens hearing aid business), Press Ganey (surgery survey company) and Apceth (cell therapy manufacturing company). Helmut Jeggle and Michael Motschmann, on behalf of the Strüngmann family and MIG, respectively, along with Dr. Huber, were founding members of our Supervisory Board.

BioNTech has been supported since its inception by Prof. Rolf Zinkernagel, M.D., Ph.D. and Prof. Hans Hengartner, Ph.D., who serve on our Scientific Advisory Board. Dr. Zinkernagel is a Professor Emeritus at the University of Zurich, University Hospital, and former head of the Institute of Experimental Immunology in Zurich. Prof. Zinkernagel was awarded the Nobel Prize in 1996 for the discovery of how the immune system recognizes virus-infected cells. Prof. Hengartner is a world-renowned immunologist and Professor Emeritus at the Federal Institute of Technology ETH Zurich and the University of Zurich.

At the time of BioNTech's founding, Dr. Sahin and Dr. Türeci were the Chief Scientific Officer and the Chief Medical Officer, respectively, of Ganymed, a private biotechnology company that was founded in 2001 and was focused on developing a monoclonal antibody targeting CLDN18.2 (zolbetuximab). The Strüngmann family office and MIG were majority investors in Ganymed. When Dr. Sahin became Chief Executive Officer of BioNTech, he stepped down from the management board of Ganymed and became the chair of its Scientific Advisory Board. Dr. Türeci continued to lead Ganymed as its Chief Executive Officer until it was sold to Astellas Pharma Inc. in 2016 for up to $1.4 billion.

Our initial group of scientific founders have been joined by experienced pharmaceutical executives, immunologists and biotechnology specialty investors. Sean Marett, our Chief Business Officer and Chief Commercial Officer, led the business development teams at Evotec, and previously was an executive at GlaxoSmithKline in the United States. Dr. Sierk Poetting, our Chief Financial Officer and Chief Operating Officer, joined us from Sandoz, where he served as the Chief Financial Officer in North America. We have also attracted talented scientists such as Katalin Karikó, our Senior Vice President & Head of RNA Protein Replacement, who has more than 30 years of experience working with RNA, has published more than 70 peer-reviewed papers and is co-inventor on mRNA-related patents, including a foundational patent relating to modified mRNA. In addition to the Strüngmann family and MIG, our investors include Fidelity Management & Research Company, Redmile Group, Janus Henderson Investors, the Invus Group, LLC, Salvia GmbH, Eli Lilly, Sanofi, Pfizer and the Bill & Melinda Gates Foundation.

A. Our Pipeline of Product Candidates

We are advancing a deep and broad portfolio of product candidates derived from our four drug classes focused on the treatment of cancer, infectious and rare diseases:

Oncology

Drug Class	Platform	Product Candidate	Indication (Targets)	Pre-clinical	Phase 1	Phase 2	Phase 3	Rights/ Collaborator	Milestones
mRNA	FixVac (fixed combination of shared cancer antigens)	BNT111	Advanced melanoma (Adjuvant & Metastatic)					Global	Report Phase 1 data and Phase 2 start 1H 2020; Phase 3 start 2H 2020
		BNT112	Prostate cancer					Global	
		BNT113	HPV16+ head and neck cancer[1]					Global	Phase 2 start 2H 2020
		BNT114	Triple negative breast cancer					Global	Data update 1H 2020
		BNT115	Ovarian cancer[1]					Global	
		BNT116	NSCLC					Global	
	iNeST (patient specific cancer antigen therapy)	RO7198457 (BNT122[2])	1L melanoma with CPI[3]					Genentech (global 50:50 profit/loss share)	Top line data 2H 2020[4]
			Multiple solid tumors						Data update 2020
	Intratumoral Immunotherapy	SAR441000 (BNT131)	Solid tumors (*IL-12sc, IL-15sushi, GM-CSF, IFNα*)					Sanofi (global profit/ loss share)	Data update 2H 2020[5]
Engineered Cell Therapies	RiboMabs (mRNA-encoded antibodies)	BNT141	Multiple solid tumors					Global	Phase 1 start 2H 2020
		BNT142	Multiple solid tumors (*CD3+CLDN6*)					Global	Phase 1 start 2H 2020 or 1H 2021
	RiboCytokines (mRNA-encoded cytokines)	BNT151	Multiple solid tumors (*Optimized IL-2*)					Global	Phase 1 start 1H 2020
		BNT152, BNT153	Multiple solid tumors (*IL-7, IL-2*)					Global	Phase 1 start 2H 2020 or 1H 2021
	CAR-T Cells	BNT211	Multiple solid tumors (*CLDN6*)					Global	Phase 1/2 start 1H 2020
		BNT212	Pancreatic, other cancers (*CLDN18.2*)					Global	
	TCRs	To be selected	Solid tumors					Eli Lilly (exclusive license option)	
		To be selected	All tumors					Global	
Antibodies	Next-Gen CP[6] Immunomodulators	GEN1046 (BNT311)	Multiple solid tumors (*PD-L1×4-1BB*)					Genmab (global 50:50 profit/loss share)	Data update 2H 2020
		GEN1042 (BNT312)	Multiple solid tumors (*CD40×4-1BB*)						
	Targeted Cancer Antibodies	BNT321 (MVT-5873)	Pancreatic cancer (*sLe[a]*)					Global	
SMIM[1]	Toll-Like Receptor Binding	BNT411	Solid tumors (*TLR7*)					Global	Phase 1 start 1H 2020

Other

Drug Class	Platform	Product Candidate	Indication (Targets)	Pre-clinical	Phase 1	Phase 2	Phase 3	Rights/ Collaborator	Milestones
mRNA	Infectious Disease Immunotherapies	BNT161	Influenza					Pfizer	Start first study by end of 2020
		To be selected	Up to 10 indications					Penn[5]	First Phase 1 trial to start 1H 2021
		To be selected	HIV					Bill & Melinda Gates Foundation	
		To be selected	Tuberculosis					Bill & Melinda Gates Foundation	
	Rare Disease PRT[5]	BNT171	Not disclosed					Genevant (global 50:50 profit/loss share)	First Phase 1 trial to start 2H 2020
		To be selected	4 more rare disease indications						

1 BNT113 and BNT115 are currently being studied in investigator-initiated phase 1 trials
2 BNT122 (iNeST) is investigated in arm 2 (N=15) of the 3 arm TNBC-MERIT trial, with BNT114 as an optional treatment; BNT114 is investigated in arm 1 (N=12) and arm 3 (N=15) of the TNBC-MERIT trial (total patients in study: N=42)
3 Checkpoint Inhibitor
4 Update on the ongoing study including patient enrollment number, efficacy and safety data for an interim update expected in the second half of 2021
5 As the trial is sponsored and conducted by Sanofi, the timing of data updates is not under our control and is subject to change by Sanofi
6 Checkpoint

7 Small Molecule Immunomodulators
8 We are eligible to receive worldwide licenses
9 Protein Replacement Therapy

1. Oncology

FixVac. Our FixVac product candidates contain selected combinations of pharmacologically optimized uridine mRNA encoding known cancer-specific shared antigens. They feature our proprietary immunogenic mRNA backbone and proprietary RNA-lipoplex, or RNA-LPX, delivery formulation, designed to enhance stability and translation, target dendritic cells and trigger both innate and adaptive immune responses. We are currently evaluating five FixVac product candidates in clinical trials, including BNT111 in a Phase 1 trial in advanced melanoma, BNT112 in a Phase 1/2 trial in prostate cancer, BNT113 in a Phase 1 trial in HPV+ head and neck cancers, BNT114 in a Phase 1 trial in triple negative breast cancer and BNT115 in a Phase 1 trial in ovarian cancer.

As of the July 2019 interim cut-off, 95 patients with metastatic melanoma had been dosed at least once in our Phase 1 clinical trial of BNT111. Forty-two of these patients had macroscopic tumor lesions at the time they were enrolled, and these patients were evaluated for preliminary clinical activity, with 25 receiving BNT111 as a monotherapy and 17 receiving BNT in combination with a checkpoint inhibitor. Three of the 25 patients who received BNT111 as a monotherapy demonstrated a partial response, one patient had a metabolic complete response as measured by FGD-PET imaging and seven had stable disease following treatment. Six of the 17 patients who received BNT111 in combination with a checkpoint inhibitor demonstrated a partial response and two had stable disease following treatment.

We expect to initiate a Phase 2 trial for BNT111 in metastatic melanoma in the first half of 2020. Moreover, we plan to initiate a registrational, randomized Phase 3 trial for BNT111 in the second half of 2020. We enrolled the first patient in a Phase 1/2 trial for BNT112, our FixVac product candidate targeting prostate cancer, in the second half of 2019. In addition, we are planning to initiate a Phase 2 trial for BNT113 in HPV+ head and neck cancers by the second half of 2020.

Individualized neoantigen specific immunotherapy (iNeST). Our iNeST immunotherapies contain unmodified, pharmacologically optimized mRNA encoding up to 20 patient-specific neoantigens and also feature our proprietary RNA-LPX formulation. We are conducting, in collaboration with Genentech, clinical trials of our iNeST product candidate, RO7198457 (BNT122). The iNeST Phase 1a (monotherapy)/1b (in combination with atezolizumab) trial is a non-registrational, signal seeking study recruiting mostly patients with late stage advanced cancers, including patients that failed multiple lines of prior treatment. We believe that iNeST is particularly well suited for patients with a lower tumor burden. This notion is supported by clinical activity shown in our previously reported Phase 1 trial, in which BNT121 was administered intranodally in 13 patients with metastatic melanoma. In this trial, as of October 2019 we have observed stable, progression-free survival in nine patients for up to 41 months following surgery and treatment with BNT121. In addition, three out of five patients had an objective response, two patients received iNeST alone and the third patient also received checkpoint immunotherapy. We also observed a significant decrease in the cumulative recurrence rate post-treatment as compared to pre-treatment. Based on these findings, we, in collaboration with Genentech, initiated a randomized iNeST Phase 2 trial in first-line metastatic melanoma in combination with pembrolizumab. We and Genentech expect to report a data update from our RO7198457 (BNT122) Phase 1 trial in multiple solid tumors in 2020, and topline data update from our RO7198457 (BNT122) Phase 2 trial in first-line melanoma in the second half of 2020. We expect this topline data update to include an update on the ongoing study, including patient enrollment numbers, with full efficacy and safety data for an interim update expected in the second half of 2021. We and Genentech plan to initiate two additional clinical trials for RO7198457 (BNT122) in 2020 in first-line solid cancers in the adjuvant setting, one in combination with atezolizumab and the other as a monotherapy.

mRNA intratumoral immunotherapy. In collaboration with Sanofi, we are conducting a Phase 1 trial of SAR441000 (BNT131), our first mRNA-based intratumoral immunotherapy, as a monotherapy and in combination

with cemiplimab in patients with solid tumors. SAR441000 (BNT131) consists of a modified mRNA that encodes the IL-12sc, IL-15sushi, GM-CSF and IFN-a cytokines. SAR441000 (BNT131) is 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 within the tumor (proximal) as well as in other untreated locations (distal).

CLDN6 CAR-T cell immunotherapy. We are developing a proprietary chimeric antigen receptor T cell, or CAR T, product candidate, BNT211, targeting Claudin-6, or CLDN6, a novel solid tumor-specific antigen. We developed BNT211 utilizing our target discovery engine, and we plan to administer it along with a CARVac "primer" to boost the immune response and promote CAR-T cell persistence. We expect to initiate a Phase 1/2 clinical trial for BNT211 in patients with advanced CLDN6 + solid tumors in the first half of 2020.

Next-generation checkpoint immunomodulators. We are developing, in collaboration with Genmab, novel next-generation bispecific antibodies that are designed for conditional activation of immunostimulatory checkpoint molecules. Our first bispecific candidates are GEN1046 (BNT311), which targets PD-L1 in conjunction with 4-1BB, and GEN1042 (BNT312), which targets CD40 in conjunction with 4-1BB. While 4-1BB is a known immune checkpoint target that is expressed on T cells and natural killer, or NK, cells, prior attempts to target 4-1BB with monoclonal antibodies have been severely limited by liver toxicities. Our 4-1BB targeting product candidates are designed to avoid toxicities by conditionally activating a 4-1BB receptor only together with the binding of either PD-L1 or CD40. We have initiated Phase 1/2a trials of GEN1046 (BNT311) and GEN1042 (BNT312) in solid tumors.

Targeted Cancer Antibodies. We recently acquired an antibody with a novel mode of action, MVT-5873 (BNT321). BNT321 is a fully human IgG1 monoclonal antibody targeting sialyl Lewis A (sLe^a), a novel epitope expressed specifically in pancreatic and other solid tumors. MVT-5873 (BNT321) is currently in Phase 1 clinical development in pancreatic cancer, which we resumed in December 2019 upon the enrollment of the first patient. Positive interim data were announced in February 2018.

In addition, we have several other cancer immunotherapy programs in development, including:

- *RiboMabs*: novel classes of mRNA-based therapeutics that are designed to encode antibodies directly in the patient's body. We expect to initiate a Phase 1 and a Phase 1/2 clinical trial, respectively for our first two RiboMab product candidates, BNT141 and BNT142, in the second half of 2020 and first half of 2021, respectively.
- *RiboCytokines*: novel classes of mRNA-based therapeutics that are designed to encode cytokines directly in the patient's body. We expect to initiate Phase 1 clinical trials for our first RiboCytokine product candidates, BNT151 and BNT152/BNT153 (combination), in the first halves of 2020 and 2021, respectively.
- *TCR therapy*: T cells with engineered TCRs that are designed to specifically target cancer cells.
- *Small molecule immunomodulators*: novel intratumoral agents that trigger inflammation and improvement of antigen presentation by antigen-presenting cells. We filed an IND for our first small molecule immunomodulator product candidate, BNT411, in the fourth quarter of 2019 and expect to initiate a Phase 1 clinical trial for BNT411 in solid tumors in the first half of 2020.

2. Infectious Disease Immunotherapies

We have collaborated with third parties to exploit the immunotherapeutic properties of our mRNA drug class for the treatment and prevention of infectious diseases. We expect to advance our flu vaccine into the clinic by the end of 2020, and our first programs under our Penn collaboration into the clinic by the first half of 2021.

- *Flu vaccine*: In August 2018, we entered into a collaboration with Pfizer to the develop mRNA-based immunotherapies for the prevention of influenza.

- *Infectious diseases*: In October 2018, we entered into a research collaboration with Penn, under which we have the exclusive option to develop and commercialize mRNA immunotherapies for the treatment of up to 10 infectious disease indications. In August 2019, we entered into a letter agreement and investment agreement with the Bill & Melinda Gates Foundation to advance the development of immunotherapies for the prevention and/or treatment of HIV and tuberculosis and up to three additional infectious diseases.

3. Rare Disease Protein Replacement Therapies

We are collaborating with Genevant in order to capitalize on opportunities for our mRNA technology in rare disease indications potentially featuring expedited paths to market. We are combining our mRNA technology with Genevant's lipid nanoparticle, or LNP, delivery technology to create up to five mRNA protein replacement therapies for the treatment of rare diseases with high unmet medical needs. We expect our first compound to enter the clinic in the second half of 2020.

II. Our Strengths

We are developing a broad portfolio of technologies and product candidates that we believe position us at the forefront of the next generation of targeted, specific immunotherapies. Our key strengths include:

We are a next-generation immunotherapy powerhouse pioneering individualized immunotherapies to address the shortcomings of existing treatments for cancer and other indications with significant unmet need.

- We have established leadership and expertise in immunology and oncology. Through 11 years of rigorous scientific investigation and clinical translation, we have developed a portfolio of disruptive immunotherapy technologies designed to address the challenges of disease heterogeneity and patient variability.
- Our team has consistently been first-movers and has published over 150 scientific papers in leading peer-reviewed journals. We were the first to develop an intravenously delivered mRNA-based human therapeutic, the first to advance an individualized mRNA-based cancer immunotherapy into clinical trials, and the first to establish scaled in-house manufacturing for such a product candidate.
- Since our founding in 2008, we have advanced four of our therapeutic platforms into human clinical trials, generated promising early evidence of clinical activity in several cancer types, raised $1.4 billion of capital from renowned global biopharmaceutical investors, formed collaborations with seven leading pharmaceutical companies, and acquired complementary assets ranging from research and manufacturing units to clinical programs.
- Our efforts are driven by a group of over 1,300 employees including over 400 in research and development, overseen by our founders who are internationally recognized thought leaders in their disciplines.

We are developing product candidates addressing highly specific immuno-oncology targets, employing a technology-agnostic approach.

- Our portfolio includes four drug classes, spanning mRNA therapeutics, engineered cell therapies, antibodies and small molecule immunomodulators, which can be used alone or in combination to enhance therapeutic effect and produce potentially synergistic effects, as demonstrated in our combination of our BNT211 CAR-T product candidate with a CARVac immune primer.
- Our oncology pipeline includes 10 product candidates in 11 ongoing clinical trials, and more than 10 preclinical programs.

- We have developed significant expertise in the selection of optimal combinations of targets for the specific and individualized treatment of particular cancers. We have assembled libraries of more than 200 proprietary or known shared antigens and have developed predictive algorithms capable of efficiently identifying multiple neoantigens on an individualized basis for any patient.
- Our approach enables real-time monitoring of therapeutic effect on the immune system in a feedback loop of biological surveillance that we believe has the potential to further enhance the success of individualized immunotherapy approaches.

We have tested our lead mRNA candidates in over 250 patients and have already demonstrated signs of single-agent clinical activity in our two lead programs.

- Our most advanced programs are focused on oncology where we haveto-date dosed over 400 patients across 17 solid tumor types.
- In our Phase 1 trials, we observed single-agent antigen specific immune responses in over 90% of advanced melanoma patients treated with BNT111, our lead off-the-shelf immunotherapy product candidate leveraging our wholly owned FixVac platform. In addition, we observed single-agent antigen-specific immune responses in patients treated with BNT121, the precursor to our lead individualized neoantigen specific immunotherapy product candidate derived from our iNeST platform. For both candidates, we have observed durable objective responses in both the monotherapy and checkpoint combination settings.

We have developed a very broad and advanced mRNA therapeutic portfolio for the treatment of cancer.

- We have over a decade of experience pioneering the use of mRNA as a drug class, yielding five distinct mRNA platforms in oncology, each with the potential to generate multiple first-in-class product candidates.
- We have developed four distinct mRNA formats, each tailored to specific therapeutic applications. We have also developed and optimized multiple delivery formulations for our mRNA product candidates, including our proprietary non-viral RNA-LPX, to deliver our mRNA systemically and target it to relevant organs in the body.
- The combination of these platforms, formats and delivery formulations is designed to address a wide range of disease targets, and tailor drug products for systemic or intratumoral delivery, as well as directly encode mAbs or cytokines *in vivo*.
- This broad mRNA expertise is a core strategic asset of our company. It is protected by a global patent portfolio and our proprietary technical knowledge and trade secrets.

We have a deep, diversified pipeline and expect data updates for up to five oncology programs by the end of 2020.

- We have already advanced our portfolio to a critical stage of maturity with multiple programs progressing in parallel. We expect numerous near-term product candidate development updates, including:
  - data updates in up to five clinical programs by the end of 2020; and
  - advancement of up to five product candidates into the clinic in 2020.
- Our preclinical oncology pipeline is progressing rapidly. We initiated clinical trials for both of our lead checkpoint immunomodulator antibody product candidates in 2019, enrolled the first patients in clinical trials of BNT112 and BNT321 (MVT-5873) and we expect to initiate a clinical trial for our lead CAR T, RiboMab, RiboCytokine and small molecule product candidates in the first half of 2020.
- We expect to report our target indications and first product candidates for our infectious and rare disease platforms in 2020.

We have formed multiple collaborations with leading pharmaceutical companies and have retained significant development, commercial and financial rights across our portfolio.

- We have chosen to form collaborations in oncology to rapidly advance our science and enhance our development capabilities, bring our potentially disruptive therapies to patients more quickly and provide non-dilutive capital.
- We are currently collaborating with four pharmaceutical companies with expertise in oncology, including Genentech, Sanofi, Genmab and Eli Lilly, and have retained significant rights in each of our collaborations.
- In addition, we have formed collaborations with leading pharmaceutical companies to broaden our footprint beyond oncology. We have a collaboration with Pfizer focused on influenza. We are collaborating with Penn to develop mRNA-based immunotherapies for up to 10 additional infectious disease indications. We have also formed a collaboration with Genevant for up to five rare disease indications.
- We have retained worldwide rights to all product candidates under our FixVac, RiboMabs, RiboCytokines and CAR T platforms.

We have created a vertically integrated business with comprehensivein-house manufacturing capabilities.

- We believe that to successfully bring individualized immunotherapies to patients, it is critical to control the manufacturing and supply processes. We therefore have chosen to invest early in scaling our in-house capabilities.
- We currently operate four manufacturing facilities in Germany spanning mRNA and peptide production, viral vectors and engineered T cells, and we continue to invest significant human and financial capital into these activities.
- In collaboration with Siemens, we are optimizing our iNeST production process, reducing turnaround time from over three months to less than six weeks currently, with the goal of delivering on-demand commercial supply.

Our Company's scientific DNA, which is the foundation of the BioNTech approach, has attracted a talented team from nearly 50 countries around the world.

- Prof. Ugur Sahin, M.D., our co-founder and Chief Executive Officer, and Özlem Türeci, M.D., our Chief Medical Officer, are physicians, scientists and innovators. They have made groundbreaking scientific and technological contributions in the field of personalized cancer immunotherapy and are co-inventors on more than 100 patents. Their daily work is motivated by their experience as researchers and cancer physicians aiming to exploit scientific insights and drive technological progress to develop commercially viable products that could help individual patients, an attitude and culture that has become the DNA of BioNTech.
- Our DNA, with a deep culture of intellectual curiosity and innovation, has made us a destination of choice for scientific pioneers. This culture has attracted an exceptionally talented team from nearly 50 countries around the world.
- We have participated in nearly 300 scientific publications, of which over 100 are in leading peer-reviewed journals.

III. Our Strategy

Our vision is to harness the power of the human immune system to develop truly individualized and patient-centric therapies for cancer and other serious diseases. We aim to rapidly develop, manufacture and, if approved, commercialize a portfolio of novel immunotherapies, including both off-the-shelf drugs and individualized treatments. The key elements of our strategy to achieve this vision are as follows:

Rapidly advance our potential first-in-class product candidates derived from our FixVac and iNeST platforms toward market approvals in oncology, either on our own or with our collaborators.

- We are conducting four Phase 1 clinical trials with our wholly owned off-the-shelf FixVac mRNA immunotherapy. Our most advanced current FixVac product candidate, BNT111, is currently being evaluated in 115 patients with advanced melanoma, and we expect to initiate a Phase 2 trial in the first half of 2020 and a Phase 3 trial in the second half of 2020.
- We are also advancing, in collaboration with Genentech, our iNeST individualized neoantigen specific mRNA immunotherapy in two clinical trials, targeting more than eight tumor types, and have two additional clinical trials planned for 2020. Our most advanced iNeST program is a Phase 2 trial of our product candidate, RO7198457 (BNT122), in 132 patients with metastatic melanoma, evaluating iNeST in combination with pembrolizumab as a first-line therapy.
- We believe both FixVac and iNeST have therapeutic potential in a wide variety of solid tumors. We have identified significant market opportunities in additional indications and plan to pursue potentially expedited routes to market approval.

Progress additional product candidates through clinical development, leveraging our multiple drug classes and the synergies between them in order to expand our oncology pipeline.

- In addition to FixVac and iNeST, we are also conducting a Phase 1 clinical trial of our intratumoral immunotherapy product candidate SAR441000 (BNT131) in collaboration with Sanofi, as a monotherapy in patients with advanced melanoma and as a combination therapy with an anti-PD-1/PD-L1 checkpoint inhibitor in patients with certain solid tumors.
- Beyond mRNA, we plan to rapidly advance other product candidates from our immunotherapy drug classes into clinical proof-of-concept studies in solid tumor indications.
- In collaboration with Genmab, we have initiated Phase 1/2a clinical trials for our product candidates GEN1046 (BNT311) and GEN1042 (BNT312) in solid tumors. These product candidates are based on our novel checkpoint immunomodulator bispecific monoclonal antibodies, which we believe have potential in a broad range of cancers.
- We also plan to initiate a Phase 1/2 clinical trial in the first half of 2020 for our wholly owned CAR T product candidate, BNT211, in multiple solid tumors, targeting a novel solid-tumor specific antigen, CLDN6.

Maximize the potential and leverage the broad applicability of our mRNA drug class in additional therapeutic areas beyond cancer, including through selective collaborations.

- Beyond oncology, we intend to leverage our mRNA technology to direct the immune system to fight a range of infectious diseases and address missing or defective proteins in certain rare diseases.
- Our collaborations with Pfizer in influenza and with Genevant in rare diseases underscore the potential of our approach. We intend to continue to seek value adding collaborations with leading industry players who contribute their competencies and know-how to complement our powerful suite of technologies to address challenging diseases outside of our core therapeutic focus on oncology.

Strengthen our position as a leader in the highly automated, on-demand manufacturing of individualized therapies with the goal of delivering our therapies globally.

- We will continue to invest to reduce cycle times and increase the automation of our processes, and to expand our manufacturing capacity across all platforms to support the efficient progression of our product candidates into late-stage clinical trials and commercialization.
- We will continue to invest in and scale up our advanced,in-house GMP manufacturing capabilities and capacity across mRNA and cell therapy production.

Establish a commercial organization to bring our portfolio of cancer immunotherapies to patients.

- We believe that developing our own commercial infrastructure will be key to maximizing the value of our programs. We intend to jointly participate in the commercialization of our collaborative programs where we retain significant commercial rights.
- We plan to expand our footprint to support our global clinical development activities and intend to establish operations in the United States by the end of 2020.

Expand our current technology suite by continuing to develop existing and new drug classes and platforms, and selectivelyin-licensing technologies that are complementary to our existing pipeline.

- As our understanding of immunology and oncology evolves, we plan to continue developing existing as well as new drug classes and platforms that are consistent with our strategy, with particular focus on those that can benefit from our in-house expertise.
- As evidenced by our recent acquisition of MabVax Therapeutics, we also continuously assess the external environment for novel drug classes, platforms and product candidates that can further expand and improve our pipeline of innovative immunotherapeutics, and help us to execute our strategy.

Maintain our culture of scientific excellence to continue to drive future innovation.

- We are committed to maintaining close ties to the scientific and academic community by fostering our many long-standing university relationships.
- We also intend to continue our leadership in the Association for Cancer Immunotherapy, or CIMT, which provides us potential new sources of innovation and academic collaboration opportunities.

IV. Immunotherapy in Cancer

The immune system has evolved over hundreds of millions of years to identify and eradicate what is foreign to the body with a high level of efficiency. The immune system's efficacy is attributable to approximately one trillion highly diversified immune cells that constantly travel throughout the body and interact in a coordinated manner. They are able to detect and eliminate diseased cells and pathogens with high precision by relying on a broad range of immune recognition receptors. Their powerful mechanisms both synergize and regulate each other.

The goal of immunotherapy in the field of oncology is to harness the power of the immune system to recognize malignant cells as "foreign," overcome immune evasion mechanisms employed by cancers, eradicate cancer cells and thereby eliminate tumors.

Immunotherapy approaches in cancer have a long history. Recent years have seen an acceleration of scientific advancements and clinical breakthroughs in this field. The introduction over the last decade of checkpoint inhibitors such as Yervoy, Opdivo and Keytruda, and CAR T therapies such as Yescarta and Kymriah has demonstrated that even leveraging one single mechanism to harness the immune system may result in unprecedented, significantly improved clinical outcomes for a subset of patients.

While these first-generation immunotherapies have ignited the paradigm shift toward immuno-oncology, they also have limitations. For example, less than 40% of patients respond to checkpoint inhibitors, while CAR T therapies have been primarily limited to blood cancers in subsets of patients, and have been hampered by toxicities.

Realizing the full potential of immunotherapy is the objective of the next generation of immuno-oncology drugs to be developed.

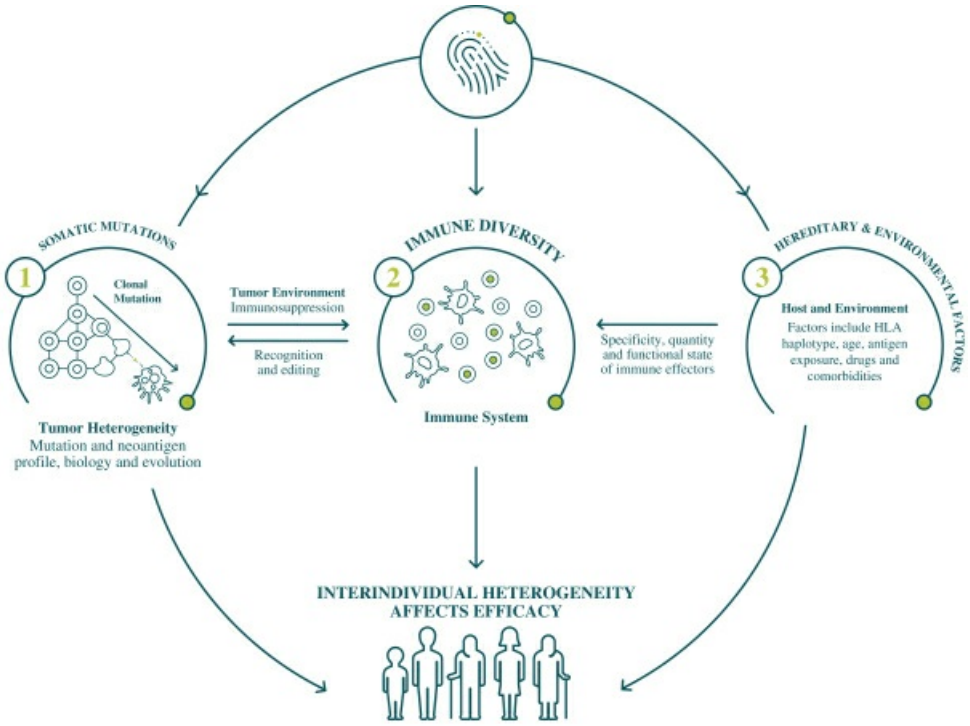
V. Challenges and Opportunities of Cancer Therapies

Cancer results from an accumulation of abnormalities, known as somatic mutations, in the genome of cells over time leading to malignant transformation, combined with a failure by the immune system to detect and eradicate such transformed cells. Due to their random nature, the vast majority of these aberrations are unique to the individual patient.

As a consequence, heterogeneity is an intrinsic hallmark of cancer, posing a key challenge for cancer therapy:

- **Interindividual tumor heterogeneity.** Tumors, even within the same cancer type, differ at the molecular level. For example, two patients with the same type of cancer usually share less than five percent of their mutations. As a result, patients often respond very differently to the same drug.
- **Intratumor heterogeneity.** Within the same patient, cancer also evolves over time so that different tumor cell clonesco-exist, in a manner known as clonal evolution. As a result, a patient's cancer may be intra-tumorally as well as inter-tumorally heterogeneous. Therapies might target only a subfraction of tumor cell clones. This can lead to immune escape and therapy failure.
- **Cancer evolution and immune escape.**Cancer cells can adapt to therapeutic pressure, which results in treatment resistance. During immunotherapy, tumor cell clones may evolve that no longer express T cell recognized antigens or have defects in their antigen presentation machinery.
- **Tumor microenvironment.** Tumors induce various forms of immunosuppressive microenvironments that prevent T cells from proliferating and executing their anti-tumor effector function.
- **Host, environment and immune system.** The functional state of each patient's immune system is dependent on the patient's age, genetic makeup and environmental exposures. For example, the HLA haplotype, or the genetic makeup that encodes the major histocompatibility complex, is highly individual and decisive for which epitopes of an antigen are presented to T cells. Whereas a given tumor antigen might be a good target in one patient, a second patient might not be able to respond to it at all.

The graphic below depicts the interaction between three key factors influencing the patient unique tumor profile:



Interindividual heterogeneity of patients. The interaction between cancer and immune system is shaped by various host, tumor and environmental factors. The complex interplay of these sources of interpatient heterogeneity affects both the course of disease and the efficacy of immunotherapy.

Together, these factors make cancer an extremely complex and heterogeneous disease. As a consequence, in the majority of cancer types, less than 40% of treated individuals benefit from highly potent approved therapies, and responses are often not durable. While these hallmarks of cancer are a challenge for cancer therapy, they also present opportunities for immunotherapy. These interconnected layers of complexity and variability require a deep understanding of an individual cancer and call for a patient-centric approach in order to find an optimal treatment.

Transformation of Cancer Therapies

We believe the recent convergence of breakthrough technologies in life sciences has enabled innovative concepts to address the immunobiology of cancer at its core. One of these breakthroughs has been the establishment of cancer immunotherapy in the armamentarium of cancer treatments. Another has been the emerging progress towards individualized medicine. Technologies such as next-generation sequencing, or NGS, have confirmed beyond doubt the problematic diversity of tumors on the inter-patient level. At the same time, NGS enables fast, cost-efficient and precise high-resolution mapping of each patient's individual disease. We believe the application of these breakthrough technologies has the potential to change drug development and profoundly alter the oncology treatment landscape.

The ability to translate a comprehensive molecular map of an individual tumor into treatment decisions, and make individually tailored therapeutics available, have become the focus of the next generation of cancer therapy. The technology necessary for leapfrog advancements in oncology now exists, but to realize its potential, a radical paradigm shift is required in drug development.

VI. The BioNTech Approach

We are focused on bringing cancer immunotherapy into the next generation. We believe that we can accomplish this by applying the following principles:

- **Exploiting the full potential of the immune system.** Our broad pipeline includes 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.
- **Broadening the universe of patients benefiting from cancer immunotherapy.** We discover and 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. One example are patients with low mutational load tumors, such as pancreatic and prostate cancer, which we address with tumor-associated antigens.
- **Improving the success rate.** We engineer and develop highly potent drug candidates designed to achieve precision 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 curative approaches.** The root cause of recurrence or for 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 four guiding principles to a broad suite of therapeutic platforms optimized for a distinct mode of action, high precision targeting, high potency and efficacy. We expect each platform to yield a pipeline of drug candidates for further development.

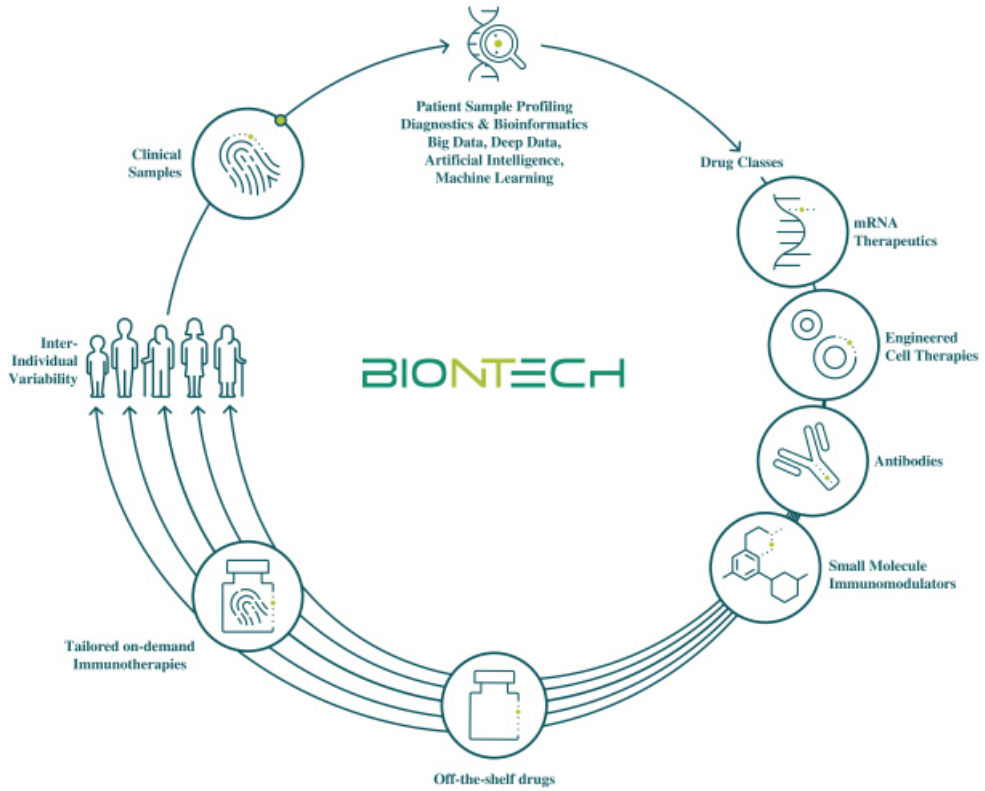
We believe this technology-agnostic range of platforms and product candidates positions us to remain at the forefront of the shift toward an individually tailored, patient-centric therapeutic approach in oncology.

Patient-Centric Model

We believe the next generation of cancer immunotherapy will start from the perspective of the molecular changes that have occurred in an individual patient, and then will provide a specific therapy *for that patient.* We believe that BioNTech is ideally positioned to drive this transformation.

Our patient-centric model starts with profiling and diagnostics by utilizing a target identification engine. This engine combines next generation sequencing, genomics, bioinformatics, machine learning and artificial intelligence to (a) identify gene targets of interest, (b) characterize the functional relevance of these targets (i.e. the ability to raise an immune response to or through a target) and (c) demonstrate their drugability. From our very beginning onwards, we have been developing the novel technologies needed to match the identified targets to the optimal individualized treatment approach.

Our patient-centric model is illustrated and described below:



Our patient-centric model. Utilizing patient profiling, diagnostics and bioinformatics, we select from our suite of drug classes to provide optimal individualized treatment. Our treatments include off-the-shelf drugs as well as highly tailored immunotherapies that are produced on-demand for the individual patient.

Utilizing this model:

1. We develop and leverage our competencies in target discovery, biomarker science and computational medicine to thoroughly profile a patient's tumor sample and immune cells for the selection of suitable targets and treatments. Combined with our deep domain expertise in immuno-oncology and product vision, we are able to use this data to develop next-generation product candidates.

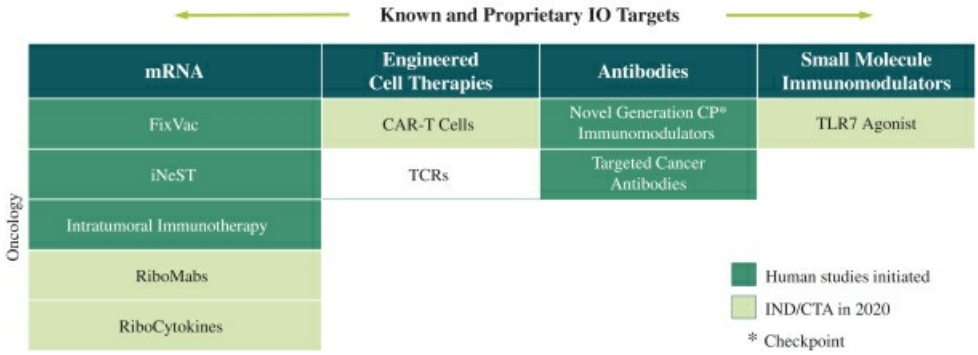
2. We have developed and are iteratively optimizing next-generation therapeutic platforms leveraging four drug classes. Each therapeutic platform bundles innovations designed to deliver a distinct mode of action with high-precision targeting, high potency and efficacy. Each platform is being developed to provide a pipeline of drug candidates with complementary and potentially synergistic modes of action.

3. Our drug platforms are highly versatile and support the fast development of scalable manufacturing processes. We develop and establish highly digitalized and automated manufacturing technologies and quality controlled processes enabling fast delivery of customized therapies comprising off-the-shelf drugs, on-demand immunotherapies, and combinations thereof.

We invest in innovation whenever we encounter technology barriers which may constrain clinical success. We are technology-agnostic and we seek to utilize the technology that is most suited for the respective purpose. By focusing on the three pillars discussed above over the last decade, we have integrated all of the building blocks of immunotherapy under one roof, enabling an approach with the potential to optimize patient outcomes.

Broad and Potentially Synergistic Suite of Platforms

We believe the depth and breadth of our understanding of immune system and cancer biology allows us to create an extensive pipeline of specific and potentially efficacious product candidates. We are exploiting a comprehensive repertoire of known and proprietary therapeutically relevant immuno-oncology targets and are developing a diverse spectrum of immunotherapeutic approaches, as shown in the chart below.



We believe that harnessing complementary, potentially synergistic modes of action increases the likelihood of therapeutic success, reduces the risk of emergence of secondary resistance mechanisms, and also unlocks a larger potential market. Critically, this approach allows us to pursue a technology agnostic approach, providing the most appropriate therapeutic platform or a combination thereof for the intended patient and purpose.

For example, we believe our neoantigen immunotherapies are particularly well-suited to treat high mutation load cancers in the adjuvant setting to prevent the tumor from spreading or recurring following initial treatment such as surgery. In this setting, tumor volumes tend to be low and there remains the potential for strong T cell responses since the patient's immune system has not been weakened by prior lines of treatment, and checkpoint inhibition alone often offers a poor risk-benefit profile or low response rate. Similarly, we believe our FixVac, CAR T and next-generation checkpoint immunomodulator platforms may have especially strong potential in lower mutation burden tumors such as ovarian or prostate cancers, which comprise a significant proportion of tumors and often also have a poor response to checkpoint inhibition. Likewise, we believe that monoclonal targeted cancer antibodies and CAR-T cell therapies are particularly well-suited for tumors that have defects in their antigen-presentation machinery.

We believe our technology breadth is greater than the sum of its parts in that it positions us to combine modes of action in a coordinated way to treat cancer in a more efficacious manner than current existing therapies. We further believe that our patient-centric approach and our broad, potentially synergistic portfolio of drug platforms place us at the forefront of the paradigm shift toward individualized immunotherapies.

Cancer segment	Patient Population	Challenge	Our Therapeutic Strategy
High mutational burden/ adjuvant stage cancers	Significant portion of cancer patients	Poor risk-benefit profile of checkpoint inhibitors	• ***mRNA Neoantigen Immunotherapy*** *(iNeST)*
Low mutational burden cancers	>60% of cancers	Poor response to checkpoint inhibitors	• ***Shared Antigens*** *(FixVac, CAR-T cells, Antibodies)*
"Immune desert" cancers	>40% of high-mutational cancers	Poor infiltration and activation of T-cells in tumor microenvironment	• ***mRNA Immunotherapy*** • ***Immunostimulatory Compounds*** *(intratumoral, RiboCytokines)*
Cancers with MHC / B2M loss	20-30% of CPI-experienced advanced cancers	Failure of immune system to recognize tumor cells	• ***Antibodies*** • ***CAR-Ts***
Refractory tumors	Patients with large tumors and multiple resistance mechanisms	Few treatment options	• ***Engineered Cell Therapies*** • ***Combination Therapies***

Diversity of cancer patient populations, challenges and our therapeutic strategies. We believe our diversified portfolio allows us to potentially address a large share of cancer patients. Abbreviations: B2M, beta-2 microglobulin, a component of MHC.

VII. Selection of Therapeutic Targets and Therapies

Immunotherapy targets can be categorized as *antigens* for targeted immunotherapy with antibody- or T cell-based effector mechanisms and *immunomodulatory targets* to be exploited to improve the anti-tumoral function of immune cells.

A. Targeting Cancer Antigens

In order to address the broadest possible number of patients, our therapeutically targeted cancer antigen library comprises tumor associated antigens, viral neoantigens and mutant neoantigens:

1. Tumor Associated Antigens

Tumor associated antigens, or TAAs, are cancer selective targets that typically have a highly restricted expression pattern in normal tissues but are frequently expressed in a wide range of human cancers. Over the last 15 years, we have built up a database of approximately 200 cancer-selective antigens, including proprietary disease targets that could be used as targets for immunotherapy-based approaches.

- Cancer-Germline and Cancer-Embryo-Fetal Antigens, which are normally expressed during embryonal development and silenced after birth or restricted to germline cells. These antigens are aberrantly expressed in a variety of human malignancies and are generally not expressed in healthy tissue, making them particularly suitable for our FixVac-, antibody- and CAR-T cell-based therapeutic approaches.
- Differentiation antigens, which are normally expressed in a highly tissue-specific manner in normal tissues (*e.g.*, on melanocytes or on prostate cells) but are also present in a high proportion of tumors derived from these tissues, are well-suited for therapeutic targeting with FixVac and antibody approaches.
- Tumor-associated carbohydrate antigens are carbohydrate-based cell surface tumor antigens generated by cancer cell-specific aberrant glycosylation that enable the development of antibody and CAR-T cell therapies.

2. Viral Neoantigens

Viral oncoproteins, or viral neoantigens, are virus-derived proteins that drive the oncogenic transformation of infected cells by viruses that can cause cancer. Examples are the E6 and E7 oncoproteins from human papilloma virus, or HPV. Viral oncoproteins are commonly acknowledged as safe and promising targets for immunotherapy as they are (i) absent from any non-infected tissue, (ii) highly immunogenic since they are not prone to central tolerance mechanisms and (iii) not subject to immune escape by gene silencing as they are crucial to maintaining the transformed state of the tumor cells. We leverage viral neoantigens as targets for our BNT113 FixVac program in HPV16+ head and neck cancer.

3. Mutant Neoantigens

Somatic mutations, or mutations of non-germline cells, are a hallmark of cancer. Driver mutations promote the oncogenic process, whereas passenger mutations are considered as functionally irrelevant. Both types of mutations, however, can alter the sequence of proteins and create new epitopes which are processed and presented on specialized major histocompatibility complex, or MHC, molecules. Mutated epitopes that are recognized by T cells are called neoepitopes and the sequence-altered proteins they are derived from are neoantigens. They are promising targets for cancer immunotherapy as (i) activation of the immune system against such antigens is highly specific (they are only expressed on cancer cells) and (ii) mutant neoantigens are exempt from central tolerance and thus T cell affinity for neoantigens may be significantly superior. We utilize individualized mutant neoantigens as targets for our iNeST product candidates.

B. Immunomodulatory Targets

The activity of immune cells can be controlled or manipulated by the targeting of receptors that control key biological processes in these cells, known as immunomodulation. Immunomodulatory targeting strategies include:

1. Checkpoint Inhibition

Checkpoint inhibition is a therapeutic approach by which T cell function is stimulated with mAbs that block their inhibitory receptors, which can be exploited by cancer cells to shut down T cell activity. Examples of checkpoint targets are PD-1, PD-L1, CTLA-4, TIGIT, LAG3 and many others. The concept is known as “releasing the brakes” and has been shown to be therapeutically effective in tumors with strong pre-existing immune cell infiltration. Our GEN1046 (BNT311) product candidate is a next-generation bispecific checkpoint immunomodulator, with one arm targeting PD-L1.

2. Immunostimulation

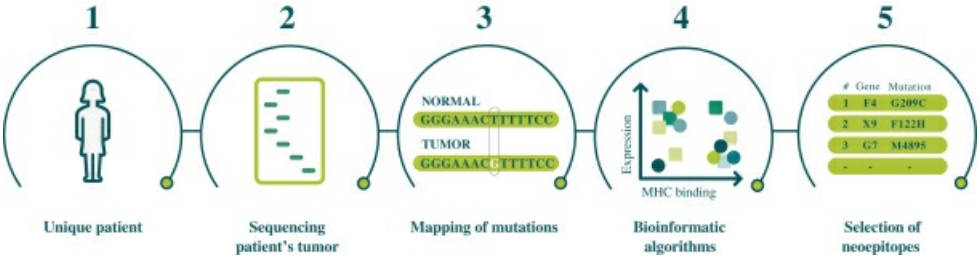
Immunostimulatory approaches are directed against receptors known to directly activate immune cells. Examples of these targets include co-stimulatory molecules such as CD40 and 4-1BB or cytokine receptors such as IL-2R, IL-7R and IL-12R. Immunostimulatory approaches provide a powerful opportunity to enhance immune activation, even in types of cancer that are not responsive to checkpoint inhibition due to lack of immune cell infiltration. However, this approach is often limited by a narrow therapeutic window associated with dose-limiting toxicity.

We believe that both concepts can be combined in a potentially synergistic and safe fashion by developing precisely engineered molecules, such as our BNT151 RiboCytokine program or GEN1042 (BNT312), our next-generation bispecific checkpoint immunomodulator targeting both CD40 and 4-1BB.

C. Our Computational Approach to Individualized Immunotherapy

Bioinformatics are critical in the production of individualized therapies. We have accumulated a high level of experience in bioinformatic approaches to mutation detection, cancer genomics and immunotherapy through our ongoing research and preclinical studies and clinical trials.

Our validated patient-centric bioinformatic process, as illustrated below, allows the application of complex algorithms to the patient's data in the context of drug manufacturing. Our bioinformatics processes are robust and scalable, incorporating our experience handling genomic data in a high-throughput environment, as we target making on-demand production of individualized immunotherapies commercially viable.



From Patient to Analysis. Our bioinformatic process for the selection of neoepitopes.

1. Sequencing

We sequence the patient's tumor and healthy tissue samples using NGS technology. Comparison of the patient's sequenced tumor and healthy samples provides us with the data from which we can identify targets for the design of individualized cancer immunotherapies. This is a multi-step process in which mutation detection and neoantigen prediction are particularly important.

2. Mutation Detection

Mutation detection, which defines which tumor-specific mutations are present in any cancer, is the starting point for defining targets for individualized immunotherapy. Determining mutations from NGS data with high precision and sensitivity is challenging because numerous factors can lead to false positives, which can mask mutations. Despite advances in the field, commonly used mutation detection algorithms still exhibit high false positive mutation detections. In order to address these challenges, we have exclusively licensed a technology from TRON that combines tumor modeling with mutation detection, called MyMUT. MyMUT is a next-generation mutation detection system, which we believe has the following key characteristics:

- **High specificity and robustness.** By combining tumor modeling, sophisticated statistical and genomic filters, and replicate sampling, MyMUT achieves clinical precision in detecting mutations with comparable sensitivity to state-of-the-art mutation detection systems. Higher specificity translates to potentially more effective immunotherapies, with faster and cheaper production. MyMUT is designed to deliver uniform performance for all patients regardless of tumor complexity, mutation burden or sample purity. MyMUT's performance with low mutation tumors also allows us to offer individualized immunotherapies to patients with low tumor mutation burdens.
- **Intratumor heterogeneity.** By performing tumor modeling, MyMUT can also identify clonal and subclonal mutations with high precision, allowing us to prioritize the former in neoantigen-directed immunotherapies and address intratumoral heterogeneity by targeting mutations that are common in a higher proportion of cancer cells within a tumor.
- **Quality control (QC).** By analyzing the genomic properties of sequenced samples, MyMUT can detect errors that pass standard sequencing QC, ensuring the quality and safety of individualized immunotherapies.

3. Neoepitope Selection

Only a portion of mutated peptides (neoepitopes) are suitable for raising an immune response *in vivo*. Our approach focuses on evoking responses involving both $CD8^+$ T cells and $CD4^+$ T cells. We do this by discerning

the likelihood of presentation of the neoepitope to the T cell receptor as an MHC peptide complex using data from mRNA expression levels and MHC binding affinity predictions, among other factors. For example, in our first individualized neoepitope immunotherapy clinical study, all 13 stage III and IV melanoma patients selected for treatment developed a $CD4^+$ and/or $CD8^+$ T cell response, achieving an overall 60% immune response rate to predicted neoepitopes.

Presentation of a neoepitope on an MHC molecule does not, however, guarantee recognition by T cells, and an integrated view combining several properties impacting immunogenicity is necessary. Our algorithms are continuously being improved and extended with data collections from various sources such as our past and current clinical studies as well as HLA data. By using machine learning approaches applied to these large datasets we aim to further improve prediction of overall presentation of neoepitopes tailored to patients' specific HLA types.

VIII. Our mRNA Drug Class

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 an inexpensive and flexible therapeutic to produce.

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

Considering that all mRNA is generated with four different building blocks, but with unique sequence order, all therapeutic mRNAs have highly similar compositions, while having the capacity to encode a variety of different proteins. These characteristics allow for rapid development of mRNA therapeutics that are broadly applicable for treatment of many diseases, including cancer, infectious diseases and rare diseases. Our mRNA pipeline addresses all of these therapeutic areas.

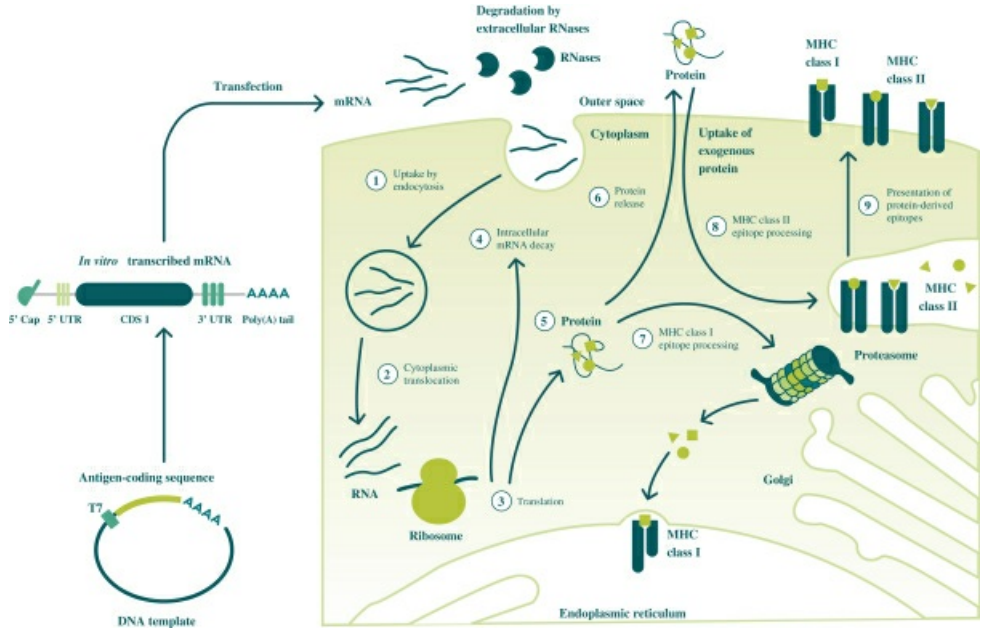
A. General Principles of mRNA Pharmacology

As a drug, manufactured mRNA provides instructions to a target cell to produce a desired therapeutic protein. The mRNA drug will temporarily change the status of the target cell where these instructions are translated into proteins. 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:

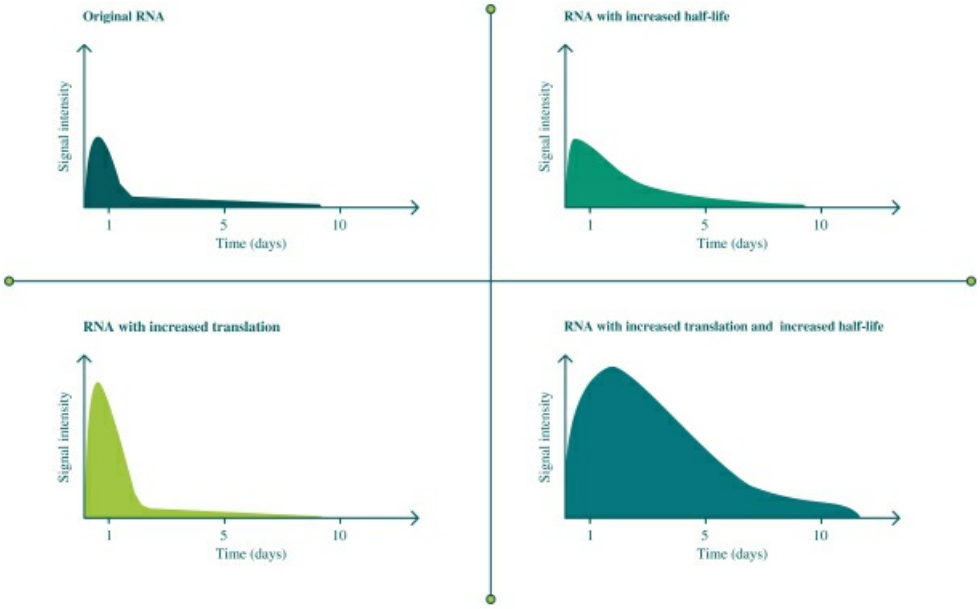
- an open reading frame, or ORF, which encodes for the protein of interest;
- untranslated regions, or UTRs, which flank the ORF; and
- the cap and the poly(A) tail, which are the two terminal structures of the linear mRNA, and are responsible for increased stability and translational efficiency of mRNA.

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. In case of an immunotherapy application, the protein is degraded into immunogenic epitopes. These are loaded onto specialized molecules, namely MHC I or MHC II. These molecules 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 either delivered in a buffered solution as naked molecules or 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.

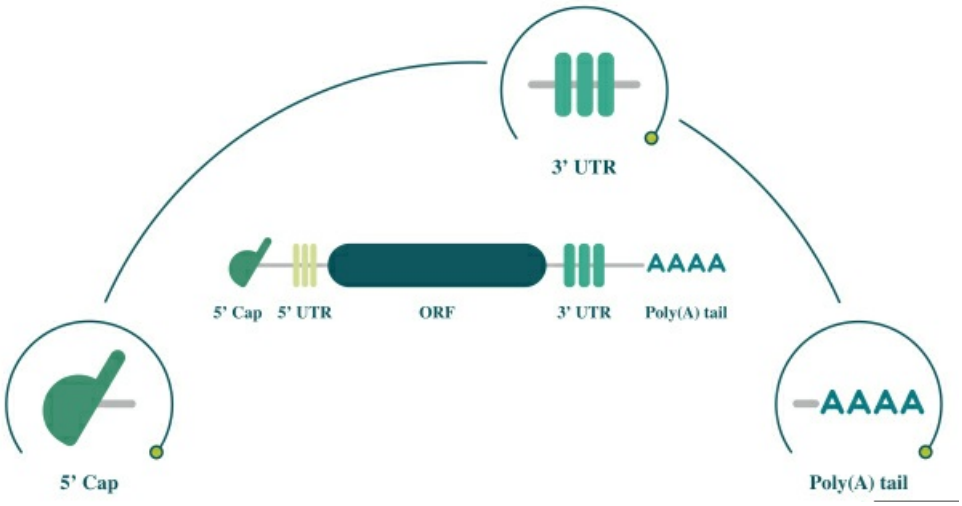
The structural elements of the mRNA have an impact on its performance. This includes potential immunogenicity, efficacy of translation and stability of the molecule. We leverage our extensive experience to design, synthesize, manufacture and formulate our therapeutic mRNA, and adapt its composition to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



Our strategy for optimizing mRNA potency. The pharmacological properties of mRNA can be improved by biochemical optimization of the molecule for either (i) increasing the half-life of the mRNA, i.e., the mRNA is translated for a longer period of time before it is degraded, which results in sustained protein production after mRNA delivery, or for (ii) increasing the mRNA translation efficiency, i.e., the peak protein production is increased. Our optimization approach relies on combining both strategies in order to maximize the mRNA therapeutic effect.

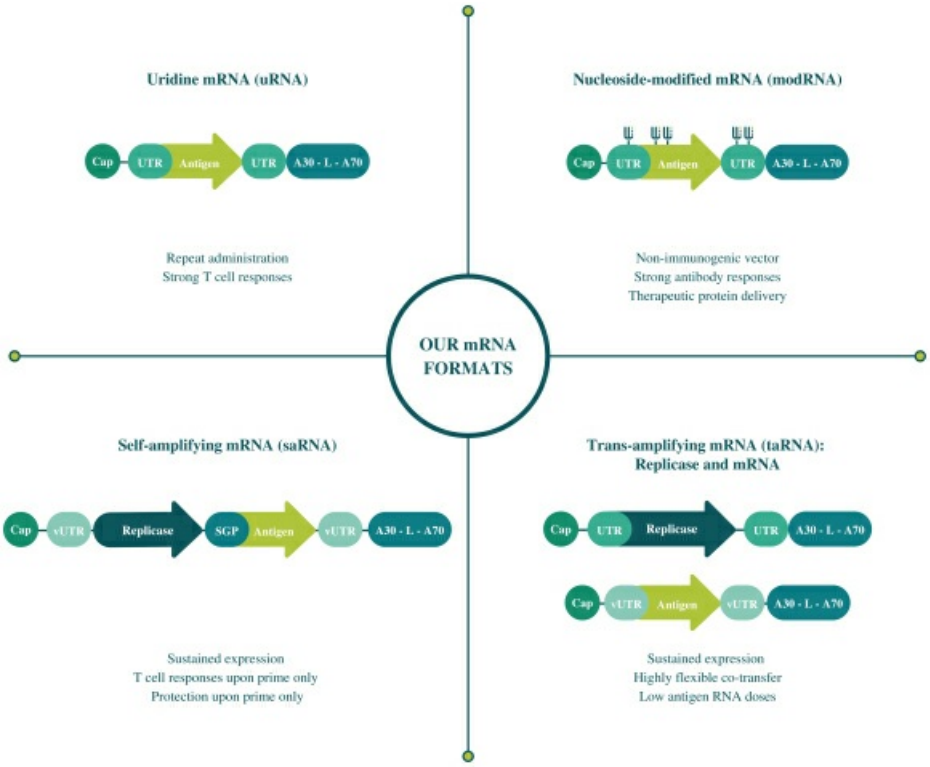
B. Our mRNA Backbone Concepts and Technologies

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 all 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 unique 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 are essential for 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-methylpseudouridine; 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. 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. Our mRNA Delivery Formulation Technologies

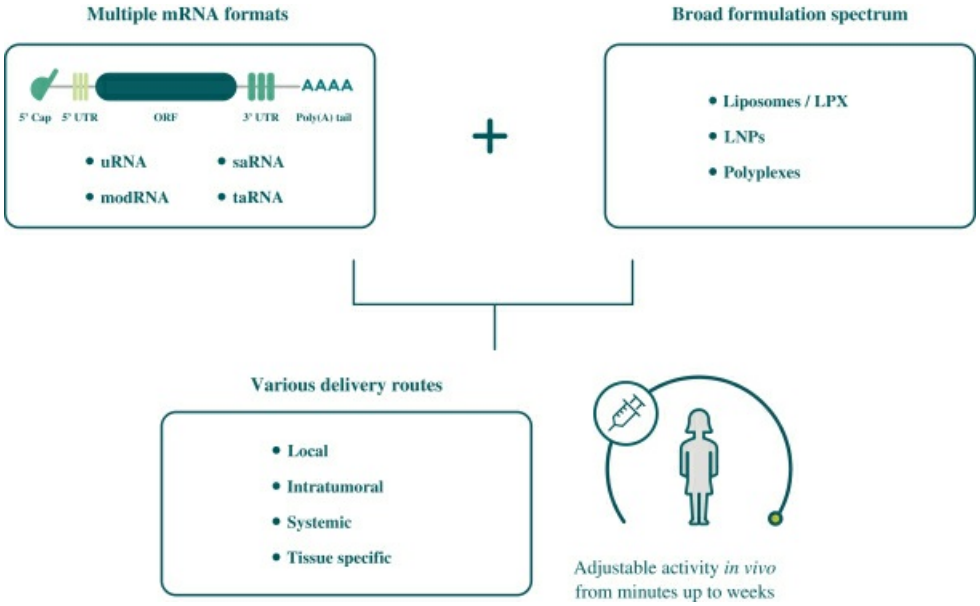
We have deep and broad expertise in the targeted delivery of mRNA therapeutics. We are convinced that our development of suitable delivery formulations in conjunction with our own therapeutic mRNAs is a key competitive advantage.

Our mRNA delivery formulation technologies. We utilize a range of mRNA delivery formulations for different therapeutic needs.

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.

As shown in the graphic below, our mRNA platforms utilize our wide range of mRNA formats, mRNA delivery formulations and mRNA delivery routes to optimize and tailor treatments.



Our therapeutic mRNA technology toolbox. Our product candidates utilize multiple mRNA formats, a broad spectrum of delivery formulations and applications using various delivery routes.

D. Our 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.

	mRNA Platform	Drug Targets	mRNA Formats	Delivery Formulations
	7 mRNA platforms	*Broad range of biological targets*	*4 types of mRNA*	*Multiple optimized formulations*
Oncology	FixVac	Shared Antigens	uRNA	RNA-LPX
Oncology	iNeST	Neoepitopes	uRNA	RNA-LPX
Oncology	Intratumoral Immunotherapy	Immunomodulators	modRNA	Various formulations Intratumoral
Oncology	RiboMabs	mAb targets	modRNA	LNPs Intravenous delivery
Oncology	RiboCytokines	Cytokines	modRNA	Various LNP formulations
Other	Infectious Disease Vaccines	Pathogens	saRNA, taRNA modRNA	Various LNPs for i.m. & s.c. delivery
Other	Rare Disease Protein Replacement Therapy	Diverse Proteins	modRNA	Liver targeted LNPs

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.

1. Cancer Immunotherapies

Our goal is to develop safe, potent, efficacious and cost-effective cancer immunotherapies which stimulate and potently expand tumor cell specific $CD4^+$ and $CD8^+$ T cells in cancer patients. Our cancer immunotherapy development integrates our competencies in mRNA backbone optimization, formulation development and immunological research.

We have developed novel immunotherapy approaches to replicate the highly potent and effective natural activation of the immune system in response to a viral infection. Our first generation mRNA cancer immunotherapies were delivered as naked mRNA by ultrasound guided injection into a patient's lymph node and induced T cell responses and antitumoral activity when targeting mutant neoantigens in advanced melanoma patients. To further improve this potency and antigen specificity we have developed a nano-particulate mRNA lipoplex immunotherapy for intravenous delivery.

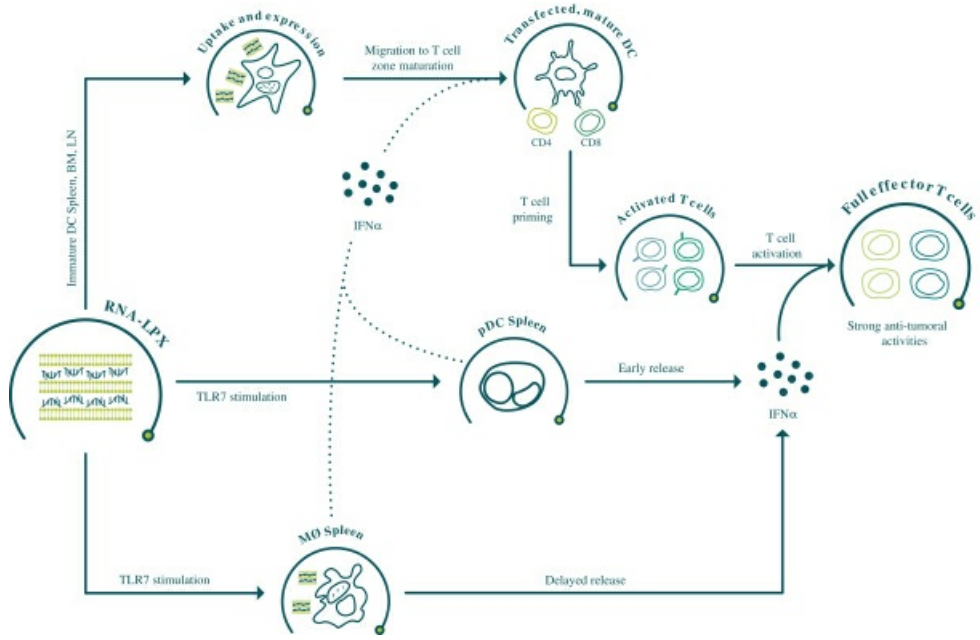
RNA-LPX Technology

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 toll-like receptor 7 (TLR7)-triggering and type-I interferon-driven innate and adaptive immune stimulation.

- Preclinical anti-tumoral activity demonstrated against multiple tumors.
- Unprecedented clinical immune responses against shared TAAs.
- Beneficial clinical activity demonstrated in advanced melanoma patients.

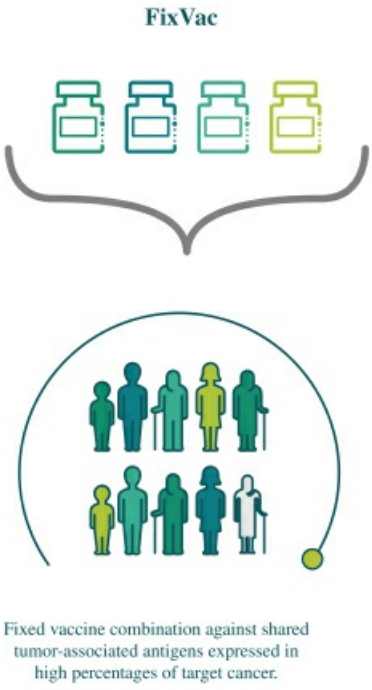
To advance from local to systemic dendritic cell, or DC, targeting, we developed an innovative liposome-based RNA-lipoplex formulation, RNA-LPX, that allows for intravenous administration of our mRNA cancer immunotherapies. We have demonstrated in the clinic that systemic DC targeting by mRNA cancer 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.



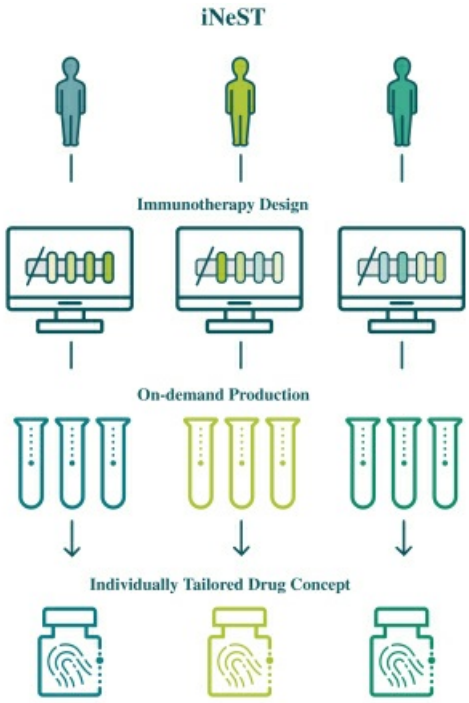
Our RNA-LPX technology. Our proprietary RNA-LPX formulation is designed to deliver vaccine mRNA precisely into DCs and macrophages in the spleen and other lymphoid compartments. The RNA-LPX has an inherent adjuvant function stimulating the release of cytokines such as IFN-a thereby promoting the activation 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-a, 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.



Fixed vaccine combination against shared tumor-associated antigens expressed in high percentages of target cancer.



Individualized Neoantigen Specific Immunotherapy (iNeST) concept. Truly individualized immunotherapies tailored for every different patient targeting individual patient's cancer mutation.

a) FixVac

At a glance: Our FixVac Platform

- **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 mRNA providing superior immunogenicity.
- **mRNA Delivery Formulation:** Proprietary size- and charge-based RNA-LPX targeting DCs.
- **Development Approach:** Worldwide rights; wholly owned.
- **Lead Candidate:** BNT111 for metastatic melanoma.
- **Data Highlights:** Three partial responses and seven stable diseases in 25 patients with metastatic lesions at enrollment, following BNT111 monotherapy.

Our FixVac approach involves off-the-shelf mRNA immunotherapies targeting cancer cell-specific shared tumor associated antigens for selected patient populations. Our FixVac product candidates target TAAs which are

commonly expressed by a significant portion of patients in a given cancer type. We have developed a sophisticated target selection process which enables us to produce poly-specific FixVac immunotherapies that cover up to 95% of patients with a given cancer type. The use of off-the-shelf FixVac immunotherapies allows for large-batch manufacturing and prompt supply to patients with ready-to-use medication, ensuring a straight-forward cost- and time-efficient manufacturing process with favorable logistics.

Besides targeting commonly expressed TAAs, our target selection strategy facilitates the identification of suitable viral oncoproteins for the treatment of virus-induced cancers like HPV+ head and neck cancer. Patient stratification, if needed, can easily be performed at the clinical site or a central lab using standard biotechnological methods, thereby reducing treatment costs. As the viral genome is comparatively small, encoding only for a few proteins, we believe our FixVac approach is ideally suited for the treatment of virus-induced cancers.

Our FixVac Development Plan

We currently have six FixVac programs in development, with five in human trials, including our ongoing Phase 1 trial in advanced melanoma, a Phase 1 trial in HPV+ head and neck cancer and a Phase 1 trial in triple negative breast cancer. We expect to progress our advanced melanoma program into Phase 2 clinical trials in the first half of 2020, and into Phase 3 in the second half of 2020. We enrolled the first patient in a Phase 1/2 trial in prostate cancer and the first patient was dosed in a Phase 1 ovarian cancer trial in the second half of 2019. In addition, we are planning to initiate a Phase 2 study for FixVac in HPV+ cancers in the second half of 2020.

Candidate	Antigens	Development Phase	Next Potential Milestone
BNT111	Melanoma-specific antigens: NY-ESO-1, tyrosinase, MAGE-A3 and TPTE	Phase 1: Advanced melanoma	Report Phase 1 data and initiate Phase 2 trial in 1H 2020; initiate Phase 3 trial in 2H 2020
BNT112	Five prostate cancer-specific antigens, including PAP and three internally identified antigens	Phase 1/2: Prostate cancer	—
BNT113	HPV E6 and E7 oncoproteins	Phase 1: HPV+ head and neck cancer (IST)	Initiate Phase 2 trial in 2H 2020
BNT114	Selected breast cancer-specific antigens	Phase 1: TNBC	Report data update in 1H 2020 and assess antigen immunogenicity
BNT115	Selected ovarian cancer-specific antigens	Phase 1	—
BNT116	Non-small cell lung cancer	Preclinical	—

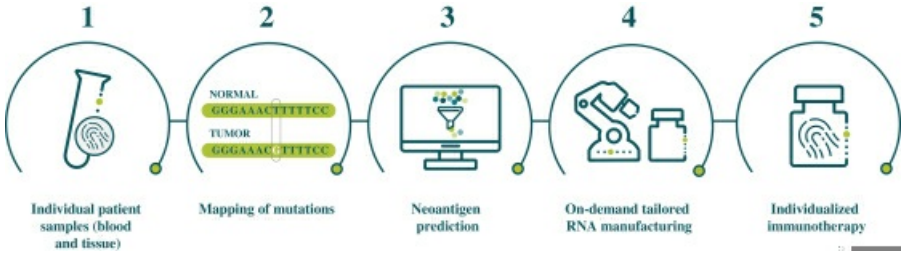
b) Individualized Neoantigen Specific Immunotherapy (iNeST)

At a glance: Our iNeST Platform

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

- **mRNA Format:** Optimized uridine mRNA providing superior immunogenicity.
- **mRNA Delivery Formulation:** Proprietary size- and charge-based RNA-LPX targeting DCs.
- **Development Approach:** 50:50 cost share with Genentech.
- **Lead Indication:** RO7198457 (BNT122) as a first-line melanoma therapy in combination with pembrolizumab.
- **Data Highlights:** In a previous Phase 1 trial of BNT121, we observed first-in-human data in 13 patients with metastatic melanoma demonstrating stable progression-free survival in nine patients for up to 41 months, and additional objective responses in three of five patients with metastatic disease at time of treatment with iNeST, including one patient receiving combination therapy. We also observed a significant decrease in the cumulative recurrence rate post-treatment as compared to pre-treatment.

We are a pioneer and global leader in developing fully individualized cancer immunotherapies. We have developed a first of its kind, on-demand manufacturing process to treat each individual patient based on the mutation profile of the patient's tumor. We are investigating this treatment approach in the clinic in collaboration with Genentech.



Our iNeST process. The figure above depicts our iNeST process for the on-demand production of individualized mRNA cancer immunotherapies.

Our iNeST process is summarized below:

- A blood sample and tumor biopsy is taken from the patient to obtain healthy cells and tumor tissue. We extract healthy cells from the patient's blood sample and tumor cells from the tumor sample. We use NGS to analyze genetic material (DNA and RNA) of these cells to identify which mutations are present in the cancer cells compared to healthy cells.
- We apply proprietary bioinformatic algorithms to identify tumor-specific mutations. The mutations within a cancer cell differ widely from patient to patient and form a unique signature for each tumor. This genomic information can be further utilized to analyze tumor heterogeneity and microenvironment as well as individual aspects of the immune system like the HLA type.
- Based on these bioinformatic algorithms, we then select mutations that are the most promising therapeutic targets. The specific traits of the patient's immune system, including HLA type, are key to the selection of the most appropriate targets. Picking multiple mutations increases the chance to induce potent T cell responses and reduces the risk that the tumor evades T cell attack over time. We account for heterogeneity of each tumor by preferentially selecting mutations that are expressed on all tumor cells. Importantly, the selected mutations are intended to ensure both $CD4^+$ and $CD8^+$ T cell induction.
- Following mutation selection, we design the structure for the iNeST product. The chosen mutations have to be arranged in a certain order and the DNA sequence of the mutations has to be optimized. This is important to ensure a robust production of the starting material, or DNA matrix, for the GMP manufacturing of the iNeST product.

- Next we produce the patient-specific iNeST product under GMP conditions and the iNeST product undergoes numerous different quality control tests.
- The iNeST product is transferred to the hospital and injected into the same patient by the physician.
- This process has been designed for the on-demand delivery of our iNeST products, and currently takes approximately six weeks.

Our iNeST Development Plan

We are currently developing iNeST therapeutics for the treatment of metastatic melanoma and multiple solid tumors. We are conducting two clinical trials of iNeST in collaboration with Genentech, including one randomized Phase 2 trial in first-line melanoma in combination with pembrolizumab and a Phase 1a/1b trial in patients with locally advanced or metastatic tumors (including in melanoma, non-small cell lung cancer, bladder cancer and other solid tumors) as a monotherapy and in combination with atezolizumab. We expect to announce a topline data update from the first-line melanoma trial in the second half of 2020 and a data update from the Phase 1a/1b trial in solid tumors in 2020. We and Genentech plan to initiate two additional clinical trials for RO7198457 (BNT122) in 2020 in first-line solid cancers in the adjuvant setting, one in combination with atezolizumab and the other as a monotherapy.

Candidate	Antigens	Development Phase	Next Potential Milestone
RO7198457 (BNT122)	Up to 20 neoantigens selected on a patient by patient basis	Phase 2: first-line melanoma in combination with pembrolizumab	Report topline data update in 2H 2020[1]
		Phase 1a/1b: multiple solid tumors	Report data update in 2020

1 We expect this topline data update to include an update on the ongoing study, including patient enrollment numbers, with full efficacy and safety data for an interim update expected in the second half of 2021.

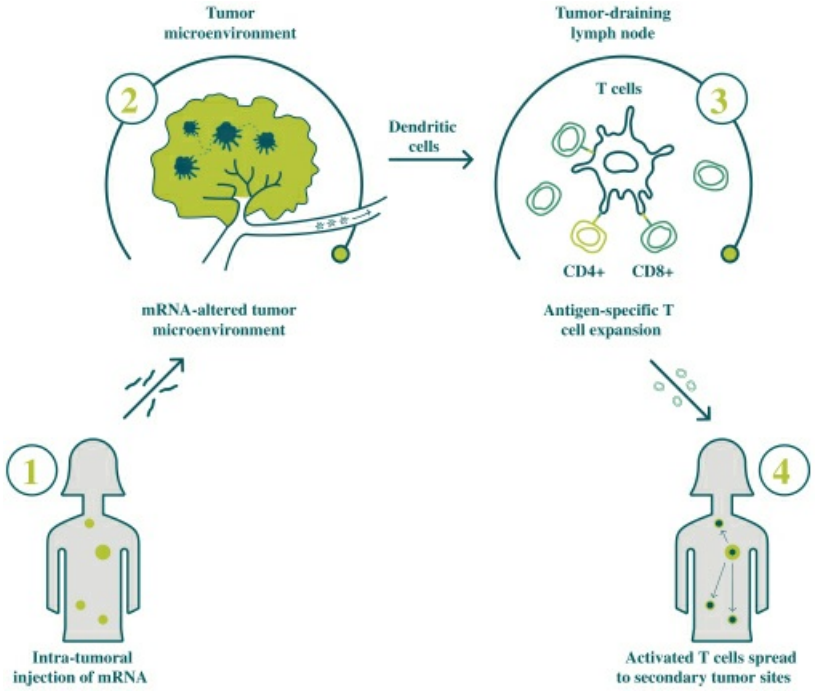
c) Intratumoral mRNA Immunotherapy

At a glance: Our Intratumoral mRNA Platform

- **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.
- **Lead Candidate:** SAR441000 (BNT131) for advanced solid tumors as a monotherapy and in combination with cemiplimab.

In collaboration with Sanofi, we are leveraging our mRNA technology to develop intratumoral immunotherapies for the treatment of solid tumors. Intratumoral immunotherapy is designed to promote innate and adaptive immune responses against tumors, without toxicities related to systemic administration. Our intratumoral immunotherapy involves injection of cytokine-encoding mRNA directly into a tumor in order to alter the tumor microenvironment and promote greater T cell activity. This approach has been found in preclinical studies to boost cancer-specific immune responses locally, while also producing tumor responses in remote parts of the body due to the circulation of properly activated anti-tumor immune cells, known as an abscopal effect.

The first intratumoral immunotherapy product candidate arising from our collaboration, SAR441000 (BNT131), includes modified mRNA that encodes for the IL-15sushi, IL-12sc, GM-CSF and IFN-α cytokines. In preclinical studies, SAR441000 (BNT131) promoted increased levels of local cytokine expression within the tumor microenvironment and activated innate and adaptive immune responses against tumors.



Therapeutic mode of action of intratumoral mRNA immunotherapy . The figure above demonstrates how SAR441000 (BNT131) promotes cytokine expression within the tumor itself.

Our Intratumoral Development Plan

The lead intratumoral mRNA collaboration product candidate from our collaboration is being investigated in a Phase 1 clinical trial sponsored by Sanofi. This trial is expected to enroll approximately 264 patients with certain advanced solid tumors, as a monotherapy and in combination with cemiplimab. This trial is currently being run at four sites in Europe. A data update from this trial may be reported in the second half of 2020. As the trial is sponsored and conducted by Sanofi, the timing of data updates is not under our control, and is subject to change by Sanofi.

Candidate	Encoded Cytokines	Development Phase	Next Steps
SAR441000 (BNT131)	IL-15sushi, IL-12sc, GM-CSF and IFN-α	Phase 1: Advanced solid tumors as a monotherapy and in combination with cemiplimab	Data update in 2H 2020*

* As the trial is sponsored and conducted by Sanofi, the timing of data updates is not under our control, and is subject to change by Sanofi.

2. Infectious Disease Vaccines

At a glance: Our Infectious Disease Vaccine Platform

- **Concept:** mRNA-based vaccines targeting infectious disease pathogens.
- **mRNA Format:** Self-amplifying mRNA providing high immunogenicity with smaller amounts of mRNA.
- **mRNA Delivery Formulation:** LNPs.
- **Development Approach:** Collaboration with Pfizer and exclusive option arrangement with Penn.
- **Lead Candidate:** Influenza vaccine.

Expanding beyond our research in oncology, we are leveraging our mRNA technologies to direct the immune system more effectively against infectious diseases. Our infectious disease vaccine candidates contain self-replicating or trans-replicating, modified mRNA-encoding antigens specific to a target pathogen, delivered in various LNP formulations in order to activate and direct T cells and B cells to fight the pathogen.

Influenza Vaccine

We are collaborating with Pfizer to develop an influenza vaccine using our mRNA-based immunotherapy technology. Current influenza vaccines consist of antigens from inactivated influenza viruses, recombinant influenza haemagglutinin, or HA, proteins or live attenuated influenza viruses and are available as trivalent (containing two influenza A strains and one influenza B strain) or quadrivalent (containing two influenza A strains and two influenza B strains) vaccines. Currently available influenza vaccines are produced in chicken eggs or cell culture and take about five to six months to produce. This requires the composition of the coming season's vaccine to be selected by the World Health Organization, or WHO, far in advance for the vaccine to be available on time, which reduces the reliability of that prediction.

We anticipate that our mRNA-based vaccine can be manufactured within three months from the time the recommendation is published, including cloning and production and therefore the WHO's review of the vaccine components can occur closer to the influenza season to obtain a more reliable prediction. In addition, the mRNA manufacturing process is designed to produce an HA vaccine antigen that matches the HA of circulating influenza strains, in contrast to egg- or cell-based processes which can introduce mutations in the HA amino acid sequence. The flexibility of the mRNA vaccine platform could allow for generation of vaccines against genetically drifted seasonal viruses or pandemic strains. We currently expect to initiate a first clinical trial for one of our influenza vaccine mRNA formulations by the end of 2020.

Other Infectious Diseases

In October 2018, we entered into a research collaboration with Penn, under which we have the exclusive option to develop and commercialize prophylactic mRNA immunotherapies for the treatment of up to 10 infectious disease indications. We expect to report our first product candidates under this collaboration, and advance our first product candidate into the clinic, in the first half of 2021.

In August 2019, we entered into a letter agreement and investment agreement with the Bill & Melinda Gates Foundation to advance the development of immunotherapies for the prevention and/or treatment of HIV and tuberculosis and up to three additional infectious diseases.

3. mRNA-based Protein Replacement Platform for Rare Diseases

At a glance: Our Protein Replacement Platform for Rare Diseases

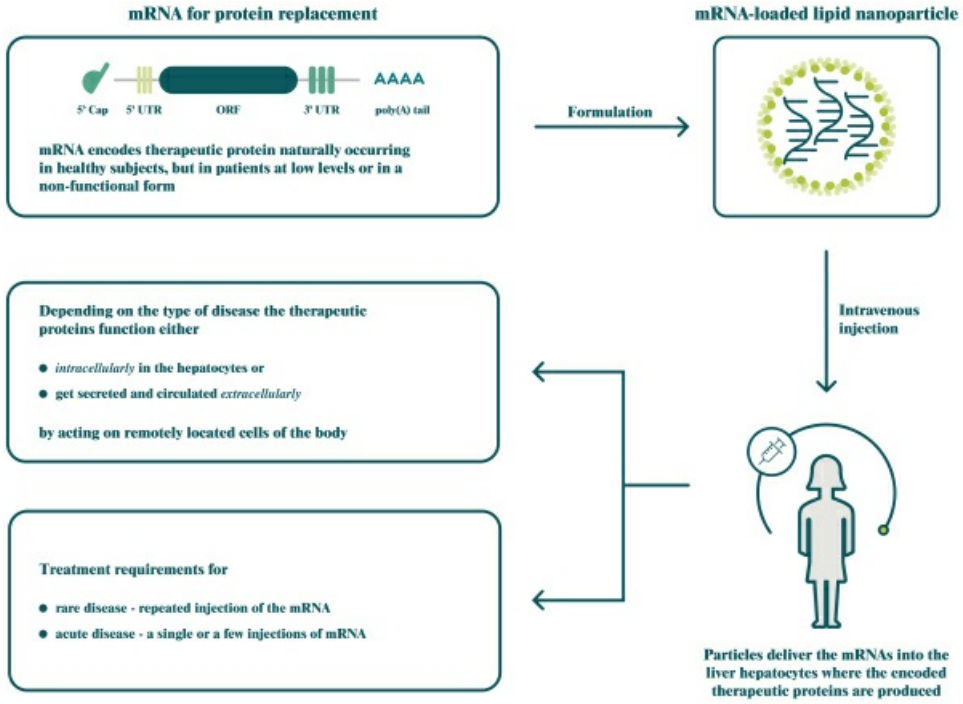
- **Concept:** Therapeutic proteins encoded by mRNA and produced in the patient as an alternative to recombinant protein replacement.

- **mRNA Format:** Nucleoside-modified mRNA, deimmunized to avoid immune activation in order to allow for translation of the therapeutic protein in the cells.
- **mRNA Delivery Formulation:** Liver-targeting LNPs.
- **Development Approach:** 50:50 cost and profit share with Genevant.

By incorporating modified nucleosides into our mRNA, we are able to reduce the immunogenicity of our product candidates, thereby allowing their use for therapeutic protein production. In addition, we utilize advanced mRNA delivery methods to protect the mRNA cargo *en route* to its target and promote its uptake into liver cells. Current protein-based replacement therapies were developed to treat rare diseases by administering recombinant proteins. Such therapies are limited to diseases where the missing protein function is extracellular. However, mRNA-based protein replacement therapy also has the potential to treat illnesses with intracellular protein defects, as long as the mRNA can be delivered into the affected cells.

Our mRNA-based protein replacement therapy features:

- **Nucleoside-modified mRNA.** Replacing uridines in mRNA with modified analogues is important to avoid immune activation that can provoke anti-drug antibody production and would limit efficacy of the treatment.
- **Liver targeted expression.** mRNA encoding therapeutic proteins are formulated into LNPs using in-licensed clinically-validated LNP delivery technology owned by Genevant. The mRNA-loaded LNPs are less than 100nm in size. When injected intravenously, these particles are selectively taken up by hepatocytes, the major cell component of the liver.



Our mRNA-based protein replacement technology. The illustration above depicts our mRNA-based protein replacement process for the treatment of rare diseases.

Our protein replacement technology is designed for the treatment of:

- Genetic disorders that manifest due to a missing or defective protein, where mRNA would need to be administered regularly for a lifetime.
- Acute diseases caused by transient depletion of a protein, such as a hormone, where treatment of such diseases with a single or a few doses of the encoding mRNA could be curative.

Therapeutic proteins encoded by the mRNA can either act intracellularly or be secreted and act extracellularly, in order to produce the desired therapeutic effect.

mRNA-based protein replacement technology has several advantages over recombinant proteins:

- **No need to develop a procedure for protein purification.** The development of recombinant proteins is a laborious and expensive procedure due to the requirement for a unique purification protocol for each protein. During mRNA-based protein replacement the protein is produced by the patient, which we believe avoids the need for purification and also accelerates drug development.
- **The protein has proper post-translational modification.** To function properly, most recombinant proteins need to be modified after synthesis. Proteins produced in patients from mRNA are more likely to obtain the correct modifications than recombinant proteins produced in cultured bacterial or mammalian cells.
- **Continuous *in vivo* supply of encoded protein.** Recombinant proteins, especially those with short half-lives, can be cleared from the body very quickly, thereby limiting therapeutic effect. During mRNA-based therapy, the encoded therapeutic protein is produced for a longer duration (*e.g.*, 10-14 days).
- **Production of intracellular proteins.** Recombinant proteins have limited intracellular therapeutic effects. In contrast, proteins encoded by mRNA can reach any cellular compartment and potentially help to cure diseases where the therapeutic protein needs to function in different subcellular locations, including the mitochondria, nucleus or cell membrane.

Our Protein Replacement Development Plan in Rare Diseases

We expect to initiate our first rare disease clinical trial in the second half of 2020.

4. RiboMabs

At a glance: Our RiboMab Platform

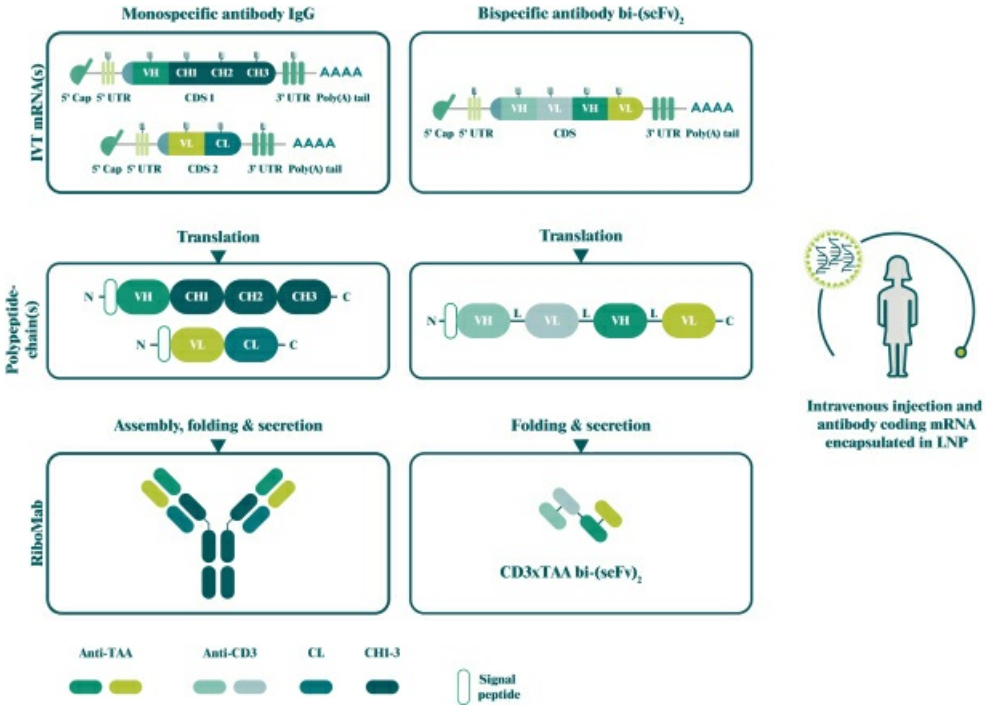
- **Concept:** Antibodies encoded by mRNA and produced in the patient as an alternative to recombinant antibodies.
- **mRNA Format:** Nucleoside-modified mRNA engineered for minimal immunogenicity in order to avoid immune detection and allow translation of the encoded antibodies to occur within the cells.
- **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.
- **Lead Candidate:** BNT141 in multiple solid tumors.

Our RiboMab product candidates are designed to encode secreted antibodies for expression *in vivo* by the patient's cells. We believe our RiboMab technology represents the next generation of antibody-based drugs. Antibody drugs are a leading class of biologics for the treatment of various diseases, but have a number of limitations. The development of antibodies is currently challenged by demanding and costly procedures of

production, purification and formulation of a recombinant protein, which we believe hampers the rapid development and clinical testing of new drugs in this class. Recombinant protein antibodies require development of a cell line, establishment and adaptation of processes for production, purification and analytical testing. The whole process typically takes 18 to 30 months to optimize, scale-up and produce first clinical batches. Some of these antibodies are produced in low yields making them unsuitable for therapeutic application.

By contrast, mRNA not only involves a simpler and less expensive manufacturing process, but also is effective in much lower volumes than are required to produce similar effects using recombinant proteins. RiboMabs provide an antibody's mRNA sequence, and the body does the production work itself. This simplicity is designed to allow for both shorter development times and a greater diversity of druggable targets. For efficient RiboMab production, the encoding mRNA is encapsulated in LNPs that deliver the mRNA to the liver cells. For cancer treatment, we focus on tumor-associated antigens to keep adverse effects for the patients as low as possible. We believe we can integrate any antibody sequence in our RiboMab-encoding mRNA.

We have demonstrated the feasibility of our RiboMab technology for a variety of antibody formats, such as full immunoglobulins (Ig), primarily IgG, or different bispecific antibody variants, all of which engage the patient's own immune cells to eradicate antigen-positive tumor cells.



Our RiboMab technology. The figure above depicts the structure of *in vitro* transcribed (IVT) IgG and bi-(scFv)2 RiboMabs. IVT-mRNA encoding the therapeutic antibody is encapsulated in LNPs and injected intravenously into patients. The mRNA is delivered to the liver where it is translated into antibodies and secreted into the blood stream. Abbreviations: A100, poly adenosine tail; bi-(scFv)2, bispecific single chain variable fragment; C, C-terminus; CH, constant heavy domain; CL, constant light domain; IgG, immunoglobulin G; IVT, *in vitro* transcribed; L, linker; LNP, lipid nanoparticles; m1 y, 1-methylpseudouridine; N, N-terminus; TAA, tumor-associated antigen; VH, variable heavy domain; VL, variable light domain; UTR, untranslated region.

We believe our broad portfolio of antibody formats will enable us to produce mRNAs encoding the appropriate antibody format for the individual patient's medical need and the desired treatment regimen (*e.g.,* monotherapy or combination therapy).

Our RiboMab Development Plan

Our first development candidate, BNT141, is an IgG antibody, which we expect to enter the clinic in the second half of 2020 in a basket trial targeting multiple solid tumor types. We are also currently evaluating multiple additional RiboMab development candidates in the preclinical setting, including RiboMabs encoding bispecific antibodies, one of which, BNT142, we expect to enter the clinic in the first half of 2021.

Candidate	Target	Development Phase	Next Potential Milestone
BNT141 (monospecific)	Undisclosed	Preclinical	Initiate Phase 1 trial in 2H 2020
BNT142 (bispecific)	CD3xCLDN6	Preclinical	Initiate Phase 1/2 trial in 1H 2021

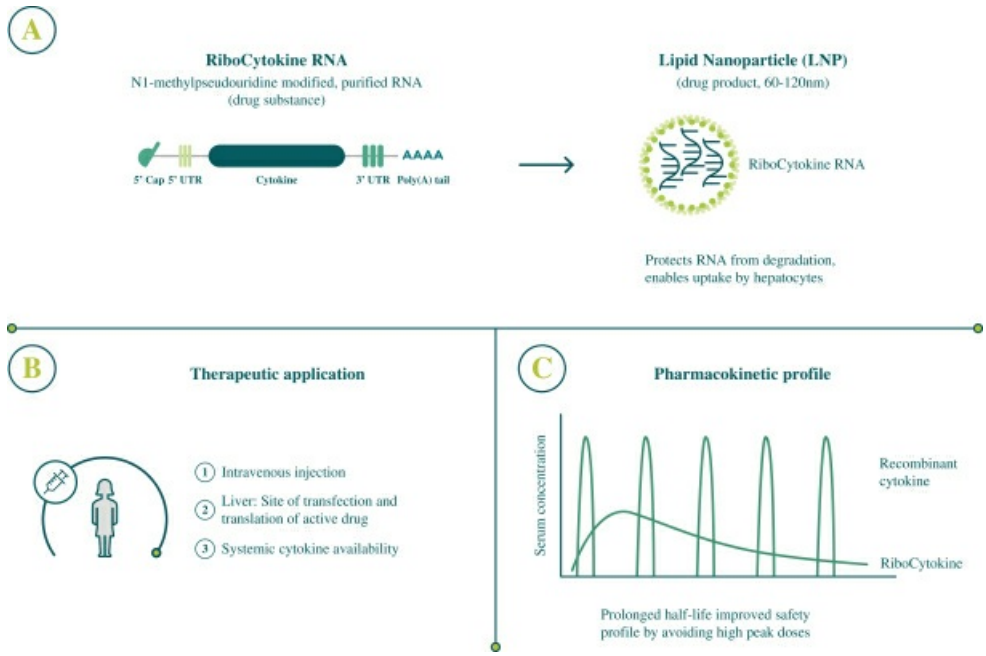
5. RiboCytokines

At a glance: Our RiboCytokine Platform

- **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.
- **Lead Candidate:** BNT151 in multiple advanced malignancies.

Our RiboCytokine product candidates utilize mRNA that encodes the desired cytokines for expression *in vivo* by the patient's cells. Cytokines represent a large group of relatively small proteins (<30 kDa) that regulate a variety of biological functions as they elicit signaling for immune and non-immune cells. In particular, cytokines play a pivotal role in orchestrating the initiation, execution and extinction of innate and adaptive immunity against pathogens as well as malignant cells. Due to their natural role as immunomodulators, recombinant cytokines are currently used for the treatment of a number of infectious, inflammatory, autoimmune and malignant diseases. One of the major challenges associated with the therapeutic use of cytokines relates to their short serum half-life and low bioavailability. This impedes therapeutic efficacy as it necessitates high and frequent dosing, which often results in dose-limiting toxicities.

We have developed a wholly owned, novel mRNA-based platform technology called RiboCytokines, designed to address the limitations of recombinantly expressed cytokines.



Concept of our RiboCytokine technology. The graphic above depicts our RiboCytokine technology, including mRNA formulated in LNPs and administered by injection, having a beneficial pharmacokinetic profile.

Our RiboCytokine platform allows for sustained delivery of the encoded cytokines with prolonged half-life, including through:

- **Usage of N1-methylpseudouridine modified mRNA.** N1-methylpseudouridine as a nucleoside analogue prevents the recognition of mRNA by TLRs, avoiding immune attack against the RiboCytokines.
- **Liver targeted expression.** RiboCytokines are formulated using clinically validated LNP delivery technology owned by Genevant. LNPs selectively target the liver resulting in high-level expression.

We believe that apart from a beneficial pharmacokinetic profile, our mRNA-based RiboCytokine technology has a number of additional advantages over other types of cytokine therapies:

- **Less immunogenic than recombinant cytokines.** Expression of self and foreign antigens in the liver is associated with immune tolerance due to a unique anti-inflammatory microenvironment. We expect RiboCytokines to be less likely to trigger an immune response when compared to their recombinant counterparts.
- **Shorter development times and greater diversity.** The development of recombinant cytokines is a challenge due to demanding and costly CMC procedures of production, purification and formulation. The simplicity of our mRNA manufacturing allows for both shorter development times and a greater diversity of druggable targets.

We believe that our RiboCytokine technology is particularly well-suited to identify candidates for combination treatment with our proprietary CAR-T cell and cancer immunotherapies platforms.

Our RiboCytokine Development Plan

We expect our first two RiboCytokine product candidates, BNT151 and BNT152/BNT153 (combination), to enter the clinic in the first half and second halves of 2020, respectively, in basket trials targeting multiple advanced malignancies.

Candidate	Cytokines	Development Phase	Next Potential Milestone
BNT151	Optimized IL-2	Preclinical	Initiate Phase 1 trial in 1H 2020
BNT152/BNT153	IL-7/IL-2	Preclinical	Initiate Phase 1/2 trial in 1H 2021

IX. Our Engineered Cell Therapies Drug Class

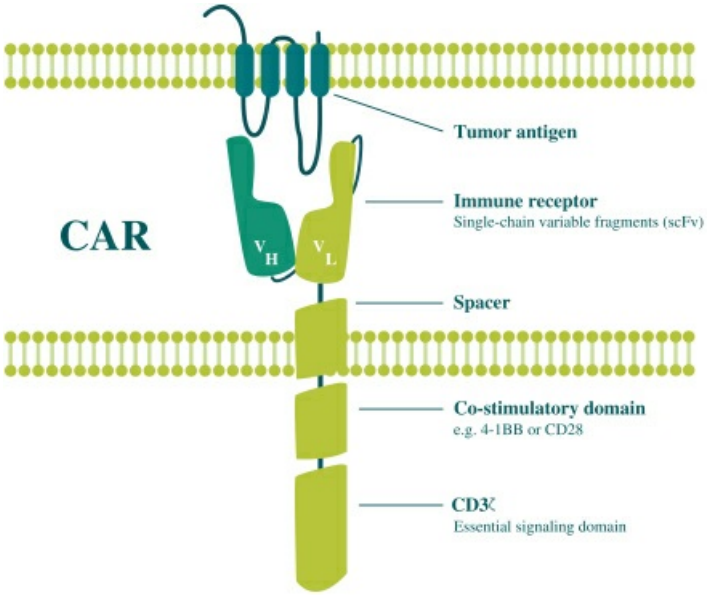
The tailored reprogramming of autologous T cells from cancer patients to recognize and attack their tumors has become a disruptive medical innovation. Retargeting of T cells can be achieved via introduction of tumor-specific receptors into patient-derived T cells. For that purpose, T cells are mostly engineered by retroviral gene transfer to express either T cell receptors, or TCRs, or chimeric antigen receptors, or CARs. Recently, CAR expressing T cells, or CAR-T cells, became the first engineered T cell therapy to obtain FDA approval for some B cell derived hematological malignancies.

A. CAR-T Cells

At a glance: Our CAR T Platform

- **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.
- **Lead Candidate:** BNT211 for multiple solid tumors.

CARs are artificial receptors that consist of an antigen recognition domain derived from a tumor-specific antibody linked to intracellular T cell signaling domains. CARs redirect T cells to eradicate tumors through specific recognition of native surface proteins expressed on tumor cells in a non-MHC-restricted manner. Therefore, CAR-T cells can be used for the treatment of all individuals whose tumor expresses the respective target, independent of the individual's HLA genotype. CARs can be used for redirection of both $CD4^+$ and $CD8^+$ T cells.



Second-generation CAR. The figure above illustrates the basic structure of a second-generation CAR, such as those included in our BNT211 and BNT212 product candidates.

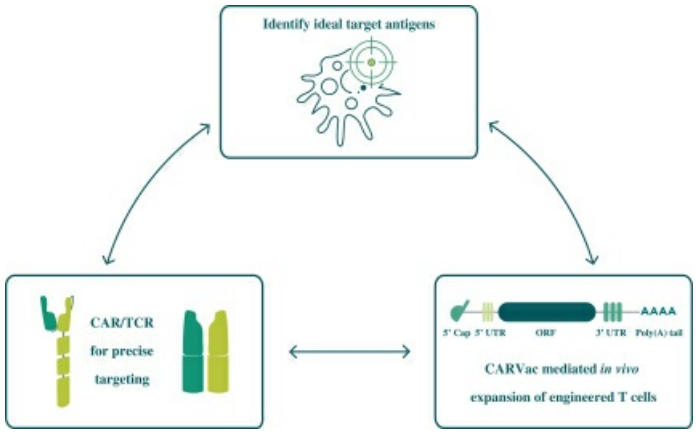
While CAR T therapy has shown potent anti-tumor responses in patients with B cell malignancies, clinical efficacy in solid tumors so far is limited. The main hurdles for application of CAR T therapies in solid tumors are:

- Lack of highly tumor-selective targets, which are needed for safe and effective tumor targeting; and
- Low anti-tumoral activity due to insufficient expansion of engineered T cells.

We are developing the next generation of engineered T cell therapies that:

- target novel and known tumor-specific antigens, including mutant neoantigens, and a broad spectrum of tumor-associated antigens expressed in a wide range of cancers; and

- leverage our proprietary CARVac technology for controlled *in vivo* stimulation, activation and expansion of engineered T cells.



Our platforms for development of next-generation engineered T cell therapies. Our engineered cell therapies combine our antigen selection capabilities with our vaccine immunotherapy to enhance T cell activation and expansion.

The powerful characteristics of CAR-T cells, including their potential to eradicate targeted tumor cells in combination with their potentially life-long persistence in the host, require careful target selection. We believe the essential features of an ideal antigen for T cell-based immunotherapy are:

- Absence of expression from any toxicity-relevant non-malignant tissue, to prevent off-tumor/on-target toxicity; and
- Expression on the cell surface of tumor cells at sufficient levels to allow for recognition and lysis by CAR-T cells.

We are developing CAR T programs targeting two different members of the Claudin family, namely CLDN6 and CLDN18.2. Claudins, or CLDNs, are central components of tight junctions that regulate epithelial-cell barrier function and polarity. Most of the CLDNs are broadly expressed, while CLDN6 and CLDN18.2 are exclusively expressed in different high medical need cancers. Disturbance and dysregulation of tight junction molecules is a frequent hallmark of cancer cells and often associated with malignant transformation and metastasis and, hence, disease progression.

CLDN6 is an oncofetal cell surface antigen expressed in embryonic stem cells during fetal development. The gene encoding CLDN6 is strictly silenced and not expressed in healthy adult tissues but re-activated in different cancers with a high medical need including ovarian, endometrial, testicular and lung cancers.

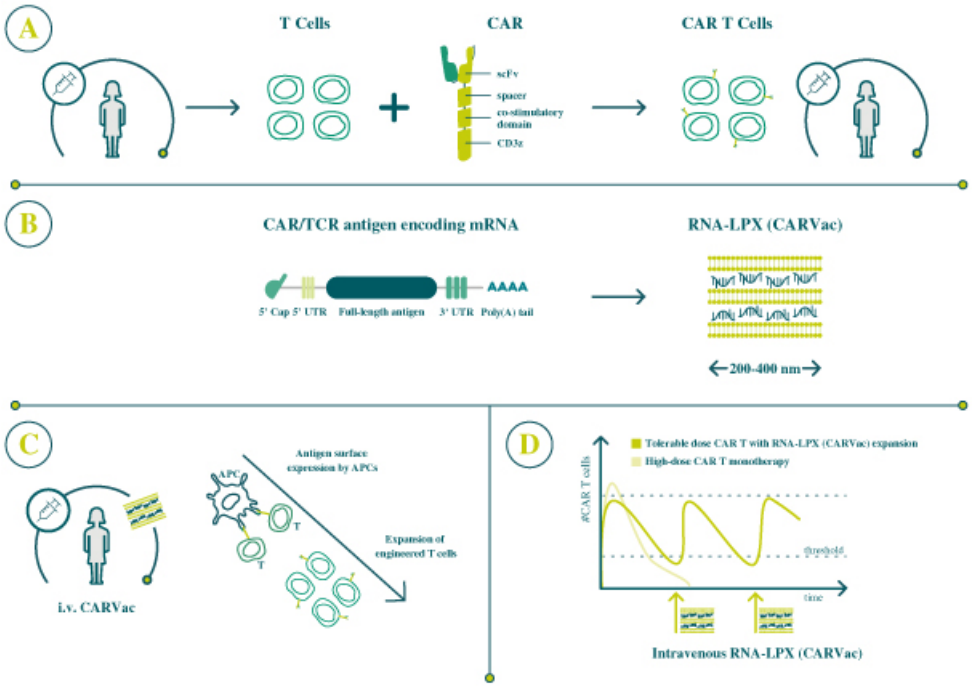
In contrast to CLDN6, CLDN18.2 is a tissue restricted marker that is exclusively expressed in short-lived differentiated cells of the gastric mucosa. CLDN18.2 is observed in a large fraction of gastric cancers. In addition, CLDN18.2 is aberrantly activated in a variety of tumor entities, including esophageal cancer, pancreatic adenocarcinoma and cholangiocarcinoma.

In-vivo *expansion of engineered T cells using liposomally formulated mRNA*

Besides targeting an ideal tumor-specific antigen, the frequency and the persistence of CAR-T cells in the respective patient is a critical factor determining antitumor efficacy. A positive correlation between clinical

outcome and CAR-T cell engraftment and persistence has been shown in several CD19-targeting CAR T trials. Both tend to be much more limited in the solid tumor setting, likely due to the lack of circulating antigen-presenting cells, or APCs, such as dendritic cells expressing the target CAR antigen.

To address this critical factor, we developed an approach for*in vivo* stimulation of CAR-T cells that relies on our proprietary FixVac technology for systemic mRNA delivery in combination with our CAR T product candidates. Intravenous administration of a FixVac encoding for the tumor antigen induces expression of the desired target on antigen-presenting cells in secondary lymphoid tissues. FixVac treatment facilitates *in vivo* expansion of CAR-T cells in a dose-dependent manner. Moreover repetitive administration of FixVac results in an improved CAR-T cell persistence as well as increased anti-tumor activity.



Our CAR-T cell immunotherapies combined with CARVac-mediated *in vivo* expansion. (A) Autologous T cells engineered to express a CAR are adoptively transferred into the patient. (B) Full-length CAR target-encoding mRNA is complexed with liposomes to form RNA-LPX lipoplexes (CARVac). (C) Intravenously administered CARVac selectively targets APCs in secondary lymphoid organs facilitating uptake, antigen expression and maturation of APCs. Exposure of CAR-T cells to their target results in CAR-T cell *in vivo* expansion. (D) CARVac can be administered repetitively to achieve controlled expansion and persistence of CAR-T cells within the therapeutic window.

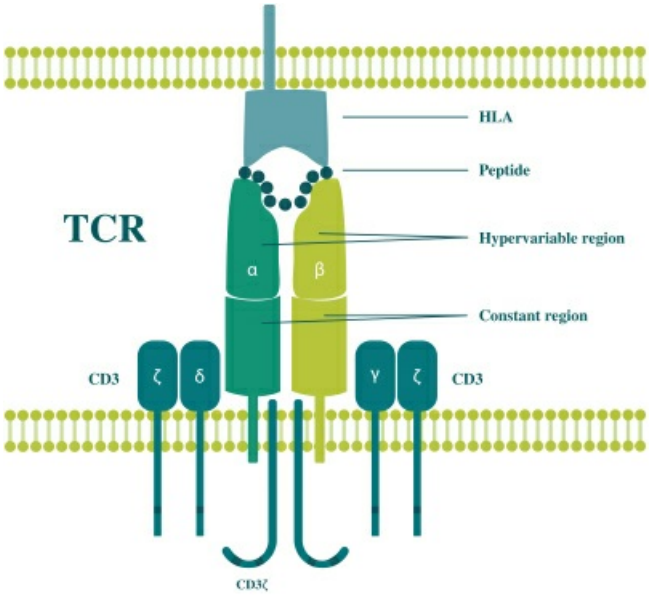
Our CAR T Development Plan

Our first CAR T product candidate, BNT211, includes a second-generation CAR directed against CLDN6. Our second product candidate is BNT212, which includes a CLDN18.2-targeting CAR. We expect to initiate a Phase 1/2 basket trial of our novel combination CLDN6CAR-T cell and CLDN6 CARVac product candidate in multiple solid tumors in the first half of 2020.

Candidate	Antigen Target	Development Phase	Next Potential Milestone
BNT211	CLDN6	Preclinical	Initiate Phase 1/2 trial in 1H 2020
BNT212	CLDN18.2	Preclinical	—

B. TCRs

The T cell receptor, or TCR, is part of a complex signaling machinery, which includes the TCRa and ß chains that are responsible for antigen recognition, the co-receptor $CD4^+$ or $CD8^+$ and the CD3 signal transduction complex. TCRs recognize antigens presented on the cell surface as small peptides loaded on the patients' HLA molecules. Those peptides are derived from proteins after intracellular degradation. In contrast to CARs that recognize solely native membrane proteins, the repertoire of suitable TCR target antigens include TAAs and mutant neoantigens.



TCR Complex. The illustration above shows the basic structure of a TCR complex.

Our TCR Discovery and Validation Platform

We have developed an integrated technology platform for the systematic identification of functional, fully human TCRs from single antigen-reactive T cells. This technology consists of a proprietary high-throughput approach for the fast retrieval, cloning and rapid validation of novel paired T cell receptor sequences. Our approach facilitates the isolation of tumor cell specific TCRs against multiple antigens and various HLA class I and II alleles.

We believe our TCR discovery technology has the potential to unlock an array of patient- and tumor-specific TCRs suitable for clinical use. We believe this technology has potential utility for:

- therapeutic TCR products encompassing single TCRs to target a specific antigen;
- a therapeutic TCR warehouse encompassing multiple TCRs to target one or more tumor antigens; or
- individualized T cell therapy involving on-demand identification and timely manufacturing of customized, engineered T cells with autologous TCRs against neoepitopes for adoptive transfer.

Our TCR Development Plan

We and our collaborator Eli Lilly are studying potential TCR product candidates in preclinical studies. On September 5, 2019, Eli Lilly notified us that it has selected its first target under the collaboration.

X. Our Antibodies Drug Class

In the past decades, monoclonal antibodies, or mAbs, have transformed from scientific tools to powerful human therapeutics. As one of the fastest growing classes of drugs, to date, more than 40 mAbs have been approved to treat a variety of diseases including cancer, inflammation, autoimmune diseases and others. In addition, identified antigen-binding domains are also fundamental elements for the construction of novel therapeutic formats and formulations, such as CAR-T cells, bispecific therapeutics and targeted nanoparticles.

We have developed and integrated multiple complementary antibody and antibody-mimetic protein technologies into our overall portfolio of treatment approaches.

A. Our Next-generation Checkpoint Immunomodulators

At a glance: Our Next-generation Checkpoint Immunomodulators

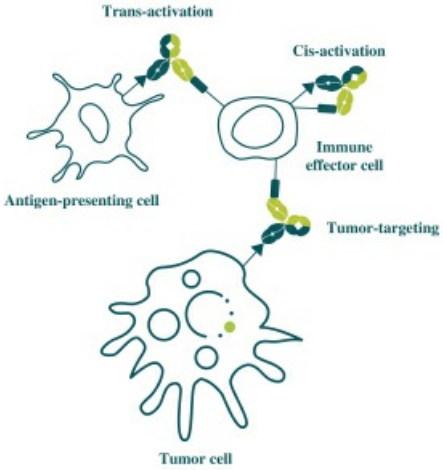
- **Concept:** Bispecific antibodies for dual immunomodulation, initially targeting4-1BB, an immune checkpoint that is expressed on T cells and NK cells and can enhance immune cell proliferation and activation, in combination with simultaneous checkpoint inhibition.
- **Mechanism:** Conditional activation of4-1BB checkpoint only upon simultaneous binding of PD-L1 or CD40 (in the case of our initial candidates), potentially avoiding toxicities seen in prior attempts at 4-1BB agonism by localizing 4-1BB activation to the tumor environment.
- **Development Approach:** 50:50 cost and profit share with Genmab, combining our and Genmab's immunostimulatory antibodies and extensive immunology expertise with Genmab's DuoBody® bispecific antibody platform.
- **Lead Candidate:** GEN1046 (BNT311), our PD-L1x4-1BB product candidate for multiple solid tumors.

Following the success of immune checkpoint-blocking antibodies targetingCTLA-4, PD-1 or PD-L1 in cancer treatment, bispecific antibody approaches represent the next generation of emerging immunotherapies with the potential to further improve clinical efficacy. In addition to bispecific T cell engager formats, which redirect T-cell cytotoxicity to malignant cells, bispecific antibodies can be formatted as tumor-targeted immunomodulators and dual immunomodulators. Tumor-targeted immunomodulators direct potent immune costimulation to the tumor-infiltrating immune cells, whereas dual immunomodulators simultaneously address two immunomodulating targets, resulting in blockade of inhibitory targets, depletion of suppressive cells or activation of immune effector cells.

We are developing, in collaboration with Genmab, bispecific antibodies that function as tumor-targeted and dual immunomodulators, applying Genmab's proprietary DuoBody® technology in combination with our joint

target identification and product concept expertise. These next-generation checkpoint immunomodulators are thought to induce beneficial co-stimulation, promoting specific T cell activation, survival, proliferation and T cell effector functions. Our collaboration encompasses three potential classes of immunotherapeutic bispecific antibodies:

- Tumor-targeted DuoBody® molecules are bispecific antibodies targeting a tumor-specific antigen expressed by the malignant cell, and an immunomodulatory receptor expressed by tumor-infiltrating immune cells. This is expected to induce powerful activation of tumor-specific effector immune cells with reduced risk of immune-related adverse events.
- Cis-activating DuoBody® molecules are bispecific antibodies that bind two distinct immunomodulating targets presented on the same cell. These targets are specifically expressed on activated immune cells with the rationale to boost existing immune responses by additive or synergistic effects of dual immunomodulation.
- Trans-activating DuoBody® molecules are bispecific antibodies that bind two distinct immunomodulating targets expressed on two separate cell subsets. By simultaneously targeting, for example, effector immune cells and antigen-presenting cells, these compounds are thought to amplify the immune cell priming process and augment subsequent effector responses.



Next-generation checkpoint immunomodulators. Our collaboration with Genmab potentially includes bispecific antibodies from three different classes: trans-activating, cis-activating and tumor-targeting antibodies.

Our Next-generation Checkpoint Immunomodulator Development Plan

We are currently developing two next-generation checkpoint immunomodulator product candidates in collaboration with Genmab: GEN1046 (BNT311), our jointly owned PDL1x4-1BB bispecific antibody, and GEN1042 (BNT312), our jointly owned CD40x4-1BB bispecific antibody.

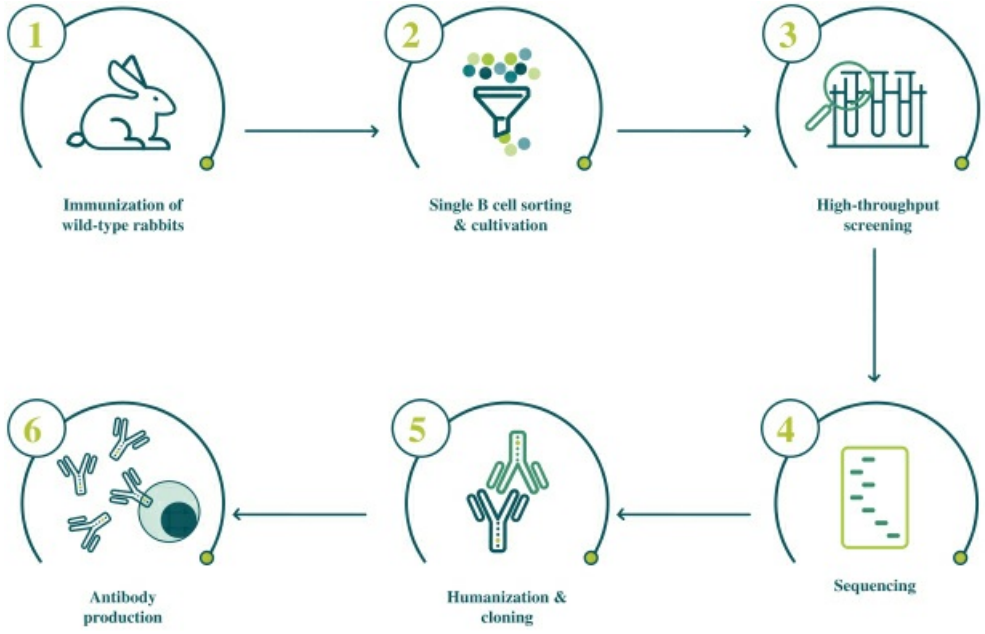
Candidate	Targets	Development Phase	Next Potential Milestone
GEN1046 (BNT311)	PD-L1x4-1BB	Phase 1/2a trial in multiple solid tumors	Data update in 1H 2021
GEN1042 (BNT312)	CD-40x4-1BB	Phase 1/2a trial in multiple solid tumors	—

B. Our Antibody Discovery Engines

We believe that our multiple antibody discovery engines significantly expand our targeting repertoire and enable us to directly, rapidly and efficiently produce new mAb candidates. In addition, antigen-binding domain sequences identified through our antibody discovery engines also feed into our proprietary CAR T cell and mRNA-encoded RiboMab platforms as well as our next-generation checkpoint immunomodulator collaboration. For instance, binders to human 4-1BB were identified from a previous antibody generation campaign and are currently under clinical and preclinical development as part of our next-generation checkpoint immunomodulator collaboration with Genmab. HuMab, our human antibody discovery engine acquired from MabVax Therapeutics in 2019, led to the clinical development of our fully human IgG1 monoclonal antibody product candidate targeting Sialyl Lewis^a (sLe^a), a carbohydrate moiety that is present in over 90% of pancreatic and a large percentage of gastrointestinal cancers.

1. Our Rabbit-based Antibody Discovery Engine

With the acquisition of MAB Discovery GmbH's antibody generation unit in 2019, we integrated a unique and proprietary rabbit-based antibody discovery platform that can generate and develop high quality, functional mAbs targeting traditional proteins and receptors as well as a wide variety of more challenging targets. Rabbit monoclonal antibodies are highly diverse and do not require affinity maturation, due to consistently high affinities. They often recognize epitopes on human antigens that are not immunogenic in rodents, thus increasing the total number of targetable epitopes. The mechanisms of antibody diversification in rabbits allow an easy and quick translation of preclinical data into the clinic with an improved probability of success. We established a streamlined semi-automated process of rabbit immunization for the efficient production of high-affinity rabbit mAbs.

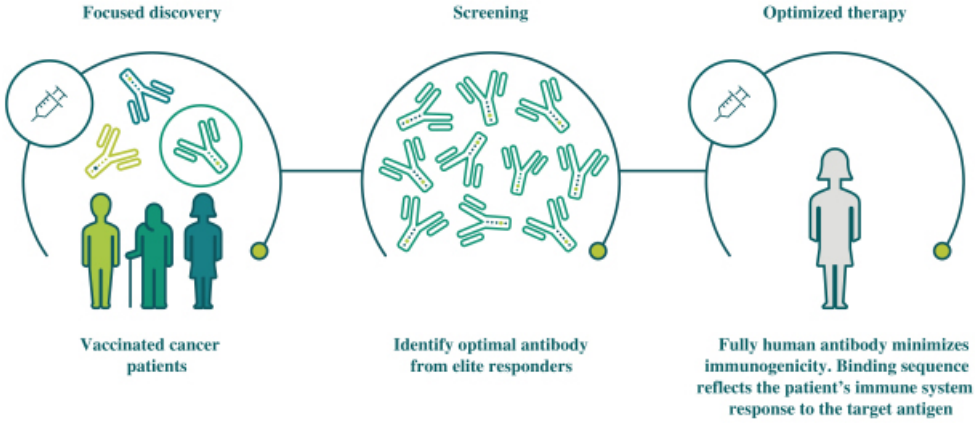


Our rabbit-based antibody discovery engine. The figure above depicts our semi-automated process for the discovery and production of high-affinity rabbit mAbs.

2. Our Fully Human Antibody Discovery Engine

Our HuMab discovery technology focuses on abnormal carbohydrate targets upregulated on solid tumors. Aberrant glycosylation is a common phenotypic change of cancer cells that mainly affects the outer part of glycans. These abnormal carbohydrate structures are known as tumor-associated carbohydrate antigens, or TACAs, and are associated with malignancy grade, invasion, metastasis and poor prognosis. TACAs are considered promising novel targets for therapeutic intervention using, in particular, mAbs or CAR-T cells. However, TACAs usually induce only low-affinity humoral immune responses, since carbohydrate moieties do not trigger the necessary T cell responses.

Using B cell sorting, hit identification, sequencing, antibody production and high-throughput antibody screening, we are able to select optimal TACA-specific antibodies from multiple clinically confirmed immunotherapy responders. All antibodies emanating from this platform are fully human with no need for additional humanization at minimal risk for immunogenicity.



Our fully human antibody discovery engine. The figure above shows our proprietary approach to the discovery and development of novel fully human antibody therapeutic and diagnostic agents.

Our Targeted Cancer Antibody Development Plan

Candidate	Targets	Development Phase	Next Potential Milestone
MVT-5873 (BNT321)	sLe[a]	Phase 1 basket trial in multiple solid tumors; first patient enrolled	—

XI. Our Small Molecule Immunomodulator Drug Class

At a glance: Our Small Molecule Immunomodulators

- **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.
- **Lead Candidate:** BNT411, our TLR7 agonist product candidate intended for combination therapies.

Small molecule cancer therapeutics can be used to regulate cancer growth, halt blood vessel formation in tumors, deliver toxins to cancer cells and mark cancer cells for destruction by the immune system. Unlike larger antibody-based cancer therapies, small molecule compounds are often developed for targets located within cells

since they can enter the cells more easily as a result of their physical properties and low molecular weight. Small molecules also often have other intrinsic benefits including relative ease and cost of production compared to larger compounds, as well as more frequently having the potential for oral administration to patients. They can also often be used synergistically in combination with other therapeutics such as mRNA, checkpoint inhibitors, radiation therapy and chemotherapy.

We aim to discover and develop the next generation of small molecule immunomodulatory compounds to improve the standard of care. We have a team of approximately 25 scientists and technicians, with extensive small molecule experience, focused on drug discovery.

Our immunomodulatory small molecule product class focuses on a range of endosomal and intracellular targets that are known to stimulate the activity of a wide range of immune cells. We have a particular emphasis on TLRs. TLRs are a family of pattern recognition receptors that function as primary sensors of the innate immune system to recognize pathogens. We believe TLRs represent a promising target class for cancer immunotherapy, particularly for inflammatory re-programming of the tumor microenvironment. In many cancers, tumors are protected by an anti-inflammatory environment, which reduces the ability of the immune system to attack the cancer cells. TLR7 agonists are able to initiate a direct cellular immune response, for example, by activating immature dendritic cells, cytotoxic T cells and NK cells, as well as stimulating the release of signal molecules such as cytokines and chemokines including IFN-a and IP-10, which can be directed against tumor cells. The activation of the innate and adaptive immune system and the release of cytokines and chemokines, for instance by our small molecule TLR7 agonist, results in the potent stimulation of antigen-specific T cells, B cells and innate immune cells such as NK cells and macrophages.

Our initial focus is on small molecule product candidates that activate the innate and adaptive immune system via TLR7 and are designed to be used in combination with chemotherapeutics as well as checkpoint inhibitors.

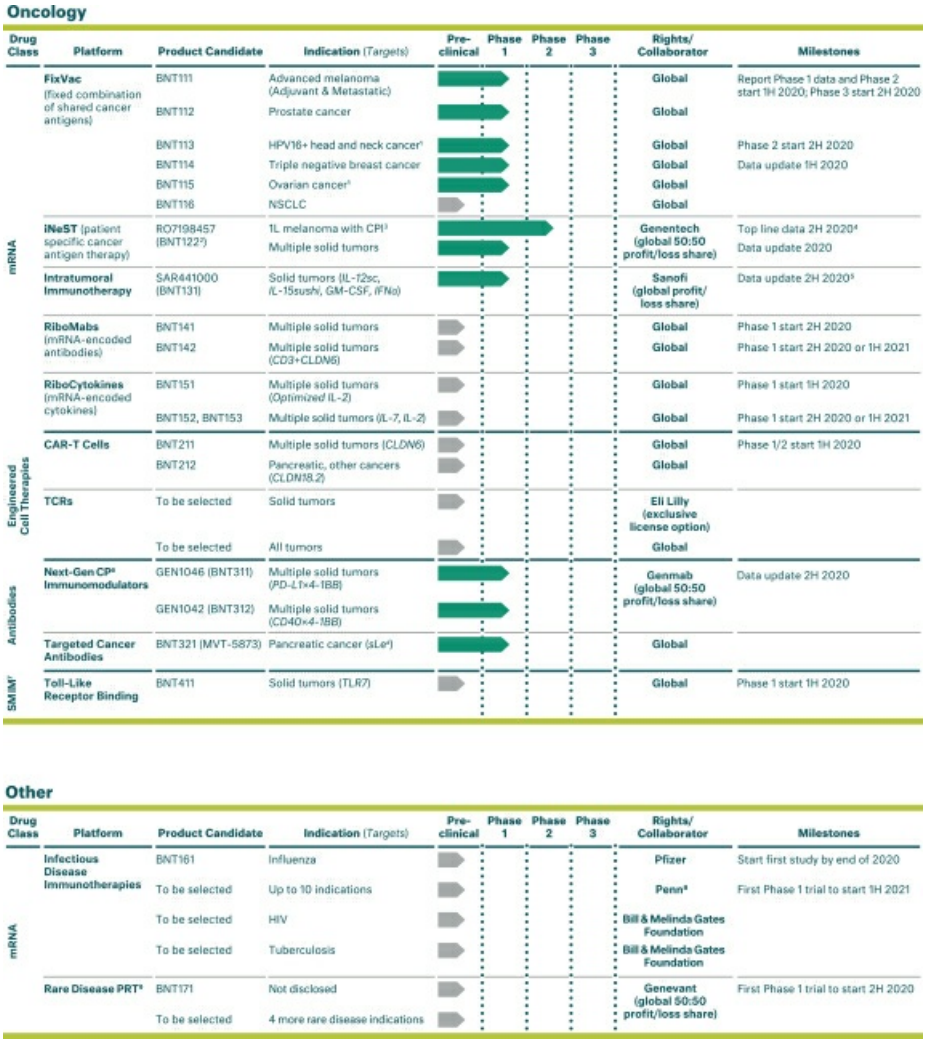
Our Small Molecule Immunomodulator Development Plan

Our initial development candidate is a potent TLR7 agonist, which we plan to develop as a combination therapy for small cell lung cancer and other solid tumors.

Candidate	Target	Development Phase	Next Potential Milestone
BNT411	TLR7	Preclinical	Initiate Phase 1 trial in 1H 2020

XII. OUR PRODUCT CANDIDATES

We are developing a broad and deep pipeline of over 20 product candidates across our four drug classes. Our product candidates are currently being investigated in 11 clinical trials.



1 BNT113 and BNT115 are currently being studied in investigator-initiated phase 1 trials
2 BNT122 (iNeST) is investigated in arm 2 (N=15) of the 3 arm TNBC-MERIT trial, with BNT114 as an optional treatment; BNT114 is investigated in arm 1 (N=12) and arm 3 (N=15) of the TNBC-MERIT trial (total patients in study: N=42)
3 Checkpoint Inhibitor
4 Update on the ongoing study including patient enrollment number, efficacy and safety data for an interim update expected in the second half of 2021
5 As the trial is sponsored and conducted by Sanofi, the timing of data updates is not under our control and is subject to change by Sanofi
6 Checkpoint

7 Small Molecule Immunomodulators
8 We are eligible to receive worldwide licenses
9 Protein Replacement Therapy

A. Our mRNA Product Class in Oncology

1. FixVac

FixVac is our wholly owned, systemic, off-the-shelf mRNA-based cancer immunotherapy platform, from which we are developing several first-in-human and potential first-in-class product candidates. Our FixVac product candidates contain selected combinations of pharmacologically optimized uridine mRNA encoding known cancer-specific shared antigens. FixVac product candidates feature our proprietary immunogenic mRNA backbone and proprietary RNA-LPX delivery formulation, which are designed to enhance stability and translation as well as trigger both innate and adaptive immune responses.

a) BNT111: Our FixVac Cancer Immunotherapy for the Treatment of Advanced Melanoma

We are developing our mRNA-based FixVac product candidate BNT111 for the treatment of advanced melanoma in patients with metastatic tumors and as an adjuvant treatment after tumor resection. We are currently studying BNT111 in an ongoing Phase 1 clinical trial.

Melanoma

Melanoma is an increasingly prevalent, deadly form of skin cancer in which melanocytes, which are the cells that color the skin, form malignant cells. With 132,000 new cases diagnosed globally each year, melanoma constitutes less than five percent of all skin cancers. In recent decades, however, the incidence rate of melanoma has risen faster than almost any other cancer type, on average by 1.5% per year over the last 10 years. In 2018, approximately 91,000 new melanoma cases were diagnosed in the United States, representing 5.3% of all new cancer cases in the United States.

Melanoma is the most lethal form of skin cancer, accounting for the majority of skin cancer deaths. There were an estimated 9,300 deaths from melanoma in the United States in 2018. While the five-year survival rate for melanoma, regardless of disease stage, is approximately 91.8%, patients with stage III melanoma have a five-year survival rate of approximately 63%. The five-year survival rate for metastatic melanoma (stage IV) is approximately 20%.

The current treatment regimen involves surgical removal for earlier stages, while a number of targeted therapies, such as BRAF and MEK inhibitors, and checkpoint inhibitors, or CPIs, are approved for advanced disease. CPIs include nivolumab (Opdivo) for advanced or metastatic melanoma after resection, and pembrolizumab (Keytruda) in unresectable or metastatic disease.

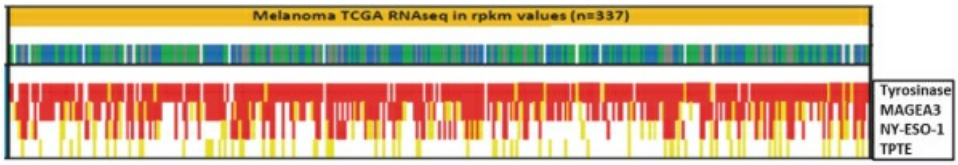
Our BNT111 Targets

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 and the placenta;
- tyrosinase, an enzyme that is required for melanin production and that is produced in increased levels in melanoma; and

- trans-membrane phosphatase with tensin homology, or TPTE, a novel cancer/testis antigen that we discovered internally.

We sequenced 337 melanoma tumors and detected at least one of these four antigens 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 expressed each antigen.

Our BNT111 Clinical Trials

Ongoing Phase 1 Trial in Advanced Melanoma Patients (LIPOMERIT study)

We are conducting 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. This is the first clinical trial worldwide in which an mRNA-based cancer immunotherapy is administered intravenously for systemic treatment.

The trial employs a conventional 3+3 design in which patients are dosed in groups of three at incrementally greater dosages until the maximum tolerated dose is identified, during the dose escalation phase, which is then followed by expanded dose cohorts. Patients are treated with doses from 7.2µg up to the highest administered dose of 400µg of total mRNA.

July 2019 Interim Data

As of the July 2019 interim cut-off date, 95 patients with metastatic melanoma had been dosed at least once at one of four centers in Germany. Baseline and demographic characteristics were largely as expected for a trial recruiting advanced stage IIIB-IIIC and stage IV melanoma patients with and without measurable disease. Approximately half of the patients were resected and had radiographically non-evaluable disease at baseline. The other half of the patients had radiographically evaluable disease at baseline and most of these patients were heavily pretreated. Only the subset of patients with evaluable disease at baseline was assessed for preliminary clinical activity.

Immunogenicity. Immune responses induced by BNT111 were assessed using various orthogonal assay systems by analyzing T cells against each vaccine antigen in pre- and post-treatment blood samples of patients. So far, about half of the dosed patients have been analyzed for immune responses in this ongoing study. A first analysis in a subset of 18 patients evaluated vaccine antigen reactivity of $CD4^+$ and $CD8^+$ T cells by IFN-α ELISpot after *in vitro* stimulation. All tested patients showed either a de novo or an augmented (as compared to baseline) immune response against at least one of the BNT111-encoded tumor antigens. Most patients exhibited either $CD4^+$ or concurrently $CD4^+$ and $CD8^+$ T cell responses against the individual vaccine targets. A second analysis looked at the magnitude of immune responses on the individual level by using an *ex vivo* IFN-α ELISpot, which due to its sensitivity level would capture only very strong T cell responses, and showed that more than 75% of patients exhibited vaccine-induced $CD4^+$ or $CD8^+$ T cell responses. The kinetics of *de novo*-induced $CD8^+$ T cells were further characterized in selected patients of interest by a third method using *ex vivo* MHC peptide multimer staining of blood samples collected at baseline and at different time points after start of

vaccination. Mostly, antigen-specific T cell counts showed a fast ramp-up from being undetectable at baseline to levels ranging from 1,000 to more than 100,000 per million circulating $CD8^+$ T cells within the first 4-8 weeks. Under monthly maintenance treatment, frequencies of individual antigen-specific T cells continued to slowly increase or remained stable up to over one year.

Clinical activity. As of the July 2019 cut-off date, in our review of interim data, we assessed 42 patients with radiographically evaluable, measurable disease at baseline for preliminary clinical activity according to Response Evaluation Criteria in Solid Tumors, Version 1.1, or RECIST v1.1. Twenty-five of these 42 patients received BNT111 as a monotherapy, and 17 patients received BNT111 in combination with an anti-PD-1 checkpoint inhibitor, or CPI (either pembrolizumab or nivolumab).

In the BNT111 monotherapy cohort, we observed clinical activity for all 25 patients. All of these patients had received at least one line of prior treatment with a checkpoint inhibitor, and 24 of the 25 patients had failed prior sequential or combination treatment with anti-PD-1 and anti-CTLA4 antibodies. Three of 25 patients (12%) showed a partial response, or PR, one patient had a metabolic complete response as measured by FGD-PET imaging and seven patients (28%) demonstrated stable disease. The clinical benefit rate, or CBR, is 44%. Two of the PRs manifested early on during treatment (at imaging day 90); the two others manifested at imaging days 180 and 360, respectively.

In the BNT111 in combination with anti-PD-1 checkpoint inhibitor cohort, 16 of the 17 patients had prior treatment with CPI. Six patients (35%) showed a partial response, and two patients (12%) demonstrated stable disease. The CBR is 47%. Objective responses were observed across all dose levels explored in expansion cohorts (14µg, 50 µg and 100µg). Five of 10 (50%) patients who received the highest target dose of 100µg demonstrated a PR. By contrast, the expected ORR for anti-PD1 treatment in an anti-PD1 experienced patient population is in the range of 10%.

Safety. As of the July 2019 cut-off date, no dose-limiting toxicities to BNT111 have been reported. The highest explored dose level is 400µg total mRNA and doses up to 100µg total mRNA were tested further in expansion cohorts. The overall adverse event profile was dominated by mild-to-moderate, transient and manageable flu-like symptoms. This profile may have been driven by the mode of action of the RNA-LPX, which activates antigen presenting cells via signaling of TLRs, resulting in a temporary, self-limiting release of a distinct range of pro-inflammatory cytokines upon intravenous application. These symptoms were managed by pre-medication with non-steroidal antipyretics, such as ibuprofen and acetaminophen. Eight subjects dosed with BNT111 experienced related treatment-emergent serious adverse events, or TESAEs. The related TESAEs were comprised of two cases of Grade 2 pyrexia, and one case each of Grade 2 asthenia, Grade 2 dizziness, Grade 3 anaphylactic reaction, Grade 3 dizziness, Grade 3 syncope, Grade 3 exudative retinopathy, Grade 3 posterior reversible encephalopathy syndrome, Grade 3 epileptic seizure, and Grade 2 suspected pancreatitis. There were confounding factors, such as treatment with other therapies or underlying medical conditions, for the subjects with related TESAEs. We could not establish a clear causal relationship between BNT111 and the cases of anaphylactic reaction, retinopathy, encephalopathy syndrome, seizure and suspected pancreatitis. There have been no deaths in this study that were assessed by the investigators as related to BNT111.

Completed Phase 1 Trial in Patients with Advanced Melanoma (MERIT study)

In 2016, we published results of a first-in-human dose escalation study evaluating the safety and tolerability of intranodal administration of an earlier generation of BNT111 in patients with advanced melanoma. In this study, the earlier formulation of BNT111 targeted only NY-ESO-1 and tyrosinase.

This international, multi-center, open-label interventional study's primary endpoints were the maximum tolerated dose for multiple dosing, safety and adverse reactions and tolerability profile of multiple dosing. The secondary endpoints were (i) to observe immunotherapy-induced immune responses following multiple treatment cycles and (ii) clinical benefit (complete response, partial response and stable disease).

Five dosages were administered to patients sequentially: 50µg, 100µg, 300µg, 600µg, and 1,000µg. The sample size for the first three doses was three each. The 600µg dose cohort was comprised of 13 patients and the 1,000µg dose cohort was comprised of seven patients. In the 100µg, 300µg and 600µg dose cohorts, seven patients in total received continued treatment. The overall individual treatment period was 43 to 51 days and comprised eight treatment cycles of ultrasound-guided intranodal injections on days one, four, eight, 11, 15-17, 22-26, 29-35 and 43-51. In case of an optional continued treatment for patients who neither exhibited unacceptable drug-related toxicity nor disease progression, four additional treatment cycles were administered at the same dosage that the patient had received in his or her cohort. The first cycle of continued treatment was scheduled 14-42 days after the last visit, with the second and third additional treatment cycles following after a one-month interval each. The fourth treatment cycle then followed after an interval of three months.

The occurrence of new measurable lesions was observed in only one patient of the 1,000µg dose cohort, while newnon-measurable lesions were identified in seven patients. Twenty-one patients, or 75%, were classified as having immune-related stable disease and six patients, or 21.4%, had immune-related progressive disease.

The most frequent adverse events included administration-site conditions, infections and infestations, musculoskeletal and connective tissue disorders, nasopharyngitis, fatigue, headache and back pain. No life-threatening adverse events nor deaths occurred in this study. Thirteen severe adverse events were reported, including infections and infestations and vascular disorders. Sixteen patients were affected by adverse events with a suspected relationship to the study drug. These were most frequently fatigue, application site erythema and application site pain. None of the drug-related adverse events was categorized as serious. No dose-limiting toxicities were observed.

Next Steps

We expect to report Phase 1 data from the LIPOMERIT trial and to initiate a Phase 2 clinical trial for BNT111 in the U.S. and Europe in the first half of 2020. Moreover, we plan to initiate a registrational Phase 3 trial in metastatic melanoma patients in the second half of 2020.

b) BNT112: Our FixVac Cancer Immunotherapy for the Treatment of Prostate Cancer

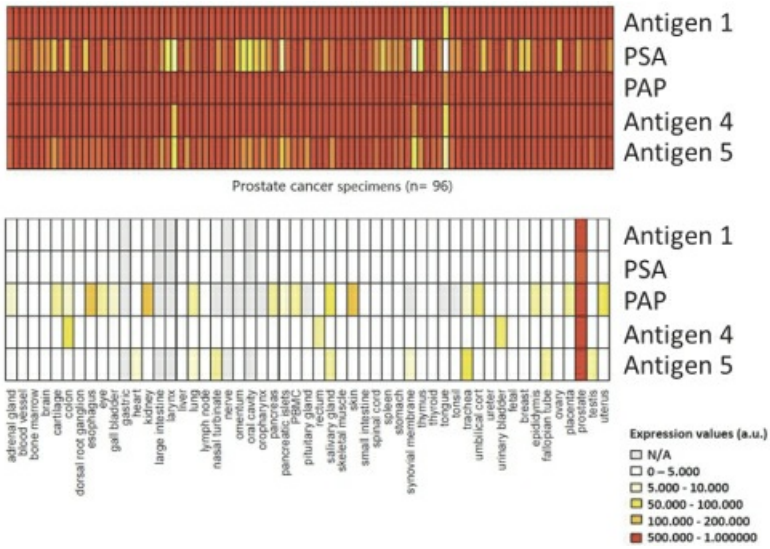
We are developing BNT112 for the treatment of prostate cancer.

Prostate Cancer

Prostate cancer is the second most common cancer amongst men worldwide and the fourth most commonly occurring cancer overall, with around 1.3 million new cases recorded worldwide in 2018 and 174,650 cases expected in 2019 in the United States alone. The stage of the prostate cancer (I-IV), alongside the prostate-specific antigen and Gleason score, are the key factors for defining the treatment options for individual cases. Surgical or radiation based approaches are often used in first-line therapy, however after relapse (up to 30-40% of patients), androgen-deprivation therapies are employed, which in turn also often becomes redundant (metastatic castration-resistant prostate cancer, or mCRPC) at which point patients are treated with either further hormonal agents or chemotherapy.

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.



Our BNT112 Clinical Trials

Phase 1/2 Clinical Trial

We enrolled the first patient in an open-label, multi-center, first-in-human Phase 1/2 individual dose titration study of BNT112 in patients with mCRPC and high-risk localized prostate cancer, or LPC, in the second half of 2019. Eligible patients have newly-diagnosed, high-risk, localized prostate cancer and will be treated with BNT112 as a single agent, in combination with cemiplimab and goserelin acetate or in combination with goserelin acetate alone. We anticipate a total enrollment of 60 to 80 patients at up to 20 investigational sites.

The study is designed to evaluate the safety, tolerability, immunogenicity and preliminary efficacy of BNT112 in mCRPC and LPC patients. The primary objective of this study will be to establish the safety and tolerability of BNT112 alone, or in combination with goserelin acetate with or without cemiplimab. The secondary objectives of the trial will be to examine the immunogenicity of BNT112 alone or in combination with goserelin acetate with or without cemiplimab, and to evaluate anti-tumor activity based on levels of prostate-specific antigen, or PSA.

The study will consist of three arms. The first arm will start with a dose titration phase for the initial safety assessment and recommended expansion dose range assessment. We anticipate enrollment of approximately 20 patients in arm one who will receive BNT112 alone, with up to nine patients participating in the dose titration part of the arm (with staggered starting groups of three patients one week apart). Titration will continue until unacceptable toxicity or disease progression. Efficacy in the first arm will be assessed by on-treatment imaging and in the second and third arms by tumor volume measurement.

After at least six patients are treated and evaluable for at least one treatment cycle, we plan to commence enrollment of the second and third arms, each enrolling approximately 20 patients with newly diagnosed LPC.

Patients in the second arm will receive BNT112 combined with goserelin acetate and cemiplimab, and patients in the third arm will receive BNT112 combined with goserelin acetate alone. Treatment periods in the second and third arms will last until unacceptable toxicity or until the end of the eighth cycle, which will be followed by planned radical prostatectomy.

c) BNT113: Our FixVac Cancer Immunotherapy for the Treatment of HPV+ Head and Neck Cancer

We are developing BNT113 for the treatment of HPV+ head and neck cancer. BNT113 is currently being studied by the University of Southampton in an ongoing investigator-sponsored Phase 1/2 basket study in HPV+ cancers, including head and neck cancer.

HPV+ Head and Neck Cancer

Head and neck cancer defines an heterogeneous group of tumors originating in the squamous cells that line the moist, mucosal surfaces inside the head and neck. Head and neck cancer is the sixth most common malignancy worldwide, accounting for approximately 6% of all cancer cases, and is responsible for 1-2% of all cancer deaths. An increasing percentage of this cancer is now attributed to HPV infection in the United States and Europe, particularly those arising from the oropharynx. In the U.S., HPV-related oropharynx cancer, or OPC, is one of only five cancers with rising incidence and prevalence. The percentage of OPC related to HPV rose from approximately 16% in 1984 to 1989 to approximately 72% during 2000 to 2004. Early stage head and neck cancer is typically either treated with surgery or radiation alone, however approximately 66% of patients present with advanced disease and fewer than 30% of these are cured. The management of advanced disease consists of multiple-modality therapy with surgery, radiation and chemotherapy. Long-term survival rates in these patients have not increased significantly in the past 30 years: five-year survival rates are 60-80%.

Our BNT113 Targets

BNT113 is designed to elicit an immune response against the well-characterized HPV16-derived oncoproteins E6 and E7, which are strongly immunogenic, viral neoantigens that are found in HPV16+ solid cancers such as head and neck squamous cell carcinoma.

Our BNT113 Clinical Trials

Ongoing Phase 1/2 Basket Study (Investigator-Sponsored)

BNT113 is being studied in an investigator sponsored open-label, Phase 1/2 dose escalation basket study with two different arms in approximately 44 patients with HPV+ head and neck and other cancers. The first arm will perform dose escalation in patients with previously treated HPV+ 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 HPV+ cancers, including head and neck, anogenital, penile and cervical cancers, using a single cohort to establish a safe, tolerable and recommended dose.

Next Steps

We intend to initiate a Phase 2 trial of BNT113 in HPV+ cancers in the second half of 2020.

d) BNT114: Our FixVac Cancer Immunotherapy for the Treatment of Triple Negative Breast Cancer

We are currently studying antigens selected for BNT114 in athree-arm clinical trial as both a monotherapy and in combination with our RO7198457 (BNT122) individualized iNeST immunotherapy in patients with triple negative breast cancers.

Triple Negative Breast Cancer (TNBC)

Breast cancer is the most commonly occurring cancer in women and the second most common cancer overall with over two million new cases globally in 2018 with an expected 268,600 cases in 2019 in the United States alone. There are three broadly defined categories of breast cancer. About 80% of breast cancers are defined as ER+, meaning that they grow in response to the hormone estrogen, while 65% of these are also defined as PR+, as they also grow in response to another hormone, progesterone. Such cancers can be identified by the presence of estrogen receptors, or ER, and/or progesterone receptors, or PR, on the cancer cell surface and are more likely to be treatable by hormone therapies than cancers that are ER or PR negative. In about 20% of cancers, the tumor can be identified by its production of an excess of the HER2 protein. Such HER2+ cancers tend to be aggressive and fast moving. Breast cancers that neither express ER or PR, nor over-express HER2-, are known as triple negative breast cancers, or TNBCs. TNBC patients represent approximately 12-15% of all breast cancer cases, however it remains an area of high unmet medical need given it is typically the most aggressive form of breast cancer. There are currently no effective treatments for TNBC. While initial treatment options include surgery or chemotherapy, TNBC is characterized by rapid resistance to chemotherapy, and few remaining treatment options remain thereafter.

Our BNT114 Targets

BNT114 is designed to elicit an immune response to selected antigens that are found in breast cancers.

Our BNT114 Clinical Trials

Ongoing Phase 1 Clinical Trial (BNT114 monotherapy and in combination with RO7198457 (BNT122))

We are currently conducting an international, multi-center, open-label, three-arm Phase 1 study of BNT114 as a monotherapy and in combination with our RO7198457 (BNT122) individualized iNeST immunotherapy in 39 TNBC patients who had previously received the standard of care therapy (*i.e.*, surgery, chemotherapy and/or radiotherapy). The primary endpoints of the study are to assess safety and tolerability. Safety will be analyzed by adverse event documentation and clinical observation and tolerability will be analyzed based on patients' vital signs and clinical chemistry. The secondary endpoint of the study is the observation of the treatment-induced immune responses, expressed as treatment-induced T cell responses, resulting from multiple treatment cycles.

Patients in the first arm receive BNT114, patients in the second arm receive BNT114 in combination with RO7198457 (BNT122) and patients in the third arm receive BNT114 in combination with mRNA encoding tetanus-toxin help epitopes.

Next Steps

We expect to report a data update in the first half of 2020 and assess the immunogenicity of the selected antigens.

e) BNT115: Our FixVac Cancer Immunotherapy for the Treatment ofOvarian Cancer

We are developing BNT115 for the treatment of ovarian cancer. BNT115 is currently being studied in an ongoing investigator-sponsored Phase 1 study in ovarian cancer.

Our BNT115 Targets

BNT115 is designed to elicit an immune response to selected antigens that are found in ovarian cancers.

Our BNT115 Clinical Trial

Ongoing Phase 1 Trial (Investigator Sponsored)

BNT115 is being studied in a 10 patient investigator sponsored, first-in-human, open label, Phase 1 dose escalation study in ovarian cancer patients eligible for standard-of-care treatment with neo-adjuvant chemotherapy. Eight doses of BNT115 will be administered prior to and in combination with the neo-adjuvant chemotherapy to induce an anti-tumor immune response. Systemic immune responses will be determined using peripheral blood mononuclear cells collected before, during and after vaccinations. Intratumoral accumulation of T-cells recognizing vaccine-encoded tumor associated antigens will be determined before vaccination in a tumor biopsy and after 3 cycles of chemotherapy and the 5th vaccination using tumor tissue derived from interval surgery.

f) Other FixVac Indications

We are also exploring FixVac development candidates in other cancer indications, including non-small cell lung cancer.

2. Individualized Neoantigen Specific Immunotherapy (iNeST)

Our iNeST product candidate is an individualized cancer immunotherapy that targets specific neoantigens that are present on a patient's tumor. Our iNeST immunotherapies contain pharmacologically optimized uridine mRNA encoding up to 20 patient-specific neoantigens, as well as our proprietary RNA-LPX formulation. We are developing our iNeST cancer immunotherapy in collaboration with Genentech.

a) BNT122: Our iNeST Cancer Immunotherapy for Multiple Potential Indications

We and our collaborator Genentech are developing RO7198457 (BNT122) for the treatment of metastatic melanoma and other solid tumors. We are currently conducting a randomized Phase 2 trial of RO7198457 (BNT122) in collaboration with Genentech in first-line melanoma in combination with pembrolizumab. In collaboration with Genentech, we are also studying RO7198457 (BNT122) as a monotherapy and in combination with atezolizumab in a Phase 1a/1b study of patients with locally advanced or metastatic solid tumors (including in melanoma, non-small cell lung cancer, bladder cancer as well as other solid tumors). The Phase 1a/1b trial is a non-registrational, signal-seeking study recruiting mostly patients with late-stage advanced cancers including patients who failed multiple lines of prior treatment.

Our RO7198457 (BNT122) Targets

RO7198457 (BNT122) is an individualized neoantigen-specific immunotherapy. Each RO7198457 (BNT122) dose includes up to 20 different neoepitopes selected on a patient-by-patient basis. We believe that neoepitope-specific T cells induced by RO7198457 (BNT122) can enhance the therapeutic efficacy of immune checkpoint blockade.

Our RO7198457 (BNT122) Clinical Trials

Ongoing Phase 2 Clinical Trial (First-line with pembrolizumab)

In January 2019, we and Genentech initiated a Phase 2, open-label, multi-center, randomized clinical trial investigating the safety and efficacy of RO7198457 (BNT122) in combination with pembrolizumab in 132 patients with previously untreated metastatic melanoma. Patients in the experimental arm will receive pembrolizumab by intravenous infusion every three weeks, plus a selected dose of RO7198457 (BNT122) at defined intervals. Patients in the active comparator arm will receive 200mg of pembrolizumab by intravenous infusion every three weeks. Following treatment in the comparator arm, patients will be permitted to cross over to combination therapy with RO7198457 (BNT122).

The primary endpoint is:

- progression-free survival, or PFS, of patients treated with RO7198457 (BNT122) compared with patients receiving pembrolizumab alone, according to RECIST v1.1; and

Secondary endpoints include:

- objective response rate, or ORR, in patients treated with RO7198457 (BNT122) compared with patients receiving pembrolizumab alone, defined as the proportion of participants with complete response, or CR, or partial response, or PR.
- overall survival, or OS, of patients treated with RO7198457 (BNT122) compared with patients receiving pembrolizumab only;
- duration of response according to RECIST v1.1 of patients treated with RO7198457 (BNT122) compared with patients receiving pembrolizumab only;
- mean change in health-related quality of life, scores of patients treated with RO7198457 (BNT122) compared with patients receiving pembrolizumab only;
- percentage of patients with CR or PR following cross-over from pembrolizumab monotherapy to combination therapy following cross-over, according to RECIST v1.1; and
- incidence and severity of adverse events.

Ongoing Phase 1 Clinical Trial

We and Genentech are currently conducting a global Phase 1a/1b open-label, global dose-escalation study to assess the safety, tolerability, immune response and pharmacokinetics of RO7198457 (BNT122) as a single agent and in combination with Tecentriq® (atezolizumab), an anti-PD-L1 mAb, in patients with locally advanced or metastatic tumors, including in melanoma, non-small cell lung cancer, bladder cancer, colorectal cancer, TNBC, renal cancer, H&N cancer and other solid cancers. This trial is a non-registrational, signal-seeking study recruiting mostly patients with late-stage advanced cancers including patients who failed multiple lines of prior treatment.

In the Phase 1a portion of the study, patients receive RO7198457 (BNT122), administered intravenously every 21 days at escalating doses. In the Phase 1b portion, patients receive RO7198457 (BNT122), administered intravenously every 21 days at escalating dosages, in combination with atezolizumab at a fixed dose of 1200mg.

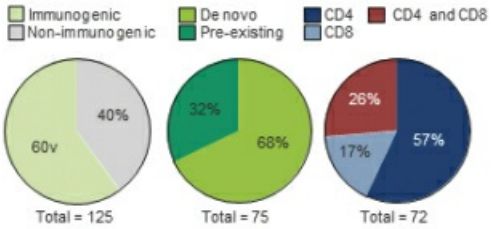
In addition, we are investigating RO7198457 (BNT122) in three Phase 1b arms in combination with atezolizumab at a fixed dose of 1200mg, in (i) patients with non-small cell lung cancer or melanoma that have received cancer checkpoint inhibitors, (ii) patients with selected tumor types who consent to optional serial biopsies and (iii) patients with different indications as per inclusion criteria.

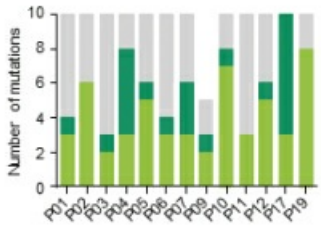
Completed Phase 1 Clinical Trial (BNT121 First Generation iNeST)

In 2017, we published the results of a 13-patient, first-in-human trial of our first-generation intranodal iNeST product candidate, BNT121, in patients with late-stage malignant melanoma. The objective of this clinical trial was to study the feasibility, safety, tolerability, immunogenicity and potential anti-tumoral activity of iNeST. All patients had stable disease at enrollment with a high risk for relapse.

All 13 patients developed T cell immune responses against multiple immunotherapy neoepitopes at up to high single-digit percentages. As shown below, 60% of the selected neoepitopes elicited a T cell response. The detected immune response was elicited by both $CD4^+$ and $CD8^+$ T cells and the majority was induced *de novo*, which we believe to be an important requirement for an effective immune response and an added benefit beyond checkpoint inhibition alone.

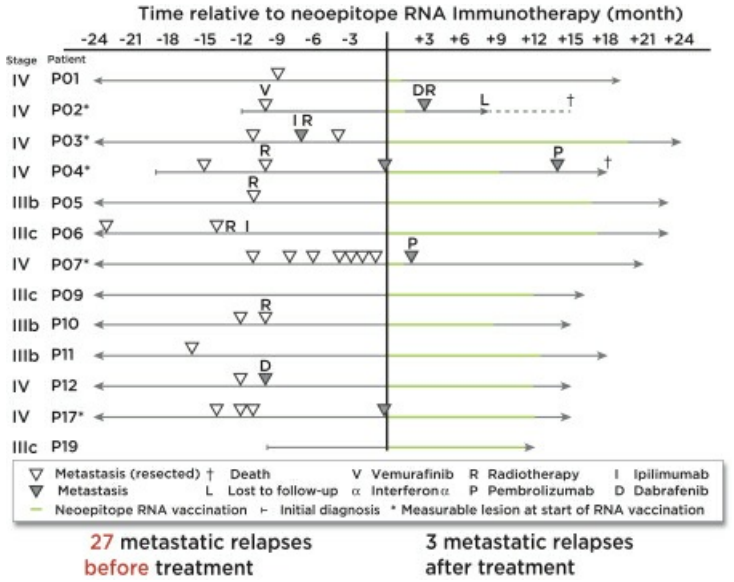
No severe adverse drug reactions were reported in the study. Common adverse events includedflu-like symptoms.





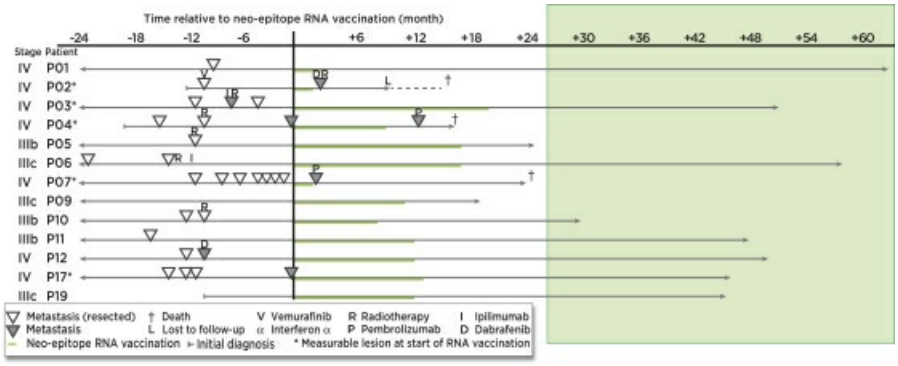
Immune responses documented in our prior BNT121 study. Patients showed immune responses, including both CD4 + and CD8+ responses, against multiple neoantigens. Source: Nature 547, 222-226 (13 July 2017)**.**

In addition, metastases resected from two patients following treatment with BNT121 demonstrated evidence of treatment-induced infiltration with BNT121-induced neoepitope-specific T cells and neoepitope-specific killing of tumor cells. The cumulative rate of metastatic events was significantly reduced after the start of treatment, resulting in a sustained progression-free survival. Of the 13 patients entering the trial, eight patients that had no radiologically detectable lesions at start of neo-epitope vaccination were relapse free and remained recurrence-free for the wholefollow-up period (12 to 23 months). Five patients experienced melanoma relapses shortly after inclusion in the trial and despite initiation of standard treatment had progressing metastases at start of their neoepitope treatment. Of these, three patients developed neoepitope treatment-related objective clinical responses. One of these patients exhibited a complete response and remained relapse-free for 26 months. The second patient had an immunotherapy-related partial response. This patient had a late relapse owing to outgrowth of ß2-microglobulin-deficient melanoma cells as an acquired resistance mechanism. A third patient developed a complete response to treatment in combination with PD-1 blockade therapy.



Metastatic relapses before and after treatment with BNT121. The chart above shows the metastatic relapses of patients before and after treatment with BNT121. Each horizontal line represents the time course of a single patient. The vertical line indicates the treatment start of BNT121. Source: Nature 547, 222-226 (13 July 2017).

As of October 2019, nine out of 13 patients had remained recurrence-free through follow-up of up to 41 months post-vaccination.



Next Steps

We expect to report a topline data update from our RO7198457 (BNT122) first-line Phase 2 melanoma trial in the second half of 2020 and report a data update from our RO7198457 (BNT122) Phase 1a/1b solid tumor trial in 2020. We and Genentech plan to initiate two additional clinical trials for RO7198457 (BNT122) in 2020 in first-line solid cancers in the adjuvant setting, one in combination with atezolizumab and the other as a monotherapy.

3. Intratumoral Immunotherapy

We, in collaboration with Sanofi, are developing intratumoral immunotherapies utilizing our proprietary mRNA technology. These immunotherapies are 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 within the tumor (proximal) as well as in other untreated locations (distal).

a) SAR441000 (BNT131): Our Initial Intratumoral Immunotherapy for the Treatment of Solid Tumors

We and Sanofi are developing SAR441000 (BNT131) as an intratumoral immunotherapy for the treatment of solid tumors. SAR441000 (BNT131) consists of modified mRNA that is injected directly into the tumor, where it is thought to express cytokines to alter the tumor microenvironment. SAR441000 (BNT131) is being studied in a Sanofi-sponsored Phase 1 clinical trial as a monotherapy in patients with advanced melanoma and in combination with an anti-PD-1/PD-L1 checkpoint inhibitor in patients with advanced melanoma and certain advanced solid tumors.

Our SAR441000 (BNT131) Targets

SAR441000 (BNT131) comprises mRNA that encodes the cytokines IL-12sc, IL-15sushi, IFN-α and GM-CSF. By expressing these cytokines in the tumor microenvironment, the immune system may more easily recognize and fight cancer.

Our SAR441000 (BNT131) Clinical Trials

Ongoing Phase 1 Clinical Trial

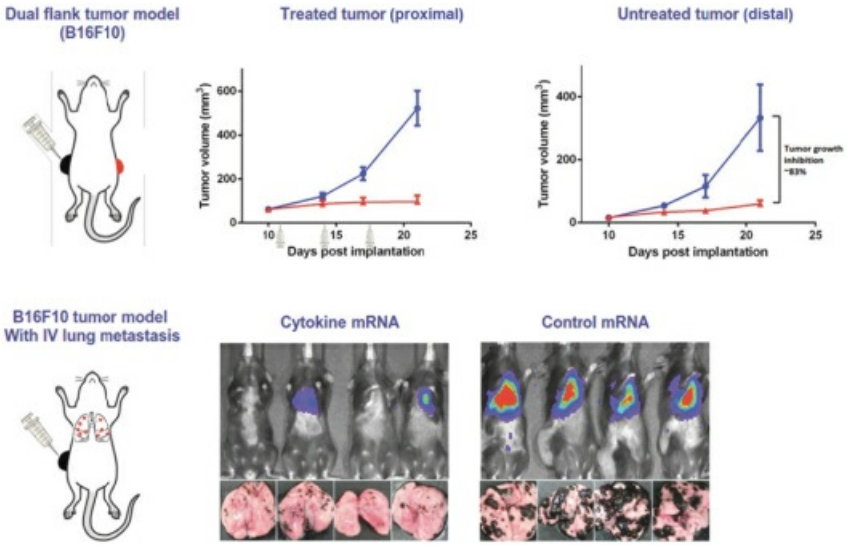
Sanofi, in collaboration with BioNTech, has commenced a first-in-human, multi-center, open-label, Phase 1, dose escalation and expansion trial to evaluate the safety, pharmacokinetics, pharmacodynamics and anti-tumor

activity of SAR441000 (BNT131) administered intratumorally as monotherapy and in combination with cemiplimab, with an estimated enrollment of 264 patients with certain advanced solid tumors.

Our SAR441000 (BNT131) Preclinical Studies

In collaboration with Sanofi, we conducted a preclinical study of SAR441000 (BNT131) in mouse tumor models. In these*in vivo* models, the anti-tumor activity of cytokines encoded by mRNA was driven by the action of T cells as well as NK cells and was accompanied by robust intratumoral induction of interferon gamma, systemic expansion of antigen-specific T cells and increased granzyme B positive $CD8^+$ T cell infiltration.

SAR441000 (BNT131) was shown to form immunological memory toward both dominant and subdominant antigens, which protected long-term survivors from re-challenge with autologous tumors. Importantly, although cytokine mRNAs were administered intratumorally, resulting in local target expression, anti-tumor activity extended beyond the injected tumor to effectively control the growth of distal tumors in both a dual-tumor model and an experimental lung metastasis model. Finally, SAR441000 (BNT131) demonstrated improved overall survival and higher incidence of complete tumor regressions across several preclinical models.



Systemic anti-tumor effects in mouse model. As shown above, BNT131 demonstrated local and systemic anti-tumor effects of intratumoral cytokine mRNA. In this study, mice were implanted with a tumor on each of the right and left flank. One tumor was injected with intratumoral cytokine mRNA (or control mRNA) while the other was not. The top center figure shows the tumor volume of the treated tumor (red line) against the control (blue line). The top right figure shows an anti-tumor effect on the untreated tumor (red line) against the control (blue line). The figures on the bottom show the abscopal effect of an intratumoral cytokine mRNA (center bottom) on distal lung metastases compared to the control mRNA (right bottom). Source: Wagenaar et al., Local immunotherapy with a mixture of mRNAs encoding pro-inflammatory cytokines promotes potent anti-tumor immunity and tumor eradication across multiple preclinical tumor models; poster presented at SITC 2018.

Based on these preclinical results, we intend to investigate whether our synthetic mRNA technology can potentially deliver localized cytokine-based cancer immunotherapy with broad anti-tumor activity against treated and untreated lesions.

Next Steps

A data update from this trial may be reported in the second half of 2020. As the trial is sponsored and conducted by Sanofi, the timing of data updates is not under our control, and is subject to change by Sanofi.

4. RiboMabs

Our RiboMab product candidates are designed to encode secreted antibodies for expression *in vivo* by the patient's cells. RiboMab product candidates consist of our proprietary nucleoside-modified mRNA that is designed to minimize the immunomodulatory activity of the mRNA, and these candidates are formulated using liver-targeting LNPs for intravenous delivery. RiboMabs potentially address the limitations of recombinent antibodies, including costly manufacturing processes and unfavorable pharmacokinetics, such as short plasma half-life. We are conducting preclinical studies for two development candidates, and have published compelling preclinical data.

RiboMab Preclinical Studies

We have generated RiboMabs targeting different tumor antigens and tested their therapeutic potency in mice engrafted with human tumors that were repopulated with human immune cells. We demonstrated in preclinical studies that injection with a RiboMab product candidate encoding bispecific RiboMabs directed against CD3 and CLDN6 antigens resulted in elimination of aggressively growing, large tumors. Intravenously administering a microgram dose of mRNA encoding RiboMabs resulted in bispecific RiboMab production in the liver cells and rapid secretion into circulation, reaching peak plasma concentration within hours and remaining at therapeutically effective levels for one week. The dosage and frequency of dosing of recombinant bispecific antibodies required to produce similar effects was substantially greater. This was the first preclinical study to demonstrate *in vivo* application of mRNA-encoded antibodies for the successful treatment of cancer.

a) BNT141: Our Initial RiboMab for the Treatment of Solid Tumors

BNT141 is our RiboMab product candidate for the treatment of solid tumors. BNT141 is designed to encode secreted IgG antibodies.

Our BNT141 Targets

BNT141 is designed to encode secreted antibodies that target multiple epithelial solid tumors, including gastric and pancreatic cancers.

Next Steps

We expect to initiate a Phase 1 basket trial of BNT141 for the treatment of various solid tumors, including gastrointestinal tumors, in the second half of 2020.

b) BNT142: Our Second RiboMab for the Treatment of Solid Tumors

BNT142 is our RiboMab product candidate for the treatment of solid tumors. BNT142 is designed to encode a secreted bispecific antibody that targets CD3 and CLDN6.

Our BNT142 Targets

BNT142 is designed to encode bispecific antibodies that target CD3, a T cell receptor that plays a key role in the activation of $CD8^-$ and $CD4^+$ T cells, and CLDN6, a highly specific oncofetal cell surface antigen that is found in solid tumors, but not in normal cells.

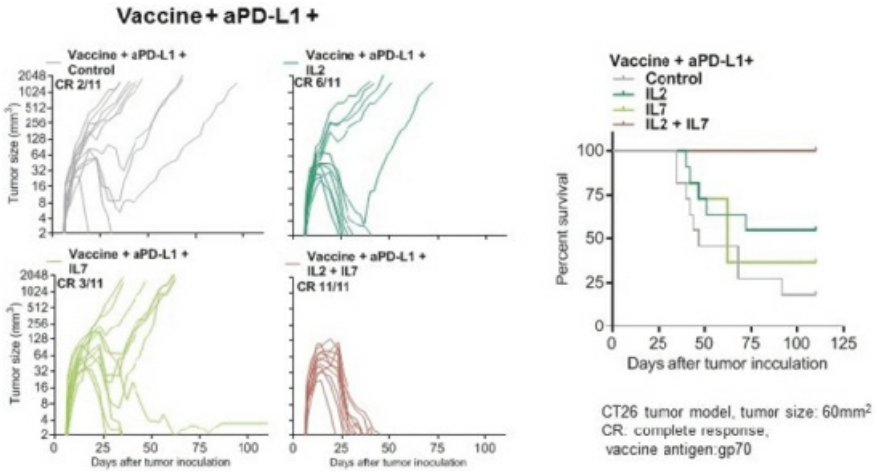
Next Steps

We expect to initiate a Phase 1 basket trial of BNT142 for the treatment of numerous solid tumors in the first half of 2021.

5. RiboCytokines

Our RiboCytokine product candidates utilize mRNA that encodes the desired cytokines for expression *in vivo* by the patient's cells. RiboCytokine product candidates consist of modified mRNA designed to encode secreted cytokines that are formulated to use liver-targeting LNP for intravenous delivery.

Our RiboCytokine product candidates are designed to address the limitations of recombinantly expressed cytokines, including limited serum half-life and production costs. We are developing RiboCytokines to be used primarily in combination with other drugs, including our other pipeline candidates.



In a preclinical mouse model, we observed RiboCytokines boost the activity of our RNA-LPX vaccination and a PD-L1 blockade in large tumors. Two out of 11 mice treated with our RNA-LPX vaccination and an anti PD-L1 alone achieved complete response. We observed three out of 11 mice achieve complete response with our RNA-LPX vaccination, an anti PD-L1 and IL7 RiboCytokine, six out of 11 mice with complete response after receiving our RNA-LPX vaccination, an anti PD-L1 and IL2 RiboCytokine and 11 out of 11 mice with complete response when given our RNA-LPX vaccination, an anti PD-L1 and both IL7 and IL2 RiboCytokines.

a) BNT151: Our Initial RiboCytokine for the Treatment of Solid Tumors

We are developing BNT151, our RiboCytokine designed to encode a modified version of the humaninterleukin-2, or optimized IL-2, cytokine for the treatment of solid tumors. BNT151 is designed to stimulate T cells without triggering immunosuppression in the tumor microenvironment.

Our BNT151 Target

BNT151 comprises our nucleoside-modified mRNA that encodes mRNA for a function-modified IL-2. IL-2 is a key cytokine in T cell immunity, supporting the differentiation, proliferation, survival and effector functions of T cells.

Recombinant IL-2, aldesleukin, was the first approved cancer immunotherapy, and has been marketed globally for the treatment of late stage melanoma and renal cell cancer for decades. Most patients with complete

responses after IL-2 treatment remain regression free for more than 25 years after initial treatment, but overall response rates are low due in part to the limitations of recombinant cytokines. Recombinant IL-2 has a very short half-life, requiring high and frequent dosing and a partially unfavorable activity profile, which leads to increased side effects, thus limiting its utility as a cancer treatment.

Next Steps

We expect to initiate a Phase 1 clinical basket trial of BNT151 for the treatment of multiple solid tumors in the first half of 2020.

b) BNT152: Our Second RiboCytokine for the Treatment of Solid Tumors

We are developing BNT152, our RiboCytokine designed to encode IL-7 for the treatment of solid tumors.

Next Steps

We expect to initiate a Phase 1/2 clinical trial of BNT152 in combination with BNT153 for the treatment of multiple solid tumors in the first half of 2021.

c) BNT153: Our IL-2 variant RiboCytokine for the Treatment of Solid Tumors

We are developing BNT153, our RiboCytokine designed to secrete IL-2 for the treatment of solid tumors.

Next Steps

We expect to initiate a Phase 1/2 clinical trial of BNT153 in combination with BNT152 for the treatment of multiple solid tumors in the first half of 2021.

B. Our Oncology Engineered Cell Therapy Product Candidates

1. CAR T

We are advancing multiple CAR T product candidates, the most advanced of which, BNT211, is targeting the novel and highly specific target CLDN6+ in solid tumors, and which we expect to enter the clinic in the second half of 2019 for the treatment of CLDN6 solid tumors, including ovarian cancer. We plan to use our initial CAR-T cell product candidates in combination with a FixVac immunotherapy that encodes the same target as the CAR T. The FixVac selectively targets dendritic cells, which leads to uptake, antigen expression and maturation of the dendritic cells. The co-stimulation provided by dendritic cell maturation has been shown in preclinical studies to amplify and expand CAR-T cells *in vivo*, leading to increased persistence of the CAR T.

a) BNT211: Our CAR T Cell Therapy for the Treatment of CLDN6+ Solid Tumors

BNT211 is our CAR-T cell therapy for the treatment of CLDN6+ solid tumors. BNT211 targets CLDN6 and will initially be evaluated in combination with a CARVac that encodes CLDN6.

Our BNT211 Target

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

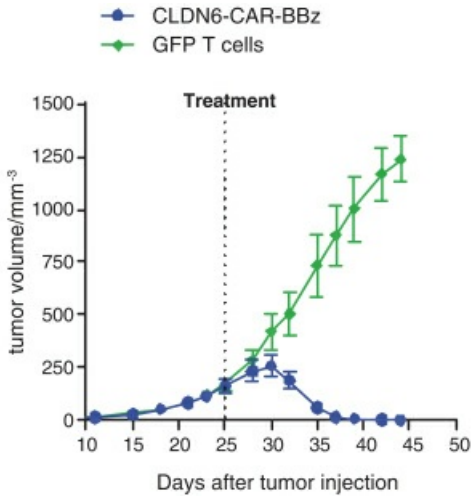
Our BNT211 Trials

Planned Phase 1/2 Clinical Trial

We anticipate initiating a Phase 1/2 open-label, multi-center dose escalation and dose expansion basket study of BNT211 with or without a CLDN6 CARVac immunotherapy in the first half of 2020. We anticipate enrolling patients with advanced solid tumor malignancies who express CLDN6. While our preclinical focus has been on ovarian cancer, we expect patients with uterine, testicular, lung and gastric cancers may also be enrolled in our upcoming CAR T trials.

Preclinical Studies

We have observed compelling preclinical data of BNT211 demonstrating potent anti-tumoral activity, including eradication of advanced tumors in an ovarian carcinoma xenograft model.



Potent anti-tumoral activity. As shown above, BNT211 demonstrated eradication of advanced tumors in a mouse model.

In January 2020, we published results for a preclinical study in which BNT211 was evaluated both in vitro in tumor cell lines and in vivo in mice with human ovarian cancer transplants. In mice, BNT211 demonstrated complete tumor regression of transplanted large human tumors within two weeks after treatment initiation. Furthermore, the combination with CARVac achieved improved engraftment, proliferation and expansion of CAR-T cells in vivo, resulting in tumor regression even at sub-therapeutic CAR-T doses. CARVac was also successfully applied forCAR-T cells targeting the pan-cancer antigen CLDN18.2 and CD19, the target of approved CAR-T cell therapies. The combination ofCAR-T cell therapy with CARVac underlines the value of cross-platform synergies to address key development challenges in the treatment of cancer.

Next Steps

We are planning to initiate a Phase 1/2 clinical trial of the combination of BNT211 and a CLDN6-encoded CARVac in the first half of 2020 for the treatment of CLDN6^{+} solid tumors, including ovarian, testicular, uterine and lung cancer.

b) BNT212: Our CAR T Cell Therapy for the Treatment of CLDN18.2^{+} Solid Tumors

BNT212 is our CAR-T cell therapy for the treatment of CLDN18.2-positive solid tumors. BNT212 will initially be evaluated in combination with a CARVac that encodes CLDN18.2.

Our BNT212 Target

BNT212 targets Claudin 18.2, or CLDN18.2, a highly specific target that is only expressed in cancer and in differentiated epithelial cells of the gastric mucosa, but it is absent from the gastric stem cell zone. CLDN18.2 is expressed in numerous epithelial solid tumors, including gastric, pancreatic, esophageal, ovarian and lung tumors.

C. Our TCR Product Candidates in Oncology

We are developing T cell receptor therapies for the treatment of cancer, including in collaboration with Eli Lilly. Under our collaboration, Eli Lilly has an exclusive option to pursue clinical development of certain potential TCR product candidates. We and Eli Lilly have concluded the research phase of the collaboration and Eli Lilly has exercised its option and selected a target to develop and commercialize.

D. Our Antibody Product Candidates in Oncology

1. Next-Generation Checkpoint Immunomodulators

In our 50:50 collaboration program with Genmab, we are currently studying two bispecific antibody checkpoint immunomodulators.

a) GEN1046 (BNT311): Our Jointly Owned DuoBody® PD-L1x4-1BB Bispecific Antibody for the Treatment of Solid Tumors

GEN1046 (BNT311), 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. The first patient in a Phase 1/2a trial of GEN1046 (BNT311) for the treatment of malignant solid tumors was dosed in May 2019.

Our GEN1046 (BNT311) Targets

GEN1046 (BNT311) is a PD-L1x4-1BB bispecific antibody that induces conditional activation of T cells through4-1BB 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, also in the absence of4-1BB binding. PD-L1 is a validated target that is expressed on tumor cells. 4-1BB is a trans-membrane receptor belonging to the TNF super-family and is expressed predominantly on activated T cells. DuoBody® is a registered trademark of Genmab.

GEN1046 (BNT311) Trials

Ongoing Phase 1/2a Clinical Trial

The ongoing Phase 1/2a, open-label, single-arm GEN1046 (BNT311) trial with multiple expansion cohorts, conducted in collaboration with Genmab, is expected to enroll approximately 192 patients with malignant solid tumors. The trial consists of a dose escalation part and an expansion part. The dose escalation part will determine the safety profile of GEN1046 (BNT311) in subjects with certain relapsed or refractory, advanced and/or metastatic malignant solid tumors who are no longer candidates for standard therapy. The expansion part will be initiated once the recommended Phase 2 dose has been established in Phase 1. In the expansion part, GEN1046 (BNT311) will be administered intravenously once every 21 days. The primary endpoints of the trial are dose-limiting toxicities, adverse events and safety laboratory parameters, including hematology, biochemistry, coagulation and endocrinology.

Preclinical Studies

In preclinical settings, GEN1046 (BNT311) induces conditional activation of T cells through4-1BB 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.

Next Steps

We expect to report a data update for our ongoing Phase 1/2 trial in the first half of 2021.

b) GEN1042 (BNT312): Our Jointly Owned DuoBody® CD40x4-1BB Bispecific Antibody for the Treatment of Solid Tumors

GEN1042 (BNT312), our jointly owned CD40x4-1BB antibody product candidate, is a potential first-in-class bispecific antibody designed to induce conditional immune activation by crosslinking CD40 and 4-1BB positive cells. We and Genmab began recruitment and screening for a Phase 1/2a trial of GEN1042 (BNT312) for the treatment of malignant solid tumors in August 2019.

GEN1042 (BNT312) Targets

GEN1042 (BNT312) is a bispecific antibody designed to enhance an anti-tumor immune response through conditional CD40-mediated stimulation of antigen presenting cells crosslinked with conditional stimulation of 4-1BB$^+$ T cells. It has demonstrated increased tumor infiltrating lymphocyte expansion in human tumor tissue cultures *ex vivo* and has induced tumor regression of murine tumors superior to pure PD-L1 blockage associated with an increase in tumor-specific CD8 T-cells. The cell surface molecule CD40 is a member of the tumor necrosis factor receptor superfamily.

GEN1042 (BNT312) Preclinical Studies

GEN1042 (BNT312) is designed to target CD40 and 4-1BB to enhance both dendritic cell and antigen-dependent T cell activation. In preclinical settings, GEN1042 (BNT312) activated antigen presenting cells and enhanced T cell activation. Preclinical studies also indicated the conditional activation and (clonal) expansion of previously activated CD8$^+$ T cells and cytokine production resulting from GEN1042 (BNT312).

2. Targeted Cancer Antibodies

a) MVT-5873 (BNT321): Our Targeted Cancer Antibody for the Treatment of Pancreatic Cancer

In May 2019, we acquired certain antibody assets from MabVax Therapeutics Holding, Inc., including MVT-5873 (BNT321), a clinical-stage targeted cancer antibody.

Pancreatic Cancer

The American Cancer Society estimates that approximately 56,770 people will be diagnosed with pancreatic cancer in the United States in 2019. Pancreatic cancer is an aggressive cancer, with a five-year survival rate from diagnosis, across all stages combined, of 9%.

Our MVT-5873 (BNT321) Target

MVT-5873 (BNT321) is a fully human IgG1 monoclonal antibody targeting sialyl Lewis A (sLe^a), 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.

Our MVT-5873 (BNT321) Trials

MVT-5873 (BNT321) is being investigated in an open-label, multi-center, non-randomized dose escalation Phase 1/2 study evaluating the safety and recommended Phase 2 dose of MVT-5873 (BNT321) both as a monotherapy and in combination with a standard of care chemotherapy in approximately 68 subjects 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.

Interim data for the combination cohort was reported in February 2018. In this cohort,MVT-5873 (BNT321) was given in combination with nab-paclitaxel and gemcitabine to patients newly diagnosed with CA19-9+ pancreatic cancer. MVT-5873 (BNT321) at a dose of 0.125mg/kg when added to first-line chemotherapy was generally well tolerated by all subjects. All six patients evaluated had measurable tumor reductions by RECIST, with four patients meeting the criteria for partial response and two patients meeting the criteria for stable disease.

Next Steps

This trial is currently enrolling patients.

E. Our Oncology Small Molecule Immunomodulator Product Candidates

1. BNT411: Our Small Molecule TLR7 Agonist for the Treatment of Colorectal and Bladder Cancer

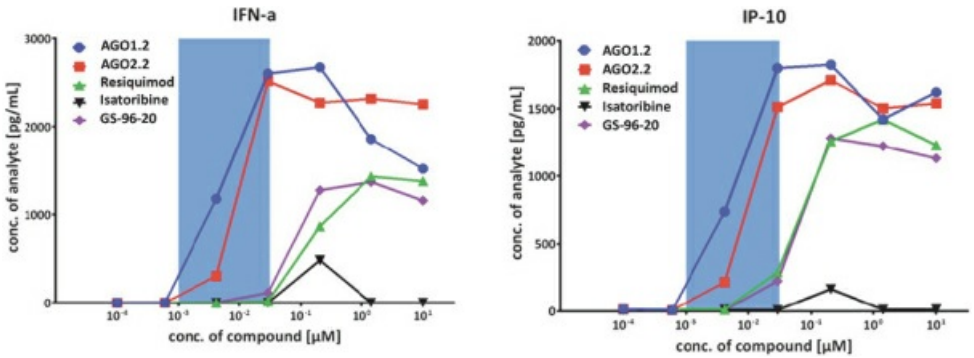
BNT411 is our novel small molecule TLR7 agonist product candidate. BNT411 is designed to activate both the adaptive and innate immune system through the TLR7 pathway. We are designing BNT411 to be used in combination with chemotherapy and checkpoint inhibitors. We filed an IND for BNT411 in November 2019.

Our BNT411 Target

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.

Our BNT411 Preclinical Studies

In preclinical studies, BNT411 (SC1.2/Ago1.2) was shown to be more potent in the induction ofIFN-α compared to the clinical competitor compound resiquimod (R848), even at lower concentrations (minimal effective concentration of BNT411 *in vitro* is 4nM). In contrast to the tested competitor compound, BNT411 was shown to induce at low concentrations especially IFN-α whereas other (pro-)inflammatory and CRS-related cytokines (IL-6, IL-10, TNF-a, IL-8) are only observed at higher concentrations.



Next Steps

We expect to initiate a Phase 1 clinical trial of BNT411 as a combination therapy in solid tumors in the first half of 2020.

F. Our Infectious Disease mRNA Product Candidates

1. Prophylactic Vaccine for the Prevention of Influenza

We are collaborating with Pfizer to develop an influenza vaccine based on our mRNA drug classes. The product candidate will encode influenza virus antigens selected by the WHO in advance of the flu season.

Next Steps

We anticipate beginning a first clinical trial by the end of 2020.

2. Other Infectious Diseases

We have a research collaboration with Penn, under which we have the exclusive option to develop and commercialize prophylactic mRNA immunotherapies for the treatment of up to 10 infectious disease indications. On September 20, 2019, Penn announced positive preclinical results of a vaccine product candidate using its mRNA technology. The preclinical study vaccinated mice and guinea pigs against Herpes simplex virus type 2. Penn reported that the immunization led to "mostly sterilizing immunity" from the virus.

Next Steps

We expect to initiate our first Phase 1 clinical trial under this collaboration in the first half of 2021.

G. Our Rare Disease Protein Replacement mRNA Product Candidates

We are collaborating with Genevant, in order to combine our mRNA technology with Genevant's LNP delivery technology, to create up to five mRNA protein replacement therapies for the treatment of rare diseases with high unmet medical needs. We expect our first compound from this collaboration to enter the clinic by the second half of 2020. The first product candidate under the Genevant collaboration, BNT171, is currently being developed for an undisclosed indication. Our mRNA replacement product candidate is associated with a favorable tolerability profile and good protein expression (in mice) and demonstrated phenotype rescue in a mouse disease model.

H. Other

Our legacy commercial stage product, MammaTyper, is a molecular *in vitro* diagnostic test for the quantitative detection of the mRNA expression of ERBB2, ESR1, PGR and MKI67 in breast cancer tissue. MammaTyper has been shown in a variety of scientific publications to offer superior diagnostics insights compared to conventional immunohistochemical detection methods.

XIII. Manufacturing

We are building a fully integrated biotechnology company, with operations spanning from research through clinical development, and manufacturing through sales and marketing. We operate three GMP-certified manufacturing facilities in Germany, where we manufacture mRNA therapeutics and engineered cell therapies for our own pipeline and for external customers. We operate a fourth facility in Germany where we manufacture custom peptides to support our extensive immunomonitoring activities within our development programs. Our subsidiary BioNTech Innovative Manufacturing Services GmbH, or BioNTech IMFS, has been manufacturing GMP-certified cellular products since 1999. It was granted its first GMP license for manufacturing mRNA in 2011 and has been manufacturing individualized mRNA products since 2014.

We have expanded our capability to produce and supply drug products to support clinical development of our, and our collaborators', product candidates. To date, we have manufactured over 500 drug substance batches in our manufacturing facilities.

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 a fully-automated, on-demand production of mRNA therapies.

Our Manufacturing Operations

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 and our BioNTech East Wing facility, the latter being dedicated to iNeST 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. Batch sizes range from a few milligrams for individualized applications (*i.e.*, iNeST) to 3g for standard mRNA applications (*i.e.*, FixVac and intratumoral immunotherapies), with batch sizes of up to 10g currently possible.

To date, we have produced more than 500 batches of mRNA drug substance to support our studies. We currently have infrastructure capable of producing more than 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 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 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, 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. We believe this is achievable, and 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 culturing, 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.

Our Manufacturing Facilities

We operate four manufacturing and packaging facilities in Germany. In these facilities, we manufacture and package individualized mRNA, bulk mRNA, retroviral vectors, cellular products and peptides. In Mainz, we are currently constructing another facility for iNeST manufacturing at a commercial scale, which is planned to start manufacturing in 2022 and will supply markets mainly in Europe and the United States.

BioNTech IMFS. Our manufacturing operations for retroviral vectors, cell therapy products and mRNA are housed in our wholly owned subsidiary, BioNTech IMFS. Founded in 1997, BioNTech IMFS specializes in services for innovative therapeutic approaches. In 2009, BioNTech IMFS became our wholly owned subsidiary, giving us access to synergistic platforms and complementary expertise for development, testing and manufacturing services. BioNTech IMFS and its predecessors have had GMP-certified cell and gene therapy manufacturing capabilities since 1999, and obtained GMP manufacturing authorization for mRNA production in 2011. In 2017, BioNTech IMFS began automated manufacturing of the iNeST product candidate and entered into its first commercial supply contract for retroviral vectors. Located near Mainz, the BioNTech IMFS facility occupies over 30,000 square feet. Two hundred and twenty staff members are employed at this facility, with collective expertise in molecular biology, cell biology and virology.

BioNTech iNeST Clinical Manufacturing (East Wing). We dedicate our GMP-certified manufacturing facility at our headquarters in Mainz, Germany to the production of iNeST immunotherapies. In 2015, our wholly owned subsidiary, BioNTech RNA Pharmaceuticals GmbH, or BioNTech RNA, and Siemens announced a collaboration for developing an automated, paperless and digitalized production site for individualized mRNA. We obtained our GMP manufacturing authorization for iNeST production at our East Wing facility in June 2018 and released our first drug product there the following month.

This facility contains approximately 17,000 square feet of laboratory and office space, including 4,300 square feet of GMP facilities. 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.

BioNTech Clinical Manufacturing. Our GMP-certified manufacturing facility in Kupferbergterrasse, Mainz, Germany 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.

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, Germany and occupies over 16,000 square feet of clean rooms, laboratory and office space.

Other Certifications

BioNTech Diagnostics has a quality management system that is certified according to ISO 13485:2016 and JPT maintains a ISO 9001:2015 certified Quality Management System to allow production of European CE marked companion diagnostics.

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.

Future Manufacturing Outlook

We are committed to the continued development of world-class manufacturing operations to support our clinical manufacturing needs, to prepare for commercial scale manufacturing of our product candidates, and to

realize external commercial opportunities. We expect to commit approximately an additional €250 million through 2023. Our planned manufacturing investments include:

- two new buildings at our BioNTech IMFS facility, including three floors each of clean rooms and additional development and quality control laboratories;
- our planned commercial scale facility in Mainz, which will occupy more than 100,000 square feet and will house cleanrooms, laboratories and offices; and
- an expansion of our JPT facility, which is designed to more than double our capacity.

XIV. 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:

- Genentech for our iNeST platform in our mRNA drug class;
- Sanofi for our intratumoral therapy platform in our mRNA drug class;
- Genmab for our next-generation checkpoint immunomodulator platform in our antibodies drug class;
- Pfizer for our influenza vaccine program, which leverages technology from our infectious disease mRNA-based platform;
- Penn for up to 10 prophylactic indications in our infectious disease mRNA-based platform; and
- Genevant for our rare disease protein replacement therapy platform in our mRNA 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.

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 Collaboration Agreement at our sole expense, and any future material changes in the operation of such clinical studies require Genentech's approval. Genentech may access and use any data generated in these ongoing clinical studies.

In addition to the clinical studies included in the global development plan, we may propose certain additional clinical studies for indications not included in the global development plan, and if the joint development committee formed by the parties does not elect to include the proposed studies in the global development plan, then we may conduct the study at our sole expense under certain conditions, and subject to certain restrictions. Genentech has the option to select any candidate in such studies for potential further joint development and/or commercialization by Genentech as a Genentech Collaboration Product. In the case that Genentech wishes to pursue the clinical development of a Genentech Collaboration Product in an indication that we are not interested in pursuing, then under certain conditions, we may opt out of the co-funding of such development and Genentech may continue do so at its own costs, except that we are obligated to repay Genentech's development costs in the event that such product subsequently receives regulatory approval.

Genentech has the sole right to commercialize the Genentech Collaboration Products on a worldwide basis, with all profits and losses from such commercialization to be split equally with us. If we exercise our right to opt out of sharing equally in future development costs for any Genentech Collaboration Products, then we will no longer split all such profits and losses for such Genentech Collaboration Products equally with Genentech and will instead receive a royalty on annual worldwide net sales of such Genentech Collaboration Products that are covered by a valid claim included in certain of our patents and certain joint patents that arise out of the collaboration. Furthermore, for certain Genentech Collaboration Products for which we share co-promotion rights with Genentech, we have the option to assume a percentage to be determined of the total sales force in the United States and certain other countries, including Germany and other major European markets. In addition, under certain regulatory and other circumstances, we have the right to independently commercialize Genentech Collaboration Products in indications that the joint development committee declines to pursue and that Genentech does not subsequently elect to commercialize, provided that we market such Genentech Collaboration Products under a separate brand and trademark that is approved by the joint commercialization committee established by the parties as not confusingly similar to the Genentech Collaboration Products being commercialized by Genentech. Our ability to research, develop, co-promote and/or independently commercialize Genentech Collaboration Products may be terminated or limited in the event we undergo a change of control.

We granted to Genentech an exclusive license under certain of our intellectual property, and our interest in any jointly-owned intellectual property developed under this agreement, to research, develop, make, sell and import any pharmaceutical products that comprise neoepitope RNA. Genentech granted to us an exclusive, non-transferable, sublicensable licenses under certain Genentech intellectual property, our intellectual property exclusively licensed to Genentech, and their interest in any jointly-owned intellectual property developed under this agreement for the performance of our ongoing clinical studies and the exercise of our rights and obligations under the Genentech Collaboration Agreement.

Until the first marketing approval for a Genentech Collaboration Product, we have granted Genentech the first right to negotiate an exclusive license to develop, manufacture and commercialize combination therapies involving pharmaceutical products based on neoepitope RNA and pharmaceutical products based on non-neoepitope RNA for the treatment of cancer in humans.

The Genentech Collaboration Agreement will remain in effect so as long as Genentech Collaboration Products are in development or commercialization, or until the date of the expiration of the last royalty term if BioNTech has exercised its option to opt-out of joint development of Genentech Collaboration Products. If the agreement expires, the licenses granted to Genentech become fully-paid up, royalty-free and irrevocable. Genentech may terminate the Collaboration Agreement if we fail to achieve certain milestone targets or at any time for convenience with or without reason upon 60 days' prior written notice. In the event of any such termination, all rights to the development and commercialization of Genentech Collaboration Products developed

under the collaboration would revert to us and Genentech would grant us licenses under its intellectual property to further develop and commercialize Genentech Collaboration Products. We would be required to pay certain royalties to Genentech for such license(s). In addition, either party may terminate the agreement upon the other party's uncured material breach or insolvency.

Manufacturing Development and Supply Agreement

Concurrent with the Genentech Collaboration Agreement, we and BioNTech RNA entered into a Manufacturing Development and Supply Agreement with Genentech and F. Hoffman-La Roche Ltd, or the Genentech Manufacturing Agreement, which governs the manufacturing, related manufacturing development activities and supply of Genentech Collaboration Products. Pursuant to the Genentech Manufacturing Agreement, we are responsible for clinical manufacturing and supply, for developing and implementing manufacturing processes (including pursuant to specified target turnaround times), and for constructing, commissioning, qualifying and obtaining permits for the clinical facilities. We are permitted to subcontract certain steps in the clinical manufacturing process to our affiliate, BioNTech IMFS.

In addition, we are responsible for developing the commercial manufacturing process, which requires more stringent turnaround times than the clinical manufacturing process. Genentech will generally be responsible for commercial manufacturing. We are obligated to use commercially reasonable efforts to achieve certain predetermined clinical manufacturing capacity commitments.

Under the Genentech Manufacturing Agreement, we and Genentech will jointly develop a manufacturing network plan detailing the location, capacity, scale-out, associated timing and other appropriate details of the commercial manufacturing facilities. We may participate in commercial manufacturing through our right to include as part of the commercial manufacturing network one of our own facilities in the European Union or the United States and one of our own facilities in another region to be agreed upon with Genentech (provided that in each region our facility is not the first facility to be included in the commercial manufacturing network).

Sanofi—Intratumoral Therapy Collaboration

On November 2, 2015, BioNTech RNA entered into a Collaboration and License Agreement with Sanofi, which we refer to as the Sanofi Agreement. Pursuant to the Sanofi Agreement, we and Sanofi will collaborate on intratumorally administered mRNA-based therapeutics for the treatment of solid tumors in humans.

The Sanofi Agreement contemplates: (i) research, (ii) development and commercialization and (iii) possibleco-development and co-commercialization activities with us.

During the research phase, the parties seek to identify, characterize and validate up to five "mixtures" of two or more mRNAs encoding different proteins administered together in the same solution. Sanofi at its sole discretion may select up to five mixtures created under the research plan for further development and commercialization, which we refer to as Sanofi Collaboration Products.

After selection of a Sanofi Collaboration Product, Sanofi would be responsible for all development and commercialization activities involving that product. We have the option, by payment of an exercise fee, to co-develop and co-commercialize up to two Sanofi Collaboration Products primarily in the United States and in some European countries, including the United Kingdom, France, Germany, Italy and Spain. If we exercise such an option, the costs for co-development and co-commercialization of the chosen Sanofi Collaboration Products would be allocated between the parties. In turn, Sanofi has an option to co-develop and co-commercialize certain mixtures developed by us or with third parties that contain a certain amount of the mRNAs of a Sanofi Collaboration Product.

In March 2018, Sanofi selected the first Sanofi Collaboration Product for further development and commercialization and we exercised our option for co-development and co-commercialization of the Sanofi

Collaboration Product. Effective as of March 2018, the parties entered into a separate development agreement for the co-development of this Sanofi Collaboration Product.

Under the Sanofi Agreement, Sanofi has paid upfront and near-term milestone payments of approximately €60 million. We are entitled to receive up to approximately €260 million per product upon achievement of certain development, regulatory and commercial milestones. If commercialized successfully, we would also be eligible for mid-single digit to very low double-digit tiered royalties on net sales on a country-by-country and product-by-product basis until the later of (i) expiration of the last relevant patent covering such product in such country, (ii) 10 years following first commercial sale of such product in such country, (iii) expiration of regulatory data exclusivity for such product in such country and (iv) the market entry of a generic biological product with a certain market share in relation to such product in such country.

The Sanofi Agreement will remain effective until the last-to-expire royalty term (or, when a co-development option has been exercised, the completion of all co-development and co-commercialization activities). The parties may terminate the Sanofi Agreement in its entirety or terminate certain co-development activities for convenience, with or without cause.

The Sanofi Agreement provides that we may not engage in certain research and development activities relating to the intratumoral injection of mRNAs.

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 in humans 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 is currently set to expire on May 31, 2021, but has in the past been extended.

During the research and evaluation phase, we and Genmab may propose clinical candidates for consideration by a joint research committee for further preclinical and clinical development. If a party, through the joint research committee, indicates that it is not interested in further development and commercialization of any clinical candidate, the other party may continue development and commercialization of such products on a unilateral basis, at its sole expense. The party that continues such development and commercialization is obligated to pay the other party certain development, regulatory and sales milestone payments and royalties on net sales of the applicable Unilateral Products. During either party's development and commercialization of a Unilateral Product, the other party must not develop or commercialize any bispecific antibody targeting the same target combination of such Genmab Unilateral Product if such bispecific antibody was generated as part of the collaboration under this agreement.

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 provides regular updates to us on regulatory activities.

Each party grants to the other party a worldwide, co-exclusive, sublicensable, royalty-free license under certain of such first party's intellectual property, including certain patents and know-how, to perform the research under this agreement and to research, develop, make, import, use and sell Genmab Collaboration Products in the Genmab Agreement Field pursuant to the terms of the Genmab Agreement. These licenses shall continue on a country-by-country and product-by-product basis for as long as development or commercialization activities are contemplated under the Genmab Agreement.

During the research and evaluation phase prior to the selection of a Genmab Collaboration Product, neither we nor Genmab may engage in any research and development activity in the Genmab Agreement Field relating to the development of any bispecific antibody which targets any combination that is the subject of our joint research plan. During the preclinical and clinical development phase for any Genmab Collaboration Product, engagement in research and development activities in the Genmab Agreement Field unilaterally by a party relating to a Genmab Collaboration Product or its Genmab Back-up Candidate or any bispecific antibody which targets the same target combination for which such Genmab Collaboration Product or GenmabBack-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 suchpre-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 thelast-to-expire royalty term for any Unilateral Product and (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.

Eli Lilly TCR Therapy Collaboration

In May 2015, BioNTech C&GT entered into a drug discovery research, development and commercialization agreement with Eli Lilly regarding TCR-based therapeutics for the treatment of cancer. We refer to this agreement as the Lilly Agreement.

Under the Lilly Agreement, BioNTech C&GT is obligated to use commercially reasonable efforts to perform specified research and development activities relating to potential TCR targets. Additionally, BioNTech C&GT is obligated to work exclusively with Eli Lilly in the field of non-small cell lung cancer outside of certain permitted personalized TCR and RNA therapy activities. In consideration of these activities, Eli Lilly is obligated to pay to BioNTech C&GT an annual research and development fee. Additionally, Eli Lilly made an upfront payment of $30 million to BioNTech C&GT in connection with entry into the Lilly Agreement and an additional $30 million equity investment in BioNTech C&GT. In March 2019, we agreed to exchange Eli Lilly's shares in BioNTech C&GT for our (BioNTech SE's) shares. Eli Lilly is obligated to pay up to an aggregate of approximately $300 million to BioNTech C&GT upon the occurrence of certain development, regulatory and commercial milestones. Finally, upon commercialization of a product, Eli Lilly would be obligated to pay tiered royalties on net sales of the product ranging from the low single-digit to very low double-digit percentages. BioNTech C&GT would be obligated to pay to Eli Lilly tiered royalties in the mid-single-digit percentages on net sales of certain products targeted at any new MHC peptide complexes, as well as up to an aggregate of $70 million upon the occurrence of commercial milestones.

BioNTech C&GT agreed to grant to Eli Lilly a worldwide, exclusive license to certain of its intellectual property necessary to exploit any selected targets and worldwide, non-exclusive licenses to BioNTech C&GT's background intellectual property and interest in collaboration intellectual property to exploit any selected targets, non-platform products, and small molecule and antibody products. Furthermore, BioNTech C&GT granted to Eli Lilly a worldwide, non-exclusive, sublicensable, royalty-free license to its background intellectual property and interest in collaboration intellectual property to exploit companion diagnostics for platform products and diagnostics generally.

In turn, Eli Lilly granted to BioNTech C&GT a worldwide exclusive, sublicensable license under its interest in collaboration intellectual property to exploit personalized RNA therapies and TCR therapies and a worldwide, non-exclusive, sublicensable license under its interest in collaboration intellectual property to exploit diagnostics and companion diagnostics.

Eli Lilly has the sole right to select targets investigated during the research term for development and commercialization. Upon selection of a target Eli Lilly is obligated to use commercially reasonable efforts to develop and commercialize at least one product in the United States and in one other country from a specified list of major countries. On September 5, 2019, Eli Lilly selected its first target under the Agreement, resulting in a $2 million milestone payment to us.

The Lilly Agreement may be terminated in its entirety or in part by either party upon an uncured material breach or insolvency of the other party. Eli Lilly may terminate the Lilly Agreement with or without reason by giving 30 days' advance written notice to BioNTech C&GT.

Pfizer—Influenza Collaboration

On July 20, 2018, we and BioNTech RNA entered into a Research Collaboration and License Agreement with Pfizer, or the Pfizer 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 Agreement Field.

We and Pfizer agreed to collaborate on the research in the Pfizer Agreement Field for an initial period of three years. The details of such research were set forth in a research plan that is governed by a joint steering

committee, with Pfizer holding the final decision-making right. Each party will bear its own costs under the research plan. The research term will be extended automatically by a reasonable amount of time if the activities or deliverables under the research plan are delayed due to our material breach of our research obligations under the research plan. In addition, Pfizer may unilaterally extend the research term by up to a year by making an additional payment to us.

After the research term expires, Pfizer has the sole responsibility, authority and control of the development, manufacturing and commercialization of all candidates and products. Pfizer undertakes to use commercially reasonable efforts to seek regulatory approval for one product in the United States and in two countries out of France, Germany, Italy, Spain, the United Kingdom and Japan, and to commercialize such product in such countries where such product has received regulatory approval.

Under the Pfizer 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 Agreement Field as well as certain intellectual propertyin-licensed by us from third parties, to use, research, develop, manufacture, commercialize and otherwise exploit candidates and products selected under the Pfizer 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 Agreement in the Pfizer 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 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 Agreement, Pfizer made an upfront payment of $50 million and agreed to potential payments of up to $325 million upon the achievement of specified development, regulatory and commercial milestones. Pfizer further agreed to a mid-single digit to very low double-digit tiered royalty on net sales if a product is commercialized. Royalties are subject to stacking provisions. The obligation of Pfizer to pay royalties ends, on a country-by-country and a product-by-product, basis upon the later of (i) the expiration of the last valid licensed patent right covering such product category in such country, (ii) 10 years after the first commercial sale of a product of such product category in such country and (iii) the lapse of regulatory data exclusivity for the first product in such product category in such country. There are only two product categories: one for modified RNA and a second for replicon products.

During the term of the Pfizer Agreement, we have committed not to research, develop, manufacture, commercialize or otherwise exploit immunogenic compositions compromising RNA in the Pfizer Agreement Field other than pursuant to the Pfizer Agreement.

The Pfizer 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.

Bill & Melinda Gates Foundation—HIV and Tuberculosis Collaboration

On August 30, 2019, we entered into a letter agreement and an investment agreement with the Bill & Melinda Gates Foundation, or BMGF, pursuant to which BMGF acquired 3,038,674 of our ordinary shares for $55 million at the price of our Series B financing. The primary purpose of BMGF's investment is to further its charitable purposes, and the investment will be utilized to advance the development of products for the prevention and/or treatment of HIV and tuberculosis, or TB. About one-third of the investment will be used to help fund our infrastructurebuild-out; this expansion of the company's infectious disease capabilities is necessary to enable us to conduct BMGF projects.

In addition to the HIV and TB projects, BMGF has the right to initiate up to three additional projects focused on infectious diseases (from a list of mutually agreed upon diseases) within the first five years of the partnership. BMGF may also continue to fund certain projects beyond initial funding agreements. These additional activities may be funded through grants from BMGF of up to $45 million. We must accept funding for the HIV and TB projects until the occurrence of defined event stamps and for the additional projects until the eighth anniversary of the closing of the investment. The event stamps involve the completion of Phase 1 safety and immunogenicity studies in healthy and/or infected individuals showing specific results.

If we elect not to proceed with any project following achievement of the event stamps, a new partner may further develop the project and manufacture any resulting products. Such partner will be identified through a series of defined steps and a technology transfer would take place. If a suitable manufacturing partner is not identified, we must manufacture the clinical and commercial supply of any product until a partner is identified. Such manufacturing may require us to increase our manufacturing capacities, which may be funded by BMGF. We retain the right to manufacture at any time.

The primary objective of BMGF is to provide funding to accelerate the development of lifesaving,low-cost drugs to reduce the burden of diseases in developing countries. This objective is known as global access commitments, or GAC. The projects in this partnership are separate and distinct from our current proprietary and partnered product candidates; all BMGF programs, however, will utilize our proprietary technology platforms. We retain rights for commercialization of products in the developed world. We can also independently develop any of the project results under new proprietary projects. The results which are funded under this partnership are always accessible by BMGF and are subject to GAC.

We have granted a non-exclusive, perpetual, royalty-free license (with limited rights to sub-license) to our platform technology that is specifically used in the defined projects for the purpose of benefiting people in developing countries. This license is known as the global health license and only becomes exercisable upon the occurrence of a charitability default (as detailed below) or if we become insolvent. BMGF has granted us a de-blocking license to ensure freedom to operate of our platform technology. We will negotiate in good faith to expand the geographic scope of the global health license to include developed countries if requested by the new partner.

The objective is to generate products that are affordable and accessible for the developing world. The final price, however, will not fall below our full costs of manufacturing the product.

We are required to publish, in accordance with certain "open access" terms and conditions, results and information developed under the projects.

BMGF has a right to withdraw from its investment in certain specified circumstances, including if we become insolvent or in the event of a charitability default, namely material breach of the GAC or breach of other specified requirements in the agreement. If we do not cure the charitability default within a specified period of time (if curable), we must repurchase all of the shares held by BMGF, to the extent consistent with applicable law, if we have sufficient free reserves and available liquidity, or we must locate a third-party purchaser of those

shares. If we are not able to repurchase the shares or find a third-party purchaser, we must use our best efforts to effect BMGF's withdrawal right as soon as practicable, which may mean acquiring the shares in tranches over time. To the extent permitted by law, we must compensate BMGF for any shortfall if the price achieved on a sale to a third party is lower than its initial investment. During the period before a charitability default occurs, we can pay dividends on our shares, provided that our cash reserves exceed the price per share paid by BMGF times the number of shares BMGF holds (which is initially $55 million), and to the extent permitted by law, we must contribute annual profits of that amount to the cash reserves. After a charitability default has occurred and until the withdrawal right has been satisfied in full, we may only pay dividends in excess of the aggregate minimum purchase price if BMGF has not exercised any option to require us to repurchase any remaining shares held by them. For any purchase resulting from a charitability default, the aggregate minimum purchase price of BMGF's shares will be valued at the greater of the original purchase price of the shares or the fair market value of such shares.

The term of the letter agreement continues in perpetuity.

Genevant—Rare Disease Protein Replacement Therapy Strategic Collaboration

In July 2018, our wholly owned subsidiary BioNTech RNA Pharmaceuticals GmbH, or BioNTech RNA, entered into a license and co-development agreement with Genevant Sciences GmbH, or Genevant for the joint development of certain pharmaceutical products and the licensing of specified rights to Genevant's lipid nanoparticle delivery technology to BioNTech RNA. We refer to this agreement as the Genevant Agreement.

Under the Genevant Agreement, BioNTech RNA and Genevant have agreed to collaborate to develop pharmaceutical products that contain any of five mRNA payloads created by BioNTech RNA encapsulated within a Genevant (or, if the parties agree, a third party) LNP, or the Co-Development Products, for the treatment, prevention and diagnosis of liver diseases, excluding any oncology diseases, or the Co-Development Field. Each party granted to the other party a worldwide, co-exclusive license or sublicense, with limited sublicensing rights, under certain of its patents and know-how to research, develop, make, have made, use, distribute, sell, offer for sale, have sold, import, export and otherwise commercialize the Co-Development Products in the Co-Development Field as provided in development and commercialization plans approved by a joint steering committee and subject to certain restrictions under the Genevant Agreement.

In addition, BioNTech RNA obtained an exclusive, worldwide, royalty-bearing license or sublicense under Genevant's LNP delivery technology to research, develop, make, have made, use, distribute, sell, offer for sale, have sold, import, export and otherwise commercialize pharmaceutical products containing BioNTech mRNA payloads encapsulated within an LNP, or the BioNTech Products, for the treatment, prevention and diagnosis of illnesses in the field of oncology, or the BioNTech Field.

Each party retained certain rights to practice its intellectual property for all purposes outside of the Co-Development Field or in the Co-Development Field with any product that is not a Co-Development Product, subject to the next sentence as to BioNTech. During the term of the Genevant Agreement for each Co-Development Product or BioNTech Product, BioNTech RNA has agreed not to conduct or enable any clinical development, promotion or commercialization of any product involving the use of LNP with the BioNTech mRNA payload contained in the Co-Development Product or BioNTech Product other than in collaboration with Genevant pursuant to the Genevant Agreement. Genevant has also retained rights to practice its intellectual property for all purposes outside the BioNTech Field, or in the BioNTech Field with any product that is not a BioNTech Product.

The parties are jointly responsible for the development of, and must use commercially reasonable efforts to develop, the Co-Development Products in accordance with a development plan approved by a joint steering committee. Genevant is responsible for the preclinical, clinical and commercial manufacture of the Co-Development Products, and BioNTech RNA is obligated to supply the mRNA payloads for use in

manufactured Co-Development Products. The parties share equally all costs for the development ofCo-Development Products as well as any profits and losses. For each Co-Development Product, one or the other party will take the lead responsibility for commercialization of the Co-Development Product in the Co-Development Field. Each party must use commercially reasonable efforts to perform the commercialization activities allocated to it in a commercialization plan approved by a joint steering committee.

Each party may opt-out of the co-development of any Co-Development Product with 90 days' prior notice at any time after the filing of an IND or equivalent for the Co-Development Product. In such event, the other party may continue the development of theCo-Development Product on its own, at its sole cost and expense apart from specified obligations to support manufacturing and any ongoing clinical studies, but has to pay to the party that opted out pre-defined regulatory and sales milestones for the Co-Development Product of up to a low nine figure U.S. dollar amount in the aggregate and tiered low to mid-single digit percentage royalties on aggregate net sales of the Co-Development Product. In the event that a party opts out of the co-development of any Co-Development Product, the license granted by the party opting out to the other party shall become exclusive licenses, even as to the opting out party.

BioNTech RNA is solely responsible for the development and commercialization of the BioNTech Products, including the performance of preclinical and clinical trials, all regulatory activities, and marketing and sales, and bears all related costs. BioNTech RNA must use commercially reasonable efforts to develop and obtain regulatory approval for BioNTech Products in the BioNTech Field in the United States, Germany, United Kingdom, France, Spain and Italy. Genevant is responsible for the manufacturing of the BioNTech Products, and the details of such manufacturing are to be agreed in a separate manufacturing and supply agreement. BioNTech RNA is obligated to pay regulatory and sales milestone payments on each BioNTech Product, and royalties based on aggregate net sales of all BioNTech Products, to Genevant.

The Genevant Agreement continues until later of (i) the expiration of the last-to-expire royalty term for any BioNTech Product worldwide and (ii) the date on which all Co-Development Products cease being developed or commercialized. BioNTech RNA may terminate the agreement for convenience with respect to one or more BioNTech Products at any time with 90 or 180 days' prior notice, depending on whether regulatory approval has been granted. The Genevant Agreement grants each party termination rights: if the other party challenges the validity, enforceability or scope of any patents licensed to it under the Genevant Agreement; for uncured material breaches of the other party; for the other party's insolvency; or if the other party undergoes a change of control through which it is controlled by a competitor, if specified by the parties at the time of the Genevant Agreement, before the earlier of July 4, 2021 or when the other party undergoes an initial public offering.

Under certain scenarios, if BioNTech RNA terminates the Genevant Agreement with respect to a particular BioNTech Product, before granting a license to a third party for the BioNTech mRNA payload included in the BioNTech Product, Genevant has the right of negotiation with BioNTech. Under certain scenarios, if Genevant terminates the Genevant Agreement, Genevant keeps all licenses and have certain rights, but not the obligation, to continue the development and commercialization of Co-Development Products, and BioNTech RNA has certain obligations to provide assistance, documentation, and certain know-how and inventions to enable Genevant's continued development and commercialization ofCo-Development Products.

XV. Government Regulation

Government authorities in the United States, at the federal, state and local levels, and in the European Union and other countries and jurisdictions, extensively regulate, among other things, the research, development, testing, manufacture, quality control, approval, packaging, storage, record-keeping, labeling, advertising, promotion, distribution, marketing, post-approval monitoring and reporting and import and export of pharmaceutical products, including biological products. In addition, some jurisdictions regulate the pricing of pharmaceutical products. The processes for obtaining marketing approvals in the United States and in 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.

Regulation and Procedures Governing Approval of Drug and Biological Products in the United States

In the United States, the FDA regulates drugs under the Federal Food, Drug, and Cosmetic Act, or the FDCA, and its implementing regulations and biologics under the FDCA, the Public Health Service Act, or the PHSA, and their implementing regulations. Both drugs and biologics also 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 to administrative or judicial sanctions. These sanctions could include, among other actions, the FDA's refusal to approve pending applications, withdrawal of an approval, license revocation, clinical hold, untitled or warning letters, voluntary or mandatory product recalls, market withdrawals, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement and civil or criminal penalties. Any agency or judicial enforcement action could have a material adverse effect on us.

A sponsor seeking approval to market and distribute a new drug or biological product in the United States generally must satisfactorily complete each of the following steps:

- preclinical laboratory tests, animal studies and formulation studies all performed in accordance with applicable regulations, including the FDA's good laboratory practices, or GLP, regulations;
- submission to the FDA of an IND application for human clinical testing, which must become effective before human clinical trials may begin;
- approval by the IRB representing each clinical site before each clinical trial may be initiated;
- performance of adequate and well-controlled human clinical trials to establish the safety, potency and purity of the product candidate for each proposed indication, in accordance applicable regulations, including with GCP, regulations;
- 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 GCPs, 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 any post-approval requirements, including 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 investigational medicines and any future investigational medicines 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 human research subjects 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 research subjects provide their informed consent for their participation. Clinical trials are conducted under study protocols detailing, among other things, the objectives of the study, inclusion and exclusion criteria, the parameters to be used in monitoring safety, dosing procedures and the effectiveness criteria to be evaluated. A protocol for each clinical trial and any subsequent protocol amendments must be submitted to the FDA as part of the IND.

A sponsor who wishes to conduct a clinical trial outside the United States may, but need not, obtain FDA authorization to conduct the clinical trial under an IND. If a foreign clinical trial is not conducted under an IND, the sponsor may submit data from the clinical trial to the FDA in support of the NDA or BLA so long as the clinical trial is well-designed and well-conducted in accordance with GCP, including review and approval by an independent ethics committee, and the FDA is able to validate the study data through an onsite inspection, if necessary.

Further, each clinical trial must be reviewed and approved by an IRB either centrally or individually at each institution at which the clinical trial will be conducted. The IRB will consider, among other things, clinical trial design, patient informed consent, ethical factors and the safety of human subjects. 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 subjects or 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 must monitor the clinical trial until completed. Additionally, some clinical trials are overseen by an independent group of qualified experts organized by the clinical trial sponsor, known as a data safety monitoring board or committee, or DSMB. This group may recommend continuation of the study as planned, changes in study conduct, or cessation of the study at designated check points based on access to certain data from the study.

Clinical trials typically are conducted in three sequential phases, but the phases may overlap or be combined. Additional studies may be required after approval.

- Phase 1 clinical trials (or Phase 1) are initially conducted in a limited population to test the product candidate for safety, including adverse effects, dose tolerance, absorption, metabolism, distribution, excretion and pharmacodynamics in healthy humans or, on occasion, in patients, such as in the case of some products for severe or life-threatening diseases, especially when the product may be too inherently toxic to ethically administer to healthy volunteers.
- Phase 2 clinical trials (or Phase 2) are generally conducted in a limited patient population to identify possible adverse effects and safety risks, preliminarily evaluate the efficacy of the product candidate for specific targeted indications and determine dose tolerance and optimal dosage. Multiple Phase 2 clinical trials may be conducted by the sponsor to obtain information prior to beginning larger Phase 3 clinical trials. When a drug is intended to treat life-threatening or severely debilitating illnesses, the FDA may accept well-controlled Phase 2 clinical trials as adequate to provide sufficient data on the drug's safety and effectiveness to support a decision on its approvability for marketing, in which case Phase 3 clinical trials would not be required.
- Phase 3 clinical trials (or Phase 3) proceed if the Phase 2 clinical trials demonstrate that a certain dose or dose range of the product candidate is potentially effective and has an acceptable safety profile. Phase 3 clinical trials are undertaken within an expanded patient population, often at geographically dispersed clinical trial sites, to gather additional information about safety and effectiveness necessary to evaluate the overall benefit-risk relationship of the product and to provide an adequate 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 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 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 human subjects, 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 research subjects or 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, or effective, for its intended use, and has an acceptable purity profile, and whether the

product is being manufactured in accordance with GMP requirements to assure and preserve the product's identity, safety, strength, quality, potency and purity. On the basis of the FDA's evaluation of the application and accompanying information, including the results of the inspection of the manufacturing facilities and any FDA audits of clinical trial sites to assure compliance with GCPs, the FDA may issue an approval letter, denial letter or complete response letter. An approval letter authorizes commercial marketing of the product with specific prescribing information for specific indications. Under the FDCA, the FDA may approve an NDA if it determines that the product is safe and effective for its intended use, the benefits of the drug outweigh any risks, and the methods used in manufacturing the drug and the controls used to maintain the drug's quality are adequate to preserve the drug's identity, strength, quality and purity. Under the PHSA, the FDA may approve a BLA if it determines that the product is safe, pure and potent and the facility where the product will be manufactured meets standards designed to ensure that it continues to be safe, pure and potent. If the application is not approved, the FDA may issue a complete response letter, which will contain the conditions that must be met in order to secure final approval of the application, and when possible will outline recommended actions the sponsor might take to obtain approval of the application. If a complete response letter is issued, the sponsor may either resubmit the NDA or BLA, addressing all of the deficiencies identified in the letter, or withdraw the application.

Sponsors that receive a complete response letter who elect to address the deficiencies may submit to the FDA information that represents a complete response to the issues identified by the FDA in the response letter. Such resubmissions are classified under PDUFA as either Class 1 or Class 2, based on the information submitted by a sponsor in response to an action letter. Under the goals and policies agreed to by the FDA under PDUFA, the FDA aims to review and act on a Class 1 resubmission with two months of receipt and, with respect to a Class 2 resubmission, within six months of receipt. The FDA will not approve an application until issues identified in the complete response letter have been addressed.

The FDA may also refer the application to an Advisory Committee for review, evaluation and recommendation as to whether the application should be approved and under what conditions. In particular, the FDA may refer applications for novel drug or biological products or drug or biological products that present difficult questions of safety or efficacy to an advisory committee. Typically, an Advisory Committee is a panel of independent experts, including clinicians and other scientific experts. The FDA is not bound by the recommendations of an Advisory Committee, but it considers such recommendations carefully when making decisions.

If the FDA approves a new product, it may limit the approved indications for use of the product, or limit the approval to specific dosages. It may also require that certain contraindications, warnings or precautions be included in the product labeling. In addition, the FDA may call for post-approval studies, including Phase 4 clinical trials, to further assess the product's safety after approval. The agency may also require testing and surveillance programs to monitor the product after commercialization, or impose other conditions, including distribution restrictions or other risk management mechanisms, including risk evaluation and mitigation strategies, or REMS, to help ensure that the benefits of the product outweigh the potential risks. REMS can include medication guides, communication plans for healthcare professionals, and elements to assure safe use, or ETASU. ETASU can include, but are not limited to, special training or certification for prescribing or dispensing, dispensing only under certain circumstances, special monitoring and the use of patent registries. If the FDA concludes a REMS is needed, the sponsor of the NDA or BLA must submit a proposed REMS; the FDA will not approve the NDA or BLA without a REMS, if required. The FDA may prevent or limit further marketing of a product based on the results of post-marketing studies or surveillance programs. After approval, many types of changes to the approved product, such as adding new indications, manufacturing changes and additional labeling claims, are subject to further testing requirements and FDA review and approval.

Fast Track, Breakthrough Therapy and Priority Review Designations

The FDA may designate certain products for expedited review if they are intended to address an unmet medical need in the treatment of a serious or life-threatening disease or condition. These programs include fast track designation, breakthrough therapy designation and priority review designation.

The FDA may designate a product for fast track review if it is intended, whether alone or in combination with one or more other products, for the treatment of a serious or life-threatening disease or condition, and it demonstrates the potential to address unmet medical needs for such disease or condition. Fast track designation applies to the combination of the product and the specific indication for which it is being studied. The sponsor of a new drug or biologic may request that the FDA designate the drug or biologic as a fast track product at any time during the clinical development of the product. For fast track products, sponsors may have greater interactions with the FDA and the FDA may initiate review of sections of a fast track product's application before the application is complete. This rolling review may be available if the FDA determines, after preliminary evaluation of clinical data submitted by the sponsor, that a fast track product may be effective. The sponsor must also provide, and the FDA must approve, a schedule for the submission of the remaining information and the sponsor must pay applicable user fees. However, the FDA's time period goal for reviewing a fast track application does not begin until the last section of the application is submitted. Fast track designation may be withdrawn by the FDA if the FDA believes that the designation is no longer supported by data emerging in the clinical trial process.

In 2012, Congress enacted the Food and Drug Administration Safety and Innovation Act, or the FDASIA. This law established a new regulatory scheme allowing for expedited review of products designated as "breakthrough therapies." A product may be designated as a breakthrough therapy if it is intended, either alone or in combination with one or more other products, to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the product may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. The FDA may take certain actions with respect to breakthrough therapies, including holding meetings with the sponsor throughout the development process; providing timely advice to the product sponsor regarding development and approval; involving more senior staff in the review process; assigning a cross-disciplinary project lead for the review team; and taking other steps to facilitate the design of clinical trials in an efficient manner.

The FDA may designate a product for priority review if it is a product that treats a serious condition and, if approved, would provide a significant improvement in safety or effectiveness. The FDA determines, on a case-by-case basis, whether the proposed product represents a significant improvement when compared with other available therapies. Significant improvement may be illustrated by evidence of increased effectiveness in the treatment of a condition, elimination or substantial reduction of a treatment-limiting product reaction, documented enhancement of patient compliance that may lead to improvement in serious outcomes and evidence of safety and effectiveness in a new subpopulation. A priority designation is intended to direct overall attention and resources to the evaluation of such applications, and to shorten the FDA's goal for taking action on a marketing application to six months (compared to 10 months under standard review).

Fast track designation, priority review and breakthrough therapy designation may expedite the development or approval process, but do not change the standards for approval.

Accelerated Approval Pathway

The FDA may grant accelerated approval to a product for a serious or life-threatening condition that provides meaningful therapeutic advantage to patients over existing treatments based upon a determination that the product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit. The FDA may also grant accelerated approval for such a condition when the product has an effect on an intermediate clinical endpoint that can be measured earlier than an effect on irreversible morbidity or mortality, or IMM, and that is reasonably likely to predict an effect on IMM or other clinical benefit, taking into account the severity, rarity or prevalence of the condition and the availability or lack of alternative treatments. Products granted accelerated approval must meet the same statutory standards for safety and effectiveness as those granted traditional approval.

For the purposes of accelerated approval, a surrogate endpoint is a marker, such as a laboratory measurement, radiographic image, physical sign or other measure that is thought to predict clinical benefit, but is not itself a measure of clinical benefit. Surrogate endpoints can often be measured more easily or more rapidly than clinical endpoints. An intermediate clinical endpoint is a measurement of a therapeutic effect that is considered reasonably likely to predict the clinical benefit of a product, such as an effect on IMM. The FDA has stated that although it has limited experience with accelerated approvals based on intermediate clinical endpoints, such endpoints generally may support accelerated approval where the therapeutic effect measured by the endpoint is not itself a clinical benefit and basis for traditional approval, if there is a basis for concluding that the therapeutic effect is reasonably likely to predict the ultimate clinical benefit of a product.

The accelerated approval pathway is most often used in settings in which the course of a disease is long and an extended period of time is required to measure the intended clinical benefit of a product. Thus, accelerated approval has been used extensively in the development and approval of products for treatment of a variety of cancers in which the goal of therapy is generally to improve survival or decrease morbidity and the duration of the typical disease course requires lengthy and sometimes large trials to demonstrate a clinical or survival benefit.

The accelerated approval pathway is usually contingent on a sponsor's agreement to conduct, in a diligent manner, additional post-approval confirmatory studies to verify and describe the product's clinical benefit. As a result, a product candidate approved on this basis is subject to rigorous post-marketing compliance requirements, including the completion of Phase 4 or post-approval clinical trials to confirm the effect on the clinical endpoint. Failure to conduct required post-approval studies, or to confirm a clinical benefit during post-marketing studies, may lead the FDA to withdraw the product from the market. All promotional materials for product candidates approved under accelerated regulations are subject to prior review by the FDA.

Accelerated approval pathways are available for regenerative medicine therapies that meet certain conditions. Regenerative medicine therapies include cell therapies (both allogenic and autologous), therapeutic tissue engineering products, human cell and tissue products, and combination products using any such therapies or products, except those regulated under section 361 of the PHSA. Human gene therapies, including genetically modified cells, that lead to a sustained effect on cells or tissues, may also meet the definition of a regenerative medicine therapy, as may xenogeneic cell products.

Regenerative medicine therapies designed to treat, modify, reverse or cure serious conditions are eligible for FDA's expedited programs, including fast track designation, breakthrough therapy designation, priority review and accelerated approval, if they meet the criteria for such programs. They may also be eligible for Regenerative Medicine Advanced Therapy Designation, or RMAT designation.

An investigational drug is eligible for RMAT designation if it meets the definition of regenerative medicine therapy, it is intended to treat, modify, reverse or cure a serious condition, and preliminary clinical evidence indicates that the regenerative medicine therapy has the potential to address unmet medical needs for such condition. An unmet medical need is a condition whose treatment or diagnosis is not addressed adequately by available therapy.

RMAT designation confers all the benefits of the fast track and breakthrough therapy designation programs, including early actions 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 or subjects, 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.

Post-Approval Regulation

If regulatory approval for marketing of a product or for a new indication for an existing product is obtained, the sponsor will be required to comply with rigorous and extensive post-approval regulatory requirements as well as any post-approval requirements that the FDA has imposed on the particular product as part of the approval process. The sponsor will be required, among other things, to report certain adverse reactions and production problems to the FDA, provide updated safety and efficacy information and comply with requirements concerning advertising and promotional labeling. Manufacturers and certain of their subcontractors are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with ongoing regulatory requirements, including GMP regulations, which impose certain procedural and documentation requirements upon manufacturers. Accordingly, the BLA holder and its third-party manufacturers must continue to expend time, money and effort in the areas of production and quality control to maintain compliance with GMP regulations and other regulatory requirements. In addition, changes to the manufacturing process or facility generally require prior FDA approval before being implemented, and other types of changes to the approved product, such as adding new indications and additional labeling claims, are also subject to further FDA review and approval.

Once an approval is granted, the FDA may withdraw the approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information; imposition of post-market study requirements or clinical trial requirements to assess new safety risks; or imposition of distribution restrictions or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market or product recalls;
- fines, untitled letters or warning letters or holds on post-approval clinical trials;
- adverse publicity;
- refusal of the FDA to approve pending applications or supplements to approved applications, or suspension or revocation of product license approvals;
- product seizure or detention, or refusal to permit the import or export of products; or
- injunctions, fines, debarment, disgorgement of profits or the imposition of civil or criminal penalties.

The FDA strictly regulates marketing, labeling, advertising and promotion of products that are placed on the market. Pharmaceutical products may be promoted only for the approved indications and in accordance with the provisions of the approved label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability.

Orphan Drug Designation

Orphan drug designation in the United States is designed to encourage sponsors to develop products intended for rare diseases or conditions. In the United States, a rare disease or condition is statutorily defined as a disease or condition that affects fewer than 200,000 individuals in the United States or that affects more than 200,000 individuals in the United States but for which there is no reasonable expectation that the cost of developing and making available the product for the disease or condition will be recovered from sales of the product in the United States.

Orphan drug designation qualifies a company for certain financial incentives, including tax advantages and, if the product receives the first FDA approval for the indication for which it has orphan designation, market

exclusivity for seven years following the date of the product's marketing approval. An application for designation as an orphan product can be made any time prior to the filing of an application for approval to market the product. Once a product receives orphan drug designation from the Office of Orphan Products Development at the FDA, the product must then go through the review and approval process like any other product.

In addition, a sponsor of a product that is otherwise the same product as an already approved orphan drug may seek and obtain orphan drug designation for the subsequent product for the same rare disease or condition if it can present a plausible hypothesis that its product may be clinically superior to the first product. More than one sponsor may receive orphan drug designation for the same product for the same rare disease or condition, but each sponsor seeking orphan drug designation must file a complete request for designation.

The period of exclusivity begins on the date that the marketing application is approved by the FDA and applies only to the indication for which the product has been designated. The FDA may approve a second application for the same product for a different use or a second application for a clinically superior version of the product for the same use. The FDA cannot, however, approve the same product made by another manufacturer for the same indication during the market exclusivity period unless it has the consent of the sponsor, the manufacturer makes a showing of clinical superiority over the product with orphan exclusivity, or the sponsor is unable to provide sufficient quantities.

Orphan product designation does not convey any advantage in or shorten the duration of the regulatory review and approval process.

Pediatric Studies and Exclusivity

Under the Pediatric Research Equity Act of 2003, an NDA or a BLA or supplement thereto must contain data that are adequate to assess the safety and effectiveness of the product for the claimed indications in all relevant pediatric subpopulations, and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. Sponsors who are planning to submit a marketing application for a drug or biological product that includes a new active ingredient, new indication, new dosage form, new dosing regimen or new route of administration must also submit pediatric study plans prior to the assessment data, and no later than 60 calendar days following an end-of-Phase 2 meeting with the FDA or, if there is no such meeting, as early as practicable before the initiation of the Phase 3 or Phase 2/3 study. Pediatric study plans must contain an outline of the proposed pediatric study or studies the sponsor plans to conduct, including study objectives and design, any deferral or waiver requests and other information required by regulation. The sponsor, the FDA, and the FDA's internal review committee must then review the information submitted, consult with each other and agree upon a final plan. The FDA or the sponsor may request an amendment to the plan at any time.

The FDA may, on its own initiative or at the request of the sponsor, grant deferrals for submission of some or all pediatric data until after approval of the product for use in adults, or full or partial waivers from the pediatric data requirements. Additional requirements and procedures relating to deferral requests and requests for extension of deferrals are contained in FDASIA. Unless otherwise required by regulation, the pediatric data requirements do not apply to products with orphan designation.

Pediatric exclusivity is another type of non-patent marketing exclusivity in the United States and, if granted, provides for the attachment of an additional six months of marketing protection to the term of any existing regulatory exclusivity, including the non-patent and orphan exclusivity. This six-month exclusivity may be granted if an NDA or a BLA sponsor submits pediatric data that fairly respond to a written request from the FDA for such data. The data do not need to show the product to be effective in the pediatric population studied; rather, if the clinical trial is deemed to fairly respond to the FDA's request, the additional protection is granted. If reports of requested pediatric studies are submitted to and accepted by the FDA within the statutory time limits, whatever statutory or regulatory periods of exclusivity or patent protection cover the product are extended by six months. This is not a patent term extension, but it effectively extends the regulatory period during which the FDA cannot approve another application.

Biosimilars and Reference Product Exclusivity

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively, the ACA, signed into law in 2010, includes a subtitle called the Biologics Price Competition and Innovation Act of 2009, or the BPCIA, which created an abbreviated approval pathway for biological products that are biosimilar to or interchangeable with an FDA-approved reference biological product. To date, a number of biosimilars have been licensed under the BPCIA, and numerous biosimilars have been approved in Europe.

Under the BPCIA, an application for a biosimilar product may not be submitted to the FDA until four years following the date that the reference product was first licensed by the FDA. In addition, the approval of a biosimilar product may not be made effective by the FDA until 12 years from the date on which the reference product was first licensed. During this 12-year period of exclusivity, another company may still market a competing version of the reference product if the FDA approves a full BLA for the competing product containing that sponsor's own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity and potency of its product. The BPCIA also created certain exclusivity periods for biosimilars approved as interchangeable products. At this juncture, it is unclear whether products deemed "interchangeable" by the FDA will, in fact, be readily substituted by pharmacies, which are governed by state pharmacy law.

The FDA has issued several guidance documents outlining an approach to review and approval of biosimilars. Biosimilarity, which requires that there be no clinically meaningful differences between the biological product and the reference product in terms of safety, purity and potency, can be shown through analytical studies, animal studies, and a clinical study or studies. Interchangeability requires that a product is biosimilar to the reference product and the product must demonstrate that it can be expected to produce the same clinical results as the reference product in any given patient and, for products that are administered multiple times to an individual, the biologic and the reference biologic may be alternated or switched after one has been previously administered without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biologic. Complexities associated with the larger, and often more complex, structures of biological products, as well as the processes by which such products are manufactured, pose significant hurdles to implementation of the abbreviated approval pathway that are still being worked out by the FDA.

The BPCIA is complex and continues to be interpreted and implemented by the FDA. In addition, recent government proposals have sought to reduce the 12-year reference product exclusivity period. Other aspects of the BPCIA, some of which may impact the BPCIA exclusivity provisions, have also been the subject of recent litigation. As a result, the ultimate implementation and impact of the BPCIA is subject to significant uncertainty.

Regulation of Combination Products in the United States

Certain products may be comprised of components that would normally be regulated under different types of regulatory authorities and frequently by different centers at the FDA. These products are known as combination products. Specifically, under regulations issued by the FDA, a combination product may be:

- A product comprised of two or more regulated components that are physically, chemically or otherwise combined or mixed and produced as a single entity;
- Two or more separate products packaged together in a single package or as a unit and comprised of drug and device products, device and biological products, or biological and drug products;
- A drug, or device or biological product packaged separately that according to its investigational plan or proposed labeling is intended for use only with an approved individually specified drug, device or biological product where both are required to achieve the intended use, indication or effect and where upon approval of the proposed product the labeling of the approved product would need to be changed, *e.g.*, to reflect a change in intended use, dosage form, strength, route of administration or significant change in dose; or

- Any investigational drug, device or biological product packaged separately that according to its proposed labeling is for use only with another individually specified investigational drug, device or biological product where both are required to achieve the intended use, indication or effect.

Under the FDCA, the FDA is charged with assigning a center with primary jurisdiction, or a lead center, for review of a combination product. That determination is based on the "primary mode of action" of the combination product. Thus, if the primary mode of action of a device-biologic combination product is attributable to the biological product, the FDA center responsible for premarket review of the biological product would have primary jurisdiction for the combination product. The FDA has also established an Office of Combination Products to address issues surrounding combination products and provide more certainty to the regulatory review process. That office serves as a focal point for combination product issues for agency reviewers and industry. It is also responsible for developing guidance and regulations to clarify the regulation of combination products, and for assignment of the FDA center that has primary jurisdiction for review of combination products where the jurisdiction is unclear or in dispute.

In order to market any product outside of the United States, a company must also comply with numerous and varying regulatory requirements of other countries and jurisdictions regarding quality, safety and efficacy governing, among other things, clinical trials, marketing authorization, commercial sales and distribution of products. Whether or not it obtains FDA approval for a product, an applicant will need to obtain the necessary approvals by the comparable foreign regulatory authorities before it can initiate clinical trials or market and sell the product in those countries or jurisdictions.

Regulation and Procedures Governing Approval of Medicinal Products in the European Union

The process governing approval of medicinal products, including biological medicinal products and advanced therapy medicinal products, or ATMPs, which comprise gene therapy products, somatic cell therapy products and tissue-engineered products, in the European Union generally follows the same lines as in the United States. It entails satisfactory completion of pharmaceutical development, nonclinical and clinical studies to establish the safety and efficacy of the medicinal product for each proposed indication. Moreover, an applicant must also demonstrate the ability to manufacture the product to a suitable quality.

Clinical Trial Approval

Pursuant to the currently applicable 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.

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, focusing in particular on traceability, apply to clinical trials of advanced therapy medicinal products. 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.

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. 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 Directive 2001/20/EC and Directive 2005/28/EC and corresponding national laws of the member states and 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.

In April 2014, the European Union adopted a new Clinical Trials Regulation (EU) No 536/2014, which is set to replace the current Clinical Trials Directive 2001/20/EC. It is expected that the new Clinical Trials Regulation will apply at earliest in 2020. It will overhaul the current system of approvals for clinical trials in the European Union. Specifically, the new regulation, which will be directly applicable in all member states, aims to simplify and streamline the approval of clinical trials in the European Union. For instance, the new Clinical Trials Regulation provides for a streamlined application procedure using a single entry point and 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. 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.

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 a centralized procedure administered by the EMA or one of the procedures administered by competent authorities in European Union member states (decentralized procedure, national procedure or mutual recognition 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 the manufacturing or quality information is currently generally protected as 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. A similar requirement is contained in the new Clinical Trials Regulation that is currently expected to take effect at earliest in 2020.

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 member states. Pursuant to Regulation (EC) No. 726/2004, the centralized procedure is compulsory for specific products, including for medicines 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 may be optional.

Under the centralized procedure, the CHMP established at the EMA is responsible for conducting the assessment of a product to define its risk/benefit profile. Under the centralized procedure, the maximum timeframe for the evaluation of an MAA is 210 days, excluding clock stops when additional information or written or oral explanation is to be provided by the applicant in response to questions from the CHMP. Accelerated evaluation may be granted by the CHMP in exceptional cases, when a medicinal product is of major interest from the point of view of public health determined by three cumulative criteria: (i) the seriousness of the disease (*e.g.*, heavy disabling or life-threatening diseases) to be treated, (ii) the absence or insufficiency of an appropriate alternative therapeutic approach, and (iii) anticipation of high therapeutic benefit.

If the CHMP accepts such a request, the time limit of 210 days will be reduced to 150 days, but it is possible that the CHMP may revert to the standard time limit for the centralized procedure if it determines that it is no longer appropriate to conduct an accelerated assessment.

The Committee for Advanced Therapies, or CAT, is responsible in conjunction with the CHMP for the evaluation of ATMPs. The CAT is primarily responsible for the scientific evaluation of ATMPs and prepares a draft opinion on the quality, safety and efficacy of each ATMP for which a MAA is submitted. The CAT's opinion is then taken into account by the CHMP when giving its final recommendation regarding the authorization of a product in view of the balance of benefits and risks identified. Although the CAT's draft opinion is submitted to the CHMP for final approval, the CHMP may depart from the draft opinion if it provides detailed scientific justification. The CHMP and CAT are also responsible for providing guidelines on ATMPs and have published numerous guidelines, including specific guidelines on gene therapies and cell therapies. These guidelines, which are not legally binding, provide additional guidance on the factors that the EMA will consider in relation to the development and evaluation of ATMPs and include, inter alia, the preclinical studies required to characterize ATMPs, the manufacturing and control information that should be submitted in a MAA; and post-approval measures required to monitor patients and evaluate the long term efficacy and potential adverse reactions of ATMPs.

The European Commission may grant a so-called "marketing authorization under exceptional circumstances." Such authorization is intended for products for which the applicant can demonstrate that it is unable to provide comprehensive data on the efficacy and safety under normal conditions of use, because the indications for which the product in question is intended are encountered so rarely that the applicant cannot reasonably be expected to provide comprehensive evidence, or in the present state of scientific knowledge, comprehensive information cannot be provided, or it would be contrary to generally accepted principles of medical ethics to collect such information. Consequently, marketing authorization under exceptional circumstances may be granted subject to certain specific obligations, which may include the following:

- the applicant must complete an identified program of studies within a time period specified by the competent authority, the results of which form the basis of a reassessment of the benefit/risk profile;
- the medicinal product in question may be supplied on medical prescription only and may in certain cases be administered only under strict medical supervision, possibly in a hospital, and in the case of a radio-pharmaceutical, by an authorized person; and

- the package leaflet and any medical information must draw the attention of the medical practitioner to the fact that the particulars available concerning the medicinal product in question are as yet inadequate in certain specified respects.

A marketing authorization under exceptional circumstances is subject to annual review to reassess the risk-benefit balance in an annualre-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) 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 may contain specific obligations to be fulfilled by the marketing authorization holder, including obligations with respect to the completion of ongoing or new studies, 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.

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 State. 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.

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 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 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 are governed by regulations in each member state and can differ from one country to another.

Human Cells and Tissues

Human cells and tissues that are intended for human applications but that do not fall within the scope of rules governing medicinal products or medical devices are not subject to premarket review and approval, nor do they require extensive preclinical and clinical testing. However, there are European Union rules governing the donation, procurement, testing and storage of human cells and tissues intended for human application, whether or not they are ATMPs. These rules also cover the processing, preservation and distribution of human cell and tissues that are not ATMPs. Establishments that conduct such activities must be licensed and are subject to inspection by regulatory authorities. Such establishments must implement appropriate quality systems and maintain appropriate records to ensure that cells and tissues can be traced from the donor to the recipient and vice versa. There are also requirements to report serious adverse events and reactions linked to the quality and safety of cells and tissues. More detailed rules may exist at the national level.

Named Patient Supplies

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.

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 market exclusivity. During this 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 because, for example, the product is sufficiently profitable not to justify market exclusivity.

European Data Collection and Data Protection Laws

We are required to comply with strict data protection and privacy legislation in the jurisdictions in which we operate, including the General Data Protection Regulation (EU) 2016/679, or GDPR. The GDPR governs our collection and use of personal data in the European Union relating to individuals (*e.g*., patients). The GDPR imposes several requirements on organizations that process such data, including: to observe core data processing principles; to comply with various accountability measures; to provide more detailed information to individuals about data processing activities; to establish a legal basis to process personal data (including enhanced consent requirements); to maintain the integrity, security and confidentiality of personal data; and to report personal data breaches. The GDPR also restricts the transfer of personal data outside of the European Economic Area (*e.g*., to the United States and other countries that are not deemed to provide adequate protection under their domestic laws). The GDPR may impose additional responsibility and liability in relation to personal data that we process, and require us to put in place additional mechanisms ensuring compliance with the new data protection rules. This may be onerous and adversely affect our business, financial condition, results of operations and prospects. Failure to comply with the requirements of the GDPR and related national data protection laws of European Union member states may result in a variety of enforcement measures, including significant fines and other administrative measures. The GDPR has introduced substantial fines for breaches of the data protection rules, increased powers for regulators, enhanced rights for individuals, and new rules on judicial remedies and collective redress. We may be subject to claims by third parties, such as patients or regulatory bodies, that we or

our employees or independent contractors inadvertently or otherwise breached GDPR and related data protection rules. Litigation may be necessary to defend against these claims. There is no guarantee of success in defending these claims, and if we do not prevail, we could be required to pay substantial fines and/or damages and could suffer significant reputational harm. Even if we are successful, litigation could result in substantial cost and be a distraction to management and other employees.

Regulation of Diagnostic Products in the European Union

In the European Union, *in vitro* diagnostic products are regulated as *in vitro* diagnostic medical devices, or IVDs. The marketing of IVDs is subject to compliance with the In Vitro Diagnostic Medical Devices Directive 98/79/EC (IVD Directive). An IVD may be placed on the market within the European Union only if it conforms to certain "essential requirements" and bears the CE Mark. The most fundamental and essential requirement is that an IVD must be designed and manufactured in such a way that it will not compromise the clinical condition or safety of patients, or the safety and health of users and others. In addition, the IVD must achieve the performance(s) stated by the manufacturer and be designed and manufactured in a suitable manner.

Manufacturers must demonstrate that their IVDs conform to the relevant essential requirements through a conformity assessment procedure. The nature of the assessment depends upon the classification of the device. For IVDs intended to determine certain conditions or detect certain diseases, conformity assessment procedures involve a notified body. Notified bodies are often private entities and are authorized or licensed to perform such assessments by government authorities. Conformity assessment procedures require an assessment of available clinical evidence, literature data for the product and post-market experience in respect of similar products already marketed. Notified bodies also may review the manufacturer's quality systems. If satisfied that the product conforms to the relevant essential requirements, the notified body issues a certificate of conformity, which the manufacturer uses as a basis for its own declaration of conformity and application of the CE Mark. For all other IVDs, the manufacturer performs its own conformity assessment procedure and self-declares conformity before applying the CE Mark. Application of the CE Mark allows the general commercializing of an IVD in the European Union. The manufacturer or, if the manufacturer is located outside the European Union, its authorized representative in the European Union must also register with the competent authority in the European Union member state in which it is located.

In May 2017, the European Union adopted a new In Vitro Diagnostic Medical Devices Regulation (EU) 2017/746, or the IVD Regulation, which will apply in the European Union from May 26, 2022. The IVD Regulation does not set out a radically new system, but clearly envisages, among other things, stricter controls of IVDs, including the involvement of notified bodies in conformity assessments of many more categories of IVD and increased expectations as regards clinical data for IVDs. The IVD Regulation also envisages greater control over notified bodies and their standards, increased transparency, more robust device vigilance requirements and clarification of the rules for clinical investigations. Under transitional provisions, IVDs with notified body certificates issued under the IVD Directive prior to May 26, 2022 may continue to be placed on the market for the remaining validity of the certificate, until May 27, 2024 at the latest. After the expiry of any applicable transitional period, only IVDs that have been CE marked under the IVD Regulation may be placed on the market in the European Union.

Coverage, Pricing and Reimbursement

Significant uncertainty exists as to the coverage and reimbursement status of any product candidates for which we may obtain regulatory approval. Even if our product candidates are approved for marketing, sales of such product candidates will depend, in part, on the extent to which third-party payors, including government health programs in the United States (such as Medicare and Medicaid), commercial health insurers and managed care organizations, provide coverage and establish adequate reimbursement levels for such product candidates. In the United States, the member states of the European Union and markets in other countries, patients who are prescribed treatments for their conditions and providers performing the prescribed services generally rely on

third-party payors to reimburse all or part of the associated healthcare costs. Reimbursement rules and levels are not harmonized in the European Union and therefore differ from member state to member state. Patients are unlikely to use any product candidates we may develop unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of such product candidates. The process for determining whether a payor will provide coverage for a product may be separate from the process for setting the price or reimbursement rate that the payor will pay for the product once coverage is approved. Third-party payors are increasingly challenging the price and examining the medical necessity and cost-effectiveness of medical products and services and imposing controls to manage costs.

In order to secure coverage and reimbursement for any product that might be approved for sale, a company may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of the product, and the cost of these studies would be in addition to the costs required to obtain FDA or other comparable marketing approvals. Even after pharmacoeconomic studies are conducted, product candidates may not be considered medically necessary or cost effective. A decision by a third-party payor not to cover any product candidates we may develop could reduce physician utilization of such product candidates once approved and have a material adverse effect on our sales, results of operations and financial condition. Additionally, a payor's decision to provide coverage for a product does not imply that an adequate reimbursement rate will be approved. For example, the payor may require co-payments that patients find unacceptably high. Further, one payor's determination to provide coverage for a product does not assure that such coverage will continue or that other payors will also provide coverage and reimbursement for the product, and the level of coverage and reimbursement can differ significantly from payor to payor. Third-party reimbursement and coverage may not be adequate to enable us to maintain price levels sufficient to realize an appropriate return on our investment in product development. The insurance coverage and reimbursement status of newly approved products for orphan diseases is particularly uncertain, and failure to obtain or maintain adequate coverage and reimbursement for any such product candidates could limit a company's ability to generate revenue.

The containment of healthcare costs also has become a priority of 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 United States, we will face challenges in ensuring and obtaining adequate coverage and payment for any product candidates we may develop. Pricing of prescription pharmaceuticals is subject to governmental control in many countries, including in particular the member states of the European Union. Pricing negotiations with governmental authorities or other third-party payors such as statutory health insurance funds can extend well beyond the receipt of regulatory marketing approval for a product and may require us to conduct a clinical trial that compares the cost effectiveness of any product candidates we may develop to other available therapies. The conduct of such a clinical trial 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. Moreover, 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.

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 clearinghouses 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.

Current and Future Healthcare Reform Legislation

In the United States 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 investigational medicines, restrict or regulate post-approval activities, and affect our ability to profitably sell any investigational medicines for which we obtain marketing approval. We expect that current laws, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we, or any collaborators, may receive for any approved products.

The ACA, for example, contains provisions that subject biological products to potential competition by lower-cost biosimilars and may reduce the profitability of drug products through increased rebates for drugs reimbursed by Medicaid programs, extension of Medicaid rebates to Medicaid-managed care plans, mandatory discounts for certain Medicare Part D beneficiaries, and annual fees based on pharmaceutical companies' share of sales to federal health care programs. 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, which may impact reimbursement for drugs and biologics. On January 20, 2017, an Executive Order was signed directing federal agencies with authorities and responsibilities under the ACA to waive, defer, grant exemptions from, or delay the implementation of any provision of the ACA that would impose a fiscal or regulatory burden on states, individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices. On October 13, 2017, an executive order was signed terminating the cost-sharing subsidies that reimburse insurers 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. In addition, CMS has recently 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, each chamber of Congress has put forth multiple bills this year designed to repeal or repeal and replace portions of the ACA. While Congress has not passed repeal legislation, 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." Congress may consider other legislation to repeal and replace elements of the ACA. Litigation and legislation over the ACA are likely to continue, with unpredictable and uncertain results.

Additionally, other federal health reform measures have been proposed and adopted in the United States since the ACA was enacted:

- The Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. These changes included aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, which went into effect in April 2013 and will remain in effect through 2025 unless additional Congressional action is taken.
- 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 manufacturer 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 United States have also become increasingly aggressive in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation, from other countries and bulk purchasing.

Packaging and Distribution in the United States

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.

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.

XVI. Intellectual Property

A. Introduction

We pursue a layered intellectual property strategy to protect our various technology platforms and their application to the treatment of cancer and other serious diseases. One focus of our intellectual property strategy is to provide protection for our platforms and product candidates currently in development. 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 by 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, given the early stage of development of our product candidates, 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 product candidates that may ultimately be commercialized. Our most advanced 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” for a more comprehensive description of risks related to our intellectual property.

As of January 15, 2020, our overall owned and in-licensed patent portfolio included more than 200 patent families, each of which includes at least one filing in the United States or Europe, and several of which are pending or granted in multiple jurisdictions. The patent families include at least 100 patent families that are solely or jointly owned by BioNTech, including certain families acquired through our acquisitions of antibody assets and infrastructure from MabVax Therapeutics Holdings, Inc., and the rest that we have licensed from a third party.

An issued patent provides its owner (or possibly its licensee) with a right to exclude others from making, using or selling that which is claimed in the patent, for a specified period of time (the “term” of the patent), in the

jurisdiction in which the patent is issued. In the United States, and in many other countries, patents have a presumptive term of 20 years from their effective filing date (which is the earliest non-provisional filing date to which the patent claims priority). However, many jurisdictions, including the United States, require the payment of periodic maintenance fees in order for patents to remain in force for the full 20-year term. The United States also has provisions that require a patent term to be shortened if its claims are too similar to another patent owned by the same party that has a shorter term. The United States and certain other jurisdictions also have provisions that permit extension of patent term for patents that claim a drug or drug product, or its approved use, if the patent was issued before clinical trials were completed and certain other requirements were satisfied. In the United States, such extension is called a Patent Term Extension, or PTE, and it is limited to a period of not more than five years, or the total patent term including the PTE cannot exceed 14 years after the date of regulatory approval; only one patent can be extended per product approval. The United States also offers a different form of patent term extension, known as Patent Term Adjustment, or PTA, whereby a particular patent's term is automatically extended beyond the 20-year date if the United States 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 20-year terms for filings included in the portfolio that are directed to such aspects. Particularly given our pre-commercial state of development, we cannot be certain that any of the patent filings in our portfolio will provide meaningful protection for any product we ultimately attempt to commercialize.

B. Patent Portfolio

The patent portfolios for our most advanced programs are summarized below. Patent prosecution is a lengthy process, during which the scope of the claims initially submitted 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 current development candidates. Our patent portfolio also includes patent filings directed to mRNA formulations, including the lipoplex formulations currently utilized with our FixVac and iNeST platforms, and the lipid nanoparticles currently utilized with our 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, 3' UTR structures, polyA tails and reduced-uracil content mRNAs. Filings directed to each of these features, or collectively, the mRNA Structure Filings, have been made in the United States and various foreign jurisdictions. Some such mRNA Structure Filings are owned solely by BioNTech SE or BioNTech RNA 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." 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 mid-2030s.

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, with 20-year terms that extend into 2038, if issued, or collectively, the mRNA Lipoplex Filings, although none of these filings is currently an issued patent. Such mRNA Lipoplex Filings are solely owned by BioNTech RNA.

In addition, our portfolio includes U.S. and foreign patent filings directed to lipid nanoparticles and polyplex technologies, which are jointly owned by BioNTech RNA and TRON, or collectively, the mRNA Lipid Nanoparticle/Polyplex Filings. Issued mRNA Lipid Nanoparticle/Polyplex Filings have, and pending mRNA Lipid Nanoparticle/Polyplex Filings, if issued, would have, 20 year terms that extend into the mid- to late-2030s. Some such mRNA Lipid Nanoparticle/Polyplex Filings were granted in certain foreign jurisdictions, but do not currently include any 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 RNA, or jointly owned by BioNTech RNA and TRON and, if issued, would have 20-year terms that would extend into mid to late 2030s, although none is currently an issued patent.

mRNA Product Candidates

Our most advanced mRNA product candidate development programs are in oncology and involve various platforms. Our pipeline also includes mRNA product candidates for treatment of certain infectious diseases and mRNA product candidates for protein replacement therapy in certain rare diseases.

Oncology mRNA Product Candidates

Our current clinical programs are all in oncology. The most advanced involve iNeST immunotherapy product candidates being developed with our collaborator, Genentech. We also have FixVac product candidates in Phase 1 clinical trials, and have recently initiated Phase 1 clinical trials of our mRNA-based intratumoral immunotherapy developed through our collaboration with Sanofi.

FixVac

Our FixVac product candidates share many of the structural elements involved in our iNeST product candidates. Thus, some or all of the mRNA Structure Filings relevant to our iNeST product candidates and discussed above are also relevant to our FixVac product candidates. These patent filings, or the FixVac Platform Filings, include mRNA Structure Filings relating to antigen-MHC fusions, phosphorothioate stabilized 5' cap structures, 3' UTR structures containing a specific sequence element, and interrupted polyA tails, which are solely or jointly owned by BioNTech or BioNTech's licensors. Issued FixVAC Platform Filings have, and pending FixVac Platform Filings, if issued, would have, 20-year terms extending into the mid-2020s to the mid-2030s. While we have pursued or obtained patent protection covering components of FixVac product candidates, manufacturing-related methods and/or formulations, we do not currently have any claims in our owned or in-licensed issued patents that cover the overall construct used in our FixVac product candidates.

Our patent portfolio further includes U.S. and 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 RNA and TRON.

Our current Phase 1 clinical trials for FixVac product candidates are studying such product candidates in treatment of advanced melanoma, head and neck cancer, and breast cancer (particularly triple negative breast cancer). 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 each of these indications. Additionally, our patent portfolio relevant to FixVac product candidates further includes U.S. and foreign patent filings relating to use of particular tumor antigens for treatment of triple negative breast cancer included in Phase 1 clinical trials, or the Triple Negative Breast Cancer FixVAC Filings. Issued Triple Negative Breast Cancer FixVac Filings have, and pending Triple Negative Breast Cancer FixVac Filings, if issued, would have, 20-year terms that extend into 2034, and are jointly owned by BioNTech SE and TRON.

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.*, phosphorothioate stabilized 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 mid- to late-2030s, although none is a U.S. issued patent. The Neoantigen Filings are solely owned by BioNTech RNA, or jointly owned by BioNTech RNA and TRON.

We are currently studying our iNeST product candidates for the treatment of metastatic melanoma 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 recently entered Phase 1 clinical trials. For example, mRNA Structure Filings relating to 3' UTR structures containing a specific sequence element, interrupted polyA tail structures, and reduced-uracil content mRNAs, which, as noted above are solely or jointly owned by BioNTech and, if issued, would have 20-year terms extending into the mid-2030s, provide protection to our current intratumoral immunotherapy development candidate. However, these filings do not currently include any issued patents.

We have also obtained third-party licenses to technologies relating to certain features of the mRNA structure relevant to the intratumoral immunotherapies. These include two non-exclusive sublicenses—one from

mRNA RiboTherapeutics, Inc., or MRT, and one from its affiliate CellScript, LLC (these licenses, together, the MRT-CellScript Sublicenses). MRT-CellScript Sublicenses allow us to use, make and/or sell nucleoside-modified mRNA products that are covered by U.S. and European Patent Office patent filings owned by the Trustees of the University of Pennsylvania, or the Penn Modified RNA Patent Rights, which sublicenses are further summarized below in "—C. In-Licensing."

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. However, these filings do not currently include any issued patents.

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 relevant to our iNeST and/or FixVac product candidates, specifically relating to 3' UTR structures containing a specific sequence element, interrupted polyA tail structures, and reduced-uracil content mRNAs; mRNA Lipid Nanoparticle/Polyplex Filings; and patent filings under the MRT-CellScript Sublicenses relating to nucleoside-modified mRNAs.

We have also recently acquired patent assets from MabVax Therapeutics, 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.

Infectious Diseases

As is discussed elsewhere in this prospectus, we have collaborated with third parties, including Pfizer and Penn, to develop infectious disease mRNA vaccines.

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.

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 CellScript Licenses include 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, interrupted poly A tail structures and reduced-uracil content mRNAs, which, as noted above are solely or jointly owned by BioNTech, and, if issued, would have 20-year terms that would extend into the mid-2030s. However, these filings do not currently include any issued patents.

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, the Genevant Filings are owned by Arbutus Biopharma Corporation, which is a Genevant affiliate, and relate primarily to lipid or non-liposomal formulations that might be useful in these programs, and have been filed primarily in the U.S. and Europe, with 20-year terms that extend into mid-2020s to mid-2030s for the issued Genevant Filings and the pending Genevant Filings, if issued.

2. Engineered Cell Therapy

Our engineered cell therapy product class features use of chimeric antigen receptor, orCAR-, 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 Cell & Gene Therapies GmbH, or BioNTech C&GT, 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 processes of identifying and/or making individualized T cell receptors. The CAR T/TCR Patent Filings, if issued, would have 20-year terms that would extend into themid- to late-2030s. However, these filings do not currently include any issued patents.

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 C&GT, TRON and Ganymed, or the Claudin-Specific CAR-T Cell Filings. The issued Claudin-SpecificCAR-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. However, these filings do not currently include any U.S. issued patents. The terms of our co-ownership of such patent filings with TRON and Ganymed are summarized below in "—C. In-Licensing."

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 and do not currently include any issued patents.

4. Small Molecule Immunomodulators

Our small molecule therapeutics product class features oncology treatment using small molecule product candidates that activate the immune system via TLR7 agonism. Our patent portfolio includes patent filings relevant to these TLR7 agonists, or the TLR7 Agonist Filings. Certain TLR7 Agonist Filings are directed to substituted imidazoquinolines, and, if issued, would have 20-year terms that would extend into the late 2030s. However, these filings do not currently include any issued patents.

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 Penn, TRON, Louisiana State University and MRT-CellScript.

The key terms of these arrangements are summarized below.

Penn Agreement

In October 2018, BioNTech RNA entered into a collaboration and license agreement with the Trustees of the University of Pennsylvania regarding the development and commercialization of certain mRNA vaccines and mRNA diagnostics for the diagnosis, detection, evaluation, prophylaxis and treatment of infectious diseases. We refer to this agreement as the Penn Agreement.

Under the Penn Agreement, BioNTech RNA and Penn agree to collaborate with respect to research and development activities and are obligated to use commercially reasonable efforts to develop products that use formulated mRNAs encoding one or more immunogens for 10 disease indications in the field of infectious diseases (each, a Penn Product). Penn is responsible for all research and development work up to completion of studies enabling an IND as well as IND-supporting preclinical work, and BioNTech RNA is responsible for the manufacture of mRNA amounts to support the preclinical andIND-enabling studies. If a Penn Product developed under the research program achieves certain acceptance criteria for a specified indication, BioNTech RNA has the right to obtain an exclusive worldwide license under Penn's patent rights (and a non-exclusive license under Penn's know-how and materials) to research, develop, make, use or commercialize Penn Products in such indication. Under the Penn Agreement, Penn retains certain rights to conduct and authorize non-commercial third-party research, educational and patient care activities under any licensed intellectual property. Moreover, the license granted by Penn is subject to certain rights granted to the U.S. government in connection with government funding provided by the United States, including the requirement that products that result from intellectual property funded by the U.S. government that are sold in the United States be substantially manufactured in the United States.

BioNTech RNA has an obligation to use commercially reasonable efforts to clinically develop, obtain regulatory approval for and commercialize at least one Penn Product for each indication licensed under the Penn Agreement. Moreover, BioNTech RNA is obligated to achieve certain clinical and regulatory milestones within specified time periods, and its failure to do so would provide Penn the right to terminate the Penn Agreement on an indication-by-indication basis.

BioNTech RNA paid to Penn an upfront fee of $5 million to fund research activities and has agreed to pay Penn additional funds through quarterly payments, not to exceed an aggregate of $15 million, upon depletion of the previously advanced funds. Under the Penn Agreement, BioNTech RNA also agreed to pay Penn an annual alliance management fee. In addition, if any Penn Product is covered by a Penn patent, BioNTech RNA will pay to Penn development and commercialization milestone payments up to $44.4 million for each Penn Product licensed under this agreement and royalties in a low-single digit percentage on net sales of all Penn Products licensed under the Penn Agreement. Further, Penn will receive a percentage of any income from sublicenses BioNTech RNA grants to third parties, subject to certain caps set forth in the Penn Agreement.

BioNTech RNA has the sole responsibility for and decision-making authority over clinical development and commercialization activities relating to any Penn Product arising from the collaboration. BioNTech RNA is also responsible for the manufacture of mRNA to support clinical development and commercialization efforts.

The Penn Agreement remains in effect until the expiration of the last Penn patent covering any licensed Penn Product or developmental product candidate. BioNTech RNA may terminate the Penn Agreement for convenience in its entirety or on an indication-by-indication basis upon 90 days' prior notice to Penn. The Penn Agreement also grants both parties termination rights for uncured material breaches, including for BioNTech RNA's failure to achieve its obligations to achieve certain diligence milestones, and insolvency.

TRON Agreements

In 2015, we and our subsidiaries BioNTech RNA, BioNTech Diagnostics GmbH, BioNTech Protein Therapeutics GmbH, BioNTech Cell & Gene Therapies GmbH, Eufets GmbH and JPT Peptide Technologies GmbH entered into a Master Agreement for Research Services with TRON. Concurrently with this Master Agreement for Research Services, or the TRON Research Agreement, we entered into a License Agreement with Ganymed, TRON, Johannes Gutenberg-Universität Mainz and Universitätsmedizin der Johannes Gutenberg-Universität Mainz, or the TRON License Agreement. The TRON Research Agreement and TRON License Agreement together replaced and superseded our 2008 Cooperation, Purchase and Licensing Agreement with the University Mainz, or the 2008 Cooperation Agreement. In 2019, we and our subsidiaries BioNTech RNA Pharmaceuticals GmbH, 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 an agreement to include certain research and development activities regarding neoepitope RNA immunotherapies as work included in the TRON Research 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 newco-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, 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 antigene receptors and RNA-based pharmaceuticals). The University Parties may use the Development Results for internal research purposes only. We have an obligation to use reasonable efforts to develop and commercialize products in our field of use worldwide.

Under the TRON License Agreement, we and Ganymed must agree on which party will have the primary role in filing, prosecuting, maintaining and defending jointly owned patents. We and Ganymed each have the exclusive right to enforce the Development Results in our respective fields of use, subject to certain step-in rights of the other parties.

We are obligated to pay to the University Parties low single-digit tiered royalties on net sales on any product that is covered by certain of the patents including in the Development Results. If licenses are granted to third parties, we are obligated to pay to the University Parties a mid-single-digit share of all upfront payments, milestone payments and other remuneration we receive from such third parties in consideration for the license. Regarding upfront payments only, the University Parties' share will be offset against subsequent license fees on net sales. In addition, we are obligated to pay certain development and regulatory milestones up to a low seven- figure amount to Johannes Gutenberg-Universität Mainz.

The TRON License Agreement contains a limitation on liability as between the parties, wherein the parties will only be liable to each other for intentional and grossly negligent actions, and, in the case of gross negligence, liability for indirect and consequential damages and lost profits is excluded. We are obligated to indemnify the University Parties and Ganymed for third-party claims of product liability or violation of applicable law based on our distribution of our products or if we breach the TRON License Agreement or if we or one of our agents acts culpably.

The TRON License Agreement will remain in effect as long as there are any obligations on us or Ganymed to pay license fees. After expiry of the TRON License Agreement, each party will have a perpetual, non-exclusive, royalty-free license to use the Developments Results. The TRON License Agreement may be terminated by any party on six months' notice. The licenses granted between the parties will survive such termination. The TRON License Agreement also grants all parties termination rights for uncured material breaches. If only one party terminates its role in the Agreement, the Agreement will survive and continue between the other parties.

TRON Collaboration Agreement

Under the TRON Collaboration Agreement, TRON from time to time undertakes certain projects in collaboration with us under separate project specific agreements, comprising innovative non-clinical research and development projects. We and TRON meet regularly to review and update project plans, and no less than annually to agree the budget for the on-going projects for the coming calendar year. Individual project

agreements set the specific binding terms of each project. TRON is obligated to perform its obligations in accordance with the scientific standards, all applicable technical laboratory and legal provisions and with the care customary in the non-clinical biotechnology research industry.

Except for the results of a particular research project which has been funded exclusively by TRON, or the RNT Project, all of the inventions, methods, specifications, materials, documents, data, know-how and other results (together, the Results) developed or discovered by TRON or by us and TRON jointly under the TRON Collaboration Agreement are jointly owned. The Results of the RNT Project are owned exclusively by TRON. Under the TRON Collaboration Agreement, TRON grants us an exclusive, worldwide, sublicensable license under its interest in the Results to research and have researched, develop and have developed, make and have made, use, and otherwise commercialize or have commercialized, and otherwise commercially exploit, products in a field that is specified in the corresponding project agreement. The field of use is either (a) the prophylaxis, diagnosis and treatment of all indications in humans and animals; (b) the prophylaxis, diagnosis and treatment of oncological diseases, infectious diseases and rare genetic diseases; or (c) in the case of the Results from the RNT Project only, the prophylaxis, diagnosis and treatment of rectal neuroendocrine tumors in humans. We are required to use our reasonable efforts to develop and commercialize products that exploit the Results.

Under the TRON Collaboration Agreement, TRON's activities are invoiced at cost. TRON invoices us monthly and our payments are due no later than 10 days thereafter. Additionally, we are obligated to pay to TRON low single-digit tiered royalties on net sales of any product developed under the TRON Collaboration Agreement that is covered by a patent claiming any of the Results or, in certain circumstances, by a patentable invention forming part of the Results which we elect to maintain as a trade secret. If licenses under Results are granted to third parties, we are obligated to pay to TRON a mid-single-digit share of all upfront payments, milestone payments and other remuneration we receive from such third parties in consideration for the license. In addition, we are obligated to pay a one-time only milestone of a low seven-figure amount to TRON the first time annual sales of a product developed under the TRON Collaboration Agreement reach a low nine-figure number.

The TRON Collaboration Agreement limits each party's liability to the other to cases of willful misconduct and gross negligence and, in the case of gross negligence, liability for indirect and consequential damages and lost profits is excluded. We are obligated to indemnify TRON for all product liability claims in connection with the products and for third-party claims asserting that the Results violate third-party intellectual property rights.

The TRON Collaboration Agreement came into force with retroactive effect from January 2015 and has an indefinite term, but may be terminated by either party on nine months' notice. If one of our subsidiaries terminates its role in the TRON Collaboration Agreement, the agreement will survive and continue without that subsidiary.

LSU License Agreement

In May 2015, we entered into a Patent License Agreement with the Board of Supervisors of Louisiana State University and Agricultural and Mechanical College, or LSU, and the University of Warsaw, or UW. The agreement (which we refer to as the LSU Agreement) replaces and supersedes the earlier license agreement between the parties.

Under the LSU Agreement, UW and LSU granted to us an exclusive royalty-bearing license under certain patent rights relating to mRNA cap analogs and the synthesis and use of anti-reverse phosphorothioate analogs of the mRNA cap in the United States, certain jurisdictions in the European Union and other countries. As consideration for the license granted, we are obligated to pay running royalties in the low single digits on all net sales of products utilizing the licensed patents and to pay annual maintenance fees to LSU.

We are obligated to use commercially reasonable efforts to develop one or more marketable products utilizing the licensed patents, upon which we would owe additional milestone payments to LSU.

The LSU Agreement remains in effect until expiration of the licensed patents. We have the right to terminate the LSU Agreement for convenience with 60 days' prior notice, and LSU and UW may terminate for our uncured material breach.

CellScript and mRNA Ribotherapeutics License Agreement

BioNTech RNA entered into the twoMRT-CellScript Sublicenses discussed above. Together, theMRT-CellScript Sublicenses grant BioNTech RNA worldwide, non-exclusive sublicenses under the Penn Modified mRNA Patent Rights (as defined in theMRT-CellScript Sublicenses) to research, develop, make, import, use and commercialize products for *in vivo* uses in humans andnon-human animals, including therapeutic and prophylactic applications, and for certain uses in the diagnostic and prognostic field of use and certain laboratory research or screening uses. Under these sublicenses, BioNTech RNA has the right to grant sublicenses to affiliates and third parties.

BioNTech RNA must use reasonable efforts to develop and commercialize products under the sublicenses. Furthermore, BioNTech RNA is obliged to pay MRT and CellScript development milestone payments of up to approximately $26 million as well as royalties in the low to mid-single digits on net sales of licensed products, depending on the field of use.

The agreements continue until the expiration or abandonment of the last licensed patent to expire or be abandoned. BioNTech RNA may terminate the agreement for convenience with respect to all or certain patent rights with 60 days' prior written notice. MRT or CellScript may terminate the respective sublicense agreement for payment default, uncured material breach or the bankruptcy of BioNTech RNA.

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, registrations for each of FixVac®, IVAC®, MammaTyper®, RiboCytokine® and RiboMab®.

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 confidentialknow-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. See "Risk Factors—Risks Related to our Intellectual Property" for a more comprehensive description of risks related to our intellectual property.

XVII.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.

Below is a description of competition surrounding each of our technologies.

mRNA Therapies. mRNA therapies are a new medical frontier, and we expect competition in this space to be robust across diverse therapeutic areas. We compete with a number of companies focused on developing mRNA technologies for a wide range of applications, including Moderna, CureVac, eTheRNA immunotherapies, Translate Bio, Arcturus Therapeutics, ethris, Genevant and GlaxoSmithKline.

Oncology. The oncology therapeutics landscape in general is highly competitive and includes large and specialty pharmaceutical and biotechnology companies, academic research institutions and governmental agencies and public and private research institutions. It includes both competition from marketed therapies as well as potential new therapeutics in development. We may compete with products with different mechanisms of action as well as against established standards of care. Companies such as AstraZeneca, Amgen, Bristol-Myers Squibb, Celgene, Eli Lilly, GlaxoSmithKline, Incyte, Janssen Pharmaceuticals, Merck & Co., Novartis, Pfizer, Roche and Sanofi are developing diversified immuno-oncology programs and have substantial resources. We expect our intratumoral immunotherapy candidates for the treatment of solid tumors to face direct competition from companies such as Moderna and CureVac.

We also expect our FixVac and iNeST candidates to face competition from smaller specialized oncology companies such as Agenus, Gritstone, Moderna in collaboration with Merck & Co., Aduro Biotech, Advaxis Immunotherapies, Achilles Therapeutics, NousCom, ISA Pharmaceuticals, CureVac in collaboration with Eli Lilly, Genocea Biosciences, Vaccibody, PACT Pharma and ZIOPHARM Oncology in the antigen-based therapy space.

Engineered Cell Therapy Drug Class. We compete with a number of companies focused on adoptive cell therapies, including Novartis Pharmaceuticals, Gilead Sciences, Celgene, Allogene Therapeutics, CRISPR Therapeutics, bluebird bio, Medigene, Adaptimmune Therapeutics, Amgen, Atara Biotherapeutics, Autolus Limited, Cellectis, PACT, Mustang Bio, Iovance Biotherapeutics, TCR2 Therapeutics, Editas Medicine, Celyad, Celularity, Unum Therapeutics, Intrexon, and Bellicum Pharmaceuticals and Precision Biosciences.

Antibodies Drug Class. We compete with a number of companies with operations focused on checkpoint immunomodulators, including AstraZeneca, Merck, Pfizer, Novartis, Roche and Bristol-Myers Squibb.

Small Molecule Immunomodulator Drug Class. We are aware of a number of other companies developing TLR agonists, including Checkmate Pharmaceuticals, Dynavax Technologies, Exicure, Gilead, GlaxoSmithKline, Hoffmann-La Roche, Mologen and Nektar Therapeutics.

Infectious Diseases. The infectious disease space includes general competition from well-established pharmaceutical companies such as AbbVie, Bayer, Gilead, Janssen Pharmaceuticals, Merck & Co. and Novartis. In addition, Seqirus UK, Sanofi Pasteur, GlaxoSmithKline, Biomedical Corp. of Quebec and AstraZeneca produce influenza vaccines.

Rare Diseases. We compete with a number of companies focused on rare diseases, including Roche, Alexion Pharmaceuticals, Novartis, Bristol-Myers Squibb, Sanofi Novo Nordisk and Pfizer.

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, 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.

XVIII.Employees

As of December 31, 2019, we had 1,310 full-time equivalent employees working for BioNTech, of whom 316 hold a doctoral degree or higher. The following tables provide breakdowns of our full-time equivalent employees as of December 31, 2019 by function and by region:

Function	Number
Clinical Research & Development	89
Scientific Research & Development	454
Operations	412
Quality	141
Supporting Functions	138
Commercial & Business Development	76
TOTAL	**1,310**

Region	Number
Mainz (Headquarters)	952
Munich (Neuried, Martinsried)	42
Idar-Oberstein	212
Berlin	101
United States	3
TOTAL	**1,310**

Since December 2016, our workforce has grown by 168%. Within the next several years, two further new production sites are planned to be built in Mainz and Idar-Oberstein.

None of our employees has engaged in any labor strikes. We have no collective bargaining agreements with our employees, but we maintain a company agreement (*Betriebsvereinbarungen*) with respect to certain topics at our Idar-Obarstein site. We have a workers' council at our Idar-Oberstein and Mainz sites. However, we consider our relationship with our employees to be positive and have not experienced any major labor disputes.

XIX. Properties

Our headquarters are located in Mainz, Germany, where we occupy:

- Approximately 9,416 square meters (equivalent to approximately 101,353 square feet) of laboratory, GMP manufacturing, storage and office space under a lease for the entire building located at An der Goldgrube 12, 55131 Mainz under a lease that has an initial term that expires on October 30, 2027, but which we have the option to extend until April 30, 2039.
- Approximately 1,069 square meters (equivalent to approximately 11,507 square feet) of office and GMP manufacturing space under a lease for part of the building located at Kupferbergterrasse 15, 17019, 44116 Mainz under a lease that expires in March 31, 2022.
- Approximately 4,882 square meters (equivalent to approximately 52,549 square feet) of flexible use space under a lease for the entire building at Adam-Opel-Strasse 10, 55129 Mainz-Hechtsheim that has an initial term that expires on December 31, 2024, but which we have the option to extend until December 31, 2027. If the lease has not been terminated prior to December 31, 2024, and the option has not been exercised prior to this date, the lease will convert to an unlimited period terminable by either party on 12 months' prior written notice.
- Approximately 82,881 square meters (equivalent to approximately 892,124 square feet) of office space and a further area of land associated with this office space of approximately 12,600 square meters (equivalent to approximately 135,625 square feet), which is owned by BioNTech.
- Approximately 4,025 square meters (equivalent to 43,324 square feet) of office space under a lease for the entire building at Hechtsheimer Strasse 2,55131 Mainz-Hechtsheim, which commenced on July 1, 2019. The initial term of the lease expires on June 30, 2029, which we have the option to extend until June 30, 2034 and again until June 30, 2039.
- We also own a plot of land of approximately 8,753 square meters (equivalent to 94,216 square feet) at Hechtsheimer Strasse, 55131 Mainz.

In addition, our BioNTech IMFS facility in Idar-Oberstein, Germany, occupies approximately 2,800 square meters (equivalent to approximately 30,140 square feet). This 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 the right to extend by an additional five years. 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. We also recently purchased a building of approximately 802 square meters (equivalent to 8,632 square feet) near our IMFS facility in Idar-Oberstein, which will be used as office space.

At our JPT facility in Berlin, Germany, we occupy approximately 1,794 square meters (equivalent to approximately 19,299 square feet) of office, laboratory and other space. Approximately 250 square meters of that space (equivalent to approximately 2,690 square feet) is occupied under a lease which has an expiry date of June 20, 2020 and will continue for further six-month periods, unless terminated by either party on three months' prior written notice. Approximately 1,523 square meters (equivalent to approximately 16,199 square feet) are occupied under a lease for an indeterminate period of time but which may be terminated by either party on 12 months' prior written notice. The remaining approximately 20 square meters (equivalent to 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.

In Martinsried, Germany, we occupy approximately 1,681 square meters (equivalent to approximately 18,100 square feet) under a lease that has an initial term that expires on December 31, 2020, but which we have the option to extend until December 31, 2022.

In Neuried, Germany, we occupy approximately 725 square meters (equivalent to approximately 7,800 square feet) of laboratory and office space under a lease that expires on December 31, 2021, but which we have the option to extend until December 31, 2026. If the lease is not terminated before December 31, 2021 (where the option is not exercised) or December 31, 2026 (where the option is exercised) the lease will renew automatically for an additional one-year period until terminated by either party on 12 months' prior written notice.

In Halle (Saale), Germany, we have since the beginning of 2020 occupied approximately 415 square meters (equivalent to approximately 4,467 square feet) of office and other space under a lease that expires on February 28, 2022. We further occupy 90 square meters (equivalent to approximately 968 square feet) of laboratory space under a lease that also expires on February 28, 2022. Each lease will renew automatically for an additional one-year period until terminated by either party on six months' prior written notice to expire at the end of the lease period (or any extension thereof).

In San Diego, we occupy approximately 14,971 square feet of laboratory and office space under a lease to part of a building located at 11535 Sorrento Valley Road, San Diego, California, that expires on February 28, 2022.

We intend to expand our capacity as follows:

- In the third quarter of 2020, we anticipate completing the construction of two new buildings at our BioNTech IMFS facility in Idar-Oberstein, Germany, which we will own, and as a result of which we will occupy an additional 780 square meters (equivalent to approximately 8,395 square feet) of clean room space and 550 square meters (equivalent to approximately 5,900 square feet) of laboratory space, expanding our capacity for GMP cell therapy manufacturing and 650 square meters (equivalent to approximately 7,000 square feet) of office space.
- We anticipate completing the construction of a new complex of building for our JPT business in Berlin, Germany, possibly as early as 2023. Upon completion of the construction project we will occupy up to approximately 5,000 additional square meters (equivalent to approximately 53,820 square feet) of useable floor space split between laboratories, offices and storage.

For additional information on these additions to our facilities, see "—XIII. Manufacturing—Future Manufacturing Outlook."

XX. Legal Proceedings

From time to time, we may be involved in legal proceedings in the ordinary course of business. We are currently not a party to any material legal or administrative proceedings. In addition, we are not aware of any material legal or administrative proceedings contemplated to be brought against us. Regardless of outcome, litigation can have an adverse impact on us because of defense and settlement costs, diversion of management resources and other factors.

MANAGEMENT

Management Board and Supervisory Board

Management Board (*Vorstand*)

The following table sets forth the names and functions of the current members of our Management Board, their ages as of January 1, 2020 and their terms:

Name	Age	Position
Prof. Ugur Sahin, M.D.	54	Chief Executive Officer
Sean Marett	54	Chief Business Officer and Chief Commercial Officer
Dr. Sierk Poetting	46	Chief Financial Officer and Chief Operating Officer
Dr. Özlem Türeci	52	Chief Medical Officer
Ryan Richardson	40	Chief Strategy Officer

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. Prof. Sahin also served as the head of the Scientific Advisory Board of Ganymed Pharmaceuticals AG from 2008 until the company was acquired by Astellas Pharma Inc., or Astellas, in 2016. In 2010, Prof. Sahin co-founded TRON, and served as a Managing Director from 2010 until 2019. Prof. Sahin has also been a professor (W3) at the Mainz University Medical Center since 2014. Prof. Sahin co-founded the Ci3, the German Cluster Initiative of Individualized ImmunIntervention (Ci3), a non-profit organization. Prof. Sahin earned an M.D. in 1990 from the University of Cologne. Prof. Sahin is married to Dr. Özlem Türeci.

Sean Marett joined BioNTech in 2012. Prior to joining BioNTech, he worked in global strategic and regional marketing and sales roles at GlaxoSmithKline in the United States and Pfizer in Europe before taking business development executive roles at Evotec and Lorantis, the latter of which he helped to successfully sell to Celldex Therapeutics, Inc. He has successfully executed complex licensing transactions with large pharmaceutical companies, negotiated M&A transactions and raised finance from investors. Mr. Marett built and ran a contract clinical manufacturing organization with operations across Europe and the United States for over half a decade for the contract manufacturer, NextPharma. Mr. Marett has been Chairman of PHMR Ltd, a company specializing in market access and pharmaceutical reimbursement, since 2017. He previously held non-executive directorship of KWS BioTest Ltd (successfully sold to Charles River) from 2011 until 2018 and was a member of the investment committee of Mann BioInvest Ltd, a fund dedicated to biotechnology and pharmaceutical company investments from 2013 until 2016. He holds a BSc (Hons) in Biochemistry from Kings College London and an MBA from Manchester Business School.

Dr. Sierk Poetting is our Chief Financial Officer and Chief Operating Officer. Dr. Poetting joined BioNTech in September 2014 from Novartis, where he served from May 2012 to August 2014 as Vice President and Chief Financial Officer for the Sandoz Division in North America. Dr. Poetting started his career as a consultant with McKinsey & Company. A German citizen, Dr. Poetting holds a Master of Science in Optical Sciences from the University of Arizona and a Ph.D. in Physics from the Ludwig-Maximilians University in Munich.

Dr. Özlem Türeci is our Chief Medical Officer. Dr. Türeci joined BioNTech in 2008 as a clinical and scientific advisory board member, before becoming our Chief Medical Officer in 2018. Dr. Türeci co-founded Ganymed Pharmaceuticals, now a subsidiary of Astellas, in 2001 as Chief Scientific Officer and became its Chief Executive Officer in 2008. Dr. Türeci is chairman and co-initiator of Ci3. Dr. Türeci is also President of the Association for Cancer Immunotherapy (CIMT). Dr. Türeci earned her M.D. from Saarland University Faculty of Medicine, Homburg. Dr. Türeci is married to Prof. Ugur Sahin, M.D.

Ryan Richardson is our Chief Strategy Officer. Mr. Richardson joined BioNTech in September 2018 from J.P. Morgan Securities LLC, where he served from June 2010 to September 2018 in various roles, including as Executive Director, Healthcare Investment Banking. Prior to his time at J.P. Morgan Securities LLC, Mr. Richardson served in various roles in the healthcare economics and consulting field, including as co-founder of Quantitative Insights. Mr. Richardson earned an MBA from the University of Chicago Booth School of Business, a MSc from the London School of Economics and Political Science and a B.S. in Biology from the University of Kansas.

Supervisory Board (*Aufsichtsrat*)

The following table sets forth the names and functions of the current members of our Supervisory Board, their ages as of January 1, 2020, their terms (which expire on the date of the relevant year's general shareholders' meeting) and their principal occupations outside of our Company:

Name	Age	Term Expires	Principal Occupation
Helmut Jeggle	49	2023	Chief Executive Officer and Chief Operating Officer of ATHOS Service GmbH
Michael Motschmann	62	2023	Member of the Board of Management and Head of Equity Investments of MIG Verwaltungs AG
Prof. Christoph Huber, M.D.	75	2023	Chairman Emeritus at the Johannes-Gutenberg University Mainz
Dr. Ulrich Wandschneider	58	2023	Independent consultant to life sciences companies

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 served as the Chairman of our Supervisory Board since 2008. Mr. Jeggle has served as the Chief Executive Officer and Chief Operating Officer of ATHOS Service GmbH since 2015. From 2007 until 2015, Mr. Jeggle served as the Head of Direct Investments of ATHOS Service GmbH. From 2002 until 2007, Mr. Jeggle held various positions with Hexal AG, including Head of Business Planning & Analyses. Mr. Jeggle is currently the Chief Executive Officer of each of Salvia GmbH (since 2014), Neula Holding GmbH (since 2010) and AT-Gruppe (since 2008) and a manager of Santo Group (since 2011). Mr. Jeggle is a member of numerous supervisory boards, including 4SC AG. Mr. Jeggle has a degree in business administration from the University of Applied Sciences Neu-Ulm and earned his Master of Business Administration from the Stuttgart Institute of Management and Technology.

Michael Motschmann has served as a member of our Supervisory Board since 2008. Mr. Motschmannco-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, Mr. Motschmann currently serves on the supervisory boards of several private portfolio companies.

Prof. Christoph Huber, M.D. is a co-founder of BioNTech and has served as a member of our Supervisory Board since 2008. Prof. Huber has more than 50 years of professional experience in hematology, oncology and translational immunology. Prof. Huber has since 2014 served as Chairman Emeritus of the Department of Hematology and Oncology at the Johannes-Gutenberg University Mainz. Prof. Huber was a co-founder of Ganymed, now a subsidiary of Astellas Pharma Inc. He is an executive board member of CIMT and a board member of Ci3. From 2018 to April 2019, Prof. Huber served as a member of the supervisory board of TRON. Prof. Huber earned his M.D. at the University of Innsbruck.

Dr. Ulrich Wandschneider, Ph.D. has served as a member of our Supervisory Board since 2018. Dr. Wandschneider 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. From 2011 to 2016 Dr. Wandschneider served as Chief Executive Officer of Asklepios Kliniken GmbH & Co. KGaA. Dr. Wandschneider currently serves on the supervisory board of Mediclin AG.

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 accordingly are subject to the European legislation on the *Societas Europaea*, namely the Council Regulation (EC) No 2157/2001 of October 8, 2001 on the Statute for a European company, 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), as well as—insofar as applicable pursuant to the SE Regulation—to the German legislation on stock corporations, most importantly the German Stock Corporation Act (*Aktiengesetz*). In accordance with these statutes, we have chosen to have a two tiered 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 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 insolvency 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 four 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. 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.

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.

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 for 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.

By resolution, the Supervisory Board has established an Audit Committee, a Remuneration, Nominating and Governance Committee and a Capital Markets Committee. Set forth in the table below are the current members of the Audit Committee, the Remuneration, Nominating and Corporate Governance Committee and the Capital Markets Committee.

Name of Committee	Current Members
Audit Committee	Dr. Ulrich Wandschneider, Michael Motschmann and Helmut Jeggle
Remuneration, Nominating and Corporate Governance Committee	Michael Motschmann, Prof. Christoph Huber, M.D. and Dr. Ulrich Wandschneider
Capital Markets Committee	Helmut Jeggle, Michael Motschmann

Audit Committee

Our Audit Committee consists of Dr. Ulrich Wandschneider, Michael Motschmann and Helmut Jeggle. Dr. Ulrich Wandschneider is the chair of the Audit Committee. 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:

- considering the commissioning of the audit engagement, as well as the compensation, retention and oversight of the independent auditor;
- evaluating the qualifications, independence and 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;
- 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 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;
- overseeing procedures for the receipt, retention and treatment of complaints received regarding accounting, internal accounting controls or auditing matters; and
- reviewing and evaluating the performance of the Audit Committee and its members.

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. The Audit Committee has legal power to enter into the contract on our behalf and we will be bound to these and will be obliged to discharge any obligations as the Audit Committee may incur on our behalf for these purposes.

Dr. Wandschneider and Mr. Motschmann qualify as "independent directors" as such term is defined inRule 10A-3 under the Exchange Act and Nasdaq Rule 5605. We intend to have a fully independent audit committee within one year from effectiveness of our initial public offering registration statement, as permitted by Rule 10A-3. Additionally, our Supervisory Board has determined that Dr. Ulrich Wandschneider qualifies as an "audit committee financial expert" as that term is defined under the Exchange Act.

Remuneration, Nominating and Corporate Governance Committee

Our Remuneration, Nominating and Corporate Governance Committee consists of Michael Motschmann, Prof. Christoph Huber, M.D. and Dr. Ulrich Wandschneider. Mr. Motschmann is the chair of the committee. The Remuneration, Nominating and Corporate Governance Committee's duties and responsibilities to carry out its purpose include, among others:

- preparing and discussing with management policies relating to the remuneration of the members of our Management Board;
- reviewing and supervising corporate goals and objectives for the remuneration of the members of the Management Board, including evaluation of the performance of the members of the Management Board in light of these goals and proposals to the Supervisory Board for remuneration based on such evaluations;
- reviewing all equity-based compensation plans and arrangements and making recommendations to the Supervisory Board regarding such plans;
- assisting with identifying and recruiting candidates to fill positions on the Management Board and the Supervisory Board;
- considering any corporate governance issue that arises and developing appropriate recommendations for the Supervisory Board;
- overseeing the evaluation of the Supervisory Board and reporting on its performance and effectiveness; and
- reviewing and evaluating the performance of the Remuneration, Nominating and Corporate Governance Committee and its members.

Capital Markets Committee

Our Capital Markets Committee consists of Helmut Jeggle and Michael Motschmann. Mr. Jeggle is the chair of the committee. The Capital Markets Committee advises 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.

Remuneration of Supervisory Board Members

Our Articles of Association provide for a fixed annual remuneration for each member of the Supervisory Board of €50,000 per year. However, the chairman is entitled to receive €150,000 per year and the vice chairman €75,000 per year. In addition, the chairman of the audit committee is entitled to be paid €20,000 per year. All members of the Supervisory Board are reimbursed for their expenses.

A member of the Supervisory Board who serves for only a portion of a given fiscal year or who holds the position of chairman or vice chairman of the Supervisory Board or of chairman of the Audit Committee for only a portion of a given fiscal year shall only be remunerated pro rata. The same is true if the clause of the Articles of Association regarding the remuneration of the members of the Supervisory Board becomes ineffective (*e.g.*, because it is repealed) during the course of a year.

In case any remuneration or reimbursement of expenses is subject to value added tax, such amount shall be paid additionally by the Company.

Management Board and Senior Management

Our Management Board consists of at least two members. Our Supervisory Board determines the exact number of members of our Management Board. Pursuant to this amendment 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 chairman 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 our 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 our 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 our 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 the us or involving an extraordinary economic risk;
- taking on new lines of business or discontinuing existing lines of business;
- investments with a total value above €100,000;
- acquisitions or sales of interests or holdings; and
- certain large transactions.

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 end dates of the current service agreements of our Management Board:

- Prof. Ugur Sahin: December 31, 2022
- Sean Marett: September 30, 2022
- Dr. Sierk Poetting: September 30, 2022
- Dr. Özlem Türeci: May 31, 2022
- Ryan Richardson: December 31, 2022

From January 1, 2019 until August 31, 2019, the annual base salaries for our Management Board members, Prof. Ugur Sahin, Sean Marett, Dr. Sierk Poetting and Dr. Özlem Türeci, were €210,000, €360,000, €300,000 and €300,000, respectively. Effective September 1, 2019 the annual base salaries for Prof. Ugur Sahin, Sean Marett, Dr. Sierk Poetting and Dr. Özlem Türeci are €360,000, €400,000, €360,000 and €360,000, respectively. Effective January 1, 2020 the annual base salary for Ryan Richardson is €320,000.

Our current service agreements with our Management Board provide for short-term incentive compensation of up to a maximum of 50% of the annual base salary. The amount of such short-term incentive compensation will depend on the achievement of certain company goals in a particular fiscal year, which goals will be set uniformly for all members of the Management Board. Half of the incentive compensation will be paid promptly upon achievement of the applicable company goals, with the remaining amount payable one year later, subject to adjustment relative to our share price performance during that year. The provisions in relation to the short-term incentive compensation will take effect from the beginning of the first year after the year in which the Company's ordinary shares or ADSs of the Company are listed on a stock exchange or other multilateral trading system, e.g., from the first year following the completion of the Offering.

The service agreements of our Management Board provide for long-term incentive compensation in terms of a yearly grant of options to purchase ordinary shares. The options granted each year will be subject to the terms, conditions, definitions and provisions of our ESOP and the applicable option agreement thereunder. The number of options to be granted each year to Prof. Ugur Sahin, Sean Marett, Dr. Sierk Poetting, Dr. Özlem Türeci and Ryan Richardson is to be calculated based on a value of €750,000, €300,000, €300,000, €300,000 and €260,000, respectively, in each case divided by the amount by which a certain target share price exceeds the exercise price (which in the case of each grant is equal to the stock price as of the time of that grant). These provisions in relation to the long-term incentive compensation took effect from January 1, 2020.

In the years ended December 31, 2018 and December 31, 2019, the members of our Management Board received aggregate remuneration of €7.2 million and €19.0 million, respectively.

The following table sets forth the aggregate compensation and benefits provided to our Management Board in the years ended December 31, 2019 and 2018.

In kEUR	Prof. Ugur Sahin, M.D.	Sean Marett	Dr. Sierk Poetting	Dr. Özlem Türeci(1)
Fixed Compensation				
2018	210	315	283	175
2019	261	373	320	320
Fringe Benefits(2)				
2018	1	12	11	—
2019	5	12	11	—
ESOP Plan Granted(3)				
2018	442	147	147	5,426
2019	6,410	1,180	1,180	9,043
Total				
2018	**653**	**474**	**441**	**5,601**
2019	6,676	1,565	1,511	9,363

(1) Dr. Özlem Türeci commenced employment with us on June 1, 2018.
(2) Includes social security, health and additional insurance, company bike and travel expenses.
(3) The fair value was determined pursuant to the regulations of IFRS 2 "Share-based Payments." This table shows thepro-rata share of personnel expenses resulting from stock-based compensation for the respective financial year.

The table below provides an overview of the share options granted to our Management Board in the years ended December 31, 2019 and 2018.

Name	Grant Date(1)	Number of Ordinary Shares Underlying Share Options(4)	Option Exercise Price (€)	Option Expiration Date
Prof. Ugur Sahin, M.D.	11/15/2018	1,830,348	10.14	9/17/2026
	10/10/2019(2)	4,374,963	13.60	10/11/2029
Sean Marett	11/15/2018	610,110	10.14	9/17/2026
Dr. Sierk Poetting	11/15/2018	610,110	10.14	9/17/2026
Dr. Özlem Türeci	11/15/2018(3)	1,952,334	10.14	9/17/2026

(1) Except as otherwise indicated, all options fully vest on September 16, 2022.
(2) Options vest in four equal installments on October 10 of 2020, 2021, 2022 and 2023.
(3) Options fully vested on March 16, 2019, however these options will not become exercisable until September 16, 2022.
(4) Share amounts reflect an 18-for-1 stock split of our ordinary shares which became effective on September 18, 2019, upon registration with the commercial register *(Handelsregister)*.

In September 2019, we agreed to grant Prof. Ugur Sahin, M.D., our co-founder and Chief Executive Officer, an option to purchase 4,374,963 of our ordinary shares, subject to Prof. Sahin's continuous employment with us. The options' per share exercise price is the public offering price from our initial public offering, $15.00. The option will vest annually in equal installments after four years commencing on the first anniversary of our initial public offering and will be exercisable four years after our initial public offering. The option will be subject to the terms, conditions, definitions and provisions of our ESOP and the applicable option agreement thereunder.

Employee Stock Ownership Plan

Based on a pertinent authorization of the general meeting on August 18, 2017, we have established a share option program under which we grant selected employees options to receive our shares. The program is designed

as an Employee Stock Ownership Plan, or ESOP. We have offered the participants a certain number of rights by explicit acceptance of 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. The option rights (other than Dr. Türeci's options referred to above 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. The option rights can be exercised at the latest eight years after the allocation date. If they have not been exercised by that date, they will forfeit without compensation.

By way of 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.

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 and was most recently amended on February 7, 2017 and published in the German Federal Gazette (*Bundesanzeiger*) on April 24, 2017. The Corporate Governance Code contains 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 recommendations and suggestions with respect to shareholders and shareholders' meetings, the management and supervisory boards, transparency, accounting policies and auditing. While the Corporate Governance Code was originally drafted with only the German stock corporation in mind, it is perceived to be also applicable to the two-tiered *Societas Europaea* and hence to us.

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) 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.

While in our opinion it is doubtful whether the above legal requirements and hence the Corporate Governance Code will apply following our listing on the Nasdaq Global Select Market, we intend to issue the

annual declaration described above on a voluntary basis. Therefore, our Management Board and Supervisory Board will comply with the Corporate Governance Code except for such provisions which are explicitly listed in the annual declaration and for which they provide an explanation of non-compliance.

We expect to deviate from certain recommendations and suggestions of the Corporate Governance Code. All deviations from the Corporate Governance Code recommendations will be published in the official annual declarations.

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 our affiliates 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 prospectus and our website address is included in this prospectus 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 our affiliates and employees, an actual, potential or perceived conflict of interest must be disclosed as soon as a Board member, director or employee discovers the conflict. If the conflict is transactional in nature and involves a member of the Management Board or the Supervisory Board, the Management or Supervisory Board, as the case may be, with the abstention of the conflicted member, shall decide whether to approve the transaction.

In addition, we have implemented compliance policies that describe the compliance management systems that have been implemented for us and our subsidiaries. Our compliance policies are designed to ensure compliance with applicable legal requirements, while at the same time implementing high ethical standards that are mandatory for both management and each employee. The overall responsibility for the compliance management system lies with the Management Board. The Audit Committee will receive regular reports on the operation of the compliance management system.

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 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 a foreign private issuer, such as 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.

RELATED PARTY TRANSACTIONS

Agreements with TRON

We have a longstanding relationship with Translational Oncology at the University Medical Center of the Johannes Gutenberg University Mainz (Translationale Onkologie an der Universitätsmedizin der Johannes Gutenberg Universität Mainz gemeinnützige GmbH), or TRON. TRON is a non-profit limited liability company engaged in biopharmaceutical research. Prof. Ugur Sahin, M.D., our co-founder and Chief Executive Officer, co-founded TRON and served as Managing Director for Science and Research at TRON, until his resignation September 10, 2019. Additionally, Prof. Christoph Huber, a member of our Supervisory Board, served on TRON's supervisory board until his resignation in April 2019.

On January 1, 2015, we and certain of our subsidiaries entered into both a Master Agreement for Research Services and a License Agreement with TRON. During 2017 and 2018, we paid to TRON an aggregate of €17.7 million pursuant to these agreements. During the nine months ended September 30, 2019, we paid to TRON an aggregate of €6.3 million pursuant to these agreements.

Agreements with Santo Service GmbH

We have several agreements with Santo Service GmbH, or Santo Service, pursuant to which Santo Service provides us with certain real property and custodial services. Santo Service is wholly owned by AT Impf GmbH, which is wholly owned by our controlling shareholder. During 2017 and 2018, we paid to Santo Service an aggregate of €8.4 million pursuant to these agreements. During the nine months ended September 30, 2019, we paid to Santo Service an aggregate of €1.5 million pursuant to these agreements.

Asset Sale and Purchase Agreement

On April 29, 2016, our wholly owned subsidiary, BioNTech Small Molecules GmbH, entered into an asset sale and purchase agreement with 4SC Discovery GmbH. 4SC Discovery GmbH is a wholly owned subsidiary of 4SC AG. Certain of our investors possess a 70% shareholding in 4SC AG. Pursuant to this agreement, BioNTech Small Molecules GmbH acquired the drug discovery business of 4SC Discovery GmbH for €650,000.

Agreement with Medine GmbH

On August 29, 2019, we entered into an agreement with Medine GmbH, or Medine, pursuant to which we acquired all of the outstanding shares of reBOOST Management GmbH, or reBOOST, which owns certain intellectual property, in exchange for total consideration of approximately €279,000. reBOOST and Medine are wholly owned by Prof. Ugur Sahin, M.D., our co-founder and Chief Executive Officer, who is also the Managing Director of reBOOST and Medine.

Series A Financing

In February 2018, we issued an aggregate of 22,587,912 of our ordinary shares to certain new and existing shareholders at a price of $11.99 per share for aggregate proceeds of $270.9 million. The following table sets forth the aggregate number of ordinary shares that we issued and sold in this transaction to our related parties and the aggregate purchase price for such shares:

PARTICIPANTS	ORDINARY SHARES (#)	AGGREGATE PURCHASE PRICE ($)
AT Impf GmbH(1)	5,002,812	59,997,612.58

(1) See "Principal Shareholders" for additional information about shares held by the parent company of this entity.

Series B 2019 Financing

In June and August 2019, we issued an aggregate of 12,465,288 of our ordinary shares (excluding 5,524,506 ordinary shares which were issued to a Hong Kong-based investor and subsequently transferred to us for no consideration) to certain new and existing shareholders at a price of $18.10 per share for aggregate proceeds of €198.6 million ($225.6 million).

The following table sets forth the aggregate number of ordinary shares that we issued and sold in this transaction to our related parties and the aggregate purchase price for such shares:

PARTICIPANTS	ORDINARY SHARES (#)	AGGREGATE PURCHASE PRICE ($)
AT Impf GmbH(1)	1,657,332	29,999,550.68

(1) See "Principal Shareholders" for additional information about shares held by the parent company of this entity.

Initial Public Offering

In October 2019, we sold 10,517,408 ADSs representing 10,517,408 of our ordinary shares to certain new and existing shareholders at a price of $15.00 per ADS for proceeds of €135.4 ($149.1 million) in our initial public offering. The following table sets forth the aggregate number of ADSs that we issued and sold in this transaction to our related parties and the aggregate purchase price for such shares:

PARTICIPANTS	ADSs (#)	AGGREGATE PURCHASE PRICE ($)
AT Impf GmbH(1)	2,800,000	42,000,000
Helmut Jeggle(1)	51,219	768,285

(1) See "Principal Shareholders" for additional information about shares held by this entity or the parent company of this entity, as the case may be.

PRINCIPAL SHAREHOLDERS

The following table presents information, as of January 23, 2020, regarding the beneficial ownership of our ordinary shares (i) prior to the consummation of this offering and (ii) as adjusted to reflect the sale of the ADSs in this offering, for:

- each person, or group of affiliated persons, known by us to own beneficially 5% or more of our outstanding ordinary 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 January 23, 2020 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.

The percentage of outstanding ordinary shares before this offering is computed on the basis of 226,779,744 ordinary shares outstanding as of January 23, 2020. This amount excludes 5,524,506 shares held in treasury.

The percentage of shares beneficially owned on an adjusted basis after this offering is based on shares to be outstanding after this offering after giving effect to the completion of this offering, assuming no exercise of the underwriters' option to purchase additional ADSs from us, and shares to be outstanding after this offering after giving effect to the completion of this offering and assuming full exercise of the underwriters' option to purchase additional ADSs from us. Ordinary shares that a person has the right to acquire within 60 days of January 23, 2020 are deemed outstanding for purposes of computing the percentage ownership of the person holding such rights, but are not deemed outstanding for purposes of computing the percentage ownership of any other person, except with respect to the percentage ownership of all members of our Supervisory Board and our Management Board as a group. Unless otherwise indicated, the address for each beneficial owner is An der Goldgrube 12, D-55131 Mainz, Germany.

Shareholder	Shares Beneficially Owned before This Offering		Shares Beneficially Owned after This Offering		Percent of Shares Beneficially Owned Assuming Full Exercise of Underwriters' Option to Purchase Additional Shares
	Number	Percent	Number	Percent	
5% Shareholders					
ATHOS KG(1)	114,141,520	50.33%		%	%
Medine GmbH	41,690,970	18.38%		%	%
Entities affiliated with MIG GmbH & Co.(2)	13,556,106	5.97%		%	%
Entities affiliated with FMR LLC	12,718,257	5.61%		%	%
Members of the Supervisory Board and the Management Board					
Prof. Ugur Sahin, M.D.(3)	41,690,970	18.38%		%	%
Sean Marett(4)	1,091,502	*		%	%
Dr. Sierk Poetting(5)	711,828	*		%	%
Dr. Özlem Türeci	—				
Ryan Richardson	—				
Helmut Jeggle(6)	116,798,941	51.50%		%	%
Michael Motschmann(7)	13,556,106	5.97%		%	%
Prof. Christoph Huber, M.D.(8)	2,552,040	1.11%		%	%
Dr. Ulrich Wandschneider(9)	4,680	*		%	%
All members of our Supervisory Board and Management Board, as a group	176,406,067	77.79%		%	%

* Less than one percent

(1) Consists of 114,141,520 ordinary shares held by ATHOS KG. Members of the Strüngmann family wholly own ATHOS KG. Dr. Andreas Strüngmann and Dr. Thomas Strüngmann may be deemed to beneficially own any or all of these shares.

(2) Consists of (a) 5,495,148 ordinary shares held by MIG GmbH & Co. Fonds 7 KG, Munich, (b) 1,780,002 ordinary shares held by MIG GmbH & Co. Fonds 8 KG, Munich and (c) 6,280,956 ordinary shares held by MIG GmbH & Co. Fonds 9 KG, Munich.

(3) Consists of the shares described in note 2 above. Prof. Sahin is the sole shareholder of Medine GmbH.

(4) Consists of 1,091,502 ordinary shares held by RLG GmbH. Mr. Marett is the sole shareholder of RLG GmbH.

(5) Consists of 711,828 shares held by Tofino GmbH. Does not include 487,800 shares held on behalf of other beneficial owners in his capacity as trustee of Tofino GmbH.

(6) Consists of (a) the shares described in note 1 above, (b) 383,535 ordinary shares held directly by Mr. Jeggle and (c) 2,273,886 ordinary shares held by Salvia GmbH. Mr. Jeggle has no voting or dispositive power with regard to such shares described in note 1 above and in clause (c) of this note and disclaims beneficial ownership of such shares except to the extent of his pecuniary interest therein.

(7) Consists of the shares described in note 3 above. Mr. Motschmann has no voting or dispositive power with regard to such shares and disclaims beneficial ownership of such shares except to the extent of his pecuniary interest therein.
(8) Consists of 2,552,040 ordinary shares held by CHuber 2008 GmbH. Prof. Huber is the sole shareholder of CHuber 2008 GmbH.
(9) Consists of 4,680 shares held by Tofino GmbH.

Holdings by U.S. Shareholders

Prior to the completion of this offering, we estimate that approximately 14.24% of our outstanding ordinary shares were held by 29 U.S. record holders.

DESCRIPTION OF SHARE CAPITAL AND ARTICLES OF ASSOCIATION (*SATZUNG*)

General

We were incorporated as a German stock corporation (*Aktiengesellschaft*) with the legal name Petersberg 91. V 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 the registration statement of which this prospectus forms a part.

Share Capital

We have share capital registered in the commercial register (*Handelsregister*) in the amount of €232,304,250, which is divided into 232,304,250 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.

Changes in Our Share Capital During the Last Three Fiscal Years

Our share capital as registered with the commercial register (*Handelsregister*) amounts to 232,304,250. Since January 1, 2017, (up until and including the capital increase of August 16, 2019, without giving effect to the 18-to-1 stock split which became effective on September 18, 2019), our share capital has changed as follows:

- On September 14, 2017, our share capital as registered with the commercial register (*Handelsregister*) was increased by issuing 9,083,000 shares;
- On February 1, 2018, our share capital as registered with the commercial register (*Handelsregister*) was increased by issuing 1,254,884 shares;
- On September 12, 2018, our share capital as registered with the commercial register (*Handelsregister*) was increased by issuing 32,373 shares;

- On October 18, 2018, our share capital as registered with the commercial register (*Handelsregister*) was increased by issuing 186,715 shares;
- On January 29, 2019, our share capital as registered with the commercial register (*Handelsregister*) was increased by issuing 282,678 shares;
- On April 24, 2019, our share capital as registered with the commercial register (*Handelsregister*) was increased by issuing 131,933 shares against contributions in kind (swap of shares in our company against shares in one of our subsidiary companies);
- On June 26, 2019, our share capital as registered with the commercial register (*Handelsregister*) was increased by issuing 666,123 shares;
- On August 16, 2019, our share capital as registered with the commercial register (*Handelsregister*) was increased by issuing 333,310 shares;
- On September 18, 2019, our share capital as registered with the commercial register (*Handelsregister*) was increased by issuing 206,595,492 shares by way of a capital increase from our funds; thus, no contribution by investors was made;
- On August 30, 2019, we entered into an agreement with BMGF pursuant to which BMGF agreed to purchase up to 3,038,674 of our ordinary shares. This capital increase from our authorized capital was resolved upon by our Management Board (*Vorstand*) with the consent of the Supervisory Board (*Aufsichtsrat*) on September 18, 2019 and came into effect upon registration with the commercial register (*Handelsregister*);
- On October 14, 2019, our share capital as registered with the commercial register (*Handelsregister*) was increased by issuing 10,000,000 shares; and
- On November 6, 2019, our share capital as registered with the commercial register (*Handelsregister*) was increased by issuing 517,408 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 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 €105,818,002 by issuing, on one or more occasions, up to 105,818,002 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 €21,874,806 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 €87,499,260 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.

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 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;
- after listing on Nasdaq, if excluding subscription rights, according to the written declaration of an internationally renowned investment bank, 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 such declaration, does not exceed the extent necessary for a successful placement; 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 eight above may not exceed 20% of the share capital, either at the time this authorization becomes effective or, if lower, at the time it is utilized. 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 to manufacture and market 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. Invitations to shareholders' meetings must be published in the German Federal Gazette (*Bundesanzeiger*) 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 (*Ertragswertmethode*).

A squeeze-out in the context of a merger (*umwandlungsrechtlicher Squeeze-Out*) only requires a majority shareholder to hold at least 90% of the share capital.

Liquidation Rights

Apart from liquidation, e.g., as a result of insolvency proceedings, we may be liquidated with a vote of the holders of at least three-quarters of the share capital represented at the shareholders' meeting at which such a vote is taken. If we are liquidated, any assets remaining after all of our liabilities have been paid off would be distributed among our shareholders in proportion to their holdings in accordance with German statutory law. The German Stock Corporation Act provides certain protections for creditors which must be observed in the event of liquidation.

Differences in Corporate Law

The applicable provisions of the SE Regulation in conjunction with the German Stock Corporation Act as applied to a European stock corporation that has its legal seat in Germany differ from laws applicable to U.S. corporations and their shareholders. Set forth below is a summary of certain differences between the provisions of the SE Regulation in conjunction with the German Stock Corporation Act applicable to us and the General Corporation Law of the State of Delaware relating to shareholders' rights and protections. This summary is not intended to be a complete discussion of the respective rights and it is qualified in its entirety by reference to Delaware law and European and German law.

	European Union/Federal Republic of Germany	Delaware
Board System	A European stock corporation may choose to have atwo-tier board structure composed of the Management Board (*Vorstand*) and the Supervisory Board (*Aufsichtsrat*). We have chosen this structure. The Management Board is responsible for running the company's affairs and representing the company in dealings with third parties. The Supervisory Board of a European stock corporation under German law has a control and supervisory function. The Supervisory Board does not actively manage the company but certain Management Board actions require the approval of the Supervisory Board.	Under Delaware law, a corporation has a unitary board structure, and it is the responsibility of the board of directors to appoint and oversee the management of the corporation on behalf of and in the best interests of the stockholders of the corporation. Management is responsible for running the corporation and overseeing its day-to-day operations.
Appointment and Number of Directors	Under applicable European and German law, a European stock corporation governed by German law with a share capital of at least €3 million generally must have at least two members on its Management Board and the number of members shall be determined by or in the manner provided in the company's articles of association.	Under Delaware law, a corporation must have at least one director and the number of directors shall be fixed by or in the manner provided in the bylaws.

	European Union/Federal Republic of Germany	Delaware
	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.	
Removal of Directors	Members of the Management Board of a European stock corporation are appointed by the Supervisory Board for a maximum period of six years with an opportunity to be reelected. The articles of association may provide for a shorter term, which in our case is up to five years. The members of the Management Board may be reelected, even repeatedly. The Supervisory Board may remove a member of the Management Board prior to the expiration of his or her term only for cause, such as gross breach of duties (*grobe Pflichtverletzung*), the inability to manage the business properly (*Unfähigkeit zur ordnungsgemäßen Pflichtausübung*) or a vote of no-confidence during the shareholders' meeting (*Vertrauensentzug*). The shareholders themselves are not entitled to appoint or dismiss the members of the Management Board. Under European law, a member of the Supervisory Board of a company may be	Under Delaware law, any director or the entire board of directors may be removed, with or without cause, by the holders of a majority of the shares then entitled to vote at an election of directors, except (i) unless the certificate of incorporation provides otherwise, in the case of a corporation whose board of directors is classified, stockholders may effect such removal only for cause; or (ii) in the case of a corporation having cumulative voting, if less than the entire board of directors is to be removed, no director may be removed without cause if the votes cast against his removal would be sufficient to elect him if then cumulatively voted at an election of the entire board of directors, or, if there are classes of directors, at an election of the class of directors of which he is a part.

	European Union/Federal Republic of Germany	Delaware
	elected for a term of up to six years. The articles of association may provide for a shorter term. Our Supervisory Board members are, if the general meeting does not resolve on a shorter term, elected for a period up to the end of the general meeting deciding on the discharge for the fourth financial year after the election. Reelection, including repeated reelection, is permissible. Members of the Supervisory Board may be removed with or without cause by way of a general meeting resolution, with the applicable majority requirement depending on the relevant company's articles of association.	
Vacancies on the Board of Directors	Under the law, vacant positions on the Management Board are filled by the Supervisory Board in accordance with the general rules of appointment, which provide that vacancies are filled by the simple majority of votes of Supervisory Board members present or represented by proxy at the vote (with, under certain circumstances, the chairman having a casting vote), unless otherwise provided by the company's articles of association. In case of emergencies, a vacant position on the Management Board may be filled by an individual appointed by the court. Vacant positions on the Supervisory Board are filled in accordance with the general rules of appointment.	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.	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	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.

	European Union/Federal Republic of Germany	Delaware
	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.	
Notice of General Meetings	Under applicable European and German law, unless a longer period is otherwise provided for in the articles of association or applies because of registration requirements stipulated in the articles of association, the shareholders must be given at least 30 days' advance notice of the shareholders' meeting. Such notices must at least specify the name of the company, the statutory seat of the company, and the location, date and time of the shareholders' meeting. In addition, the invitation must contain the agenda items as well as the Management Board's and the Supervisory Board's voting proposal for each agenda item and, depending on the circumstances, certain further information. If all shareholders entitled to attend the shareholders' meeting are present or represented and do not object to the meeting being held, the formalities of calling and holding of a shareholders' meeting do not apply.	Under Delaware law, unless otherwise provided in the certificate of incorporation or bylaws, written notice of any meeting of the stockholders must be given to each stockholder entitled to vote at the meeting not less than ten nor more than 60 days before the date of the meeting and shall specify the place, date, hour, and purpose or purposes of the meeting.
Proxy	A shareholder may designate another person to attend, speak and vote at a shareholders' meeting of the company on such shareholder's behalf by proxy. With respect to Management Board meetings, a Management Board member may transmit its (written or verbal) vote via another Management Board member. With respect to Supervisory Board meetings, a Supervisory Board member may participate in voting by issuing a written vote to another Supervisory Board member or any third party entitled to attend the Supervisory Board meeting.	Under Delaware law, at any meeting of stockholders, a stockholder may designate another person to act for such stockholder by proxy, but no such proxy shall be voted or acted upon after three years from its date, unless the proxy provides for a longer period. A director of a Delaware corporation may not issue a proxy representing the director's voting rights as a director.
Preemptive Rights	Under the law applicable to European stock corporations governed by German law, existing shareholders have a statutory	Under Delaware law, stockholders have no preemptive rights to subscribe to additional issues of stock or to any security

	European Union/Federal Republic of Germany	Delaware
	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.	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 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	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

	European Union/Federal Republic of Germany	Delaware
	against a negligent Management or Supervisory Board member only after the expiry of three years.	• 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.	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.

European Union/Federal Republic of Germany	Delaware
Statutory and fiduciary duties of members of the Management Board to the company include, among others: • to act in accordance with the law, the company's articles of association and the rules of procedure for the Management Board, if any; • to report to the Supervisory Board on a regular basis as well as on certain important occasions; • to exercise reasonable care, skill and diligence; • to maintain a proper accounting system; • to not compete, directly or indirectly, with the company without permission by the supervisory board; and • to secure that no further transactions are made in case of insolvency. Statutory and fiduciary duties of members of the Supervisory Board to the company include, among others: • to effectively supervise the Management Board's handling of the company's affairs; • to evaluate and issue a resolution on certain transactions which can only be conducted by the Management Board after approval of the Supervisory Board; • to approve the company's financial statements; • to appoint the Management Board members and to represent the company in transactions between the company and members of the Management Board; and • to approve service contracts between individual members of the Supervisory Board and the company.	Directors of a Delaware corporation owe fiduciary duties of care and loyalty to the corporation and to its stockholders. The duty of care generally requires that a director act in good faith, with the care that an ordinarily prudent person would exercise under similar circumstances. Under this duty, a director must inform himself of all material information reasonably available regarding a significant transaction. The duty of loyalty requires that a director act in a manner he reasonably believes to be in the best interests of the corporation. He must not use his corporate position for personal gain or advantage. In general, but subject to certain exceptions, actions of a director are presumed to have been made on an informed basis, in good faith and in the honest belief that the action taken was in the best interests of the corporation. However, this presumption may be rebutted by evidence of a breach of one of the fiduciary duties. Delaware courts have also imposed a heightened standard of conduct upon directors of a Delaware corporation who take any action designed to defeat a threatened change in control of the corporation. In addition, under Delaware law, when the board of directors of a Delaware corporation approves the sale or break-up of a corporation, the board of directors may, in certain circumstances, have a duty to obtain the highest value reasonably available to the stockholders.

	European Union/Federal Republic of Germany	Delaware
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 plaintiffs shares thereafter devolved on the plaintiff by operation of law; and • either (i) allege with particularity the efforts made by the plaintiff to obtain the action the plaintiff desires from the directors and the reasons for the plaintiff's failure to obtain the action, or (ii) or state the reasons for not making the effort. Additionally, the plaintiff must remain a stockholder through the duration of the derivative suit. The action will not be dismissed or compromised without the approval of the Delaware Court of Chancery.

Stock Exchange Listing

ADSs representing our ordinary shares are listed on the Nasdaq Global Select Market under the symbol "BNTX."

DESCRIPTION OF AMERICAN DEPOSITARY SHARES

American Depositary Shares

The Bank of New York Mellon, as depositary, will register and deliver the American Depositary Shares, or the ADSs. Each ADS will represent one share (or a right to receive one share) deposited with The Bank of New York Mellon SA/NV as custodian for the depositary in Germany. Each ADS will also represent any other securities, cash or other property which may be held by the depositary. The deposited shares together with any other securities, cash or other property held by the depositary are referred to as the deposited securities. The depositary's office at which the ADSs will be administered and its principal executive office are located at 240 Greenwich Street, New York, New York 10286.

You may hold ADSs either (i) directly (a) by having an American Depositary Receipt, or an ADR, which is a certificate evidencing a specific number of ADSs registered in your name, or (b) by having uncertificated ADSs registered in your name, or (ii) indirectly by holding a security entitlement in ADSs through your broker or other financial institution that is a direct or indirect participant in The Depository Trust Company, or DTC. If you hold ADSs directly, you are a registered ADS holder, or an ADS holder. This description assumes you are an ADS holder. If you hold the ADSs indirectly, you must rely on the procedures of your broker or other financial institution to assert the rights of ADS holders described in this section. You should consult with your broker or financial institution to find out what those procedures are.

Registered holders of uncertificated ADSs will receive statements from the depositary confirming their holdings.

As an ADS holder, we will not treat you as one of our shareholders and you will not have shareholder rights. European and German law governs shareholder rights. The depositary will be the holder of the shares underlying your ADSs. As a registered holder of ADSs, you will have ADS holder rights. A deposit agreement among us, the depositary, ADS holders and all other persons indirectly or beneficially holding ADSs sets out ADS holder rights as well as the rights and obligations of the depositary. New York law governs the deposit agreement and the ADSs.

The following is a summary of the material provisions of the deposit agreement. For more complete information, you should read the entire deposit agreement and the form of ADR. Those documents are filed as exhibits to the registration statement of which this prospectus forms a part.

Dividends and Other Distributions

How will ADS holders receive dividends and other distributions on the shares?

The depositary has agreed to pay or distribute to ADS holders the cash dividends or other distributions it or the custodian receives on shares or other deposited securities, upon payment or deduction of its fees and expenses. You will receive these distributions in proportion to the number of shares your ADSs represent.

Cash. The depositary will convert any cash dividend or other cash distribution we pay on the shares into U.S. dollars, if it can do so on a reasonable basis and can transfer the U.S. dollars to the United States. If that is not possible or if any government approval is needed and cannot be obtained, the deposit agreement allows the depositary to distribute the foreign currency only to those ADS holders to whom it is possible to do so. It will hold the foreign currency it cannot convert for the account of the ADS holders who have not been paid. It will not invest the foreign currency and it will not be liable for any interest.

Before making a distribution, any withholding taxes, or other governmental charges that must be paid will be deducted. See "Taxation" included elsewhere in this prospectus. 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 receiveno value for them.** The depositary will exercise or distribute rights only if we ask it to and provide satisfactory assurances to the depositary that it is legal to do so. If the depositary will exercise rights, it will purchase the securities to which the rights relate and distribute those securities or, in the case of shares, new ADSs representing the new shares, to subscribing ADS holders, but only if ADS holders have paid the exercise price to the depositary. U.S. securities laws may restrict the ability of the depositary to distribute rights or ADSs or other securities issued on exercise of rights to all or certain ADS holders, and the securities distributed may be subject to restrictions on transfer.

Other Distributions. The depositary will send to ADS holders anything else we distribute on deposited securities by any means it thinks is legal, fair and practical. If it cannot make the distribution in that way, the depositary has a choice. It may decide to sell what we distributed and distribute the net proceeds, in the same way as it does with cash. Or, it may decide to hold what we distributed, in which case ADSs will also represent the newly distributed property. However, the depositary is not required to distribute any securities (other than ADSs) to ADS holders unless it receives satisfactory evidence from us that it is legal to make that distribution. The depositary may sell a portion of the distributed securities or property sufficient to pay its fees and expenses in connection with that distribution. U.S. securities laws may restrict the ability of the depositary to distribute securities to all or certain ADS holders, and the securities distributed may be subject to restrictions on transfer.

The depositary is not responsible if it decides that it is unlawful or impractical to make a distribution available to any ADS holders. We have no obligation to register ADSs, shares, rights or other securities under the Securities Act. We also have no obligation to take any other action to permit the distribution of ADSs, shares, rights or anything else to ADS holders. **This means that you may not receive the distributions we make on our shares or any value for them if it is illegal or impractical for us to make them available to you.**

Deposit, Withdrawal and Cancellation

How are ADSs issued?

The depositary will deliver ADSs if you or your broker deposits shares or evidence of rights to receive shares with the custodian. Upon payment of its fees and expenses and of any taxes or charges, such as stamp taxes or stock transfer taxes or fees, the depositary will register the appropriate number of ADSs in the names you request and will deliver the ADSs to or upon the order of the person or persons that made the deposit.

How can ADS holders withdraw the deposited securities?

You may surrender your ADSs to the depositary for the purpose of withdrawal. Upon payment of its fees and expenses and of any taxes or charges, such as stamp taxes or stock transfer taxes or fees, the depositary will deliver the shares and any other deposited securities underlying the ADSs to the ADS holder or a person the ADS holder designates at the office of the custodian. Or, at your request, risk and expense, the depositary will deliver the deposited securities at its office, if feasible. However, the depositary is not required to accept surrender of ADSs to the extent it would require delivery of a fraction of a deposited share or other security. The depositary may charge you a fee and its expenses for instructing the custodian regarding delivery of deposited securities.

How do ADS holders interchange between certificated ADSs and uncertificated ADSs?

You may surrender your ADR to the depositary for the purpose of exchanging your ADR for uncertificated ADSs. The depositary will cancel that ADR and will send to the ADS holder a statement confirming that the ADS holder is the registered holder of uncertificated ADSs. Upon receipt by the depositary of a proper instruction from a registered holder of uncertificated ADSs requesting the exchange of uncertificated ADSs for certificated ADSs, the depositary will execute and deliver to the ADS holder an ADR evidencing those ADSs.

Voting Rights

How do ADS holders vote?

ADS holders may instruct the depositary how to vote the number of deposited shares their ADSs represent. If we request the depositary to solicit your voting instructions (and we are not required to do so), the depositary will notify you of a shareholders' meeting and send or make voting materials available to you. Those materials will describe the matters to be voted on and explain how ADS holders may instruct the depositary how to vote. For instructions to be valid, they must reach the depositary by a date set by the depositary. The depositary will try, as far as practical, subject to the laws of the State of New York and the provisions of our articles of association or similar documents, to vote or to have its agents vote the shares or other deposited securities as instructed by ADS holders. If we do not request the depositary to solicit your voting instructions, you can still send voting instructions, and, in that case, the depositary may try to vote as you instruct, but it is not required to do so.

Except by instructing the depositary as described above, you won't be able to exercise voting rights unless you surrender your ADSs and withdraw the shares. However, you may not know about the meeting enough in advance to withdraw the shares. In any event, the depositary will not exercise any discretion in voting deposited securities and it will only vote or attempt to vote as instructed or as described in the following sentence. If (i) we asked the depositary to solicit your instructions at least 30 days before the meeting date, (ii) the depositary does not receive voting instructions from you by the specified date and (iii) we confirm to the depositary that:

- we wish the depositary to vote uninstructed shares;
- we reasonably do not know of any substantial shareholder opposition to a particular question; and
- the particular question is not materially adverse to the interests of shareholders,

the depositary will consider you to have authorized and directed it to vote the number of deposited securities represented by your ADSs in favor of any resolution that we proposed in the invitation to the shareholders' meeting.

We cannot assure you that you will receive the voting materials in time to ensure that you can instruct the depositary to vote your shares. In addition, the depositary and its agents are not responsible for failing to carry out voting instructions or for the manner of carrying out voting instructions. **This means that you may not be able to exercise voting rights and there may be nothing you can do if your shares are not voted as you requested.**

In order to give you a reasonable opportunity to instruct the depositary as to the exercise of voting rights relating to deposited securities, if we request the depositary to act, we agree to give the depositary notice of any such meeting and details concerning the matters to be voted upon at least 30 days in advance of the meeting date.

Fees and Expenses

Persons depositing or withdrawing shares or ADS holders must pay:	*For*:
$5.00 (or less) per 100 ADSs (or portion of 100 ADSs)	Issuance of ADSs, including issuances resulting from a distribution of shares or rights or other property
	Cancellation of ADSs for the purpose of withdrawal, including if the deposit agreement terminates
$.05 (or less) per ADS	Any cash distribution to ADS holders
A fee equivalent to the fee that would be payable if securities distributed to you had been shares and the shares had been deposited for issuance of ADSs	Distribution of securities distributed to holders of deposited securities (including rights) that are distributed by the depositary to ADS holders
$.05 (or less) per ADS per calendar year	Depositary services
Registration or transfer fees	Transfer and registration of shares on our share register to or from the name of the depositary or its agent when you deposit or withdraw shares
Expenses of the depositary	Cable and facsimile transmissions (when expressly provided in the deposit agreement)
	Converting foreign currency to U.S. dollars
Taxes and other governmental charges the depositary or the custodian has to pay on any ADSs or shares underlying ADSs, such as stock transfer taxes, stamp duty or withholding taxes	As necessary
Any charges incurred by the depositary or its agents for servicing the deposited securities	As necessary

The depositary collects its fees for delivery and surrender of ADSs directly from investors depositing shares or surrendering ADSs for the purpose of withdrawal or from intermediaries acting for them. The depositary collects fees for making distributions to investors by deducting those fees from the amounts distributed or by selling a portion of distributable property to pay the fees. The depositary may collect its annual fee for depositary services by deduction from cash distributions or by directly billing investors or by charging the book-entry system accounts of participants acting for them. The depositary may collect any of its fees by deduction from any cash distribution payable (or by selling a portion of securities or other property distributable) to ADS holders that are obligated to pay those fees. The depositary may generally refuse to provide fee-attracting services until its fees for those services are paid.

From time to time, the depositary may make payments to us to reimburse us for costs and expenses generally arising out of establishment and maintenance of the ADS program, waive fees and expenses for services provided to us by the depositary or share revenue from the fees collected from ADS holders. In performing its duties under the deposit agreement, the depositary may use brokers, dealers, foreign currency dealers or other service providers that are owned by or affiliated with the depositary and that may earn or share fees, spreads or commissions.

The depositary may convert currency itself or through any of its affiliates and, in those cases, acts as principal for its own account and not as agent, advisor, broker or fiduciary on behalf of any other person and earns revenue, including, without limitation, transaction spreads, that it will retain for its own account. The revenue is based on, among other things, the difference between the exchange rate assigned to the currency conversion made under the deposit agreement and the rate that the depositary or its affiliate receives when

buying or selling foreign currency for its own account. The depositary makes no representation that the exchange rate used or obtained in any currency conversion under the deposit agreement will be the most favorable rate that could be obtained at the time or that the method by which that rate will be determined will be the most favorable to ADS holders, subject to the depositary's obligations under the deposit agreement. The methodology used to determine exchange rates used in currency conversions is available upon request.

Payment of Taxes

You will be responsible for any taxes or other governmental charges payable on your ADSs or on the deposited securities represented by any of your ADSs. The depositary may refuse to register any transfer of your ADSs or allow you to withdraw the deposited securities represented by your ADSs until those taxes or other charges are paid. It may apply payments owed to you or sell deposited securities represented by your ADSs to pay any taxes owed and you will remain liable for any deficiency. If the depositary sells deposited securities, it will, if appropriate, reduce the number of ADSs to reflect the sale and pay to ADS holders any proceeds, or send to ADS holders any property, remaining after it has paid the taxes.

Tender and Exchange Offers; Redemption, Replacement or Cancellation of Deposited Securities

The depositary will not tender deposited securities in any voluntary tender or exchange offer unless instructed to do by an ADS holder surrendering ADSs and subject to any conditions or procedures the depositary may establish.

If deposited securities are redeemed for cash in a transaction that is mandatory for the depositary as a holder of deposited securities, the depositary will call for surrender of a corresponding number of ADSs and distribute the net redemption money to the holders of called ADSs upon surrender of those ADSs.

If there is any change in the deposited securities such as a sub-division, combination or other reclassification, or any merger, consolidation, recapitalization or reorganization affecting the issuer of deposited securities in which the depositary receives new securities in exchange for or in lieu of the old deposited securities, the depositary will hold those replacement securities as deposited securities under the deposit agreement. However, if the depositary decides it would not be lawful and practical to hold the replacement securities because those securities could not be distributed to ADS holders or for any other reason, the depositary may instead sell the replacement securities and distribute the net proceeds upon surrender of the ADSs.

If there is a replacement of the deposited securities and the depositary will continue to hold the replacement securities, the depositary may distribute new ADSs representing the new deposited securities or ask you to surrender your outstanding ADRs in exchange for new ADRs identifying the new deposited securities.

If there are no deposited securities underlying ADSs, including if the deposited securities are cancelled, or if the deposited securities underlying ADSs have become apparently worthless, the depositary may call for surrender 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 ADSs until 30 days after the depositary notifies ADS holders of the amendment. **At the time an amendment becomes effective, you are considered, by continuing to hold your ADSs, to agree to the amendment and to be bound by the ADRs and the deposit agreement as amended.**

How may the deposit agreement be terminated?

The depositary will initiate termination of the deposit agreement if we instruct it to do so. The depositary may initiate termination of the deposit agreement if:

- 60 days have passed since the depositary told us it wants to resign but a successor depositary has not been appointed and accepted its appointment;
- we delist the ADSs from an exchange in the United States on which they were listed and do not list the ADSs on another exchange in the United States or make arrangements for trading of ADSs on the U.S. over-the-counter market;
- we delist our ordinary shares from an exchange outside the United States on which they were listed and do not list the shares on another exchange outside the United States;
- the depositary has reason to believe the ADSs have become, or will become, ineligible for registration on FormF-6 under the Securities Act of 1933;
- we appear to be insolvent or enter insolvency proceedings
- all or substantially all the value of the deposited securities has been distributed either in cash or in the form of securities;
- there are no deposited securities underlying the ADSs or the underlying deposited securities have become apparently worthless; or
- there has been a replacement of deposited securities.

If the deposit agreement will terminate, the depositary will notify ADS holders at least 90 days before the termination date. At any time after the termination date, the depositary may sell the deposited securities. After that, the depositary will hold the money it received on the sale, as well as any other cash it is holding under the deposit agreement, unsegregated and without liability for interest, for the pro rata benefit of the ADS holders that have not surrendered their ADSs. Normally, the depositary will sell as soon as practicable after the termination date.

After the termination date and before the depositary sells, ADS holders can still surrender their ADSs and receive delivery of deposited securities, except that the depositary may refuse to accept a surrender for the purpose of withdrawing deposited securities or reverse previously accepted surrenders of that kind that have not settled if it would interfere with the selling process. The depositary may refuse to accept a surrender for the purpose of withdrawing sale proceeds until all the deposited securities have been sold. The depositary will continue to collect distributions on deposited securities, but, after the termination date, the depositary is not required to register any transfer of ADSs or distribute any dividends or other distributions on deposited securities to the ADSs holder (until they surrender their ADSs) or give any notices or perform any other duties under the deposit agreement except as described in this paragraph.

Limitations on Obligations and Liability

Limits on our Obligations and the Obligations of the Depositary; Limits on Liability to Holders of ADSs

The deposit agreement expressly limits our obligations and the obligations of the depositary. It also limits our liability and the liability of the depositary. We and the depositary:

- are only obligated to take the actions specifically set forth in the deposit agreement without negligence or bad faith, and the depositary will not be a fiduciary or have any fiduciary duty to holders of ADSs;
- are not liable if we are or it is prevented or delayed by law or by events or circumstances beyond our or its ability to prevent or counteract with reasonable care or effort from performing our or its obligations under the deposit agreement;

- are not liable if we or it exercises discretion permitted under the deposit agreement;
- are not liable for the inability of any holder of ADSs to benefit from any distribution on deposited securities that is not made available to holders of ADSs under the terms of the deposit agreement, or for any special, consequential or punitive damages for any breach of the terms of the deposit agreement;
- have no obligation to become involved in a lawsuit or other proceeding related to the ADSs or the deposit agreement on your behalf or on behalf of any other person;
- may rely upon any documents we believe or it believes in good faith to be genuine and to have been signed or presented by the proper person;.
- are not liable for the acts or omissions of any securities depository, clearing agency or settlement system; and
- the depositary has no duty to make any determination or provide any information as to our tax status, or any liability for any tax consequences that may be incurred by ADS holders as a result of owning or holding ADSs or be liable for the inability or failure of an ADS holder to obtain the benefit of a foreign tax credit, reduced rate of withholding or refund of amounts withheld in respect of tax or any other tax benefit.

In the deposit agreement, we and the depositary agree to indemnify each other under certain circumstances.

Requirements for Depositary Actions

Before the depositary will deliver or register a transfer of ADSs, make a distribution on ADSs, or permit withdrawal of shares, the depositary may require:

- payment of stock transfer or other taxes or other governmental charges and transfer or registration fees charged by third parties for the transfer of any shares or other deposited securities;
- satisfactory proof of the identity and genuineness of any signature or other information it deems necessary; and
- compliance with regulations it may establish, from time to time, consistent with the deposit agreement, including presentation of transfer documents.

The depositary may refuse to deliver ADSs or register transfers of ADSs when the transfer books of the depositary or our transfer books are closed or at any time if the depositary or we think it advisable to do so.

Your Right to Receive the Shares Underlying your ADSs

ADS holders have the right to cancel their ADSs and withdraw the underlying shares at any time except:

- when temporary delays arise because (i) the 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.

SHARES AND ADSS ELIGIBLE FOR FUTURE SALE

Prior to this offering, there has been no market for our ordinary shares or ADSs. Future sales of substantial amounts of our ordinary shares or ADSs in the public market, or the perception that such sales may occur, could adversely affect prevailing market prices of our ordinary shares or ADSs.

Based on the 226,779,744 ordinary shares that were outstanding on December 31, 2019, upon the closing of this offering, ordinary shares, and ADSs representing of those ordinary shares, will be outstanding, assuming no exercise of the underwriters' option to purchase additional ADSs, and including the issuance of 10,517,408 ADS representing 10,517,408 of our ordinary shares in connection with our initial public offering. The 10,517,408 ADS sold in our IPO and the ADSs sold in this offering will be freely tradable without restriction or further registration under the Securities Act of 1933, as amended, or the Securities Act, except for any ADSs purchased by our "affiliates," as that term is defined in Rule 144 under the Securities Act, or Rule 144, whose sales would be subject to the Rule 144 resale restrictions described below. The remaining 216,262,336 ordinary shares will be held by our existing shareholders and will be deemed to be "restricted securities" under Rule 144, and we expect that substantially all of these restricted securities will be subject to the 180-day IPO lock-up period and the 90-day lock-up period in connection with this offering, under the lock-up agreements as described below. These restricted securities may only be sold in the public market upon release or waiver of any applicable lock-up agreements and only if registered or pursuant to an exemption from registration, such as Rule 144 or Rule 701 under the Securities Act, or Rule 701.

Rule 144

In general, under Rule 144, beginning 90 days after the date of our IPO prospectus, a person who is not an affiliate of ours and has held their ordinary shares for at least six months, including the holding period of any prior owner other than one of our affiliates, may sell those shares without restriction, subject to the availability of current public information about us. In addition, under Rule 144, any person who is not an affiliate of ours and has not been an affiliate of ours at any time during the preceding three months and has held their ordinary shares for at least one year, including the holding period of any prior owner other than one of our affiliates, would be entitled to sell an unlimited number of shares immediately upon the closing of this offering without regard to whether current public information about us is available.

Beginning 90 days after the date of our IPO prospectus, a person who is an affiliate of ours or who was an affiliate of ours at any time during the preceding three months and who has beneficially owned restricted securities for at least six months, including the holding period of any prior owner other than one of our affiliates, is entitled to sell within any three-month period only a number of securities that does not exceed the greater of either of:

- 1% of the number of our ordinary shares then outstanding, including ordinary shares represented by ADSs, which will equal approximately ordinary shares immediately after this offering, assuming no exercise of the underwriters' option to purchase additional ADSs; and
- the average weekly trading volume of the ADSs on the Nasdaq Global Select Market during the four calendar weeks preceding the filing of a notice on Form 144 with respect to the sale.

Such sales both by affiliates and by non-affiliates must also comply with the manner-of-sale, current public information and notice provisions of Rule 144, to the extent applicable. Rule 144 also requires that affiliates relying on Rule 144 to sell securities that are not restricted securities must nonetheless comply with the same restrictions applicable to restricted securities, other than the holding period requirement.

Regulation S

Regulation S under the Securities Act provides that ordinary shares or ADSs owned by any person may be sold without registration in the United States, provided that the sale is effected in an offshore transaction and no

directed selling efforts are made in the United States (as these terms are defined in Regulation S), subject to certain other conditions. In general, this means that our shares or ADSs may be sold outside the United States without registration in the United States being required.

Rule 701

In general, under Rule 701, any of our employees, board members, executive management, consultants or advisors who purchased ordinary shares from us in connection with a compensatory share or option plan or other written agreement before the closing of this offering is entitled to resell such shares.

The SEC has indicated that Rule 701 will apply to typical share options granted by an issuer before it becomes subject to the reporting requirements of the Securities Exchange Act of 1934, as amended, along with the shares acquired upon exercise of such options, including exercises after the date of this prospectus. Securities issued in reliance on Rule 701 are restricted securities and, subject to the lock-up restrictions described below, may be sold beginning 90 days after the date of our IPO prospectus in reliance on Rule 144 by:

- persons other than affiliates, without restriction, subject only to the manner-of-sale provisions of Rule 144; and
- affiliates, subject to the manner-of-sale, current public information and filing requirements of Rule 144, in each case, without compliance with the six-month holding period requirement of Rule 144.

Lock-up Agreements

For a description of the lock-up arrangements that we, members of our Supervisory Board and Management Board and substantially all of our shareholders have entered into in connection with this offering, see "Underwriting."

Options and Form S-8 Registration Statement

As of September 30, 2019, options to purchase a total of 11,852,784 ordinary shares were issued and outstanding. Of the total number of issued and outstanding options, 2,101,842 have vested. All of our ordinary shares issuable under these options are subject to contractual lock-up agreements with us or the underwriters.

Following the completion of this offering, we intend to file a registration statement on Form S-8 under the Securities Act to register up to 21,874,806 ordinary shares, in the aggregate, issued or reserved for issuance under the ESOP. The registration statement on Form S-8 will become effective automatically upon filing. Ordinary shares issued upon exercise of a share option and registered pursuant to the Form S-8 registration statement will, subject to vesting provisions and Rule 144 volume limitations applicable to our affiliates, be available for sale in the open market immediately unless they are subject to the 180-day IPO lock-up period and the 90-day lock-up period in connection with this offering.

EXCHANGE CONTROLS AND LIMITATIONS AFFECTING SHAREHOLDERS

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, Congo, Egypt, Eritrea, Guinea, Guinea-Bissau, Iran, Iraq, Lebanon, Libya, North Korea, Somalia, South Sudan, Sudan, Syria, Tunisia 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) in case the sum of claims against, or liabilities payable to, non-residents or corporations 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.

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 ADSs in the offering.

This discussion is based on domestic German tax laws, including, but not limited to, circulars issued by German tax authorities, which 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 prospectus. 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 and when introduced, may also be applicable on sales and/or transfer of ADSs. In addition, in Germany, for example, there are currently ongoing discussions on the raise 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 discussion.

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 prospectus is not a substitute for tax advice. Prospective holders of ADSs should consult their own tax advisors regarding the German tax consequences of the purchase, ownership, disposition, donation or inheritance of ADSs in light of their particular circumstances, including the effect of any state, local, or other foreign or domestic laws or changes in tax law or interpretation. The same applies with respect to the rules governing the refund of any German dividend withholding tax (*Kapitalertragsteuer*) withheld. Only an individual tax consultation can appropriately account for the particular tax situation of each investor.

General

Based on the circular issued by the German Federal Ministry of Finance (*BMF-Schreiben*), dated May 24, 2013, reference number IV C 1-S2204/12/10003, as amended by the circular dated December 18, 2018 (reference number IV C 1 – S 2204/12/10003), in respect of the taxation of American Depositary Receipts, or ADRs, on domestic shares, or the ADR Tax Circular, for German tax purposes, the ADSs 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 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 the material German tax consequences for a holder that is a U.S. treaty beneficiary of acquiring, owning and disposing of the ADSs. For purposes of this discussion, a "U.S. treaty

beneficiary" is a resident of the United States for purposes of the Agreement 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 on Capital 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 fully eligible for 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. holder;
- 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 othertax-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 anon-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%. 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*), do not, subject to certain prerequisites, form part of the taxable dividend income but 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). The U.S. treaty beneficiary 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, investors should note that it is unclear how the German tax authorities will apply the refund process to dividends on the ADSs with respect to non-German resident holders of the ADSs. 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 anon-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 Qualified Participation. A Qualified Participation is given if a holder at any time during the five years preceding the disposition, directly or indirectly, owned 1% or more 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 disposition of a Qualified 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 disposition of a Qualified Participation even under the circumstances described in the preceding paragraph and therefore should not be subject to German taxation on capital gains from the disposition of the ADSs.

German statutory law requires the disbursing agent to levy withholding tax on capital gains from the sale of ADSs or other securities held in a custodial account in Germany. With regard to the German taxation of capital gains, disbursing agent means a German credit institution, financial services institution, securities trading enterprise or securities trading bank (each as defined in the German Banking Act and, in each case including a German branch if a foreign enterprise, but excluding a foreign branch of a German enterprise) that holds the ADSs in custody or administers the ADSs for the investor or conducts sales or other dispositions and disburses or credits the income from the ADSs to the holder of the ADSs. The German statutory law does not explicitly condition the obligation to withhold taxes on capital gains being subject to taxation in Germany under German statutory law or on an applicable income tax treaty permitting Germany to tax such capital gains.

However, a circular issued by the German Federal Ministry of Finance, dated January 18, 2016, reference number IV C1-S2252/08/10004 :017, as most recently amended by circular dated September 16, 2019, reference number IV C 1-S2252/08/10004 :027, provides that taxes need not be withheld when the holder of the custody account is not a resident of Germany for tax purposes and the income is not subject to German taxation. The circular further states that there is no obligation to withhold such tax even if the non-resident holder owns 1% or more of the share capital of a German company. While circulars issued by the German Federal Ministry of Finance are only binding on the German tax authorities but not 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 Qualified 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*).

However, in respect of dividends, the refund described in the preceding paragraph is only possible if, due to special rules on the restriction of withholding tax credit, the following three cumulative requirements are met: (i) the holder must qualify as beneficial owner of the ADSs for an uninterrupted minimum holding period of 45 days within a period starting 45 days prior to and ending 45 days after the due date of the dividends, (ii) the holder has to bear at least 70% of the change in value risk related to the ADSs during the minimum holding period as described under (i) of this paragraph and has not entered into (acting by itself or through a related party) hedging transactions which lower the change in value risk by more than 30%, and (iii) the holder must not be obliged to fully or largely compensate directly or indirectly the dividends to third parties. If these requirements are not met, then for a holder not being tax-resident in Germany who applied for a full or partial refund of the withholding tax pursuant to a double taxation treaty, no refund is available. This restriction generally does only apply if (a) the tax underlying the refund application is below a tax rate of 15% based on the gross amount of the dividends and (b) the holder does not directly own 10% or more of the shares of BioNTech and is subject to income taxes in its state of residence, without being tax-exempt. The restriction of the withholding tax credit does not apply if the holder has beneficially owned the ADSs for at least one uninterrupted year until receipt (*Zufluss*) of the dividends.

In general, as previously discussed, investors should note that it is unclear how the German tax administration will apply the refund process to dividends on the ADSs. Further, such refund is subject to the German anti-avoidance 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-avoidance 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 of the German tax authorities exists on the practical application of this procedure with respect to the ADSs.

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's holders that are tax resident in Germany. A holder is a German tax resident if, in case of an individual, he or she maintains a domicile (*Wohnsitz*) or a usual residence (*gewöhnlicher Aufenthalt*) in Germany or if, in case of a corporation, it has its place of management (*Geschäftsleitung*) or registered office (Sitz) in Germany.

The German dividend and capital gains taxation rules applicable to German tax residents require a distinction between ADSs held as private assets (*Privatvermögen*) and ADSs held as business assets (*Betriebsvermögen*).

ADSs as Private Assets (Privatvermögen)

If the ADSs are held as private assets by a German tax resident, dividends and capital gains (other than capital gains from the disposition of a Qualified Participation) are taxed as investment income and are principally subject to 25% German flat income tax on capital income (*Abgeltungsteuer*) (plus a 5.5% solidarity surcharge (*Solidaritätszuschlag*) thereon, resulting in an aggregate rate of 26.375%), which is levied in the form of withholding tax (*Kapitalertragsteuer*). In other words, once deducted, the holder's income tax liability on the dividends will be settled. Dividend payments to the extent funded from BioNTech's tax-recognized contribution account (*steuerliches Einlagekonto*), do not, subject to certain prerequisites, form part of the taxable dividend income but 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. The deduction of expenses related to the investment income (including dividends or gains with respect to ADSs) is generally not possible for private investors.

Losses resulting from the disposal of ADSs can only be offset against capital gains from the sale of any shares (*Aktien*) and other ADSs. If, however, a holder holds a Qualifying Participation, 60% of any capital gains resulting from the sale and transfer are taxable at the holder's personal income tax rate (plus 5.5% solidarity surcharge thereon). Conversely, 60% of any capital losses are recognized for tax purposes.

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 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 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.

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 ("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.

Further, capital gains and dividend income of a German tax resident corporation are generally subject to German trade tax. 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 the latter 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. The dividend income and 60% of the capital gains are generally subject to trade tax, which is fully or partly creditable against the individual's personal income tax by a lump-sum method. Dividends (after deduction of business expenses economically related thereto) are exempt from trade tax if the holder held at least 15% of BioNTech's registered share capital at the beginning of the relevant tax assessment period.

German Inheritance and Gift Tax (Erbschaft- und Schenkungsteuer)

The transfer of ADSs to another person by inheritance or gift should be generally subject to German inheritance and gift tax only if:

(i) the decedent or donor or heir, beneficiary or other transferee (a) maintained his or her domicile or a usual residence in Germany, (b) had its place of management or registered office in Germany at the time of the transfer, (c) is a German citizen who has spent no more than five consecutive years outside of Germany

without maintaining a domicile in Germany or (d) is a German citizen who serves for a German entity established under public law and is remunerated for his or her service from German public funds (including family members who form part of such person's household, if they are German citizens) and is only subject to estate or inheritance tax in his or her country of domicile or usual residence with respect to assets located in such country (special rules apply to certain former German citizens who neither maintain a domicile nor have their usual residence in Germany);

(ii) at the time of the transfer, the ADSs are held by the decedent or donor as business assets forming part of a permanent establishment in Germany or for which a permanent representative in Germany has been appointed; or

(iii) the ADSs subject to such transfer form part of a portfolio that represents at the time of the transfer 10% or more of the registered share capital of BioNTech and that has been held directly or indirectly by the decedent or donor, either alone or together with related persons.

The Agreement between the Federal Republic of Germany and the United States of America for the avoidance of double taxation with respect to taxes on inheritances and gifts as of December 21, 2000 (*Abkommen zwischen der Bundesrepublik Deutschland und den Vereinigten Staaten von Amerika zur Vermeidung der Doppelbesteuerung auf dem Gebiet der Nachlass-, Erbschaft- und Schenkungssteuern in der Fassung vom 21. Dezember 2000*), hereinafter referred to as the "United States-Germany Inheritance and Gifts Tax Treaty," provides that the German inheritance tax or gift tax can, with certain restrictions, only be levied in the cases of (i) and (ii) above. Special provisions apply to certain German citizens living outside of Germany and former German citizens.

Other Taxes

No German transfer tax, value-added tax, stamp duty or similar taxes are assessed on the purchase, sale or other transfer of ADSs. Provided that certain requirements are met, an entrepreneur may, however, opt for value-added tax on transactions that are otherwise tax-exempt. Net wealth tax (*Vermögensteuer*) is currently not imposed in Germany. Certain member states of the European Union and also Germany on a standalone basis are considering introducing a financial transaction tax (*Finanztransaktionssteuer*) which, if and when introduced, may also be applicable on sales and/or transfer of ADSs.

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 from the dividend payment, as described above under "—German Taxation—General Rules for the Taxation of Holders Not Tax Resident in Germany," in the gross amount of dividend paid 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 includible in U.S. Holder's income will be the U.S. dollar value of the Euro payments made, determined at the spot Euro/U.S. dollar rate on the date the dividend distribution is includible in income, regardless of whether the payment is in fact converted into U.S. dollars. Generally, any gain or loss resulting from currency exchange fluctuations during the period from the date the dividend payment is included in income to the date the payment is converted into U.S. dollars will be treated as ordinary income or loss and will not be eligible for the special tax rate applicable to qualified dividend income. The gain or loss generally will be income or loss from sources within the United States for foreign tax credit limitation purposes.

To the extent a distribution with respect to ADSs exceeds our current or accumulated earnings and profits, as determined under U.S. federal income tax principles, the distribution will be treated, first, as a tax-free return of the U.S. Holder's investment, up to the holder's adjusted tax basis in its ADSs, and, thereafter, as capital gain, which is subject to the tax treatment described below in "—Gain on Sale, Exchange or Other Taxable Disposition."

Subject to certain limitations, the German tax withheld in accordance with the Treaty and paid over to the German taxing authority will be creditable or deductible against a U.S. Holder's U.S. federal income tax liability. To the extent a refund of the tax withheld is available to a U.S. Holder under German law or under the Treaty, the amount of tax withheld that is refundable will not be eligible for credit against a U.S. Holder's U.S. federal income tax liability. See "—German Taxation—Withholding Tax Refund for U.S. Treaty Beneficiaries" above for the procedures for obtaining a tax refund.

Gain On Sale, Exchange or Other Taxable Disposition

Subject to the PFIC rules described below under "—Passive Foreign InvestmentCompany 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 generally taxed 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, and do not expect to become, a PFIC. 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 or 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 regularly traded.

A U.S. Holder that makes a validmark-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 anymark-to-market gain recognized in the year the election is made.

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 our status as a PFIC, and the tax consequences to them if we were a PFIC, including the reporting requirements and the desirability of making, and the availability of, a QEF election or a mark-to-market election with respect to the ADSs.

Medicare Tax

Non-corporate U.S. Holders that are individuals, estates or trusts and whose income exceeds certain thresholds generally are subject to a 3.8% tax on all or a portion of their net investment income, which may include their gross dividend income and net gains from the disposition of ADSs. A U.S. person that is an individual, estate or trust is encouraged to consult its tax advisors regarding the applicability of this Medicare tax to its income and gains in respect of any investment in ADSs.

Information Reporting with Respect to Foreign Financial Assets

Individual U.S. Holders may be subject to certain reporting obligations on IRS Form 8938 (Statement of Specified Foreign Financial Assets) with respect to the ADSs for any taxable year during which the U.S. Holder's aggregate value of these and certain other "specified foreign financial assets" exceed a threshold amount that varies with the filing status of the individual. This reporting obligation also applies to domestic entities formed or availed of to hold, directly or indirectly, specified foreign financial assets, including the ADSs. Significant penalties can apply if U.S. Holders are required to make this disclosure and fail to do so.

U.S. Holders who acquire ADSs for cash may be required to file IRS Form 926 (Return by a U.S. Transferor of Property to a Foreign Corporation) with the IRS and to supply certain additional information to the IRS if (i) immediately after the transfer, the U.S. Holder owns directly or indirectly (or by attribution) at least 10% of our total voting power or value or (ii) the amount of cash transferred to us in exchange for ADSs, when aggregated with all related transfers under applicable regulations, exceeds $100,000. Substantial penalties may be imposed on a U.S. Holder that fails to comply with this reporting requirement.

Information Reporting and Backup Withholding

In general, information reporting, on IRS Form 1099, will apply to dividends in respect of ADSs and the proceeds from the sale, exchange or redemption of ADSs that are paid to a holder of ADSs within the United States (and in certain cases, outside the United States), unless such holder is an exempt recipient such as a corporation. Backup withholding (currently at a 24% rate) may apply to such payments if a holder of ADSs fails to provide a taxpayer identification number (generally on an IRS Form W-9) or certification of other exempt status or fails to report in full dividend and interest income.

Backup withholding is not an additional tax. A U.S. Holder generally may obtain a refund of any amounts withheld under the backup withholding rules that exceed the U.S. Holder's income tax liability by filing a refund claim with the IRS.

UNDERWRITING

We are offering ordinary shares represented by ADSs described in this prospectus through a number of underwriters. J.P. Morgan Securities LLC and BofA Securities, Inc. are acting as representatives of the underwriters. We have entered into an underwriting agreement with the underwriters. Subject to the terms and conditions of the underwriting agreement, we have agreed to sell to the underwriters, and each underwriter has severally agreed to purchase, at the public offering price less the underwriting discounts and commissions set forth on the cover page of this prospectus, the number of ADSs listed next to its name in the following table:

Name	Number of ADSs
J.P. Morgan Securities LLC	
BofA Securities, Inc.	
Total	

The underwriters are committed to purchase all the ADSs offered by us if they purchase any ADSs. The underwriting agreement also provides that if an underwriter defaults, the purchase commitments of non-defaulting underwriters may also be increased or the offering may be terminated.

The underwriters propose to offer the ADSs directly to the public at the public offering price set forth on the cover page of this prospectus and to certain dealers at that price less a concession not in excess of $ per ADS. Any such dealers may resell ADSs to certain other brokers or dealers at a discount of up to $ per ADS from the public offering price. After the initial offering of the ADSs to the public, if all of the ADSs are not sold at the public offering price, the underwriters may change the offering price and the other selling terms. Sales of ADSs made outside of the United States may be made by affiliates of the underwriters.

The underwriters have an option to buy up to additional ADSs from us to cover sales of ADSs by the underwriters which exceed the number of ADSs specified in the table above. The underwriters have 30 days from the date of this prospectus to exercise this option to purchase additional ADSs. If any ADSs are purchased with this option to purchase additional ADSs, the underwriters will purchase ADSs in approximately the same proportion as shown in the table above. If any additional ADSs are purchased, the underwriters will offer the additional ADSs on the same terms as those on which the ADSs are being offered.

For reasons of German law, Joh. Berenberg, Gossler & Co. KG will initially subscribe for all of the new ordinary shares represented by the ADSs on behalf of the underwriters, at an issue price of €1.00 per share. This issue price will be credited against the amount due from the underwriters at closing. If the underwriters exercise their option to purchase additional ADSs, unless we satisfy our obligation to sell such additional ADSs on the basis of shares that we hold in treasury, Joh. Berenberg, Gossler & Co. KG will initially subscribe for the new ordinary shares representing such additional ADSs on behalf of the underwriters, at an issue price of €1.00 per share. This issue price will be credited against the amount due from the underwriters at the option closing.

The underwriting fee is equal to the public offering price per ADS less the amount paid by the underwriters to us per ADS. The underwriting fee is $ per ADS. The following table shows the per ADS and total underwriting discounts and commissions to be paid to the underwriters assuming both no exercise and full exercise of the underwriters' option to purchase additional ADSs.

	Without exercise of the option to purchase additional ADSs	With full exercise of option to purchase additional ADSs
Per ADS	$	$
Total	$	$

We estimate that the total expenses of this offering, including registration, filing and listing fees, printing fees and legal and accounting expenses, but excluding the underwriting discounts and commissions, will be approximately $.

A prospectus in electronic format may be made available on the web sites maintained by one or more underwriters, or selling group members, if any, participating in the offering. The underwriters may agree to allocate a number of ADSs to underwriters and selling group members for sale to their online brokerage account holders. Internet distributions will be allocated by the representatives to underwriters and selling group members that may make Internet distributions on the same basis as other allocations.

We expect that delivery of the ADSs will be made against payment therefor the third business day following the pricing of the offering (such settlement being referred to as "T+3"). Under Rule 15c6-1 of the Exchange Act, trades in the secondary market generally are required to settle in two business days, unless the parties to any such trade expressly agree otherwise. Accordingly, purchasers who wish to trade the ADSs prior to the delivery of the depositary shares hereunder will be required, by virtue of the fact that the ADSs initially settle in T+3, to specify an alternate settlement arrangement at the time of any such trade to prevent a failed settlement. Purchasers of the ADSs who wish to trade the ADSs prior to their date of delivery hereunder should consult their advisors.

We have agreed that we will not (i) offer, pledge, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase, lend, or otherwise transfer or dispose of, directly or indirectly, or submit to or file with the SEC a registration statement under the Securities Act relating to, any ordinary shares or ADSs or securities convertible into or exchangeable or exercisable for any of our ordinary shares or ADSs, or publicly disclose the intention to undertake any of the foregoing, or (ii) enter into any swap or other agreement that transfers, in whole or in part, any of the economic consequences of ownership of any ADSs, ordinary shares or any such other securities (regardless of whether any of the transactions described in clause (i) or (ii) above is to be settled by the delivery of ADSs, ordinary shares or such other securities, in cash or otherwise), without the prior written consent of J.P. Morgan Securities LLC and BofA Securities, Inc. for a period of 90 days after the date of this prospectus, other than (A) the ADSs to be sold hereunder, (B) any of our ordinary shares or ADSs issued upon the exercise of options granted under our existing share-based compensation plans, (C) the filing by us of any registration statement on Form S-8 or a successor form thereto relating to a company share plan, (D) any ADSs or other securities issued in connection with a transaction with an unaffiliated third party that includes a bona fide commercial relationship (including joint ventures, marketing or distribution arrangements, collaboration agreements or licensing agreements) or any acquisition of assets of not less than a majority or controlling portion of the equity of another entity, provided that the aggregate number of the shares issued pursuant to this clause (D) shall not exceed more than five percent (5%) of the total number of outstanding ordinary shares immediately following the issuance and sale of the ADSs hereunder and (E) the issuance of shares pursuant to the Merger.

Our directors and executive officers, and certain of our significant shareholders, have entered intolock-up agreements with the underwriters prior to the commencement of this offering pursuant to which each of these persons or entities, with limited exceptions, for a period of 90 days after the date of this prospectus, may not, without the prior written consent of J.P. Morgan Securities LLC and BofA Securities, Inc., (1) offer, pledge, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase, lend, or otherwise transfer or dispose of, directly or indirectly, any of our ordinary shares or ADSs or any securities convertible into or exercisable or exchangeable for our ordinary shares (including, without limitation, ordinary shares, ADSs, restricted shares, share options or such other securities which may be deemed to be beneficially owned by such directors, executive officers, and shareholders in accordance with the rules and regulations of the SEC and securities which may be issued upon exercise of a stock option or warrant), or publicly disclose the intention to undertake any of the foregoing, (2) enter into any swap or other agreement that transfers, in whole or in part, any of the economic consequences of ownership of the ADSs, ordinary shares or such other securities, whether any such transaction described in clause (1) or (2) above is to be settled by delivery of ADSs, ordinary shares or such other securities, in cash or otherwise, or (3) make any

demand for or exercise any right with respect to the registration of any of our ordinary shares or ADSs or any security convertible into or exercisable or exchangeable for ADSs or ordinary shares.

Notwithstanding the foregoing, the terms of the lock-up agreements do not apply to or prohibit, among others, the items described below:

- transactions relating to our ordinary shares or ADSs acquired in this public offering or open market transactions on or after the date of this prospectus, provided that no filing by any party (donor, donee, transferor or transferee) under the Exchange Act (or the equivalent thereof in non-U.S. jurisdictions) (other than a filing on a Schedule 13F or 13G) or other public announcement shall be required or shall be made voluntarily;
- the exercise of a warrant or the exercise of a stock option granted under an existing or future stock incentive plan for our ordinary shares or ADSs through a "cashless" exercise;
- transfers or dispositions of our ordinary shares or ADSs in connection with the conversion of any security convertible or exercisable into securities in accordance with their terms (including the settlement of restricted stock units), provided that any such ordinary shares or ADSs received by such party shall be subject to the lock-up restrictions, and provided, further, that no public announcement or voluntary filing shall be made and if a filing by any party (donor, donee, transferor or transferee) under the Exchange Act (or the equivalent thereof in non-U.S. jurisdictions) is required to be made, such filing shall indicate that any disposition of ordinary shares or ADSs was made solely to us in connection with a conversion;
- transfers or dispositions of our ordinary shares or ADSs pursuant to (i) any outstanding equity award or any current or future employee benefit plan or (ii) any contractual arrangement that provides for the repurchase of the party subject to the lock-up restrictions or a right of first refusal with respect to transfers of such ordinary shares or ADSs, provided that no public announcement or voluntary filing shall be made and if a filing by any party (donor, donee, transferor or transferee) under the Exchange Act (or the equivalent thereof in non-U.S. jurisdictions) is required to be made, such filing shall indicate that any disposition of ordinary shares or ADSs was made solely to us;
- the establishment of a trading plan pursuant to Rule 10b5-1 under the Exchange Act for the transfer of our ordinary shares or ADSs, provided that (i) such plan does not provide for the transfer of our ordinary shares and ADSs during the lock-up period and (ii) the entry into such plan is not publicly disclosed, included in any filings under the Exchange Act (or the equivalent thereof in non-U.S. jurisdictions) or otherwise, during the lock-up period; and
- pursuant to a bona fide third-party tender offer for all our outstanding ordinary shares or ADSs, merger, consolidation or other similar transaction approved by our Supervisory Board and made to all holders of our ordinary shares or ADSs involving a change of control (including, without limitation, the entering into of any lock-up, voting or similar agreement pursuant to which the party subject to the lock-up restrictions may agree to transfer, sell, tender or otherwise dispose of our ordinary shares or ADSs in connection with such transaction, or vote any ordinary shares or ADSs in favor of any such transaction), provided that in the event that such tender offer, merger, consolidation or other such transaction is not completed, such ordinary shares or ADSs shall remain subject to the lock-up restrictions.

In addition, pursuant to the terms of our share options, holders of share options are restricted from exercising such share options for a period of at least one year following our public offering without our consent.

We have agreed to indemnify the underwriters against certain liabilities, including liabilities under the Securities Act of 1933.

ADSs representing our ordinary shares are listed on the Nasdaq Global Select Market under the symbol "BNTX."

In connection with this offering, the underwriters may engage in stabilizing transactions, which involves making bids for, purchasing and selling ADSs in the open market for the purpose of preventing or retarding a decline in the market price of the ADSs while this offering is in progress. These stabilizing transactions may include making short sales of the ADSs, which involves the sale by the underwriters of a greater number of ADSs than they are required to purchase in this offering, and purchasing ADSs on the open market to cover positions created by short sales. Short sales may be "covered" shorts, which are short positions in an amount not greater than the underwriters' option to purchase additional ADSs referred to above, or may be "naked" shorts, which are short positions in excess of that amount. The underwriters may close out any covered short position either by exercising their option to purchase additional ADSs, in whole or in part, or by purchasing ADSs in the open market. In making this determination, the underwriters will consider, among other things, the price of ADSs available for purchase in the open market compared to the price at which the underwriters may purchase ADSs through the option to purchase additional ADSs. A naked short position is more likely to be created if the underwriters are concerned that there may be downward pressure on the price of the ADSs in the open market that could adversely affect investors who purchase in this offering. To the extent that the underwriters create a naked short position, they will purchase ADSs in the open market to cover the position.

The underwriters have advised us that, pursuant to Regulation M of the Securities Act of 1933, they may also engage in other activities that stabilize, maintain or otherwise affect the price of the ADSs, including the imposition of penalty bids. This means that if the representatives of the underwriters purchase ADSs in the open market in stabilizing transactions or to cover short sales, the representatives can require the underwriters that sold those shares as part of this offering to repay the underwriting discount received by them.

These activities may have the effect of raising or maintaining the market price of the ADSs or preventing or retarding a decline in the market price of the ADSs, and, as a result, the price of the ADSs may be higher than the price that otherwise might exist in the open market. If the underwriters commence these activities, they may discontinue them at any time. The underwriters may carry out these transactions on the Nasdaq Global Select Market, in the over-the-counter market or otherwise.

In addition, in connection with this offering certain of the underwriters (and selling group members) may engage in passive market making transactions in our common stock on The Nasdaq Stock Market prior to the pricing and completion of this offering. Passive market making consists of displaying bids on The Nasdaq Stock Market no higher than the bid prices of independent market makers and making purchases at prices no higher than these independent bids and effected in response to order flow. Net purchases by a passive market maker on each day are generally limited to a specified percentage of the passive market maker's average daily trading volume in the common stock during a specified period and must be discontinued when such limit is reached. Passive market making may cause the price of our common stock to be higher than the price that otherwise would exist in the open market in the absence of these transactions. If passive market making is commenced, it may be discontinued at any time.

Other than in the United States, no action has been taken by us or the underwriters that would permit a public offering of the securities offered by this prospectus in any jurisdiction where action for that purpose is required. The securities offered by this prospectus may not be offered or sold, directly or indirectly, nor may this prospectus or any other offering material or advertisements in connection with the offer and sale of any such securities be distributed or published in any jurisdiction, except under circumstances that will result in compliance with the applicable rules and regulations of that jurisdiction. Persons into whose possession this prospectus comes are advised to inform themselves about and to observe any restrictions relating to the offering and the distribution of this prospectus. This prospectus does not constitute an offer to sell or a solicitation of an offer to buy any securities offered by this prospectus in any jurisdiction in which such an offer or a solicitation is unlawful.

Certain of the underwriters and their affiliates have provided to us and our affiliates and may provide from time to time in the future, certain commercial banking, financial advisory, investment banking and other services

for us and such affiliates in the ordinary course of their business, for which they have received and may continue to receive customary fees and commissions. In addition, from time to time, certain of the underwriters and their affiliates may effect transactions for their own account or the account of customers, and hold on behalf of themselves or their customers, long or short positions in our debt or equity securities or loans, and may do so in the future.

Notice to Prospective Investors in the European Economic Area

In relation to each Member State of the European Economic Area (each a "Member State"), no ADSs have been offered or will be offered pursuant to the offering to the public in that Member State prior to the publication of a prospectus in relation to the ADSs which has been approved by the competent authority in that Member State or, where appropriate, approved in another Member State and notified to the competent authority in that Member State, all in accordance with the Prospectus Regulation, except that offers of ADSs may be made to the public in that Member State at any time under the following exemptions under the Prospectus Regulation:

(a) to any legal entity which is a qualified investor as defined under the Prospectus Regulation;

(b) to fewer than 150 natural or legal persons (other than qualified investors as defined under the Prospectus Regulation), subject to obtaining the prior consent of the representatives; or

(c) in any other circumstances falling within Article 1(4) of the Prospectus Regulation,

provided that no such offer of ADSs shall require us or any representative to publish a prospectus pursuant to Article 3 of the Prospectus Regulation or supplement a prospectus pursuant to Article 23 of the Prospectus Regulation and each person who initially acquires any ADSs or to whom any offer is made will be deemed to have represented, acknowledged and agreed to and with each of the representatives and the Company that it is a "qualified investor" within the meaning of Article 2(e) of the Prospectus Regulation. In the case of any ADSs being offered to a financial intermediary as that term is used in the Prospectus Regulation, each such financial intermediary will be deemed to have represented, acknowledged and agreed that the ADSs acquired by it in the offer have not been acquired on a non-discretionary basis on behalf of, nor have they been acquired with a view to their offer or resale to, persons in circumstances which may give rise to an offer of any ADSs to the public other than their offer or resale in a Member State to qualified investors as so defined or in circumstances in which the prior consent of the representatives have been obtained to each such proposed offer or resale.

For the purposes of this provision, the expression an "offer to the public" in relation to ADSs in any Member State means the communication in any form and by any means of sufficient information on the terms of the offer and any ADSs to be offered so as to enable an investor to decide to purchase or subscribe for any ADSs, and the expression "Prospectus Regulation" means Regulation (EU) 2017/1129.

Notice to Prospective Investors in the United Kingdom

In addition, in the United Kingdom, this document is being distributed only to, and is directed only at, and any offer subsequently made may only be directed at, persons who are "qualified investors" (as defined in the Prospectus Regulation) (i) who have professional experience in matters relating to investments falling within Article 19 (5) of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005, as amended (the "Order") and/or (ii) who are high net worth companies (or persons to whom it may otherwise be lawfully communicated) falling within Article 49(2)(a) to (d) of the Order (all such persons together being referred to as "relevant persons") or otherwise in circumstances which have not resulted and will not result in an offer to the public of the ADSs in the United Kingdom within the meaning of the Financial Services and Markets Act 2000.

Any person in the United Kingdom that is not a relevant person should not act or rely on the information included in this document or use it as a basis for taking any action. In the United Kingdom, any investment or investment activity that this document relates to may be made or taken exclusively by relevant persons.

Notice to Prospective Investors in Canada

The ADSs may be sold only to purchasers purchasing, or deemed to be purchasing, as principal that are accredited investors, as defined in National Instrument 45-106 Prospectus Exemptions or subsection 73.3(1) of the Securities Act (Ontario), and are permitted clients, as defined in National Instrument 31-103 Registration Requirements, Exemptions and Ongoing Registrant Obligations. Any resale of the ADSs must be made in accordance with an exemption from, or in a transaction not subject to, the prospectus requirements of applicable securities laws.

Securities legislation in certain provinces or territories of Canada may provide a purchaser with remedies for rescission or damages if this prospectus (including any amendment thereto) contains a misrepresentation, provided that the remedies for rescission or damages are exercised by the purchaser within the time limit prescribed by the securities legislation of the purchaser's province or territory. The purchaser should refer to any applicable provisions of the securities legislation of the purchaser's province or territory for particulars of these rights or consult with a legal advisor.

Pursuant to section 3A.3 of National Instrument 33-105 Underwriting Conflicts (NI 33-105), the underwriters are not required to comply with the disclosure requirements of NI 33-105 regarding underwriter conflicts of interest in connection with this offering.

Notice to Prospective Investors in Switzerland

The ADSs may not be publicly offered in Switzerland and will not be listed on the SIX Swiss Exchange, or SIX, or on any other stock exchange or regulated trading facility in Switzerland. This document does not constitute a prospectus within the meaning of, and has been prepared without regard to the disclosure standards for issuance prospectuses under art. 652a or art. 1156 of the Swiss Code of Obligations or the disclosure standards for listing prospectuses under art. 27 ff. of the SIX Listing Rules or the listing rules of any other stock exchange or regulated trading facility in Switzerland. Neither this document, nor any other offering or marketing material relating to the ADSs or the offering, may be publicly distributed or otherwise made publicly available in Switzerland. Neither this document nor any other offering or marketing material relating to the offering, the Company or the ADSs have been or will be filed with or approved by any Swiss regulatory authority. In particular, this document will not be filed with, and the offer of the ADSs will not be supervised by, the Swiss Financial Market Supervisory Authority, or FINMA, and the offer of the ADSs has not been and will not be authorized under the Swiss Federal Act on Collective Investment Schemes ("CISA"). The investor protection afforded to acquirers of interests in collective investment schemes under the CISA does not extend to acquirers of ADSs.

Notice to Prospective Investors in Hong Kong

The ADSs have not been offered or sold and will not be offered or sold in Hong Kong, by means of any document other than (a) to "professional investors" as defined in the Securites and Futures Ordinance (Cap. 571 of the Laws of Hong Kong) (the "SFO") of Hong Kong and any rules made thereunder; or (b) in other circumstances which do not result in the document being a "prospectus" as defined in the Companies (Winding Up and Miscellaneous Provisions) Ordinance (Cap. 32 of the Laws of Hong Kong) (the "CO") or which do not constitute an offer to the public within the meaning of the CO. No advertisement, invitation or document relating to the ADSs has been or may be issued or has been or may be in the possession of any person for the purposes of issue, whether in Hong Kong or elsewhere, which is directed at, or the contents of which are likely to be accessed or read by, the public of Hong Kong (except if permitted to do so under the securities laws of Hong Kong) other than with respect to ADSs which are or are intended to be disposed of only to persons outside Hong Kong or only to "professional investors" as defined in the SFO and any rules made thereunder.

Notice to Prospective Investors in Japan

The ADSs have not been and will not be registered pursuant to Article 4, Paragraph 1 of the Financial Instruments and Exchange Act. Accordingly, none of the ADSs nor any interest therein may be offered or sold, directly or indirectly, in Japan or to, or for the benefit of, any "resident" of Japan (which term, as used herein means any person resident in Japan, including any corporation or other entity organized under the laws of Japan), or to others for re-offering or resale, directly or indirectly, in Japan or to or for the benefit of a resident of Japan, except pursuant to an exemption from the registration requirements of, and otherwise in compliance with, the Financial Instruments and Exchange Act and any other applicable laws, regulations and ministerial guidelines of Japan in effect at the relevant time.

Notice to Prospective Investors in Singapore

Each representative has acknowledged that this prospectus has not been registered as a prospectus with the Monetary Authority of Singapore. Accordingly, each representative has represented and agreed that it has not offered or sold any ADSs or caused the ADSs to be made the subject of an invitation for subscription or purchase and will not offer or sell any ADSs or cause the ADSs to be made the subject of an invitation for subscription or purchase and has not circulated or distributed, nor will it circulate or distribute, this prospectus or any other document or material in connection with the offer or sale, or invitation for subscription or purchase, of the ADSs, whether directly or indirectly, to any person in Singapore other than:

- to an institutional investor (as defined in Section 4A of the Securities and Futures Act (Chapter 289) of Singapore, as modified or amended from time to time (the "SFA")) pursuant to Section 274 of the SFA;
- to a relevant person (as defined in Section 275(2) of the SFA) pursuant to Section 275(1) of the SFA, or any person pursuant to Section 275(1A) of the SFA, and in accordance with the conditions specified in Section 275 of the SFA; or
- otherwise pursuant to, and in accordance with the conditions of, any other applicable provision of the SFA.

Where the ADSs are subscribed or purchased under Section 275 of the SFA by a relevant person which is:

- a corporation (which is not an accredited investor (as defined in Section 4A of the SFA)) the sole business of which is to hold investments and the entire share capital of which is owned by one or more individuals, each of whom is an accredited investor; or
- a trust (where the trustee is not an accredited investor) whose sole purpose is to hold investments and each beneficiary of the trust is an individual who is an accredited investor,

securities or securities-based derivatives contracts (each term as defined in Section 2(1) of the SFA) of that corporation or the beneficiaries' rights and interest (howsoever described) in that trust shall not be transferred within six months after that corporation or that trust has acquired the ADSs pursuant to an offer made under Section 275 of the SFA except:

- to an institutional investor or to a relevant person, or to any person arising from an offer referred to in Section 275(1A) or Section 276(4)(i)(B) of the SFA;
- where no consideration is or will be given for the transfer;
- where the transfer is by operation of law;
- as specified in Section 276(7) of the SFA; or
- as specified in Regulation 37A of the Securities and Futures (Offers of Investments) (Securities and Securities-based Derivatives Contracts) Regulations 2018.

Notice to Prospective Investors in the United Arab Emirates

The ADSs have not been, and are not being, publicly offered, sold, promoted or advertised in the United Arab Emirates (including the Dubai International Financial Centre) other than in compliance with the laws of the United Arab Emirates (and the Dubai International Financial Centre) governing the issue, offering and sale of securities. Further, this prospectus does not constitute a public offer of securities in the United Arab Emirates (including the Dubai International Financial Centre) and is not intended to be a public offer. This prospectus has not been approved by or filed with the Central Bank of the United Arab Emirates, the Securities and Commodities Authority or the Dubai Financial Services Authority.

Notice to Prospective Investors in Israel

This document does not constitute a prospectus under the Israeli Securities Law, 5728-1968, and has not been filed with or approved by the Israel Securities Authority. In Israel, this prospectus is being distributed only to, and is directed only at, and any offer of the ADSs is directed only at (i) a limited number of persons in accordance with the Israeli Securities Law and (ii) investors listed in the first addendum, or the Addendum, to the Israeli Securities Law, consisting primarily of joint investment in trust funds, provident funds, insurance companies, banks, portfolio managers, investment advisors, members of the Tel Aviv Stock Exchange, underwriters, venture capital funds, entities with equity in excess of NIS 50 million and "qualified individuals," each as defined in the Addendum (as it may be amended from time to time), collectively referred to as qualified investors (in each case, purchasing for their own account or, where permitted under the Addendum, for the accounts of their clients who are investors listed in the Addendum). Qualified investors are required to submit written confirmation that they fall within the scope of the Addendum, are aware of the meaning of same and agree to it.

EXPENSES OF THE OFFERING

The following table sets forth the total costs and expenses, other than underwriting discounts and commissions, that we expect to incur in connection with the offer and sale of the ADSs. With the exception of the SEC registration fee and the FINRA filing fee, all of these amounts are estimates:

Expenses	Amount
Securities and Exchange Commission registration fee	$
Nasdaq listing fee	
FINRA filing fee	
Printing and engraving expenses	
Legal fees and expenses	
Accounting fees and expenses	
Miscellaneous costs	
Total	$

LEGAL MATTERS

The validity of the ordinary shares and certain other matters of German law will be passed upon for us by Freshfields Bruckhaus Deringer LLP, Hamburg, Germany. Certain matters of U.S. law will be passed upon for us by Covington & Burling LLP, New York, New York. Legal counsel to the underwriters in connection with the offering are Skadden, Arps, Slate, Meagher & Flom LLP, Frankfurt, Germany with respect to German law and Davis Polk & Wardwell LLP, New York, New York with respect to U.S. law.

EXPERTS

The consolidated financial statements of BioNTech SE as of December 31, 2018 and 2017 and for each of the years in the two-year period ended December 31, 2018 have been included herein in reliance upon the report of Ernst & Young GmbH Wirtschaftsprüfungsgesellschaft, independent registered public accounting firm, as set forth in their report thereon appearing elsewhere herein, and are included in reliance upon such report given on the authority of said firm as experts in accounting and auditing. The registered business address of Ernst & Young GmbH Wirtschaftsprüfungsgesellschaft is Börsenplatz 1, 50667 Cologne, Germany.

The financial statements of Neon Therapeutics, Inc. as of December 31, 2018 and 2017 and for each of the three years in the period ended December 31, 2018 included in the registration statement have been so included in reliance on the report (which contains an explanatory paragraph relating to the Company's ability to continue as a going concern as described in Note 1 to the financial statements) of PricewaterhouseCoopers LLP, an independent registered public accounting firm, given on the authority of said firm as experts in auditing and accounting.

SERVICE OF PROCESS AND ENFORCEMENT OF LIABILITIES

We are incorporated and currently existing under European laws and the laws of the Federal Republic of Germany. In addition, all of our directors and officers reside outside of the United States and our assets and those of our non-U.S. subsidiaries are located outside of the United States. As a result, it may not be possible for investors to effect service of process on us or those persons in the United States or to enforce in the United States judgments obtained in U.S. courts against us or those persons based on the civil liability or other provisions of the U.S. securities laws or other laws.

Awards of punitive damages in actions brought in the United States or elsewhere may be unenforceable in Germany. In addition, actions brought in a German court against BioNTech or the members of our supervisory Board and Management Board, our senior management and the experts named herein to enforce liabilities based on U.S. federal securities laws may be subject to certain restrictions; in particular, German courts generally do not award punitive damages. An award for monetary damages under the U.S. securities laws would be considered punitive if it does not seek to compensate the claimant for loss or damage suffered and is intended to punish the defendant. The enforceability of any judgment in Germany will depend on the particular facts of the case as well as the laws and treaties in effect at the time.

Litigation in the Federal Republic of Germany is also subject to rules of procedure that differ from the U.S. rules, including with respect to the taking and admissibility of evidence, the conduct of the proceedings and the allocation of costs. Proceedings in Germany would have to be conducted in the German language, and all documents submitted to the court would, in principle, have to be translated into German. For these reasons, it may be difficult for a U.S. investor to bring an original action in a German court predicated upon the civil liability provisions of the U.S. federal securities laws against us, certain members of our Management and Supervisory Boards and senior management and the experts named in this prospectus. The United States and Germany do not currently have a treaty providing for recognition and enforcement of judgments (other than arbitration awards) in civil and commercial matters, though recognition and enforcement of foreign judgments in Germany is possible in accordance with applicable German laws. Even if a judgment against our company, the members of our Management Board, Supervisory Board, senior management or the experts named in this prospectus based on the civil liability provisions of the U.S. federal securities laws is obtained, a U.S. investor may not be able to enforce it in U.S. or German courts.

WHERE YOU CAN FIND MORE INFORMATION

We have filed with the SEC a registration statement on Form F-1 under the Securities Act relating to this offering of the ADSs. This prospectus, which constitutes part of the registration statement, does not include all of the information contained in the registration statement and the exhibits, schedules and amendments to the registration statement. For further information with respect to us and our ordinary shares and the ADSs, we refer you to the registration statement and the exhibits and schedules included and incorporated by reference in the registration statement. Statements made in this prospectus concerning the contents of any contract, agreement or other document are summaries of all material information about the documents summarized, but are not complete descriptions of all terms of these documents. If we file or incorporate by refernece any of these documents as an exhibit to the registration statement, we refer you to the copy of the document that has been filed for a complete description of its terms. Each statement in this prospectus relating to a document filed or incorporated by reference as an exhibit is qualified in all respects by the filed exhibit.

We are subject to the information reporting requirements of the Exchange Act that are applicable to foreign private issuers. 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 a website that contains reports, proxy and information statements and other information regarding registrants that file electronically with the SEC. These filings and our filings with the SEC are available to the public through the SEC's website at http://www.sec.gov.

As a foreign private issuer, we are exempt under the Exchange Act from, among other things, the rules prescribing the furnishing and content of proxy statements, and our board members, executive officers and principal shareholders are exempt from the reporting and short-swing profit recovery provisions contained in Section 16 of the Exchange Act. In addition, we are not required under the Exchange Act to file periodic reports and financial statements with the SEC as frequently or as promptly as U.S. companies whose securities are registered under the Exchange Act.

We will send our transfer agent a copy of all notices of our general meetings of shareholders and other reports, communications and information that are made generally available to shareholders. The transfer agent has agreed to mail to all shareholders a notice containing the information (or a summary of the information) contained in any notice of a meeting of our shareholders received by the transfer agent and will make available to all shareholders such notices and all such other reports and communications received by the transfer agent.

We maintain a corporate website at https://www.biontech.de. Information contained on, or that can be accessed through, our website does not constitute a part of this prospectus and our website address is included in this prospectus as an inactive textual reference only.

Index to Financial Statements

BioNTech SE
Interim Condensed Consolidated Statements of Operations
(in thousands, except per share data)

	Note	Nine months ended September 30, 2019	2018
		(unaudited)	
Revenues from contracts with customers	4	€ 80,601	€ 63,796
Cost of sales		(12,925)	(9,215)
Gross profit		**€ 67,676**	**€ 54,581**
Research and development expenses		(161,039)	(91,244)
Sales and marketing expenses		(1,908)	(1,984)
General and administrative expenses		(34,481)	(16,222)
Other operating income		1,340	4,043
Other operating expenses		(163)	(631)
Operating loss		**€(128,575)**	**€(51,457)**
Finance income		9,170	6,644
Finance expenses		(233)	(12)
Interest expense related to lease liability		(1,283)	(1,297)
Share of loss of equity method investees		—	(84)
Loss before tax		**€(120,921)**	**€(46,206)**
Income taxes	6	(28)	(583)
Loss for the period		**€(120,949)**	**€(46,789)**
Attributable to:			
Equity holders of the parent		(120,833)	(46,667)
Non-controlling interests		(116)	(122)
		€(120,949)	**€(46,789)**
Earnings per share			
Basic & diluted, loss for the period attributable to ordinary equity holders of the parent		€ (0.59)	€ (0.25)

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

BioNTech SE
Interim Condensed Consolidated Statements of Comprehensive Income (loss)
(in thousands)

	Note	Nine months ended September 30, 2019	2018
		(unaudited)	
Loss for the period		**€(120,949)**	**€(46,789)**
Other comprehensive income			
Other comprehensive income that may be reclassified to profit or loss in subsequent periods (net of tax)			
Exchange differences on translation of foreign operations		(2)	7
Net other comprehensive income that may be reclassified to profit or loss in subsequent periods		**(2)**	**7**
Other comprehensive income for the period, net of tax		**(2)**	**7**
Comprehensive loss for the period, net of tax		**€(120,951)**	**€(46,782)**
Attributable to:			
Equity holders of the parent		(120,835)	(46,660)
Non-controlling interests		(116)	(122)
Comprehensive loss for the period, net of tax		**€(120,951)**	**€(46,782)**

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

BioNTech SE
Interim condensed consolidated statements of financial position
(in thousands)

Assets	Note	As at September 30, 2019 (unaudited)	As at December 31, 2018
Non-current assets			
Intangible assets	8	€ 94,482	€ 88,042
Property, plant and equipment	7	142,631	115,966
Other financial assets	9	—	18
Total non-current assets		**€ 237,113**	**€ 204,025**
Current assets			
Inventories		10,869	5,789
Trade receivables	9	8,931	18,938
Other financial assets	9	356	336
Other assets		9,345	9,164
Income tax assets		546	891
Deferred expense		7,940	2,348
Cash and cash equivalents	9	463,308	411,495
Total current assets		**€ 501,295**	**€ 448,961**
Total assets		**€ 738,408**	**€ 652,986**
Equity and liabilities			
Equity			
Share capital	10	221,787	193,296
Capital reserve	10	569,751	344,115
Treasury shares		(5,525)	—
Accumulated losses		(366,604)	(245,771)
Other reserves		(3,004)	(25,487)
Equity attributable to equity holders of the parent		**€ 416,405**	**€ 266,153**
Non-controlling interest		—	847
Total equity		**€ 416,405**	**€ 267,000**
Non-current liabilities			
Financial liabilities	9	67,813	54,218
Contract liabilities		126,067	205,647
Total non-current liabilities		**€ 193,880**	**€ 259,865**
Current liabilities			
Tax provisions		297	297
Provisions		851	710
Trade payables	9	21,813	41,721
Contract liabilities		82,585	66,027
Other financial liabilities	9	15,730	8,266
Other liabilities		6,847	9,100
Total current liabilities		**€ 128,123**	**€ 126,121**
Total liabilities		**€ 322,003**	**€ 385,986**
Total equity and liabilities		**€ 738,408**	**€ 652,986**

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

BioNTech SE
Interim condensed consolidated statements of changes in equity
(in thousands)

		Attributable to the equity holders of the parent								
	Note	Issued capital	Capital reserve	Treasury shares	Accumulated losses	Other reserves	Foreign currency translation reserve	Total	Non-controlling interests	Total equity
As at January 1, 2019		**€193,296**	**344,115**	—	**(245,771)**	**(25,474)**	**(13)**	**266,153**	**847**	**267,000**
Loss for the period		—	—	—	(120,833)	—	—	**(120,833)**	(116)	**(120,949)**
Other comprehensive income		—	—	—	—	—	(2)	**(2)**	—	**(2)**
Total comprehensive income		**—**	**—**	—	**(120,833)**	**—**	**(2)**	**(120,835)**	**(116)**	**(120,951)**
Issuance of share capital	10	8,126	41,748	—	—	—	—	**49,874**	—	**49,874**
Capital increase Series B	10	17,990	186,390	(5,525)	—	—	—	**198,855**	—	**198,855**
Acquisition of non-controlling interest	10	2,375	(1,644)	—	—	—	—	**731**	(731)	**—**
Transaction costs	10	—	(858)	—	—	—	—	**(858)**	—	**(858)**
Share-based payments	11	—	—	—	—	22,485	—	**22,485**	—	**22,485**
At September 30, 2019 *(unaudited)*		**€221,787**	**569,751**	(5,525)	**(366,604)**	**(2,989)**	**(15)**	**416,405**	**—**	**416,405**

		Attributable to the equity holders of the parent								
	Note	Issued capital	Capital reserve	Treasury shares	Accumulated losses	Other reserves	Foreign currency translation reserve	Total	Non-controlling interests	Total equity
As at January 1, 2018		**€166,764**	**8,922**	—	**(197,753)**	**(27,206)**	**(23)**	**(49,296)**	**1,090**	**(48,206)**
Loss for the period		—	—	—	(46,667)	—	—	**(46,667)**	(122)	**(46,789)**
Other comprehensive income		—	—	—	—	—	5	**5**	—	**5**
Total comprehensive income		**—**	**—**	—	**(46,667)**	**—**	**5**	**(46,662)**	**(122)**	**(46,784)**
Issuance of share capital Series A	10	22,588	206,216	—	—	—	—	**228,804**	—	**228,804**
Issuance of share capital	10	3,943	48,980	—	—	—	—	**52,923**	—	**52,923**
Settlement of share-based payment plan		—	—	—	—	(5,909)	—	**(5,909)**	—	**(5,909)**
At September 30, 2018 *(unaudited)*		**€193,295**	**264,118**	—	**(244,420)**	**(33,115)**	**(18)**	**179,860**	**968**	**180,828**

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

BioNTech SE
Interim condensed consolidated statements of cash flows
(in thousands)

	Nine months ended September 30,	
	2019	2018
	(unaudited)	
Operating activities		
Loss for the period	(120,949)	(46,789)
Income taxes	28	583
Loss before tax	**€ (120,921)**	**€ (46,206)**
Adjustments to reconcile loss before tax to net cash flows:		
Depreciation and amortization of property, plant, equipment and intangible assets	24,087	13,759
Share-based payment expense	22,485	—
Net foreign exchange differences	(170)	(10)
(Gain)/Loss on disposal of property, plant and equipment	11	—
Finance income	(1,102)	(1,500)
Interest on lease liability	1,283	1,295
Finance expense	233	12
Share of loss of an associate and a joint venture	—	84
Working capital adjustments:		
Decrease/(Increase) in trade receivable and contract assets	4,575	(12,913)
Decrease/(Increase) in inventories	(4,945)	(1,525)
(Decrease)/Increase in trade and other payables, contract liabilities and provisions	(60,003)	(8,313)
Interest received	1,102	1,500
Interest paid	(1,517)	(1,308)
Income tax paid	(28)	(287)
Net cash flows used in operating activities	**€ (134,910)**	**€ (55,412)**
Investing activities		
Purchase of property, plant and equipment	(28,621)	(17,448)
Proceeds from sale of property, plant and equipment	568	565
Purchase of intangibles assets	(32,937)	(29,254)
Acquisition of subsidiaries and businesses, net of cash acquired	(6,056)	—
Net cash flows used in investing activities	**€ (67,046)**	**€ (46,137)**
Financing activities		
Proceeds from issuance of share capital, net of costs	247,871	281,727
Proceeds from loans and borrowings	8,067	2,500
Payment of finance lease liabilities	(2,215)	(1,618)
Net cash flows from/(used in) financing activities	**€ 253,723**	**€ 282,609**
Net increase/(decrease) in cash and cash equivalents	51,767	181,060
Change in cash resulting from exchange rate differences	46	10
Cash and cash equivalents at beginning of period	411,495	172,106
Cash and cash equivalents at September 30	**€ 463,308**	**€ 353,176**

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

BioNTech SE
Condensed explanatory notes to the financial statements

1 Corporate information

BioNTech SE is a limited company incorporated and domiciled in Germany. American Depository Shares (ADS) representing our shares are publicly traded on Nasdaq Global Select Market since October 10, 2019. The registered office is located in Mainz, An der Goldgrube 12, 55131 Germany. The accompanying IFRS interim condensed consolidated financial statements present the financial position and the results of operation of BioNTech SE and its subsidiaries, hereinafter also referred to as "BioNTech" or the "Group" and have been prepared on a going concern basis in accordance with the IFRS as issued by the International Accounting Standards Board (IASB).

Effective March 8, 2019, BioNTech AG changed its name and legal form to BioNTech SE. The Group is principally engaged in developing innovative molecular immunotherapies and biomarker-based diagnostic approaches for the individualized treatment of cancer and other infectious diseases.

During the nine months ended September 30, 2019, the following changes to our Group structure occurred (details are described in note 5):

- Two new entities have been founded in the United States: BioNTech USA Holding, LLC and BioNTech Research & Development, Inc. Both are wholly owned subsidiaries of BioNTech SE.

- The reBOOST Management GmbH, a related party, was acquired through a share purchase.

All entities are included in our Group's consolidated financial statements.

The interim condensed consolidated financial statements of the Group as of and for the three and nine months ended September 30, 2019 were authorized for issuance in accordance with a resolution of the directors on November 13, 2019.

2 Significant accounting policies

Basis of preparation

The interim condensed consolidated financial statements as of and for the three and nine months ended September 30, 2019 have been prepared in accordance with IAS 34 Interim Financial Reporting.

The interim condensed consolidated financial statements do not include all the information and disclosures required in the consolidated financial statements, and should be read in conjunction with the Group's consolidated financial statements as at December 31, 2018 and 2017 and for the two years then ended.

BioNTech prepares and presents its consolidated financial statements in Euros. Unless otherwise stated, the numbers are rounded to thousands of Euros.

The accounting policies adopted in the preparation of the interim condensed consolidated financial statements are consistent with those followed in the preparation of the Group's consolidated financial statements for the year ended December 31, 2018. The standards applied for the first time as of January 1, 2019, as disclosed in the notes to the consolidated financial statements as of December 31, 2018, had no impact on the interim condensed consolidated financial statements of the Group as of September 30, 2019.

3 Segment information

The following tables present revenue and operating results for the Group's operating segments consistent with the presentation in the notes to the consolidated financial statements as of December 31, 2018 for the nine months and the three months ended September 30, 2019 and 2018, respectively:

	Biotech Business Unit				External Services Business Unit			
(in thousands)	Clinical	Technology Platform	Manufacturing	Business Service	External Services	Total	Adjustments	Group
Nine months ended September 30, 2019								
Revenues								
Collaboration Revenues	€ 25,605	€ 1,972	€ 36,683	€ —	€ —	€ 64,260	—	€ 64,260
Revenues from other sales transactions	—	605	2	8	15,726	16,341	—	16,341
Cost of sales	—	—	—	—	(12,770)	(12,770)	(155)	(12,925)
Gross Profit	**€ 25,605**	**€ 2,577**	**€ 36,685**	**€ 8**	**€ 2,956**	**€ 67,831**	**€ (155)**	**€ 67,676**
Income / Expenses								
Research and development expenses	(65,634)	(52,503)	(38,905)	(3,732)	(420)	(161,194)	155	(161,039)
Sales and marketing expenses	—	—	—	(924)	(984)	(1,908)		(1,908)
General and administrative expenses	—	—	(2,741)	(29,398)	(2,204)	(34,343)	(138)	(34,481)
Other result	307	389	42	61	378	1,177	—	1,177
Segment operating loss	**€(39,722)**	**€ (49,537)**	**€ (4,919)**	**€(33,985)**	**€ (274)**	**€(128,437)**	**€ (138)**	**€(128,575)**

	Biotech Business Unit				External Services Business Unit			
(in thousands)	Clinical	Technology Platform	Manufacturing	Business Service	External Services	Total	Adjustments	Group
Nine months ended September 30, 2018								
Revenues								
Collaboration Revenues	€ 22,986	€ 4,627	€ 17,871	€ —	€ —	€ 45,484	—	€ 45,484
Revenues from other sales transactions	—	5,786	—	42	12,484	18,312		18,312
Cost of sales	—	—	—	(40)	(9,024)	(9,064)	(151)	(9,215)
Gross Profit	**€ 22,986**	**€ 10,413**	**€ 17,871**	**€ 2**	**€ 3,460**	**€ 54,732**	**€ (151)**	**€ 54,581**
Income / Expenses								
Research and development expenses	(27,777)	(42,295)	(19,340)	(1,430)	(553)	(91,395)	151	(91,244)
Sales and marketing expenses	—	—	—	(983)	(1,001)	(1,984)	—	(1,984)
General and administrative expenses	—	—	(1,894)	(12,643)	(1,685)	(16,222)	—	(16,222)
Other result	3,058	127	26	(94)	272	3,389	23	3,412
Segment operating profit/loss	**€ (1,733)**	**€ (31,755)**	**€ (3,337)**	**€(15,148)**	**€ 493**	**€(51,480)**	**€ 23**	**€(51,457)**

The goodwill recorded through the acquisitions of MAB Discovery as well as reBOOST Management GmbH during the nine months ended September 30, 2019 were allocated to the Technology Platform segment.

In order to reconcile the segment figures to the Group interim condensed consolidated financial statements, some of the research and development expenses need to be reclassified to cost of sales.

4 Revenue from contracts with customers

Disaggregated revenue information

Set out below is the disaggregation of the Group's revenue from contracts with customers:

	Nine Months ended September 30	
In kEUR	**2019**	**2018**
Revenues resulting from collaboration and license agreements	64,260	45,482
Genentech Inc.	47,620	34,528
Pfizer Inc.	10,761	3,587
Sanofi S.A.	4,058	3,951
Genmab A/S	—	2,740
Eli Lilly and Company	1,821	676
Revenues from other sales transactions	16,341	18,314
Total	**80,601**	**63,796**

The transactions resulting from product sales that are included within the revenue from other sales transactions are displayed below:

	Nine Months ended September 30,	
In kEUR	**2019**	**2018**
Product sales of JPT Peptide Technologies GmbH	8,892	7,601

5 Business combinations

MAB Discovery GmbH

In January 2019, BioNTech entered into an asset purchase agreement to acquire MAB Discovery GmbH's operational antibody generation unit based near Munich, Germany (hereinafter also referred to as "MAB Discovery"), for a total consideration of k€6,050. The employees of MAB Discovery were transferred automatically to BioNTech with effect as of the closing date. The acquisition closed on April 1, 2019.

The Group has acquired MAB Discovery because it intends to adopt and pursue the unit's current business into its own.

The fair values of the identifiable net assets of MAB Discovery as at the date of acquisition were:

	Fair value recognised on acquisition MAB Discovery GmbH
Net Assets	
Goodwill	€ 2,205
Other intangible assets	2,711
Property, plant and equipment	999
Inventories	135
Total net assets	**€ 6,050**

	Cash flow on acquisition MAB Discovery GmbH
Net cash acquired	—
Cash paid	6,050
Net cash flow on acquisition	**€ (6,050)**

The interim condensed consolidated financial statements include the results of MAB Discovery since the acquisition date. From the date of acquisition, MAB Discovery contributed kEUR 3,251 to loss before tax in the Technology Platform business segment from continuing operations of the Group. From the date of acquisition, MAB Discovery did not generate any revenue. Goodwill recognized is primarily attributed to the expected synergies and other benefits from combining the assets and activities of MAB Discovery with those of the Group.

Transaction costs related to the acquisition have been expensed and are included in the general and administrative expenses within the interim condensed consolidated statement of operations and are part of operating cash flows in the statement of cash flows.

reBOOST Management GmbH

On August 29, 2019, BioNTech entered into an agreement to purchase all of the outstanding shares of reBOOST Management GmbH from Medine GmbH, which is wholly owned by BioNTech's Chief Executive Officer, Ugur Sahin. The kEUR 279 purchase price consists of kEUR 31 cash consideration and assumption of liabilities of up to kEUR 248. The related party acquisition closed on September 2, 2019.

The Group acquired reBOOST because it expects to lift synergies and other benefits arising from the ongoing collaborations of reBOOST with different cooperations.

6 Income tax

The Group calculates the interim income tax expense using the tax rate that would be applicable to the expected total annual earnings. For the three months ended September 30, 2019 an amount of kEUR 8 was recorded. For the three months ended September 30, 2018 kEUR 573 were recorded respectively. For the nine months ended September 30, 2019 an amount of kEUR 28 was recorded. For the nine months ended September 30, 2018 kEUR 583 were recorded respectively.

7 Property, plant and equipment

During the nine months ended September 30, 2019, the Group acquired property, plant and equipment with a cost of kEUR 28,621 (nine months ended September 30, 2018: kEUR 13,948). The acquisitions during the nine months ended September 30, 2019 were related to constructions in progress and advanced payments (kEUR 12,012), land and buildings (kEUR 7,176) as well as equipment, tools and installations (kEUR 9,433). During the nine months ended September 30, 2018, the acquisitions were related to equipment, tools and installations (kEUR 6,305), land and buildings (kEUR 4,364) as well as construction in progress and advance payments (kEUR 3,279).

8 Intangible assets

During the nine months ended September 30, 2019, the Group acquired intangible assets with a cost of kEUR 13,721 (nine months ended September 30, 2018: kEUR 6,526), excluding intangible assets acquired through business combinations (see note 5). The acquisitions during the nine months ended September 30, 2019 were mainly related to advance payments (kEUR 5,403) as well as concessions, licenses and similar rights (kEUR 8,318). During the nine months ended September 30, 2018 the acquisitions were mainly related to concessions, licenses and similar rights (kEUR 4,962) as well as advance payments (kEUR 1,564).

9 Financial assets and financial liabilities

Set out below, is an overview of financial assets, other than cash and short-term deposits, held by the Group as at September 30, 2019 and December 31, 2018:

Financial assets at amortised cost

(in thousands)	September 30, 2019	December 31, 2018
Trade receivables	€ 8,931	€ 18,938
Other financial assets and receivables	356	354
Total	**€ 9,287**	**€ 19,292**
Total current	9,287	19,274
Total non-current	—	18

Set out below is an overview of financial liabilities held by the Group as at September 30, 2019 and December 31, 2018:

Financial liabilities: Interest-bearing loans and borrowings

	Maturity	September 30, 2019	December 31, 2018
2.15% € 10,000,000 secured bank loan	12/30/2027	€ 9,000	€ 4,000
2.08% € 9,450,000 secured bank loan	09/30/2028	4,600	1,600
Total		**€ 13,600**	**€ 5,600**
Total current		—	—
Total non-current		13,600	5,600

Other financial liabilities at amortised cost, other than interest-bearing loans and borrowings

	September 30, 2019	December 31, 2018
Trade and other payables	€ 21,813	€ 41,721
Lease liabilities	57,672	50,752
Other payables	12,271	6,132
Total	**€ 91,756**	**€ 98,605**
Total current	37,543	49,987
Total non-current	54,213	48,618

Risk management activities

No changes have occurred regarding our risk management activities as disclosed in the notes to the consolidated financial statements as of December 31, 2018.

Fair values

Fair values of cash and cash equivalents, trade receivables, trade payables, and other current liabilities approximate their carrying amounts largely due to the short-term maturities of these instruments.

The liabilities include two fixed-interest rate loans. The fair value of the two fixed-interest rate loans is calculated based on significant observable inputs (Level 2). As of September 30, 2019 and December 31, 2018, the carrying value approximates their fair values as there have been no significant changes in relevant interest rates.

There were no transfers between Level 1 and Level 2 fair value measurements and no transfers into or out of Level 3 fair value measurements during the three and nine months ended September 30, 2019.

10 Issued capital and reserves

On September 18, 2019, BioNTech effected a 1:18 share split by issuing 206,595,492 shares by way of a capital increase from its own funds; thus, no outside proceeds were received. This capital increase came into effect upon registration with the commercial register (Handelsregister). The accompanying financial statements and notes to the financial statements give retroactive effect to the share split for all periods presented.

During the nine months ended September 30, 2019, the issued capital of BioNTech was increased by kEUR 28,491 (nine months ended September 30, 2018: kEUR 26,531). Each share has a nominal value of EUR 1.00. As a result of the financing transactions the capital reserve increased during the nine months ended September 30, 2019 by kEUR 226,494. Costs related to equity transactions (kEUR 858) were recorded in equity as deduction from capital reserves. The financing transactions that occurred during the nine months ended September 30, 2019 were as follows:

Issuance of share capital

In January 2019, BioNTech issued 5,088,204 shares and increased its share capital by kEUR 5,088. The cash investment of kEUR 80,006 was mainly already received in 2018 (kEUR 79,997).

On August 30, 2019, BioNTech entered into agreements with the Bill & Melinda Gates Foundation (BMGF). BMGF agreed to purchase 3,038,674 ordinary shares of BioNTech for a total of kEUR 49,864 (kUSD 55,000). These agreements require BioNTech to perform certain research and development activities to advance the development of products for the prevention and treatment of HIV and tuberculosis. In the event of a breach of the underlying conditions, including such research and development activities, BMGF has the right to sell its shares back to BioNTech at the initial share price or fair market value, whichever is higher, subject to certain conditions. BioNTech's ability to pay dividends is also limited under the terms of these agreements.

Capital increase Series B

In June and August 2019, BioNTech issued an aggregate of 12,465,288 of ordinary shares (excluding 5,524,506 ordinary shares which were issued to a Hong Kong-based investor and subsequently transferred to BioNTech for no consideration; these shares are now held as treasury shares) to certain new and existing shareholders at a price of USD 18.10 per share for aggregate proceeds of kEUR 198,548 (kUSD 225,622).

Acquisition of non-controlling interest

As of March 14, 2019, BioNTech acquired the remaining 5.5% ofnon-controlling interests in BioNTech Cell & Gene Therapies GmbH held by Eli Lilly Nederland B.V. in exchange of issuing 2,374,794 new ordinary shares with an imputed share in the share capital of EUR 1.00 each. This acquisition was recognized within equity and resulted in the derecognition of the non-controlling interest of kEUR 731 as well as an increase to the share capital of kEUR 2,375. The net effect of the transaction of kEUR 1,644 was recognized as a decrease in the capital reserve.

Capital transaction in the period of nine months ended September 30, 2018

During the comparative period of nine months ended September 30, 2018, the issued capital increased by kEUR 26,531. The increase was mainly related to kEUR 22,588 issued during the Series A financing round, kEUR 3,361 issued as qualifying shares and kEUR 582k as ordinary shares each having a nominal value of EUR 1.00. As a result of the financing transactions the capital reserve increased during the nine months ended September 30, 2018 by kEUR 255,196.

11 Share-based payments

On November 15, 2018, the Group established a share option program that grants selected employees options to receive shares in the company. The program is designed as an Employee Stock Ownership Plan (ESOP) as disclosed in the notes to the consolidated financial statements as of December 31, 2018. The amounts disclosed in this note have been retrospectively adjusted to reflect the share split as described in note 10.

Set out below is an overview of changes in ESOP during the nine months ended September 30, 2019.

	Share options outstanding	Number of Ordinary Shares underlying options
As at January 1, 2019	658,109	11,845,962
Added	12,991	233,838
Forfeited	(12,612)	(227,016)
As at September 30, 2019	**658,488**	**11,852,784**

The 12,991 options granted during the nine months ended September 30, 2019 consists of 9,471 options (representing 170,478 ordinary shares) granted between February 21, 2019 and April 3, 2019 and 3,520 options (representing 63,360 ordinary shares) granted between April 29, 2019 and May 31, 2019.

The fair value of options granted during the nine months ended September 30, 2019 was estimated on the grant date using the following assumptions:

	Grant dates between February 21 - April 3, 2019	Grant dates between April 29 - May 31, 2019
Weighted average fair value	€ 6.93	€ 7.04
Weighted average share price	€ 15.72	€ 16.03
Exercise price	€ 15.03	€ 15.39
Expected volatility (%)	46.0%	46.0%
Expected life (years)	6	6
Risk-free interest rate (%)	0.05%	0.05%

During the nine months ended September 30, 2019 the Group has recognized kEUR 22,485 of share-based payment expenses in the statement of operations (nine months ended September 30, 2018: Nil).

In kEUR	Nine months ended September 30, 2019
Cost of sales	€ 684
Research and development expenses	17,249
Sales and Marketing expenses	80
General and administrative expenses	4,472
Total	**€ 22,485**

12 Related party disclosures

The following table describes the transactions that have been entered into with AT Impf GmbH or entities controlled by them during the nine months ended September 30, 2019 and 2018:

	Transaction value	
In kEUR	September 30, 2019	September 30, 2018
Purchases of various goods and services from entities controlled by AT Impf GmbH	€ 1,523	€ 1,783
Purchases of property and other assets from entities controlled by AT Impf GmbH	—	3,094
Total	**€ 1,523**	**€ 4,877**

The following table describes the outstanding balances payable (receivable) to AT Impf GmbH (parent company of the Group) or entities controlled by them as per September 30, 2019 and 2018:

	At September 30	
In kEUR	2019	2018
AT Impf GmbH	41	(1,788)
Total	**41**	**(1,788)**

The aggregate value of transactions related to key management personnel, or entities which they control, were as follows:

	For the nine months ended September 30	
In kEUR	2019	2018
Consulting services	19	19
Purchases of various goods and services from TRON	6,259	6,090
Total	6,278	6,109

The outstanding balances payable to key management personnel, or entities which they control, as per September 30, 2019 and 2018 were as follows:

	At September 30	
In kEUR	2019	2018
TRON	—	612
Total	**—**	**612**

13 Events after the reporting period

On October 10, 2019, BioNTech granted Prof. Ugur Sahin, M.D., BioNTech's Chief Executive Officer, an option to purchase 4,374,963 of its ordinary shares. The grant is subject to the terms of BioNTech's ESOP and contains vesting conditions consisting of a four-year service period (i.e. annually in equal installments over four years) and completion of an initial public offering by BioNTech. The latter has already taken place with effect of October 10, 2019. Exercise of the options is also subject to a four-year waiting period after the public offering. The option will have a per share exercise price at the price of the initial public offering.

On October 10, 2019, BioNTech increased its share capital by kEUR 10,000 in conjunction with the Initial Public Offering. American Depositary Shares which represent ordinary shares were offered on the Nasdaq Global Select Market at a price of USD 15.00. The net proceeds were kUSD 141,750 (kEUR 128,770).

On November 6, 2019, BioNTech increased its share capital by kEUR 517 upon the execution of the underwriter´s option. American Depositary Shares which represent ordinary shares were issued at a price of USD 15.00. The net proceeds were kUSD 7,334 (kEUR 6,610).

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Management and the Board of Directors of BioNTech SE (formerly BioNTech AG)

Opinion on the Financial Statements

We have audited the accompanying consolidated statements of financial position of BioNTech AG (the Company) as of December 31, 2018 and 2017 and as of January 1, 2017, the related consolidated statements of operations, comprehensive income (loss), changes in equity and cash flows for each of the two years in the period ended December 31, 2018, 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, 2018 and 2017 and as of January 1, 2017, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2018, in conformity with International Financial Reporting Standards as issued by the International Accounting Standard Board.

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 Public Company Accounting Oversight Board (United States) (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. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

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.

/s/ Titus Zwirner
Wirtschaftsprüfer
(German Public Auditor)

/s/ Oliver Conrad
Wirtschaftsprüfer
(German Public Auditor)

Ernst & Young GmbH Wirtschaftsprüfungsgesellschaft

We have served as the Company's auditor since 2018.

Cologne, Germany
June 18, 2019, except as to Note 21.7, as to which the date is September 24, 2019

BioNTech AG
Consolidated Statements of Operations
(in thousands, except share and per share data)

	Note	Year ended December 31, 2018	2017
Revenues from contracts with customers	4	€ 127,575	€ 61,598
Cost of sales	6.1	(13,690)	(9,318)
Gross profit		**€ 113,885**	**€ 52,280**
Research and development expenses	6.2	(143,040)	(85,496)
Sales and marketing expenses	6.3	(3,041)	(6,603)
General and administrative expenses	6.4	(26,334)	(23,520)
Other operating income	6.5	5,396	2,349
Other operating expenses	6.6	(720)	(288)
Operating loss		**€ (53,854)**	**€(61,277)**
Finance income	6.7	8,046	2,133
Finance expense	6.8	(48)	(26,007)
Interest expense related to lease liability	19	(1,721)	(676)
Share of loss of equity method investees	5	(84)	(78)
Loss before tax		**€ (47,662)**	**€(85,905)**
Income taxes	7	(600)	(45)
Loss for the year		**€ (48,262)**	**€(85,950)**
Attributable to:			
Equity holders of the parent		(48,019)	(85,653)
Non-controlling interests		(243)	(297)
		€ (48,262)	**€(85,950)**
Earnings per share			
Basic & diluted, loss for the year attributable to ordinary equity holders of the parent	8	€ (0.25)	€ (0.51)

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

BioNTech AG
Consolidated statements of comprehensive income (loss)
(in thousands)

	Note	Year ended December 31, 2018	2017
Loss for the year		**€(48,262)**	**€(85,950)**
Other comprehensive income			
Other comprehensive income that may be reclassified to profit or loss in subsequent periods (net of tax)			
Exchange differences on translation of foreign operations		10	(23)
Net other comprehensive income/(loss) that may be reclassified to profit or loss in subsequent periods		**10**	**(23)**
Other comprehensive income/(loss) for the year, net of tax		**10**	**(23)**
Comprehensive loss for the year, net of tax		**€(48,252)**	**€(85,973)**
Attributable to:			
Equity holders of the parent		(48,009)	(85,677)
Non-controlling interests		(243)	(297)
Comprehensive loss for the year, net of tax		**€(48,252)**	**€(85,973)**

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

BioNTech AG
Consolidated statements of financial position
(in thousands)

Assets	Note	As at December 31, 2018	As at December 31, 2017	As at January 1, 2017
Non-current assets				
Intangible assets	10	€ 88,042	€ 83,537	€ 11,184
Property, plant and equipment	9, 18	115,966	101,521	60,506
Other assets		—	—	78
Other financial assets		18	19	66
Total non-current assets		**€ 204,025**	**€ 185,076**	**€ 71,834**
Current assets				
Inventories	12	5,789	3,876	3,266
Trade receivables	13	18,938	4,575	3,161
Contract assets	4	—	—	637
Other financial assets	11	336	246	1,528
Other assets	14	9,164	6,227	4,699
Income tax assets	7	891	687	2
Deferred expense		2,348	1,872	1,153
Cash and cash equivalents	11	411,495	172,106	303,680
Total current assets		**448,961**	**189,637**	**318,125**
Total assets		**€ 652,986**	**€ 374,713**	**€ 389,959**
Equity and liabilities				
Equity				
Share capital	15	€ 193,296	€ 166,764	€ 3,270
Capital reserve		344,115	8,922	172,416
Accumulated losses		(245,771)	(197,753)	(112,100)
Other reserves		(25,487)	(27,229)	(33,115)
Equity attributable to equity holders of the parent		**€ 266,153**	**€ (49,296)**	**€ 30,471**
Non-controlling interest		847	1,090	1,387
Total equity		**€ 267,000**	**€ (48,206)**	**€ 31,858**
Non-current liabilities				
Financial liabilities	11	54,218	50,349	26,669
Other liabilities	17	—	—	1,383
Contract liabilities	4	205,647	214,026	273,414
Total non-current liabilities		**€ 259,865**	**€ 264,375**	**€ 301,466**
Current liabilities				
Tax provisions		297	—	—
Provisions		710	118	120
Trade payables	17	41,721	52,538	6,218
Contract liabilities	4	66,027	77,346	33,466
Other financial liabilities	11	8,266	3,771	12,765
Other liabilities	17	9,100	24,771	4,067
Total current liabilities		**€ 126,121**	**€ 158,544**	**€ 56,636**
Total liabilities		**€ 385,986**	**€ 422,920**	**€ 358,102**
Total equity and liabilities		**€ 652,986**	**€ 374,713**	**€ 389,959**

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

BioNTech AG
Consolidated statements of changes in equity
(in thousands)

	Note	Attributable to the equity holders of the parent				Foreign currency translation reserve	Total	Non-controlling interests	Total equity
		Issued capital	Capital reserve	Accumulated losses	Other reserves				
As at January 1, 2018		**€166,764**	**8,922**	**(197,753)**	**(27,206)**	**(23)**	**(49,296)**	**1,090**	**(48,206)**
Loss for the year		—	—	(48,019)	—	—	**(48,019)**	(243)	**(48,262)**
Other comprehensive income		—	—	—	—	10	**10**	—	**10**
Total comprehensive income		—	—	**(48,019)**	—	**10**	**(48,009)**	**(243)**	**(48,252)**
Issuance of share capital	15	25,949	329,867	—	—	—	**355,816**	—	**355,816**
Share-based payments	16	—	—	—	7,641	—	**7,641**	—	**7,641**
Settlement of share-based payment plan		583	5,326	—	(5,909)	—	**—**	—	**—**
At December 31, 2018		**€193,296**	**344,115**	**(245,771)**	**(25,474)**	**(13)**	**266,153**	**847**	**267,000**

	Notes	Attributable to the equity holders of the parent				Foreign currency translation reserve	Total	Non-controlling interests	Total equity
		Issued capital	Capital reserve	Accumulated losses	Other reserves				
As at January 1, 2017		**€ 3,270**	**172,416**	**(112,100)**	**(33,115)**	—	**30,471**	**1,387**	**31,858**
Loss for the year		—	—	(85,653)	—	—	**(85,653)**	(297)	**(85,950)**
Other comprehensive income		—	—	—	—	(23)	**(23)**	—	**(23)**
Total comprehensive income		—	—	**(85,653)**	—	**(23)**	**(85,676)**	**(297)**	**(85,973)**
Issuance of share capital	15	163,494	(163,494)	—	—	—	—	—	—
Share-based payments	16	—	—	—	5,909	—	**5,909**	—	**5,909**
At December 31, 2017		**€166,764**	**8,922**	**(197,753)**	**(27,206)**	**(23)**	**(49,296)**	**1,090**	**(48,206)**

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

BioNTech AG
Consolidated statements of cash flows
(in thousands)

	Year ended December 31,	
	2018	**2017**
Operating activities		
Loss for the year	€ (48,262)	€ (85,950)
Income taxes	600	45
Loss before tax	**€ (47,662)**	**€ (85,905)**
Adjustments to reconcile loss before tax to net cash flows:		
Depreciation and amortization of property, plant and equipment and intangible assets	21,984	10,529
Share-based payment expense	7,641	5,909
Net foreign exchange differences	459	24,820
Gain/(Loss) on disposal of property, plant and equipment	(14)	15
Finance income	(1,996)	(2,133)
Interest on lease liability	1,721	676
Finance expense	48	53
Share of loss of an associate and a joint venture	84	78
Movements in provisions	592	(2)
Working capital adjustments:		
Decrease/(Increase) in trade receivable and contract assets	(18,732)	(2,816)
Decrease/(Increase) in inventories	(1,253)	(574)
(Decrease)/Increase in trade and other payables, contract liabilities and refund liabilities	(20,976)	(4,572)
Interest received	1,996	2,133
Interest paid	(1,769)	(729)
Income tax paid	(304)	(45)
Net cash flows used in operating activities	**€ (58,180)**	**€ (52,562)**
Investing activities		
Purchase of property, plant and equipment	(30,598)	(24,320)
Proceeds from sale of property, plant and equipment	705	5,193
Purchase of intangible assets	(37,256)	(33,422)
Net cash flows used in investing activities	**€ (67,148)**	**€ (52,549)**
Financing activities		
Proceeds from issuance of share capital	361,725	—
Proceeds from loans and borrowings	5,600	—
Payment of finance lease liabilities	(2,148)	(1,643)
Net cash flows from/(used in) financing activities	**€365,177**	**€ (1,643)**
Net increase/(decrease) in cash and cash equivalents	239,848	(106,753)
Change in cash resulting from exchange rate differences	(459)	(24,820)
Cash and cash equivalents at 1 January	172,106	303,680
Cash and cash equivalents at 31 December	**€411,495**	**€ 172,106**

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

BioNTech AG
Notes to the financial statements

1 Corporate Information

BioNTech AG is a limited company incorporated and domiciled in Germany. Its shares are not publicly traded. The registered office is located in Mainz, An der Goldgrube 12, 55131 Germany. The accompanying International Financial Reporting Standards (IFRS) consolidated financial statements present the financial position and the results of operation of BioNTech AG and its subsidiaries, hereinafter also referred to as "BioNTech" or the "Group". Effective March 8, 2019, BioNTech AG changed its name and legal form to BioNTech SE. The Group is principally engaged in developing innovative immunotherapies for the individualized treatment of cancer and other infectious diseases.

Information on the Group's structure is provided in Note 5. Information on other related party relationships of the Group is provided in Note 26.

The consolidated financial statements of the Group for the year ended December 31, 2018 were authorized for issue in accordance with a resolution of the directors on June 18, 2019.

BioNTech prepares and publishes its consolidated financial statements in Euros. Unless otherwise stated, the numbers are rounded to thousands of Euros.

2 Significant accounting policies

2.1 Basis of preparation

The consolidated financial statements have been prepared on a going concern basis in accordance with the IFRS as issued by the International Accounting Standards Board (IASB).

BioNTech adopted IFRS for the first time on January 1, 2017 and therefore, an additional statement of financial position as of January 1, 2017 is presented in these consolidated financial statements due to the first-time adoption of IFRS.

2.2 Basis of consolidation

The consolidated financial statements comprise the financial statements of the Company and its controlled investees (subsidiaries) as at December 31, 2018.

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.

The Group re-assesses whether it controls an investee 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 the Group obtains control over the subsidiary and ceases when the Group loses control of the subsidiary. Assets, liabilities, income and expenses of a subsidiary acquired or disposed of during the year are included in the consolidated financial statements from the date the Group gains control of the subsidiary until the date the Group ceases to control the subsidiary.

The statement of profit or loss and each component of other comprehensive income 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 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 in full on consolidation.

A change in the ownership interest of a subsidiary, without a loss of control, is accounted for as an equity transaction.

If the Group loses control over a subsidiary, it derecognizes the related assets (including goodwill), liabilities,non-controlling interests and other components of equity, while any resultant gain or loss is recognized in the statement 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 fomon-controlling interests and any previous interest held over the net identifiable assets acquired and liabilities assumed.

After initial recognition, goodwill is tested at least annually or when there is an indication for impairment. See Note 2.3.13.

2.3.2 Current versus non-current classifications

The Group presents assets and liabilities in the consolidated statements of financial position based on current ornon-current classification. An asset is current when it is either: (i) expected to be realized within 12 months after the reporting period or (ii) cash or cash equivalents, unless it is restricted from being exchanged or used to settle a liability for at least 12 months after the reporting period. All other assets are classified as non-current. A liability is current when it is due to be settled within 12 months after the reporting period. The Group classifies all other liabilities as non-current.

Deferred tax assets and liabilities are classified asnon-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, the Group determines 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, the Group has determined classes of assets and liabilities 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

Adoption of IFRS 15

In applying IFRS 15 effective January 1, 2017, the Group has used the following practical expedients permitted by the standard:

- for completed contracts that have variable consideration, the transaction price at the date the contract was completed was used rather than estimating variable consideration amounts; and
- for contracts that were modified before the beginning of the earliest period presented, the aggregate effect of all of the modifications that occurred before the beginning of the earliest period presented were reflected.

Revenue recognition

Revenue from contracts with customers is recognized when control of the goods or services are transferred to the customer at an amount that reflects the consideration to which BioNTech expects to be entitled in exchange for those goods or services. If a contract with a customer contains more than one performance obligation, the transaction price is allocated to each performance obligation on a relative-stand-alone selling price basis. BioNTech has generally concluded that it acts as the principal in its revenue arrangements because it typically controls the goods or services before transferring them to the customer. The following is a description of these activities.

Revenue from collaboration and license agreements

BioNTech generates revenues from collaboration and license agreements under which BioNTech grants licenses to use, research, develop, manufacture and commercialize product candidates and products. If the grant of a license is bundled together with 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. For each promise to grant a license that is a separate performance obligation, it is considered whether control is transferred to a licensee either at a point in time or over time. Under the terms of its licensing arrangements, BioNTech provides the licensee with a right to access BioNTech's intellectual property as it exists throughout the license period (as BioNTech's 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 the licensee simultaneously receives and consumes the benefits of BioNTech's performance.

If the consideration in an agreement includes a variable amount, BioNTech estimates the amount of consideration to which BioNTech 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 revenue reversal in the amount of cumulative revenue recognized will not occur when the associated uncertainty with respect the variable consideration is subsequently resolved. The estimated deferred revenue is updated at each reporting date to reflect the current facts and circumstances.

Rendering of services

BioNTech provides development and manufacturing services to customers and recognizes revenue over time using an input-based method to measure progress toward complete satisfaction of the services because the customer simultaneously receives and consumes the benefits provided by BioNTech. If BioNTech has a right to consideration from a customer in the amount that corresponds directly with the value to the customer of BioNTech's performance completed to date (for example, service contracts in which BioNTech bills a fixed amount for each hour or day of service provided), BioNTech recognizes revenue in the amount for which BioNTech has a right to invoice the customer.

Sale of products

Revenue from the sale of medical products (*e.g.*, peptides and retroviral vectors for clinical supply) is recognized when BioNTech transfers control of the product to the customer. Control of the product normally transfers when the customer gains physical possession and BioNTech has not retained any significant risks of ownership or future obligations with respect to the product. A receivable is recognized, as the consideration is unconditional and only the passage of time is required before payment is due. The transaction price is quoted in the relevant price lists in force at the date of customer placing the respective order for such products. Payments from customers are due within 20 days (Europe) or 30 days (non-Europe) after invoice.

Contract balances

Contract assets

A contract asset is the right to consideration in exchange for goods or services transferred to the customer. If BioNTech performs by transferring goods or services to a customer before the customer pays consideration or before payment is due, a contract asset is recognized for the earned consideration that is conditional.

Trade receivables

A receivable represents BioNTech's right to an amount of consideration that is unconditional (*i.e.*, only the passage of time is required before payment of the consideration is due).

Contract liabilities

A contract liability is the obligation to transfer goods or services to a customer for which BioNTech has received consideration (or an amount of consideration is due) from the customer. If a customer pays consideration before BioNTech transfers 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 BioNTech performs under the contract.

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 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 deduction in calculating the carrying amount of the asset and thus in the statement of profit or loss over the life of the depreciable asset as a reduced depreciation expense.

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.

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.

Deferred tax items are recognized in relation to the underlying transaction either in other comprehensive income or directly in equity.

The Group offsets deferred tax assets and deferred tax liabilities only if it has 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 statement of financial position.

2.3.7 Foreign currencies

The Group's consolidated financial statements are presented in Euros, which is also the parent company's functional currency. For each entity, the Group determines the functional currency, and items included in the financial statements of such entity are measured using that functional currency. The Group uses the direct method of consolidation and on disposal of a foreign operation, the gain or loss that is reclassified to the statement 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

On consolidation, the assets and liabilities of foreign operations are translated into Euros at the rate of exchange prevailing at the reporting date and their 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 Property, plant and equipment

Construction in progress is stated at cost, net of accumulated impairment losses, if any. Property, plant and equipment are stated at cost, net of accumulated depreciation and accumulated impairment losses, if any. Such cost includes the cost of replacing part of the property, plant and equipment if the recognition criteria are met. All other repair and maintenance costs are expensed as incurred.

Depreciation is calculated on a straight-line basis over the estimated useful lives of the assets, as follows:

Property, plant and equipment	Useful life (years)
Buildings	7-33
Equipment, tools and installations	3-15

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 statement 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.

2.3.9 Leases

The Group adopted IFRS 16 Leases for annual periods beginning on January 1, 2017.

At the inception of a contract, the Group assesses 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, the Group assesses 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;
- the Group has the right to obtain substantially all of the economic benefits from use of the asset throughout the period of use; and
- the Group has the right to direct the use of the asset. The Group has this right when it has 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:
  - the Group has the right to operate the asset; or
  - the Group 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 Group allocates the consideration in the contract to each lease component on the basis of their relative stand-alone prices. However, for the leases of land and buildings in which it is a lessee, the Group has elected not to separate non-lease components, and instead accounts for the lease and non-lease components as a single lease component.

The Group recognizes 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 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 interest rate implicit in the lease or, if that rate cannot be readily determined, the Group's incremental borrowing rate. Generally, the Group uses its incremental borrowing rate as the discount rate.

Lease payments included in the measurement of the lease liability comprise the following:

- fixed payments, including in-substance fixed payments;
- variable lease payments that depend on an index or a rate, initially measured using the index or rate as of the commencement date;
- amounts expected to be payable under a residual value guarantee; and
- the exercise price under a purchase option that the Group is reasonably certain to exercise, lease payments in an optional renewal period if the Group is reasonably certain to exercise an extension option, and penalties for early termination of a lease unless the Group is reasonably certain not to terminate early.

The lease liability is 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 Group's estimate of the amount expected to be payable under a residual value guarantee, or if the Group changes its assessment of whether it 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 statement of profit or loss if the carrying amount of the right-of-use asset has been reduced to zero.

The Group presents right-of-use assets in 'property, plant and equipment' and lease liabilities in 'financial liabilities' in the statement of financial position.

Depreciation is calculated on a straight-line basis over the estimated useful lives of the assets or shorter lease term, as follows:

Right-of-use assets	Useful life (Years)
Buildings	1-25
Equipment, tools and installations	2-5
Automobiles	3-4

Short-term leases and leases of low-value assets

The Group has 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. The Group recognizes the lease payments associated with these leases as an expense in the statement of profit or loss on a straight-line basis over the lease term.

Adoption of IFRS 16

The right-of-use assets are measured at the amount equal to the lease liability, adjusted by the amount of any prepaid or accrued lease payments relating to that lease.

In applying IFRS 16 for the first time on January 1, 2017, the Group has used the following practical expedients permitted by the standard:

- the use of a single discount rate for a portfolio of leases with reasonably similar characteristics;
- the accounting for operating leases with a remaining lease term of less than 12 months as at January 1, 2017 as short-term leases;

- the exclusion of initial direct costs for the measurement of theright-of-use asset at the date of initial application; and
- the use of hindsight in determining the lease term where the contract contains options to extend or terminate the lease.

2.3.10 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 economic 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 at least reviewed at the end of each reporting period. The amortization expense on intangible assets with finite lives is recognized in the statement of profit or loss in the expense category that is consistent with the function of the intangible assets.

A summary of the useful lives applied to the Group's intangible assets is as follows:

Intangible assets	Useful life (years)
Industrial property rights	10-20
Licenses	3-20

Intangible assets with indefinite useful lives are not amortized, but are tested for impairment annually, either individually or at the level of a cash-generating unit. 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.

The group has classified advanced payments on intangible assets as intangible assets with an indefinite useful live. 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 statement 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 when the Group can demonstrate:

- the technical feasibility of completing the intangible asset so that the asset will be available for use or sale;
- its intention to complete and its 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.

The Group has not capitalized any development expenditures. The related expenditure is reflected in the statement of profit or loss in the period in which the expenditure is incurred.

2.3.11 Financial instruments—initial recognition and subsequent measurement

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 are initially measured at fair value, after the initial measurement the financial assets are subsequently classified as either measured at amortized cost, fair value through other comprehensive income, or fair value through profit or loss.

The classification of financial assets at initial recognition depends on the financial asset's contractual cash flow characteristics and the Group's business model for managing them. With the exception of trade receivables that do not contain a significant financing component or for which the Group has applied the practical expedient, the Group initially measures a financial asset at its fair value plus, in the case of a financial asset not at fair value through profit or loss, transaction costs. Trade receivables that do not contain a significant financing component or for which the Group has applied the practical expedient are measured at the transaction price determined under IFRS 15. Refer to the accounting policies in Note 2.3.4.

In order for a financial asset to be classified and measured at amortized cost or fair value through OCI, it needs to give rise to cash flows that are 'solely payments of principal and interest (SPPI)' on the principal amount outstanding. This assessment is referred to as the SPPI test and is performed at an instrument level.

Subsequent measurement

For purposes of subsequent measurement, financial assets are classified into four categories:

- financial assets at amortized cost (debt instruments);
- financial assets at fair value through other comprehensive income with recycling of cumulative gains and losses (debt instruments);
- financial assets designated at fair value through other comprehensive income with no recycling of cumulative gains and losses upon derecognition (equity instruments); or
- financial assets at fair value through profit or loss.

Financial assets at amortized cost (debt instruments)

The Group measures financial assets at amortized cost if both of the following conditions are met:

- the financial asset is held within a business model with the objective to hold financial assets in order to collect contractual cash flows; and
- the contractual terms of the financial asset give rise on specified dates to cash flows that are solely payments of principal and interest on the principal amount outstanding.

Financial assets at amortized cost are subsequently measured using the effective interest (EIR) method, and are subject to impairment. Gains and losses are recognized in the statement of profit or loss when the asset is derecognized, modified or impaired.

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 Group's consolidated statement of financial position) when:

- the rights to receive cash flows from the asset have expired; or
- the Group has transferred its rights to receive cash flows from the asset or has assumed an obligation to pay the received cash flows in full without material delay to a third party under a 'pass-through' arrangement; and either (i) the Group has transferred substantially all the risks and rewards of the asset, or (ii) the Group has neither transferred nor retained substantially all the risks and rewards of the asset, but has transferred control of the asset.

When the Group has transferred its rights to receive cash flows from an asset it evaluates if, and to what extent, it has retained the risks and rewards of ownership. When it has neither transferred nor retained substantially all of the risks and rewards of the asset, nor transferred control of the asset, the Group continues to recognize the transferred asset to the extent of its continuing involvement. In that case, the Group also recognizes an associated liability. The transferred asset and the associated liability are measured on a basis that reflects the rights and obligations that the Group has retained.

Continuing involvement that takes the form of a guarantee over the transferred asset is measured at the lower of the original carrying amount of the asset and the maximum amount of consideration that the Group could be required to repay.

Impairment of financial assets

An allowance for expected credit losses (ECLs) should be recognized for all debt instruments not held at fair value through profit or loss. 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 credit exposures for which there has not been a significant increase in credit risk since initial recognition, ECLs are provided for credit losses that result from default events that are possible within the next 12-months (a 12-month ECL). For those credit exposures for which there has been a significant increase in credit risk since initial recognition, a loss allowance is required for credit losses expected over the remaining life of the exposure, irrespective of the timing of the default (a lifetime ECL).

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. The Group has established a provision matrix that is based on its historical credit loss experience, adjusted for forward-looking factors specific to the debtors and the economic environment.

The Group considers a financial asset in default when contractual payments are 180 days past due. However, in certain cases, the Group may also consider a financial asset to be in default when internal or external information indicates that the Group is unlikely to receive the outstanding contractual amounts in full before taking into account any credit enhancements held by the Group. A financial asset is written off when there is no reasonable expectation of recovering the contractual cash flows.

ii) Financial liabilities

Initial recognition and measurement

Financial liabilities are classified, at initial recognition, as financial liabilities at fair value through profit or loss, loans and borrowings or as payables.

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.

The Group's financial liabilities include trade payables and other financial liabilities.

Subsequent measurement

The measurement of financial liabilities depends on their classification, as described below.

Financial liabilities at fair value through profit or loss

The Group has no financial liabilities measured at fair value through profit or loss.

Loans, borrowings, trade payables and other financial liabilities

After initial recognition, interest-bearing loans and borrowings, trade payables and other financial liabilities are subsequently measured at amortized cost using the EIR method. Gains and losses are recognized in the statement 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 statement of profit or loss.

This category generally applies to interest-bearing loans and borrowings.

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 statement of profit or loss.

2.3.12 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 services and finished goods and services: cost of direct materials and labor 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.

2.3.13 Impairment of non-financial assets

The Group assesses, at each reporting date, whether there is an indication that an asset may be impaired. If any indication exists, or when annual impairment testing for an asset is required, the Group estimates the asset's recoverable amount. An asset's recoverable amount is the higher of an asset's or cash generating unit's (CGU) 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. When the carrying amount of an asset or cash generating unit exceeds its recoverable amount, the asset is considered impaired and is written down to its recoverable amount.

In assessing value in use, the estimated future cash flows are discounted to their present value using apre-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 are taken into account. If no such transactions can be identified, an appropriate valuation model is used. These calculations are corroborated by valuation multiples, quoted share prices for publicly traded companies or other available fair value indicators.

The Group bases its impairment calculation on detailed budgets and forecast calculations, which are prepared separately for each of the Group's cash generating units to which the individual assets are allocated. These budgets and forecast calculations generally cover a period of five years. A long-term growth rate is calculated and applied to project future cash flows after the fifth year.

Impairment losses of continuing operations are recognized in the statement 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 Group estimates the asset's or cash generating unit's recoverable amount. 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 statement of profit or loss unless the asset is carried at a revalued amount, in which case, the reversal is treated as a revaluation increase.

2.3.14 Cash and cash equivalents

Cash and cash equivalents comprise cash in banks and on hand and short-term deposits with an original maturity of three months or less, which are subject to an insignificant risk of changes in value.

2.3.15 Provisions

General

Provisions are recognized when the Group has 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 the Group expects 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. The expense relating to a provision is presented in the statement of profit or loss net of any reimbursement.

2.3.16 Share-based payments

Employees (and others providing similar services) receive remuneration in the form of share-based payments. Furthermore, employees and others providing similar services to the group are granted share appreciation rights, which are settled in equity instruments (equity-settled transactions).

Equity-settled transactions

The cost of equity-settled transactions is determined by the fair value at the date when the grant is made using an appropriate valuation model, further details of which are given in Note 16.

These costs are recognized in Research and development expenses, Sales and marketing expenses or General and administrative expenses, together with a corresponding increase in equity (other capital reserves), over the period in which the service is provided (the vesting period). The cumulative expense recognized for equity-settled transactions at each reporting date until the vesting date reflects the extent to which the vesting period has expired and the Group's best estimate of the number of equity instruments that will ultimately vest.

2.4 First-time adoption of IFRS

These financial statements, for the year ended December 31, 2018, are the first the Group has prepared in accordance with IFRS. For periods up to and including the year ended December 31, 2017, the Group prepared its financial statements in accordance with German GAAP as local generally accepted accounting principles.

Accordingly, the Group has prepared financial statements that comply with IFRS applicable as at December 31, 2018 and the early adoption of IFRS 16 Leases, together with the comparative period data for the year ended December 31, 2017, as described in the summary of significant accounting policies. In preparing the financial statements, the Group's opening statement of financial position was prepared as at 1 January 2017, the Group's date of transition to IFRS. The principal adjustments made by the Group in restating its German GAAP financial statements, including the statement of financial position as at 1 January 2017 and the financial statements for the year ended December 31, 2017 as described below.

Exemptions applied

IFRS 1 allows first-time adopters certain exemptions from the retrospective application of certain requirements under IFRS.

The Group has applied the following exemptions:

- IFRS 3 Business Combinations has not been applied to either acquisitions of subsidiaries that are considered businesses under IFRS, or acquisitions of interests in associates and joint ventures that occurred before January 1, 2017. Use of this exemption means that the German GAAP carrying amounts of assets and liabilities, which are required to be recognized under IFRS, is their deemed cost at the date of the acquisition. After the date of the acquisition, measurement is in accordance with IFRS. Assets and liabilities that do not qualify for recognition under IFRS are excluded from the opening IFRS statement of financial position. The Group did not recognize or exclude any previously recognized amounts as a result of IFRS recognition requirements.
- IFRS 1 also requires that the German GAAP carrying amount of goodwill is used in the opening IFRS statement of financial position (apart from adjustments for goodwill impairment and recognition or derecognition of intangible assets). In accordance with IFRS 1, the Group has tested goodwill for impairment at the date of transition to IFRS. No goodwill impairment was deemed necessary at January 1, 2017.
- BioNTech measures the lease liability under IFRS 16 for all leases at the date of transition to IFRS. The lease liability is measured at the present value of the remaining lease payments, discounted using BioNTech's incremental borrowing rate at the date of transition to IFRS. The right-of-use asset is measured at cost, which consists of the present value of the unpaid lease payments, adjusted for any initial direct costs, prepaid payments or dismantling costs. The Group applies a single discount rate to a portfolio of leases with reasonably similar characteristics. The Group elects not to apply the requirements for lease liabilities and right-of-use assets as described above to leases for which the lease

term ends within 12 months of the transition to IFRSs, and BioNTech elects to exclude initial direct costs from measurement of the right-of-use asset at the date of transition to IFRSs and the use of hindsight, in determining the lease term if the contract contains options to extend or terminate the lease.

- Cumulative currency translation differences for all foreign operations are deemed to be zero as at January 1, 2017.

Estimates

The estimates at January 1, 2017 and at December 31, 2017 are consistent with those made for the same dates in accordance with German GAAP (after adjustments to reflect any differences in accounting policies).

The differences between German GAAP and IFRS as of January 1, 2017 were as follows:

Consolidated statement of operations

(in thousands)

	Note	German GAAP Year ended December 31, 2017	Adjustment	IFRS Year ended December 31, 2017
Revenues from contracts with customers	G, F	€ 87,741	€ (26,143)	€ 61,598
Cost of sales	I	(11,472)	2,154	(9,318)
Gross profit		**€ 76,269**	**€ (23,989)**	**€ 52,280**
Research and development expenses	J	(91,342)	5,847	(85,496)
Sales and marketing expenses	B, K	(12,355)	5,752	(6,603)
General and administrative expenses	B, K	(18,176)	(5,344)	(23,520)
Other operating income	H, L	4,508	(2,160)	2,349
Other operating expenses	L	(26,384)	26,096	(288)
Operating loss		**€ (67,479)**	**€ 6,202**	**€ (61,277)**
Finance income		2,133	—	2,133
Finance expense	L	(53)	(25,954)	(26,007)
Interest expense related to lease liability	B	—	(676)	(676)
Share of profit of equity method investees		(78)	—	(78)
Loss before tax		**€ (65,477)**	**€ (20,428)**	**€ (85,905)**
Income taxes		(24)	(21)	(45)
Loss for the year		**€ (65,501)**	**€ (20,449)**	**€ (85,950)**
Attributable to:				
Equity holders of the parent		(65,204)	(20,449)	(85,653)
Non-controlling interests		(297)	—	(297)
		€ (65,501)	**€ (20,449)**	**€ (85,950)**

Consolidated statement of comprehensive income (loss)

(in thousands)

	Note	German GAAP Year ended December 31, 2017	Adjustment	IFRS Year ended December 31, 2017
Loss for the year		**€ (65,501)**	**€ (20,449)**	**€ (85,950)**
Other comprehensive income				
Other comprehensive income that may be reclassified to profit or loss in subsequent periods (net of tax)				
Exchange differences on translation of foreign operations		—	(23)	(23)
Net other comprehensive income/(loss) that may be reclassified to profit or loss in subsequent periods		—	**(23)**	**(23)**
Other comprehensive income/(loss) for the year, net of tax		—	**(23)**	**(23)**
Comprehensive loss for the year, net of tax		**€ (65,501)**	**€ (20,473)**	**€ (85,973)**
Attributable to:				
Equity holders of the parent		(65,204)	(20,473)	(85,677)
Non-controlling interests		(297)	—	(297)
Comprehensive loss for the year, net of tax		**€ (65,501)**	**€ (20,473)**	**€ (85,973)**

Consolidated statement of financial position

(in thousands)

Assets	Notes	German GAAP as at January 1, 2017	Adjustment	IFRS as at January 1, 2017
Non-current assets				
Intangible assets	C, D	€ 11,098	€ 86	€ 11,184
Property, plant and equipment	A, B	31,118	29,388	60,506
Other assets		78	—	78
Other financial assets	B	78	(12)	66
Total non-current assets		**€ 42,372**	**€ 29,462**	**€ 71,834**
Current assets				
Inventories	E	6,928	(3,662)	3,266
Trade receivables		3,161	—	3,161
Contract assets	G	—	637	637
Other financial assets	B, C	137	1,391	1,528
Other assets		3,855	844	4,699
Income tax assets		2	—	2
Deferred expense	G	8,910	(7,758)	1,153
Cash and cash equivalents		303,680	—	303,680
Total current assets		**€ 326,672**	**€ (8,547)**	**€ 318,125**
Total assets		**€ 369,044**	**€ 20,915**	**€ 389,959**
Equity and liabilities				
Equity				
Share capital		3,270	—	3,270
Capital reserve		172,416	—	172,416
Accumulated losses		(112,100)	—	(112,100)
Other reserves	N	30	(33,145)	(33,115)
Equity attributable to equity holders of the parent		**€ 63,616**	**€ (33,145)**	**€ 30,471**
Non-controlling interest		1,387	—	1,387
Total equity		**€ 65,002**	**€ (33,145)**	**€ 31,858**
Non-current liabilities				
Financial liabilities	E	—	26,669	26,669
Other liabilities	F	1,956	(573)	1,383
Contract liabilities	G	—	273,414	273,414
Total non-current liabilities		**€ 1,956**	**€ 299,509**	**€ 301,466**
Current liabilities				
Provisions	F	13,790	(13,671)	120
Trade payables		6,218	—	6,218
Contract liabilities	G	—	33,466	33,466
Other financial liabilities	E, F	87	14,256	14,344
Other liabilities	H	38,394	(35,906)	2,488
Deferred income and accrued expenses		243,595	(243,595)	—
Total current liabilities		**€ 302,085**	**€ (245,450)**	**€ 56,636**
Total liabilities		**€ 304,042**	**€ 54,060**	**€ 358,102**
Total equity and liabilities		**€ 369,044**	**€ 20,915**	**€ 389,959**

Consolidated statement of financial position

(in thousands)

Assets	Notes	German GAAP as at December 31, 2017	Adjustment	IFRS as at December 31, 2017
Non-current assets				
Intangible assets	C	€ 81,691	€ 1,845	€ 83,537
Property, plant and equipment	A, B	44,313	57,208	101,521
Other financial assets	B	31	(13)	19
Total non-current assets		**€ 126,036**	**€ 59,040**	**€ 185,076**
Current assets				
Inventories	E	€ 5,248	€ (557)	€ 4,691
Trade receivables		4,575	—	4,575
Other financial assets	B, C	202	44	246
Other assets		5,462	—	5,462
Income tax assets		687	—	687
Deferred expense	G	9,090	(7,218)	1,872
Cash and cash equivalents		172,106	—	172,106
Total current assets		**€ 197,368**	**€ (7,730)**	**€ 189,637**
Total assets		**€ 323,403**	**€ 51,310**	**€ 374,713**
Equity and liabilities				
Equity				
Share capital		€ 166,764	€ —	€ 166,764
Capital reserve		8,922	—	8,922
Accumulated losses		(177,325)	(20,427)	(197,753)
Other reserves		7	(27,236)	(27,229)
Equity attributable to equity holders of the partent		**€ (1,633)**	**€ (47,663)**	**€ (49,296)**
Non-controlling interest		1,090	—	1,090
Total equity		**€ (543)**	**€ (47,663)**	**€ (48,206)**
Non-current liabilities				
Financial liabilities	E	€ 41,634	€ 8,715	€ 50,349
Contract liabilities	G	—	214,026	214,026
Total non-current liabilities		**€ 41,634**	**€ 222,741**	**€ 264,375**
Current liabilities				
Provisions	F	€ 7,059	€ (6,941)	€ 118
Trade payables		12,460	—	12,460
Contract liabilities	G	—	77,346	77,346
Other financial liabilities	E, F	7,968	45,484	53,452
Other liabilities	H	12,923	2,245	15,168
Deferred income and accrued expenses	F, G	241,902	(241,902)	—
Total current liabilities		**€ 282,312**	**€ (123,768)**	**€ 158,544**
Total liabilities		**€ 323,946**	**€ 98,973**	**€ 422,920**
Total equity and liabilities		**€ 323,403**	**€ 51,310**	**€ 374,714**

Consolidated statement of cash flows

(in thousands)

	Note	German GAAP Year ended December 31, 2017	Adjustment	IFRS Year ended December 31, 2017
Operating activities				
Loss for the year		€ (65,522)	€ (20,428)	€ (85,950)
Income taxes		24	21	45
Loss before tax		€ (65,498)	€ (20,407)	**€ (85,905)**
Adjustments to reconcile loss before tax to net cash flows:				
Depreciation of property, plant and equipment and intangible assets	B	10,298	231	10,529
Share-based payment expense	K	—	5,909	5,909
Net foreign exchange differences		24,707	113	24,820
Loss on disposal of property, plant and equipment		15	—	15
Finance income		(2,133)	—	(2,133)
Interest on lease liability	B	—	676	676
Finance expense		53	—	53
Share of loss of an associate and a joint venture		78	—	78
Movements in provisions		(6,731)	6,729	(2)
Working capital adjustments:				
Decrease/(Increase) in trade receivable, contract assets and further positions		(1,012)	(1,804)	(2,816)
Decrease/(Increase) in inventories		(1,211)	637	(574)
(Decrease)/Increase in trade and other payables, contract liabilities and refund liabilities		26,633	(31,205)	(4,572)
Interest received		2,133	—	2,133
Interest paid	B	(53)	(676)	(729)
Income tax paid		(24)	(21)	(45)
Net cash flows from operating activities		**€ (12,745)**	**€ (39,818)**	**€ (52,562)**
Investing activities				
Purchase of property, plant and equipment		**(24,320)**		**(24,320)**
Proceeds from sale of property, plant and equipment		5,193	—	5,193
Purchase of intangibles	M	(74,882)	41,460	(33,422)
Net cash flows used in investing activities		**€ (94,009)**	**€ 41,460**	**€ (52,549)**
Financing activities				
Payment of finance lease liabilities	B	—	(1,643)	(1,643)
Net cash flows from/(used in) financing activities		**€ —**	**€(1,642,634)**	**€ (1,643)**
Net increase/(decrease) in cash and cash equivalents		(106,754)	—	(106,754)
Change in cash resulting from exchange rate differences		(24,820)	—	(24,820)
Cash and cash equivalents at 1 January		303,680	—	303,680
Cash and cash equivalents at 31 December		**€ 172,106**	**€ —**	**€ 172,106**

Notes to the reconciliation of equity as at 1 January 2017 and December 2017, total comprehensive income and cash flow for the year ended December 31, 2017

A. Property, Plant and Equipment

Under IFRS, carrying amounts of Property, plant and equipment have been determined based on the useful lives listed in Note 2.3.8. The useful lives under IFRS reflect the economic lives of the respective assets appropriately and differ from those according to German GAAP. According to IFRS the carrying amounts of Property, Plant and Equipment as of January 1, 2017 are k€1,256 higher compared to HGB (December 31, 2017: k€5,293 higher).

B. Leasing

Under German GAAP, all leases have been classified as operating leases and no assets or liabilities have been capitalized for the Group's leases.

Under IFRS, all leases except short-term leases and leases oflow-value assets have been capitalized, which leads to right-of-use assets and corresponding lease liabilities in the balance sheet. According to IFRS the Right-of-use assets as of 1 January 2017 amount to k€28,132 (December 31, 2017: k€51,915), while the corresponding lease liabilities as of 1 January 2017 are k€28,132 (December 31, 2017: k€52,182).

In the statement of operations the finance costs have increased as a result from interest expenses, resulting from the lease liabilities.

In the statement of cash flows the Group reported cash payments for the reduction of the outstanding liability relating to leases under financing activities for the purposes of IFRS and the interest on the lease liability is reported in the cash flows from operating activities.

C. Other Intangible Assets

Carrying amounts of Intangible Assets have been determined based on the useful lives listed in note 2.3.10. The useful lives in the IFRS financial statements reflect the consumption of use of the respective assets appropriately. According to IFRS, the carrying amounts of Other Intangible Assets as of 1 January 2017 are k€86 higher compared to German GAAP (December 31, 2017: k€1,512 higher).

D. Goodwill

According to German GAAP, goodwill is amortized on a straight-line basis over a period of five years. Under IFRS goodwill is tested annually for impairment (see Note 2.3.1).

E. Inventories

Under German GAAP, inventories comprise amongst other items capitalized cost for products in the process of production for customer orders. Under IFRS, these customer orders are contracts with customers including performance obligations satisfied over time. Therefore, capitalized costs have to be expensed and revenue has to be recognized dependent on the measure of progress. As BioNTech does not have an unconditional right to consideration for goods and services transferred at this moment, BioNTech presents a contract asset or a contract liability for each contract with a customer depending on the proportion of goods and services transferred and consideration received.

F. Deferred income and accrued expenses

Under German GAAP, expenses from license payments were capitalized as prepaid expenses and released over the term of the license to the statement of operations. Under IFRS, these costs are inputs to the satisfaction of performance obligation and have to be expensed as incurred.

G. Deferred income and revenues

Under German GAAP, upfront and advance payments received are presented as deferred income. Under IFRS, if a payment from a contract with a customer is received or due (whichever is earlier) before BioNTech transfers a good or service to the customer or these payments exceed the goods and services transferred to a customer so far, a contract liability shall be presented. The contract liability is presented as current and non-current.

Furthermore, under German GAAP, revenues from advance payments received were partly recognized on a straight-line basis and additional milestone payments were recognized as revenue when the milestone payments were due. Under IFRS, the timing of revenue recognition of milestone payments as a variable consideration depends on the satisfaction of the performance obligation to which the variable consideration is allocated. Therefore, under IFRS, revenue from performance obligations satisfied over time is only recognized by measuring the progress toward complete satisfaction of the respective performance obligation. Additionally, under IFRS, reimbursed costs were presented net instead of gross presentation under German GAAP.

H. Other current liabilities and other operating income

Under German GAAP, other current liabilities are presented for a grant received from a customer related to the acquisition of property, plant and equipment and intangibles. Under IFRS, these payments received are treated as part of the transaction price and therefore presented as contract liability.

Under German GAAP, other operating income was presented for a partial release of the grant received from the customer related to amortization and depreciation of acquired assets attributable to the customer. Under IFRS, revenue has only to be recognized depending on the measure of progress of the related performance obligation.

I. Cost of sales

Under German GAAP, expenses from license payments were capitalized as prepaid expenses and released over the term of the license (see D. Accrued expenses). According to IFRS, these expenses are expensed as incurred as at January 1, 2017 as these expenses were costs of a performance obligation.

J. Research and development expenses

Under German GAAP, reimbursements of research and development costs were presented as revenue. Under IFRS, reimbursed costs are presented net instead of a presentation as revenues.

K. Share-based payments

Under German GAAP, the Group recognized only the costs for the equity-settled share-based payment plan as expenses. IFRS requires the fair value of the equity-settled share-based payment plan to be determined using an appropriate valuation model. Costs were recognized in fiscal year 2017 because the plan vested immediately. An additional expense of k€5,291 was recognized in the statement of operations for the year ended December 31, 2017. Please refer to Note 16 for further information on the share-based payment plan.

L. Other operating expenses/Finance cost

Under German GAAP, foreign exchange gains and losses are shown in other operating expenses and other operating income. Under IFRS, net foreign exchange losses of k€25,954 are reclassified and shown as finance cost within finance result.

M. Cash flow from investing activities

Under German GAAP, the Group presented the acquisition of an intangible asset*(e.g.*, patent) in the cash flow from investing activities with a corresponding increase in trade and other payables (k€41,460 were payable as of December 31, 2017).

Under IFRS, the Group only reports the cash payments made during fiscal year 2017 to acquire the intangible asset in the cash flows arising from investing activities. Please refer to Note 10 for further information on such intangible assets.

N. Equity

The change in the opening equity balance is the net accumulation of all IFRS opening balance adjustments.

2.5 Standards 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 Group's financial statements and that might have an impact on the Group's financial statements are disclosed below. The Group intends to adopt these new and amended standards and interpretations, if applicable, when they become effective.

	Standards/Interpretation	Date of application
IFRIC 23	Uncertainty over income tax treatment	January 1, 2019
Amendments to IFRS 9	Prepayment Features with Negative Compensation	January 1, 2019
Amendments to IAS 19	Plan Amendment, Curtailment or Settlement	January 1, 2019
Amendments to IAS 28	Long-term interests in associates and joint ventures	January 1, 2019
Annual improvements 2015-2017 Cycle	Annual improvement cycle to IFRS 2015-2017	January 1, 2019

The Group does not expect a significant impact of the application of these standards.

3 Significant accounting judgments, estimates and assumptions continued

The preparation of the Group's consolidated financial statements requires management to make judgements, 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.

Judgments

In the process of applying the Group's accounting policies, management has made the following judgments, which have the most significant effect on the amounts recognized in the consolidated financial statements:

Revenue from contracts with customers

BioNTech applied the following judgements that significantly affect the determination of the amount and timing of revenue from contracts with customers:

- Identification and determination of the nature of performance obligations in collaboration and license agreements.

BioNTech generates revenues from collaboration and license agreements under which BioNTech grants licenses to use, research, develop, manufacture and commercialize candidates and products. As these agreements

comprise several promises, it must be assessed whether these promises are capable of being distinct within the context of the contract. If these promises are not distinct, they have to be combined until the bundle of promised goods and services is distinct. For some agreements, this results in BioNTech accounting for all 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, it must be assessed which of these promises is the predominant promise to determine the nature of the performance obligation. BioNTech determined that the grant of the license is the predominant promise within the (combined) performance obligation to grant a license to the customers. It was assessed that BioNTech grants their customers a right to access or a right to use BioNTech's intellectual property due to the collaboration and license agreements.

Consequently, the promise to grant a license is accounted for as a performance obligation satisfied over time as BioNTech's customer simultaneously receive and consumes the benefits from BioNTech's performance.

- Estimation of variable consideration and assessment of the constraint when determining the deferred revenue.

BioNTech's collaboration and license agreements comprise variable considerations which are contingent on the occurrence ornon-occurrence of a future event *(i.e.*, reaching a certain milestone). When determining the deferred revenue of a collaboration and license agreement, BioNTech is required to estimate the amount of consideration to which it will be entitled in exchange for transferring the promised goods or services to the customer.

As there are usually only two possible outcomes (*i.e.*, milestone is reached or not), BioNTech has assessed that the method of the most likely amount is the best method to predict the amount of consideration to which BioNTech will be entitled.

The most likely amount of these milestone payments *(i.e.*, the full milestone payment) is only included in the transaction price if the occurrence of reaching future milestone is highly probable. BioNTech has 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.

BioNTech has 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.

Estimates and assumptions

The 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. The Group based its 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.

For the carrying amounts of the revenue recognition-related contract balances, see Note 4.

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.

This estimate also requires the determination of the most appropriate inputs to the valuation model, including the fair value of the share option.

Due to the lack of quoted market prices, the Group has used an external appraisal for the measurement of the cash- and equity-settled transactions' fair value at the grant date 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.

Leases

Right-of-use assets are measured at the amount equal to the lease liability, adjusted by the amount of any prepaid or accrued lease payments relating to that lease.

Significant accounting judgments are required for the determination of the appropriate incremental borrowing rate, which is to be used in the calculation of the asset and liability that are recognized in the financial statements regarding the lease contracts.

For the carrying amounts of right-of-use assets and the related lease liability, see Note 18.

Taxes

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. Significant management judgement is required to determine the amount of deferred tax assets that can be recognized, based upon the likely timing and the level of future taxable profits, together with future tax planning strategies.

The Group has tax losses carried forward and these losses relate to subsidiaries that have a history of losses. The subsidiaries neither have any taxable temporary difference nor any tax planning opportunities available that could partly support the recognition of these losses as deferred tax assets.

On this basis, the Group has determined that it cannot recognize deferred tax assets on the tax losses carried forward.

4 Revenue from contracts with customers

4.1 Disaggregated revenue information

Set out below is the disaggregation of the Group's revenue from contracts with customers:

	Year ended December 31,	
(in thousands)	2018	2017
Revenues resulting from collaboration and license agreements	€ 101,837	€ 42,333
Eli Lilly and Company	676	2,074
Genentech Inc.	49,536	27,829
Genmab A/S	2,740	6,765
Pfizer Inc.	7,174	—
Sanofi S.A.	41,712	5,665
Revenues from other sales transactions	25,738	19,265
Sum	**€ 127,575**	**€ 61,598**

Through December 31, 2018, BioNTech received k€279,542 in upfront fees from Genentech under the Genentech Collaboration Agreement. Such amounts are initially deferred and subsequently recognized as revenue as the Company performs under the agreement and measured based on the costs incurred under the respective research programs. Of these upfront fees, k€49,536 was recognized as revenue in the year ended 2018 (k€27,829 in 2017). As of December 31, 2018, k€195,582 of upfront fees is recognized as deferred revenue within Contract liabilities in the statement of financial position.

Through December 31, 2018 BioNTech received k€59,560 in upfront and near-term milestone payments from Sanofi under the Sanofi Agreement. Such amounts are initially deferred and subsequently recognized as revenue as BioNTech performs under the agreement and measured based on the costs incurred under the respective research programs. Of these upfront fees, k€8,535 was recognized as revenue in the year ended 2018 (k€5,665 in 2017). As of December 31, 2018, k€38,716 of upfront fees is recognized as deferred revenue within Contract liabilities in the statement of financial position. In addition, during the year ended December 31, 2018, BioNTech recognized k€33,177 of revenue from Sanofi for reimbursement of 50% of CellScript sublicense costs pursuant to a separate sub-sublicense agreement dated December 22, 2018.

Revenue from BioNTech's collaborators that exceeds 10% of BioNTech's total revenue is included in the segments Clinical, Manufacturing and Technology Platform. Of the revenue from other sales transactions, k€10,748 in 2018 (k€10,652 in 2017) apply to product sales.

4.2 Contract balances

(in thousands)	December 31, 2018	December 31, 2017	January 1, 2017
Trade receivables	€ 18,938	€ 4,575	€ 3,161
Contract assets	—	—	637
Contract liabilities	€ 271,674	€ 291,372	€ 306,880

Trade receivables are non-interest bearing and are generally settled within 20 to 30 days.

Contract assets are recognized for revenue earned from BioNTech's performance of creating customer-specific cell and gene therapies. Upon completion of the produced product or upon reaching a contracted progress payment, the amounts recognized as contract assets are reclassified to trade receivables. As the customers' advance payments exceeded BioNTech's transferred goods and services for which a conditional right to consideration exists in all contracts in 2017 and 2018, only contract liabilities are presented.

Additionally, contract liabilities include long-term advances received from BioNTech's major collaboration and license agreements. The outstanding balances of these accounts decreased in 2018 and 2017 as revenues resulting from these agreements exceeded further payments received from the collaborators due to the achievement of milestones. BioNTech received payments or an unconditional right of consideration of k€71,761 in 2018 (2017: k€26,552) from the collaboration and license agreements and recognized revenues resulting from collaboration and license agreements of k€101,837 in 2018 (2017: k€42,333), which reduced the contract liabilities.

Set out below is the amount of revenue recognized from:

(in thousands)	2018	2017
Amounts included in contract liabilities at the beginning of the year	€ 65,068	€ 40,428

4.3 Performance obligations

Information about BioNTech's performance obligations is summarized below:

Collaboration and license agreements

BioNTech accounts for its promises to grant licenses as performance obligations satisfied over time as the customers simultaneously receive and consume the benefit of BioNTech's performance of providing access to its intellectual property as the performance occurs. BioNTech recognizes revenue over time by measuring the progress toward complete satisfaction of that performance obligation according to the method that demonstrates BioNTech's performance towards complete satisfaction. In contracts in which the costs vary based on the stage of research, an input-based measure considering cost incurred depicts most reliably the progress of the related research activities. In other contracts, revenue recognition on a straight-line basis most reliably depicts BioNTech's performance toward complete satisfaction.

The deferred revenue allocated to the remaining performance obligations (unsatisfied or partially unsatisfied) as atyear-end are as follows:

(in thousands)	2018	2017
Within one year	€ 64,522	€ 76,582
More than one year	€ 205,647	€ 214,026
Sum	**€ 270,169**	**€ 290,608**

The deferred revenue allocated to the remaining performance obligations does not contain deferred revenues of performance obligations which are part of contracts that have an original expected duration of one year or less or of performance obligations for which the consideration from the customer corresponds directly to the value to the customer of BioNTech's performance to date.

5 Group information

Information about subsidiaries

The consolidated financial statements of the Group include the following subsidiaries:

			% equity interest		
Name	Country of incorporation	Headquarter	2018	2017	As at January, 2017
BioNTech RNA Pharmaceuticals GmbH	Germany	Mainz	100%	100%	100%
BioNTech Protein Therapeutics GmbH	Germany	Mainz	100%	100%	100%
BioNTech Diagnostics GmbH	Germany	Mainz	100%	100%	100%
BioNTech Small Molecules GmbH	Germany	Mainz	100%	100%	100%
BioNTech Business Services GmbH	Germany	Mainz	100%	100%	—
BioNTech Austria Beteiligungen GmbH	Austria	Wien	100%	100%	100%
BioNTech Innovative Manufacturing Services GmbH (Frühere Eufets GmbH)	Germany	Idar-Oberstein	100%	100%	100%
JPT Peptide Technologies GmbH	Germany	Berlin	100%	100%	100%
TheraCode JPT Inc.	United States	Acton	100%	100%	100%
BioNTech Cell & Gene Therapies GmbH	Germany	Mainz	94.50%	94.50%	94.50%
Apta IT GmbH	Germany	Munich	100%	49.99%	49.99%
BioNTech Real Estate Verwaltungs GmbH	Germany	Holzkirchen	100%	—	—
BioNTech Real Estate GmbH & Co. KG	Germany	Holzkirchen	100%	—	—

BioNTech Real Estate Verwaltungs GmbH and BioNTech Real Estate GmbH & Co. KG were established during 2018.

Parent company

AT Impf GmbH, Munich, owns 54.16% (December 31, 2017 and January 1, 2017: 62.77%) of the ordinary shares in BioNTech and is the parent company of the Group.

Entity with significant influence over the Group

Medine GmbH, Mainz, owns 21.57% (December 31, 2017: 25%; January 1, 2017: 25.99%) of the ordinary shares in BioNTech and has significant influence over the Group.

6 Income and expenses

6.1 Costs of sales

(in thousands)

	Year ended December 31,	
	2018	2017
Wages and social security expenses	€ 6,726	€6,105
Laboratory supplies	1,368	2,849
Purchased Services	2,514	—
Depreciation	1,367	—
Other	1,715	364
Total	**€13,690**	**€9,318**

6.2 Research and development expenses

(in thousands)

	Year ended December 31,	
	2018	2017
Wages and social security expenses	€ 45,668	€ 31,970
Purchased services	42,079	22,686
Lab supplies	22,921	15,762
Depreciation	18,312	9,859
Lease and lease related cost	882	2,745
Other	13,178	2,474
Total	**€ 143,040**	**€ 85,496**

Other expenses were mainly comprised of clinical studies (2018: k€3,500; 2017: k€887), travel costs (2018: k€1,281; 2017: k€776) and incidental rental costs (2018: k€1,523; 2017: k€730).

6.3 Sales and marketing expenses

(in thousands)

	Year ended December 31,	
	2018	2017
Wages and social security expenses	€1,728	€1,631
Purchased services	794	2,771
Travel costs	267	260
Other	252	1,940
Total	**€3,041**	**€6,603**

In 2018, the other costs were mainly comprised of transport costs (k€119) and depreciation (k€21). In 2017, the other costs were mainly comprised of distribution costs of the entity TheraCode JPT Inc. (k€441) and transport costs (k€146).

6.4 General and administrative expenses

(in thousands)

	2018	2017
Wages and social security expenses	€ 8,582	€ 9,861
Purchased services	5,177	3,544
IT and office equipment	3,774	2,706
Depreciation	2,284	630
Office costs	608	1,611
Other	5,908	5,167
Total	**€ 26,334**	**€ 23,520**

In 2018, the other expenses were mainly comprised of travel costs (k€1,043), job advertisement expenses (k€861) and contract staffing (k€781). In the prior year, the other expenses were mainly comprised of job advertisement expenses (k€719), travel costs (k€247), training expenses (k€210) and incidental rental costs (k€182).

6.5 Other operating income

(in thousands)

	2018	2017
Government grants	€4,228	€2,266
Other	1,168	83
Total other operating income	**€5,396**	**€2,349**

6.6 Other operating expenses

(in thousands)

	2018	2017
Impairment intangible assets	€ 0	€281
Other	720	7
Total other operating expenses	**€720**	**€288**

In 2017, the impairment loss of k€281 represented the write-down of a software program as it was no longer usable.

6.7 Finance income

(in thousands)

	2018	2017
Finance income		
Interest income on cash	€1,996	€2,133
Foreign exchange gains (net)	6,050	—
Finance income	**€8,046**	**€2,133**

Finance income results from BioNTech's interests on short-term deposits.

6.8 Finance expense
(in thousands)

	2018	2017
Finance expense		
Financial instruments measured at amortised cost	€ 48	€ 53
Foreign exchange losses (net)	—	25.955
Finance expense	**€ 48**	**€26.007**

Foreign exchange losses are a result from the Group's unhedged USD cash accounts.

7 Income tax

Tax expense for the years ended December 31, 2018 and 2017 are comprised of current income taxes.

Reconciliation of tax expense to the estimated tax rate for the years ended 2017 and 2018 is as follows (in thousands):

	Year ended December 31,	
	2018	2017
Loss before tax	**€(47,662)**	**€(85,950)**
Expected tax benefit (based on BioNTech's statutory tax rate of 30.99%; prior year: 30.86%)	14,776	26,517
Effects		
Government grants exempted from taxes	28	17
Non deductible tax-expenses	(114)	(92)
Utilization of tax losses	1,165	—
Non-recognition of deferred taxes on tax losses and temporary differences	(13,634)	(26,015)
Other effects	(2,821)	(472)
Income tax expense	**€ (600)**	**€ (45)**

Deferred taxes

Deferred taxes relate to the following (in thousands):

2018	At January 1, 2018	Recognized in P&L	At December 31, 2018
Fixed Assets	€ (877)	€ 787	€ (90)
Inventories	83	(83)	—
Leases	83	223	306
Revenues	16,631	11,810	28,441
Accruals	73	61	134
Other	684	(523)	161
Deferred Tax Assets Net (before valuation)	**16,676**	**12,275**	**28,951**
Valuation Adjustment	**€ (16,676)**	**€ (12,275)**	**€ (28,951)**
Deferred Tax Assets Net (after valuation)	—	—	—

2017	At January 1, 2017	Recognized in P&L	At December 31, 2017
Fixed Assets	€ (454)	€ (423)	€ (877)
Inventories	83		83
Leases	—	83	83
Revenues	10,560	6,071	16,631
Bank accounts	(2,467)	3,122	655
Liabilities (currency losses)	—	28	28
Accruals	29	44	73
Deferred Tax Assets (before valuation)	**7,751**	**8,925**	**16,676**
Valuation Adjustment	**€ (7,751)**	**€ (8,925)**	**€ (16,676)**
Deferred Tax Assets (after valuation)	—	—	—

Accumulated tax losses of the Group amount to the following:

(in thousands)	Year ended December 31, 2018	Year ended December 31, 2017	January 1, 2017
Corporate Tax	€ 179,264	€ 178,491	€ 124,401
Trade Tax	176,425	176,024	122,904

Deferred tax assets on tax losses have not been capitalized as there is no sufficient probability in terms of IAS 12 that there will be future taxable profits available against which the unused tax losses can be utilized. The accumulated tax losses relate entirely to Germany. There is no expiration date for any for the accumulated tax losses under German law.

8 Earnings per share

Basic earnings per share (EPS) is calculated by dividing the loss 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:

(in thousands)	Year ended December 31, 2018	Year ended December 31, 2017
Loss attributable to ordinary equity holders of the parent for basic earnings	**€ (48,018)**	**€ (85,653)**
Weighted average number of ordinary shares for basic EPS*	**190,710**	**166,764**
Effects of dilution from share options	—	—
Weighted average number of ordinary shares adjusted for the effect of dilution*	**190,710**	**166,764**

* The weighted average number of shares takes into account the weighted average effect of changes in shares during the year.

There have been no other transactions involving ordinary shares or potential ordinary shares between the reporting date and the date of authorization of these financial statements. Stock options were not included in the calculation of diluted EPS because they are antidilutive for the periods presented.

9 Property, plant and equipment

(in thousands)	Land and buildings	Equipment, tools and installations	Construction in progress and advance payments	Total
Acquisition and production costs				
As of January 1, 2017	**€ 11,126**	**€ 39,944**	**€ 3,613**	**€ 54,683**
Additions	1,951	23,233	2,636	27,820
Disposals		(5,193)	—	(5,193)
Reclassifications		96	(96)	—
As of December 31, 2017	**€ 13,077**	**€ 58,080**	**€ 6,153**	**€ 77,310**
As of January 1, 2018	**13,077**	**58,080**	**6,153**	**77,310**
Additions	8,925	11,322	6,154	26,401
Disposals	—	(858)	—	(858)
Reclassifications	145	5,069	(5,216)	—
As of December 31, 2018	**€ 22,147**	**€ 73,613**	**€ 7,091**	**€102,853**

	Land and buildings	Equipment, tools and installations	Construction in progress and advance payments	Total
Cumulative depreciation and impairment charges				
As of January 1, 2017	**€ 5,232**	**€ 17,076**	**€ —**	**€22,308**
Depreciation	458	4,937	—	5,395
As of December 31, 2017	**€ 5,690**	**€ 22,013**	**€ —**	**€27,703**
As of January 1, 2018	**5,690**	**22,013**	**—**	**27,703**
Depreciation	782	8,349	—	9,131
Reclassifications	—	(182)	—	(182)
As of December 31, 2018	**€ 6,472**	**€ 30,180**	**€ —**	**€36,652**
Carrying amount				
As of January 1, 2017	**5,894**	**22,868**	**3,613**	**32,374**
As of December 31, 2017	**7,387**	**36,067**	**6,153**	**49,606**
As of December 31, 2018	**€15,675**	**€ 43,433**	**€ 7,091**	**€66,199**

Assets under construction

Assets under construction for buildings included in property, plant and equipment amounted to k€5,725 as of December 31, 2018 (December 31, 2017: k€1,327; January 1, 2017: nil).

10 Intangible assets

(in thousands)	Goodwill	Concessions, licenses and similar rights	Advance payments	Total
Acquisition costs				
As of January 1, 2017	**€ 534**	**€ 9,421**	**€ 3,839**	**€ 13,793**
Additions	—	74,500	1,077	75,577
Reclassifications	—	1,351	(1,351)	—
As at December 31, 2017	**€ 534**	**€ 85,271**	**€ 3,565**	**€ 89,370**
As of January 1, 2018	**€ 534**	**€ 85,271**	**€ 3,565**	**€ 89,370**
Additions	—	12,150	3,128	15,278
Disposals	—	—	(765)	(765)
Reclassifications	—	4,431	(4,431)	—
As at December 31, 2018	**€ 534**	**€ 101,853**	**€ 1,497**	**€103,883**

	Goodwill	Concessions, licenses and similar rights	Advance payments	Total
Cumulative amortization and impairment charges				
As of January 1, 2017	**€ —**	**€ 2,609**	**€ —**	**€ 2,609**
Amortization	—	2,943	—	2,943
Impairment loss	—	281	—	281
As at December 31, 2017	**€ —**	**€ 5,833**	**€ —**	**€ 5,833**
As of January 1, 2018	**€ —**	**€ 5,833**	**€ —**	**€ 5,833**
Amortization	—	10,009	—	10,009
As at December 31, 2018	**€ —**	**€ 15,842**	**€ —**	**€15,842**
Carrying amount				
As January 1, 2017	**€ 534**	**€ 6,812**	**€ 3,839**	**€11,185**
As of December 31, 2017	**534**	**79,438**	**3,565**	**83,537**
As of December 31, 2018	**€ 534**	**€ 86,011**	**€ 1,497**	**€88,042**

Intangible assets comprise a license with a carrying amount of k€55,420 (December 31, 2017: k€61,876; January 1, 2017: nil) and a useful lifetime of 10 years.

Impairments

In 2017, an impairment loss of k€281 was recorded for a software program. The impairment loss was recognized under other operating expenses.

Contractual commitments

Contractual commitments for the acquisition of intangible assets amounts to k€19,482 (2017: k€40,078; January 1, 2017: nil).

Goodwill

For impairment testing, goodwill acquired through business combinations and intangible assets not yet in use have been allocated to the respective cash-generating units.

CGUs are based on the level of legal entities. Therefore, the goodwill has been allocated to the CGU JPT.

	JPT		
(in thousands)	December 31, 2018	December 31, 2017	January 1, 2017
Goodwill	€ 534	534	534

The Group performed its annual goodwill impairment for the balance sheet dates January 1, 2017, December 31, 2017 and December 31, 2018.

The recoverable amount was determined on a value in use calculation using cash flow projections from budgets approved by senior management covering a five-year period.

Management concluded that no reasonable possible change of key assumptions on which the calculation of the recoverable amount is based would cause the carrying amount of the CGU to exceed its recoverable amount.

The pre-tax discount rate applied to cash flow projections for the year ended 2018 is 12.2% (December 31, 2017: 12.3%; January 1, 2017: 12.3%) and cash flows beyond the five-year period are extrapolated using a 1.0% growth rate (2017: 1.0%; 2016: 1.0%).

As the recoverable amount exceeded the carrying amount of the CGU for every balance sheet date, no impairment charge was required.

Intangible assets not yet available for use

In 2018, there were no intangible assets not yet available that were not recognized.

In 2017, the Group performed an impairment test for intangible assets not yet in use, which had carrying amounts of k€1,190 (January 1, 2017: nil).

The recoverable amount was determined on a value in use calculation. Intangible assets of k€1,190 were available for use as planned during the current period.

Management concluded that no reasonable possible change of key assumptions on which the calculation of the recoverable amount is based would cause the carrying amount of the CGU to exceed its recoverable amount.

11 Financial assets and financial liabilities

11.1 Capital risk management

The objective of the capital management of BioNTech is primarily designed to finance the Group's growth strategy.

The Group's controlling committee reviews the total amount of cash of the Group on a weekly basis. As part of this review, the committee considers the total cash and cash equivalents, the cash outflow, currency translation differences and refinancing activities. The Group monitors 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.

	December 31,		As at 1 January
(in thousands)	2018	2017	2017
Cash and cash equivalents	€ 411,495	€ 172,106	€ 303,680
Total	**€ 411,495**	**€ 172,106**	**€ 303,680**

In meeting its financing objectives, the Group negotiates and enters into research cooperation agreements. In general, the aim is to maximize the financial resources available for further research and development projects.

BioNTech is not subject to externally imposed capital requirements. The objectives of BioNTech's capital management were achieved in the reporting year.

No changes were made in the objectives, policies or processes for managing cash during the years ended December 31, 2018 and 2017.

11.2 Categories of financial instruments

Financial assets at amortised cost

(in thousands)	2018	2017	As at 1 January 2017
Trade receivables	€18,938	€4,575	€ 3,161
Receivables from co-operation agreements	—	—	1,373
Other financial assets and receivables	354	264	221
Total	**€19,292**	**€4,839**	**€ 4,755**
Total current	19,273	4,820	4,689
Total non-current	18	19	66

Financial liabilities: Interest-bearing loans and borrowings

(in thousands)	Maturity	2018	2017	As at 1 January 2017
2.15% €10,000,000 secured bank loan	12/30/2027	€4,000	—	—
2.08% €9,450,000 secured bank loan	09/30/2028	1,600	—	—
Total		**€5,600**	—	—
Total current		—	—	—
Total non-current		5,600	—	—

Other financial liabilities at amortised cost, other than interest-bearing loans and borrowings

(in thousands)	2018	2017	As at 1 January 2017
Trade and other payables	€41,721	€ 52,538	€ 6,218
Lease liabilities	50,752	52,182	28,132
Liabilities from license agreements	—	—	8,889
Other payables	6,132	1,938	2,412
Total	**€98,605**	**€106,658**	**€ 45,651**
Total current	49,987	56,309	18,983
Total non-current	48,618	50,349	26,669

2.15% secured loan

The loan is secured by a lien over land and buildings with a carrying value of k€10,000 (2017: nil). Additionally, the loan is secured by a permanent guarantee (*Höchstbetragsbürgschaft*) of the Company to the bank to the amount of k€10,000. The loan is repayable in equal quarterly instalments of k€312.5 commencing on March 31, 2020. As at December 31, 2018, the undrawn available amount is k€6,000.

2.08% bank loan

The loan is secured by a lien over land and buildings to the amount of k€9,450. Additionally, the loan is secured by a permanent guarantee (*Höchstbetragbürgschaft*) of the Company to the bank to the amount of k€9,450 (2017: nil). The loan is repayable by quarterly instalments of k€286.4 commencing on September 30, 2020. As at December 31, 2018, the available undrawn amount of k€7,850 will be drawn on predetermined dates. The loan will be fully drawn at January 15, 2020.

11.3 Fair values

Fair values of cash and cash equivalents, trade receivables, trade payables and other current liabilities approximate their carrying amounts largely due to the short-term maturities of these instruments.

The liabilities include two fixed-interest rate loans. The fair value of the two fixed-interest rate loans is calculated based on significant observable inputs (Level 2). As of December 31, 2018, the carrying value approximates their fair values as they were agreed only recently and there have been no significant changes in relevant interest rates.

11.4 Financial instruments risk management objectives and policies

The Group's financial liabilities comprise of bank loans, lease liabilities, trade and other payables. The main purpose of these financial liabilities is to enable the Group's operations. The Group's principal financial assets include mainly cash and trade receivables that derive directly from its operations.

The Group is exposed to market risk, credit risk and liquidity risk. The Group's senior management oversees the management of these risks.

The controlling committee provides assurance to the Group's senior management that the Group's financial risk activities are governed by appropriate policies and procedures and that financial risks are identified, measured and managed in accordance with the Group's policies and risk objectives. The Board of Directors reviews and agrees policies for managing each of these risks, which are summarized below.

11.5 Market risk

Market risk is the risk that the fair value or future cash flows of a financial instrument will fluctuate due to changes in market prices. Market risk comprises of three types of risk: interest risk, foreign currency risk and other price risk. Financial instruments affected by market risk include cash and cash equivalents. Interest risk is not a risk for the Group.

The sensitivity analysis in the following sections relate to the position as at December 31, 2018 and 2017.

There were no material changes in the Group's market risk exposures or changes in the way risk was managed and valued during the periods.

11.5.1 Foreign currency risk

Foreign currency risk is the risk that the fair value or future cash flows of an exposure will fluctuate because of changes in foreign exchange rates. The Group's exposure to the risk of changes in foreign currency rates relates primarily to the Group's operating activities (when revenue or expense is denominated in a foreign currency).

In order to reduce exchange rate risk, BioNTech makes every effort to generate expenses and income in the same functional currency. The Group does not hedge exchange rate risks.

The carrying amount of the monetary assets (the Group's cash and cash equivalents) of BioNTech denominated in foreign currencies at the reporting date are as follows:

	As at December 31,	
(in thousands)	2018	2017
USD Bank accounts	€ 176,376	€ 140,822

The following tables demonstrate the sensitivity to a reasonably possible change in USD exchange rates, with all other variables held constant. The impact on the Group's profit before tax is due to changes in the fair value of monetary assets. The Group's exposure to foreign currency changes for all other currencies is not material.

		Closing rate		As at January 1,	Average rate	
	1 € =					
Currency	Country	2018	2017	2017	2018	2017
USD	United States	1.1450	1.1993	1.1194	1.1810	1.1297

In k€	Change in USD rate	Effect on loss before tax	Effect on pre-tax equity
	+5%	(8,399)	(8,399)
2018			
	-5%	9,283	9,283
	+5%	(6,706)	(6,706)
2017			
	-5%	7,412	7,412

11.6 Credit risk management

Credit risk is the risk that a counterparty will not meet its obligations under a financial instrument or customer contract, leading to a financial loss. The Group is exposed to credit risk from its operating activities, including deposits with banks and financial institutions, foreign exchange transactions and trade accounts receivable.

Trade receivables and contract assets

The Group's exposure to credit risk of trade receivables and contract assets is primarily on transactions with corporate customers in the biopharma/biotech industry that operate in Germany or in the United States. The Group evaluates this risk through detailed aging analysis and also detailed analysis of the creditworthiness of the customers at each reporting date. The Group follows risk control procedures to assess the credit quality of the customers taking into account their financial position, past experience and other factors. The compliance with credit limits by corporate customers is regularly monitored by management.

The credit risk on trade receivables and contract assets is very low as the customer portfolio of BioNTech mainly consists of medical universities, other public institutions and peers in the biopharma industry, which all have a very high credit rating and the group has not incurred bad debt expense. BioNTech does not expect that its customer portfolio will change.

Generally, trade receivables are written off if past due for more than one year and are not subject to enforcement activity. The maximum exposure to credit risk at the reporting date is the carrying value of each class of financial assets disclosed in Note 11.2. The Group does not hold collateral as security.

The credit risk exposure on the Group's trade receivables and contract assets is as follows:

Year ended December 31, 2018

(in thousands)	Contract assets	Trade receivables
Expected credit loss rate	— %	— %
Estimated total gross carrying amount at default	€ —	€ 18,938
Expected credit loss	€ —	€ —

Year ended December 31, 2017

(in thousands)	Contract assets	Trade receivables
Expected credit loss rate	— %	— %
Estimated total gross carrying amount at default	€ —	€ 4,575
Expected credit loss	€ —	€ —

As at January 1, 2017

(in thousands)	Contract assets	Trade receivables
Expected credit loss rate	— %	— %
Estimated total gross carrying amount at default	€ 637	€ 3,161
Expected credit loss	€ —	€ —

Cash deposits

Credit risk from balances with banks and financial institutions is managed by the Group's controlling department in accordance with the Group's policy. Investments of surplus funds are made only with banks.

Credit risk stemming from cash and deposits is very low.

The Group's maximum exposure to credit risk for the components of the statements of financial position at December 31, 2018 and 2017 are the carrying amounts as illustrated in Note 11.1.

11.7 Liquidity risk

Historically, BioNTech has relied on the financing from shareholders and collaborators in order to ensure sufficient liquidity. Lack of external financial support could pose a risk of going concern. The liquidity management of BioNTech ensures the availability of cash and cash equivalents 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.

The Group monitors liquidity risks using a liquidity planning tool.

Ultimately, the responsibility for liquidity risk management lies with the management, which has established an appropriate approach to managing short-, medium- and long-term financing and liquidity requirements. BioNTech manages 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 a number of counterparties are engaged in similar business activities, or activities in the same geographical region, or have economic features that would cause their ability to meet contractual

obligations to be similarly affected by changes in economic, political or other conditions. Concentrations indicate the relative sensitivity of the Group's performance to developments affecting a particular industry.

In order to avoid concentrations of risk, the Group's policies and procedures include specific guidelines to focus on the maintenance of an effective diversification in the sources of funding and distribution of cash deposits. Identified concentrations of credit risks are controlled and managed accordingly.

The maturity profile of the Group's financial liabilities based on contractual undiscounted payments is summarized as follows:

Year ended December 31, 2018 (in thousands)	**Less than 1 year**	**1 to 5 years**	**> 5 years**	**Total**
Interest bearing loans and borrowings	—	5,600	—	**€ 5,600**
Trade payables	41,721	—	—	**41,721**
Lease liability	3,822	13,346	56,524	**73,692**
Other financial liabilities	6,132	—	—	**6,132**
Total	**€ 51,675**	**€ 13,346**	**€56,524**	**€127,145**

Year ended December 31, 2017 (in thousands)	**Less than 1 year**	**1 to 5 years**	**> 5 years**	**Total**
Trade payables	52,538	—	—	**€ 52,538**
Lease liability	3,552	13,743	59,263	**76,558**
Other financial liabilities	1,939	—	—	**1,939**
Total	**€ 58,029**	**€ 13,743**	**€59,263**	**€131,035**

As at January 1, 2017 (in thousands)	**Less than 1 year**	**1 to 5 years**	**> 5 years**	**Total**
Trade payables	6,218	—	—	**€ 6,218**
Lease liability	2,392	8,193	32,606	**43,191**
Other financial liabilities	11,301	—	—	**11,301**
Total	**€ 19,911**	**€ 8,193**	**€32,606**	**€60,701**

11.8 Changes in liabilities arising from financing activities

BioNTech uses leases to acquire the right to use assets for a specified amount of time. Due to the first-time adoption of IFRS 16, lease liabilities at an amount of k€28,132 were recognized as of January 1, 2017. The liability arising from leases amounts to k€52,182 as of December 31, 2017 and 50,775 as of December 31, 2018.

Year ended December 31, 2018 (in thousands)	**January 1, 2018**	**Cash flows**	**New Leases**	**Reclassification**	**December 31, 2018**
Current obligations under lease contracts	€ 1,832	(2,126)	296	2,132	2,134
Non-current obligations under lease contracts	€ 50,349	—	401	(2,132)	48,618
Interest-bearing loans and borrowings	—	5,600	—	—	5,600
Total	**€ 52,182**	**3,474**	**€ 697**	**€ —**	**€ 56,352**

Year ended December 31, 2017 (in thousands)	**January 1, 2017**	**Cash flows**	**New Leases**	**Reclassification**	**December 31, 2017**
Current obligations under lease contracts	1,464	(2,319)	—	2,687	1,832
Non-current obligations under lease contracts	26,669	676	25,692	(2,687)	50,349
Total	**€ 28,132**	**€(1,643)**	**€25,692**	**€ —**	**€ 52,182**

12 Inventories

(in thousands)	December 31, 2018	December 31, 2017	January 1, 2017
Raw materials and supplies	€ 4,475	€ 2,874	€ 2,702
Unfinished goods and services	80	95	10
Finished goods and services	1,234	907	554
Total inventories	**€ 5,789**	**€ 3,876**	**€ 3,266**

During 2018, inventories of k€5,382 (2017: k€7,448) were recognized as an expense and recognized in cost of sales.

BioNTech has not pledged any inventories as securities for liabilities.

13 Trade receivables

(in thousands)	December 31, 2018	December 31, 2017	January 1, 2017
Trade Receivables	18,938	4,575	3,161
Total	**€ 18,938**	**€ 4,575**	**€ 3,161**

Trade receivables are non-interest bearing and are generally due on terms of 20 to 30 days. As described in Note 11.6, expected credit loss for trade receivables is immaterial.

14 Other assets

	December 31,		As of 1 January
(in thousands)	2018	2017	2017
Sales tax receivable	**€8,611**	€3,832	€ 2,172
Prepayments on inventories	**155**	815	851
Other assets	**397**	1,630	1,676
Total	**€9,164**	**€6,227**	**€ 4,699**

Other assets were mainly comprised of interest income of k€270 (2017 other assets were mainly comprised of receivables due to grants of k€1,356).

15 Issued capital and reserves

Issued capital:

Authorized shares

	December 31,		As of 1 January
(in thousands)	2018	2017	2017
Ordinary shares	167,347	166,764	3,270
Series A shares	22,588	—	—
Qualifying shares	3,361	—	—
Total	**€193,296**	**€166,764**	**€ 3,270**

During the fiscal year 2018, the issued capital of BioNTech was increased by €26.5 million (2017: €163.5 million) to €193.3 million (2017: €166.8 million) in conjunction with a cash investment of €355.8 million. The capital increase in 2017 is due to a conversion of capital reserves into share capital. There were no cash proceeds in this transaction. Each share has a par value of €1.

16 Share-based payments

16.1 Description of share-based payments

At December 31, 2018 and 2017, the Group had the following share-based arrangements.

16.1.1 Employee Stock Ownership Plan (equity-settled)

On November 15, 2018, the Group established a share option program that grants selected employees options to receive shares in the company. The program is designed as an Employee Stock Ownership Plan (ESOP). The Group has offered the participants a certain number of rights (Option Rights) by explicit acceptance of the participants. The exercise of the Option Rights in accordance with the terms of the ESOP, gives the participants the right to obtain shares against payment of the exercise price. The Option Rights vest over four years, can only be exercised if the company has executed a public offering in the United States (IPO) and when meeting the Threshold Amount. Threshold Amount means the exercise price provided that such price increases by eight percentage points on the first and then each subsequent anniversary of the Allocation Date (September 26, 2018). The Option Rights can be exercised at the latest eight years after the Allocation Date. If they have not been exercised by that date, they will forfeit without compensation.

16.1.2 Share appreciation rights (equity-settled)

On December 1, 2017, the Group granted 582,714 shares to selected employees under the share appreciation rights (SAR) program. The shares vested immediately at the grant date (December 2017) as there were no vesting conditions.

There were no other SARs granted.

16.2 Measurement of fair values

16.2.1 Equity-settled share-based payment arrangement

The fair value of the employee share options 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 grant date.

The inputs used in the measurement of the fair values at grant date of the equity-settled share-based payment plan was as follows:

	Grant date 15 November 2018
Fair value at grant date	€ 7.41
Share price at grant date	€ 14.40
Exercise price	€ 10.14
Expected volatility (%)	46.0%
Expected life (years)	5.84
Expected dividends	0.0%
Risk-free interest rate (%)	0.05%

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.

16.2.2 Share appreciation rights

The fair value of the SARs has been determined using a discounted cash flow (DCF) model as of December 2017.

The inputs used in the measurement of the fair values at grant date of the SARs were as follows.

	Grant date 1 December 2017
Fair value	€ 10.13
WACC	8.2%
Tax rate	31.2%
Debt free net working capital (in % of sales)	5.5%
Risk-free interest rate (%)	1.2%
Long-term growth rate (%)	1.8%

Growth rate estimates are based on epidemiology data for different indications in focus geographies. The average market growth rates per indication and stage have been extrapolated with data derived from published industry research.

The expected life of the SARs is based on historical data and current expectations and is not necessarily indicative of exercise patterns that may occur.

Expected dividends were not incorporated into the measurement of fair value.

16.3 Reconciliation of outstanding share-options

The number and weighted-average exercise prices of share options under the ESOP were as follows:

Reconciliation of outstanding share options

	Number of options	Weighted average exercise price
Outstanding at 1 January 2018	—	—
Granted during the year	11,845,962	€ 10.14
Outstanding at 31 December 2018	**11,845,962**	€ 10.14
Exercisable at 31 December 2018	—	—

The options outstanding at December 31, 2018 have a weighted-average contractual life of 7.75 years.

16.4 Expense recognized in the statement of operations

The expense recognized for employee services received during the year is shown in the following table:

(in thousands)	2018	2017
Expense arising from equity-settled share-based payment transactions	**€7,641**	€5,909
Total	**€7,641**	**€5,909**

The expenses were recognized in the statement of operations as follows:

(in thousands)	2018	2017
Cost of sales	€ 114	€ —
Research and development expenses	6,786	3,620
Sales and marketing expenses	14	14
Administrative expenses	728	2,275
Total	**€7,641**	**€5,909**

There were no cancellations or modifications to the awards in 2018 or 2017.

16.5 Net settlement feature for withholding tax obligation

Under the agreement, BioNTech must withhold an amount for an employee's tax obligation associated with the share-based payment and transfer that amount in cash to the tax authority on the employee's behalf. BioNTech does not withhold shares in order to settle the employee's tax obligations. The Group withheld an amount of k€7,761 that was paid to the taxation authority in relation to the SARs in 2018.

17 Other liabilities

(in thousands)	2018	2017	As at 1 January 2017
Liabilities employees	€5,236	€19,277	€ 2,919
Other	3,864	5,494	1,148
Total	**€9,100**	**€24,771**	**€ 4,067**

Other liabilities comprise accruals for outstanding invoices in the amount of k€3,739 (2017: k€1,383) and several othernon-material positions.

18 Leases

18.1 Amounts recognized in the balance sheet

The following amounts relate to leases and are included in Property, plant and equipment.

Right-of-use assets

(in thousands)	2018	2017	1 January 2017
Buildings	€49,718	€51,772	€ 27,870
Equipment	21	81	192
Cars	27	62	71
Total	**€49,766**	**€51,915**	**€ 28,132**

The following amounts are included in other financial liabilities.

Lease liability

(in thousands)	2018	2017	1 January 2017
Current	€ 2,134	€ 1,832	€ 1,464
Non-current	48,618	50,349	26,669
Total	**€50,752**	**€52,182**	**€ 28,132**

Additions to the right-of-use assets during 2018 were k€723 (2017: k€25,662; as of January 1, 2017: k€28,132).

18.2 Amounts recognized in the statement of operations

Depreciation charge of right-of-use assets

(in thousands)	2018	2017
Buildings	€2,751	€1,759
Equipment	60	111
Cars	35	39
Total depreciation charge	**€2,846**	**€1,909**
Interest on lease liabilities	1,721	676
Expense related to short-term leases (included in other expenses)	431	442
Expense relating to leases of low-value assets that are not short-term leases (included in other expenses)	90	95
Total amounts recognised in statement of operations	**€5,088**	**€3,121**

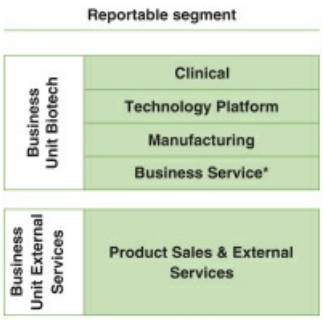
The total cash outflow for leases in 2018 amounted to k€3,847 (2017: k€2,319).

19 Segment information

BioNTech develops individualized treatments for cancer patients and improved therapeutics to treat infectious and rare diseases. This activity, together with research and development activities, forms the core of the company. External services provide the interface where medical products are sold to third parties.

BioNTech's business is managed in two business units, the biotech business unit and the external services business unit. The biotech business unit is comprised of three operation segments, which are individually monitored by the Chief Operating Decision Maker (CODM). Four operating segments have been identified in accordance with IFRS 8. No aggregation of operating segments was performed.

Resource allocation and performance assessment is performed at the level of the Management Board. The Management Board members are jointly responsible for the management and strategic decision making. Consequently, the Management Board has been identified as the CODM. BioNTech's business consist of the following reportable segments:



* Business Service bundles the Group's central functions. In line with IFRS 8.6, Business Services is not an operating segment but the information is separately disclosed

Research and Development activities form the Biotech Business Unit and are divided in the segments Clinical, Technology Platform and Manufacturing.

The **Clinical** segment subsumes all development activities relating to clinical programs. Clinical studies include testing the product candidates on humans. Clinical trials are an essential part of the development and licensing of the medicinal products and are performed before the respective product can be placed on the market. BioNTech is actively engaged in many collaborations and licensing deals with reputable pharmaceutical companies and academic partners.

Technology Platform contains all development activities relating to preclinical programs. Preclinical development is the stage of research that begins before clinical trials. It is performed to determine the desired pharmacological effects and to identify any unwanted effects that may cause adverse reactions during human exposure.

Manufacturing is an essential part of the research and development process as it comprises the manufacturing unit of mRNA and engineered cell therapies. All the medical substances and tools that form the basis for the research studies performed at BioNTech are manufactured in this segment, *(i.e.*, the Manufacturing segment contains only internally produced substances and tools).

Product Sales & External Services comprises the legal entities JPT Peptide Technology GmbH and Innovative Manufacturing Services GmbH (IMFS), which form the interface to third parties. External services and medicinal products (*e.g.*, peptides and retroviral vectors) that are in the areas of molecular immunotherapies and biomarker-based diagnostic approaches for individualized treatment of cancer and other infectious diseases are sold to customers worldwide.

Business Service contains the Group's central administrative functions (*e.g.*, Finance, Procurement, Human Resources, Legal and Intellectual Property) and overarching projects. Business Service does not fulfil the requirements for an operating segment according to IFRS 8, as it will never generate more than incidental revenues. However, financial information about Business Service is disclosed, as it contributes to the understanding of the company.

The table below reconciles segment figures to Group figures.

(in thousands)	Biotech Business Unit: Clinical	Biotech Business Unit: Technology Platform	Biotech Business Unit: Manufacturing	Biotech Business Unit: Business Service	External Services Business Unit: External Services	Total	Adjustments	Group
Year ended December 31, 2018								
Revenues								
Collaboration Revenue	€ 36,750	€ 39,452	€ 25,635	€ —	€ —	€ 101,837		€ 101,837
Revenues from other sales transactions	—	6,783	—	42	18,914	25,738		25,738
Cost of sales	—	—	—	(40)	(13,358)	(13,398)	(292)	(13,690)
Gross Profit	**€ 36,750**	**€ 46,235**	**€ 25,635**	**€ 2**	**€ 5,556**	**€ 114,177**	**€ (292)**	**€ 113,885**
Research and development expenses	(48,641)	(60,320)	(31,508)	(1,979)	(884)	(143,332)	292	(143,040)
Sales and marketing expenses	—	—	—	(2,106)	(935)	(3,041)		(3,041)
General and administrative expenses	—	—	(2,558)	(21,233)	(2,542)	(26,334)		(26,334)
Other result	3,772	178	30	85	559	4,624	52	4,676
Segment operating profit/loss	**€ (8,119)**	**€ (13,908)**	**€ (8,401)**	**€(25,231)**	**€ 1,753**	**€ (53,906)**	**€ 52**	**€ (53,854)**

	Biotech Business Unit: Clinical	Biotech Business Unit: Technology Platform	Biotech Business Unit: Manufacturing	Biotech Business Unit: Business Service	External Services Business Unit: External Services	Total	Adjustments	Group
Year ended December 31, 2017								
Revenues								
Collaboration Revenue	€ 25,721	€ 14,504	€ 2,108			€ 42,333		€ 42,333
Revenues from other sales transactions		324			18,941	19,265		19,265
Cost of sales					(9,318)	(9,318)		(9,318)
Gross Profit	**€ 25,721**	**€ 14,828**	**€ 2,108**	**€ 0**	**€ 9,623**	**€ 52,280**	**€ —**	**€ 52,280**
Research and development expenses	(25,099)	(37,019)	(14,764)	(6,701)	(1,912)	(85,496)	—	(85,496)
Sales and marketing expenses				(4,904)	(1,698)	(6,603)	—	(6,603)
General and administrative expenses			(785)	(20,309)	(2,427)	(23,520)	—	(23,520)
Other result		777		820	463	2,061	—	2,061
Segment operating profit/loss	**€ 623**	**€ (21,414)**	**€ (13,441)**	**€(31,094)**	**€ 4,049**	**€(61,277)**	**€ —**	**€(61,277)**

The segments are managed based on external sales and operating profit/loss, which represents the operating profit earned by each segment. Segment figures are reported consolidated, which reflects the way management steers the business.

BioNTech's internal reporting is generally set up in accordance with IFRS and in line with the Group's accounting policies, except for minor deviations in classification between cost of sales and research and development cost. Whenever revenues are attributable to different segments, these revenues are split based on the incurred cost. Internal overhead costs are allocated to segments based on revenues when they are directly attributable to a service rendered. Sales and marketing expenses, general and administrative expenses and the other result that are not directly attributable to one of the segments are allocated to Business Service.

To reconcile the segment figures to the Group's financial statements in 2018, the presentation of k€292 of research and development cost was adjusted.

Revenue at BioNTech can be differentiated between revenues resulting from collaboration and license agreements and revenues from other sales. The Company collaborates with reputable pharmaceutical and healthcare companies and several global academic collaborators. Revenues from other sales result from the sale of medical products (*e.g.*, peptides and retroviral vectors) for clinical supply. Research and development activities are managed on a worldwide basis but the operative manufacturing facilities and sales offices are located and managed in Germany. External sales are originated in Germany.

20 Related party disclosures

20.1 Parent and ultimate controlling party

Members of the Strüngmann family wholly own AT Impf GmbH. Dr. Andreas Strüngmann and Dr. Thomas Strüngmann may be deemed to beneficially own any or all of these shares.

20.2 Transactions with key management personnel

Key management personnel compensation

Key management personnel at BioNTech has been defined as the members of the Management Board and of the Supervisory Board. Key management personnel compensation is comprised of the following:

Compensation of key management personnel (in thousands)	**2018**	**2017**
Short-term employee benefits	€1,161	€ 880
Share-based compensation	6,163	1,855
Total compensation paid to key management personnel	**€7,324**	**€2,735**

Executive officers also participate in the Group's ESOP and SAR program (see Note 16).

Key management personnel transactions

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

The Group purchases various goods and services from research institutes where a director of BioNTech holds a key management position.

The aggregate value of transactions related to key management personnel were as follows:

Transaction

(in thousands)	2018	2017	As of 1 January 2017
Consulting services	€ 25	€ 25	€ 30
Purchases of various goods and services from TRON	€11,160	€6,553	€ 5,801

20.3 Other related party transactions

The total amount of transactions with AT Impf GmbH or entities controlled by them was as follows:.

	Transaction values for the year ended		
(in thousands)	2018	2017	As of 1 January 2017
Purchases of various goods and services from entities controlled by AT Impf GmbH	**€ 2,431**	€ 1,240	€ 1,050
Purchases of property and other assets from entities controlled by AT Impf GmbH	**€ 4,748**	€ —	€ —
Total	**€ 7,179**	**€ 1,240**	**€ 1,050**

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

21.1 In January 2019, BioNTech entered into an agreement to acquire MAB Discovery GmbH's operational antibody generation unit based near Munich, Germany for a total consideration of €6 million. The acquisition was completed on April 1, 2019.

21.2 In January 2019, BioNTech AG increased its Share Capital by k€5,088 in conjunction with a receipt of a cash investment of k€80,000.

21.3 In March 2019, BioNTech AG changed its legal form to a European company (*Societas Europaea* or "SE"). As an SE, BioNTech will be a public limited company under EU law. The supranational aspect of this legal form represents an international focus with Europe as the company's base, and is the next logical step in the development of BioNTech's worldwide operations.

21.4 In March 2019, BioNTech AG increased its share capital by k€2,375. In this transaction, an investor exchanged its shares in a subsidiary for shares of the parent company.

21.5 In May 2019, BioNTech entered into an agreement to purchase the assets of MabVax Therapeutics, Inc. The acquisition was completed on May 8, 2019. The total purchase price was $5 million.

21.6 In June 2019, BioNTech SE increased its share capital by k€11,990 in conjunction with the Series B financing.

21.7 On September 18, 2019, BioNTech effected a 1:18 share split by issuing 206,595,492 shares by way of a capital increase from our funds; thus, no contribution by investors was made. This capital increase came into effect upon registration with the commercial register (Handelsregister). The accompanying financial statements and notes to the financial statements give retroactive effect to the share split for all periods presented.

NEON THERAPEUTICS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS (UNAUDITED)
(In thousands, except share and per share amounts)

	September 30, 2019	December 31, 2018
Assets		
Current assets:		
Cash and cash equivalents	$ 44,278	$ 52,700
Marketable securities	—	50,611
Prepaid expenses and other current assets	2,036	2,116
Total current assets	46,314	105,427
Operating lease, right-of-use assets	7,848	—
Property and equipment, net	7,670	8,205
Other long-term assets	485	456
Total assets	$ 62,317	$ 114,088
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 1,935	$ 4,268
Accrued expenses	6,968	8,422
Operating lease liabilities, current	1,196	—
Total current liabilities	10,099	12,690
Operating lease liabilities, net of current portion	6,875	—
Other liabilities	9	149
Total liabilities	16,983	12,839
Commitments and contingencies (Note 8)		
Stockholders' equity:		
Common stock, $0.001 par value; 150,000,000 shares authorized as of September 30, 2019 and December 31, 2018; 28,339,196 and 28,314,274 shares issued and outstanding as of September 30, 2019 and December 31, 2018, respectively	28	28
Additional paid-in capital	281,004	275,058
Accumulated other comprehensive loss	—	(75)
Accumulated deficit	(235,698)	(173,762)
Total stockholders' equity	45,334	101,249
Total liabilities and stockholders' equity	$ 62,317	$ 114,088

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

NEON THERAPEUTICS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS (UNAUDITED)
(In thousands, except per share amounts)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Operating expenses:				
Research and development	$ 14,120	$ 14,441	$ 47,027	$ 42,403
General and administrative	5,134	4,612	16,122	12,524
Total operating expenses	19,254	19,053	63,149	54,927
Loss from operations	(19,254)	(19,053)	(63,149)	(54,927)
Other income (expense), net				
Interest income	278	672	1,252	1,136
Other expense	(4)	(10)	(39)	(20)
Total other income, net	274	662	1,213	1,116
Net loss	(18,980)	(18,391)	(61,936)	(53,811)
Accretion of redeemable convertible preferred stock to redemption value	—	—	—	(6,371)
Net loss attributable to common stockholders	$ (18,980)	$ (18,391)	$ (61,936)	$ (60,182)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.68)	$ (0.67)	$ (2.23)	$ (5.55)
Weighted average common shares outstanding, basic and diluted	27,935,073	27,357,812	27,792,148	10,833,984
Comprehensive loss:				
Net loss	$ (18,980)	$ (18,391)	$ (61,936)	$ (53,811)
Other comprehensive income (loss):				
Unrealized gains (losses) on marketable securities	—	(22)	75	(11)
Total other comprehensive income (loss)	—	(22)	75	(11)
Comprehensive loss	$ (18,980)	$ (18,413)	$ (61,861)	$ (53,822)

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

NEON THERAPEUTICS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF REDEEMABLE CONVERTIBLE PREFERRED STOCK, CONTINGENTLY REDEEMABLE RESTRICTED COMMON STOCK AND STOCKHOLDERS' EQUITY (DEFICIT) (UNAUDITED)
(In thousands, except share amounts)

	Redeemable Convertible Preferred Stock		Contingently Redeemable Restricted Common Stock	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount		Shares	Amount				
Balance at December 31, 2018	—	$ —	$ —	28,314,274	$ 28	$ 275,058	$ (75)	$ (173,762)	$ 101,249
Stock-based compensation expense	—	—	—	—	—	1,729	—	—	1,729
Exercise of stock options	—	—	—	17,070	—	45	—	—	45
Vesting of restricted common stock	—	—	—	—	—	5	—	—	5
Unrealized gains on marketable securities	—	—	—	—	—	—	67	—	67
Net loss	—	—	—	—	—	—	—	(21,024)	(21,024)
Balance at March 31, 2019	—	$ —	$ —	28,331,344	$ 28	$ 276,837	$ (8)	$ (194,786)	$ 82,071
Stock-based compensation expense	—	—	—	—	—	2,054	—	—	2,054
Issuance of restricted common stock	—	—	—	25,000	—	—	—	—	—
Vesting of restricted common stock	—	—	—	—	—	5	—	—	5
Unrealized gains on marketable securities	—	—	—	—	—	—	8	—	8
Net loss	—	—	—	—	—	—	—	(21,932)	(21,932)
Balance at June 30, 2019	—	$ —	$ —	28,356,344	$ 28	$ 278,896	$ —	$ (216,718)	$ 62,206
Stock-based compensation expense	—	—	—	—	—	2,034	—	—	2,034
Exercise of stock options	—	—	—	27,062	—	70	—	—	70
Cancellation of restricted common stock	—	—	—	(44,210)	—	—	—	—	—
Vesting of restricted common stock	—	—	—	—	—	4	—	—	4
Net loss	—	—	—	—	—	—	—	(18,980)	(18,980)
Balance at September 30, 2019	—	$ —	$ —	28,339,196	$ 28	$ 281,004	$ —	$ (235,698)	$ 45,334
Balance at December 31, 2017	93,222,418	$174,895	$ 355	3,302,927	$ 3	$ —	$ (13)	$ (93,562)	$ (93,572)
Stock-based compensation expense	—	—	99	—	—	1,551	—	—	1,551
Accretion of redeemable convertible preferred stock to redemption value	—	3,186	—	—	—	(1,557)	—	(1,629)	(3,186)
Vesting of restricted common stock	—	—	—	—	—	6	—	—	6
Unrealized gains on marketable securities	—	—	—	—	—	—	5	—	5
Net loss	—	—	—	—	—	—	—	(16,520)	(16,520)
Balance at March 31, 2018	93,222,418	$178,081	$ 454	3,302,927	$ 3	$ —	$ (8)	$ (111,711)	$ (111,716)

	Redeemable Convertible Preferred Stock		Contingently Redeemable Restricted Common Stock	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount		Shares	Amount				
Stock-based compensation expense	—	—	111	—	—	1,311	—	—	1,311
Accretion of redeemable convertible preferred stock to redemption value	—	3,185	—	—	—	(1,548)	—	(1,638)	(3,186)
Conversion of redeemable convertible preferred stock and contingently redeemable restricted common stock to common stock	(93,222,418)	(181,266)	(565)	18,644,462	19	181,812	—	—	181,831
Issuance of common stock upon completion of initial public offering, net of commissions, underwriting discounts and offering costs	—	—	—	6,250,000	6	89,661	—	—	89,667
Exercise of stock options	—	—	—	84,444	—	228	—	—	228
Cancellation of restricted common stock	—	—	—	(2,625)	—	—	—	—	—
Vesting of restricted common stock	—	—	—	—	—	6	—	—	6
Unrealized gains on marketable securities	—	—	—	—	—	—	6	—	6
Net loss	—	—	—	—	—	—	—	(18,899)	(18,899)
Balance at June 30, 2018	—	$ —	$ —	28,279,208	$ 28	$ 271,470	$ (2)	$ (132,248)	$ 139,248
Stock-based compensation expense	—	—	—	—	—	1,643	—	—	1,643
Finalization of offering costs related to initial public offering	—	—	—	—	—	253	—	—	253
Exercise of stock options	—	—	—	44,209	—	171	—	—	171
Cancellation of restricted common stock	—	—	—	(10,000)	—	—	—	—	—
Vesting of restricted common stock	—	—	—	—	—	5	—	—	5
Unrealized losses on marketable securities	—	—	—	—	—	—	(22)	—	(22)
Net loss	—	—	—	—	—	—	—	(18,391)	(18,391)
Balance at September 30, 2018	—	$ —	$ —	28,313,417	$ 28	$ 273,542	$ (24)	$ (150,639)	$ 122,907

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

NEON THERAPEUTICS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS (UNAUDITED)
(In thousands)

	Nine Months Ended September 30,	
	2019	2018
Cash flows from operating activities:		
Net loss	$ (61,936)	$ (53,811)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization expense	1,266	1,066
Non-cash lease expense	880	—
Net accretion (amortization) of premiums and discounts on marketable securities	5	(4)
Stock-based compensation expense	5,817	4,715
Loss on disposal of property and equipment	39	21
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	80	(493)
Other long-term assets	(29)	125
Accounts payable	(2,078)	490
Accrued expenses and other liabilities	(1,212)	2,349
Lease liabilities	(781)	—
Net cash used in operating activities	(57,949)	(45,542)
Cash flows from investing activities:		
Purchases of marketable securities	—	(72,939)
Sales and maturities of marketable securities	50,681	33,250
Purchases of property and equipment	(1,267)	(2,608)
Net cash provided by (used in) investing activities	49,414	(42,297)
Cash flows from financing activities:		
Proceeds from initial public offering of common stock, net of commissions and underwriting discounts	—	93,000
Payment of initial public offering costs	—	(3,030)
Proceeds from exercise of stock options	115	399
Repurchase of unvested restricted common stock	(2)	(1)
Net cash provided by financing activities	113	90,368
Net (decrease) increase in cash, cash equivalents and restricted cash	(8,422)	2,529
Cash, cash equivalents and restricted cash, beginning of period	53,156	58,857
Cash, cash equivalents and restricted cash, end of period	$ 44,734	$ 61,386
Supplemental disclosure of non-cash items:		
Accretion of redeemable convertible preferred stock to redemption value	$ —	$ 6,371
Purchases of property and equipment included in accounts payable and accrued expenses	$ —	$ 472
Conversion of redeemable convertible preferred stock and contingently redeemable restricted common stock to common stock upon closing of the initial public offering	$ —	$ 181,831

The following table provides a reconciliation of the cash, cash equivalents and restricted cash balances as of each of the periods shown above:

	September 30,	
	2019	2018
Cash and cash equivalents	$ 44,278	$ 60,779
Restricted cash included in other long-term assets	456	607
Total cash, cash equivalents and restricted cash	$ 44,734	$ 61,386

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

NEON THERAPEUTICS, INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(UNAUDITED)

1. Nature of the Business

Neon Therapeutics, Inc. (the "Company") is a clinical-stage immuno-oncology company and a leader in the field of neoantigen-targeted therapies, dedicated to transforming the treatment of cancer by directing the immune system towards neoantigens. The Company is leveraging its neoantigen platform and over a decade of insights from its founders to develop neoantigen-targeted therapies that use two distinct approaches, NEON / ONE and NEON / SELECT. These approaches focus on targeting a prioritized set of what the Company believes are the most therapeutically-relevant neoantigens. In NEON / ONE, which includes the Company's NEO-PV-01 and NEO-PTC-01 programs, these neoantigens are specific to each individual. In NEON / SELECT, these neoantigens are shared across subsets of patients or tumor types. The Company is applying these two approaches to develop neoantigen-targeted product candidates using multiple treatment modalities.

NEO-PV-01, the Company's most advanced product candidate, is a personal neoantigen vaccine that is custom-designed and manufactured based on the unique mutational fingerprint of each individual patient. The neoantigen-targeted peptides in NEO-PV-01 are intended to generate an immune response that trains each patient's immune system to target his or her individual tumor's particular neoantigens and kill the cancer cells. NEO-PV-01 is currently being evaluated in multiple Phase 1b clinical trials.

- In July 2019, the Company reported top-line results, including at least 12-month median follow-up from NT-001, the Company's ongoing, multi-center Phase 1b clinical trial evaluating NEO-PV-01 in combination with OPDIVO® (nivolumab) in patients with advanced or metastatic melanoma, smoking-associated non-small cell lung cancer ("NSCLC") and bladder cancer. Across all three distinct tumor types, patients demonstrated prolonged and consistent improvements in progression-free survival and overall survival compared to that observed in checkpoint inhibitor monotherapy, based on historical benchmark data.
- In April 2019, the Company completed enrollment in NT-002, the Company's Phase 1b clinical trial evaluating NEO-PV-01 in combination with the current standard of care, KEYTRUDA® (pembrolizumab) and chemotherapy, in first-line patients with untreated advanced or metastatic smoking-associated NSCLC.
- The Company is conducting its NT-003 trial in melanoma to evaluate NEO-PV-01 and OPDIVO in combination with other agents, including a CD40 agonist or a CTLA-4 antagonist, to potentially further enhance NEO-PV-01-induced neoantigen immune response and improve clinical outcomes.

NEO-PTC-01, the Company's personal neoantigen T cell therapy, consists of multiple T cell populations targeting what the Company predicts to be the most therapeutically-relevant neoantigens from each patient's tumor. NEO-PTC-01 is currently in preclinical development, and the Company expects to file a clinical trial application in Europe by the end of 2019 to evaluate NEO-PTC-01 in solid tumors in patients who are refractory to checkpoint inhibitors.

NEON / SELECT is the Company's precision medicine approach to neoantigen-targeted therapies. The Company's first product candidate using this approach, NEO-SV-01, is a neoantigen vaccine for the treatment of a genetically defined subset of hormone-receptor-positive breast cancer, for which an Investigational New Drug application was cleared by the U.S. Food and Drug Administration in August 2019.

The Company is subject to risks common to early-stage companies in the biotechnology industry including, but not limited to, development by competitors of new technological innovations, protection of proprietary technology, dependence on key personnel, compliance with government regulations and the ability to obtain additional financing to fund operations. Product candidates currently under development will require significant

additional research and development efforts, including extensive preclinical and clinical testing and regulatory approval, prior to commercialization. These efforts require significant amounts of additional capital, adequate personnel infrastructure and extensive compliance-reporting capabilities. Even if the Company's development efforts are successful, it is uncertain when, if ever, the Company will realize significant revenue from product sales.

Initial Public Offering

On June 29, 2018, the Company completed an initial public offering ("IPO") of its common stock and issued and sold 6,250,000 shares of common stock at a public offering price of $16.00 per share, resulting in net proceeds of $89.9 million after deducting underwriting discounts, commissions and other offering costs. Upon the closing of the IPO in June 2018, all shares of the Company's outstanding redeemable convertible preferred stock converted into an aggregate of 18,644,462 shares of common stock (see Note 9). In advance of the IPO, the board of directors and the stockholders of the Company approved a one-for-five reverse split of the Company's issued and outstanding common stock that became effective on June 13, 2018. All common share and per share amounts in these condensed consolidated financial statements have been retroactively adjusted for all periods presented to give effect to the reverse stock split.

Liquidity

In accordance with Accounting Standards Update ("ASU") No. 2014-15, *Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern (Subtopic 205-40)*, management must evaluate whether there are conditions or events, when considered in the aggregate, that raise substantial doubt about the Company's ability to continue as a going concern within one year after the date that the financial statements are issued. This evaluation initially does not take into consideration the potential mitigating effect of management's plans that have not been fully implemented as of the date the financial statements are issued. When substantial doubt exists under this methodology, management evaluates whether the mitigating effect of its plans sufficiently alleviates substantial doubt about the company's ability to continue as a going concern. The mitigating effect of management's plans, however, is only considered if both (1) it is probable that the plans will be effectively implemented within one year after the date that the financial statements are issued, and (2) it is probable that the plans, when implemented, will mitigate the relevant conditions or events that raise substantial doubt about the entity's ability to continue as a going concern within one year after the date that the financial statements are issued. Generally, to be considered probable of being effectively implemented, the plans must have been approved before the date that the financial statements are issued.

The Company's financial statements have been prepared on the basis of continuity of operations, realization of assets and the satisfaction of liabilities in the ordinary course of business. Through September 30, 2019, the Company has funded its operations primarily with net proceeds of $89.9 million from its IPO, as well as an aggregate of $161.1 million of net proceeds from sales of the Company's preferred stock and convertible debt. Since inception, the Company has incurred recurring losses and negative cash flows from operations in each period and on an aggregate basis. As of September 30, 2019 and December 31, 2018, the Company had an accumulated deficit of $235.7 million and $173.8 million, respectively. The Company expects its operating losses and negative operating cash flows to continue into the foreseeable future as it continues to develop, manufacture and commercialize its products.

As of September 30, 2019, the Company had cash and cash equivalents of $44.3 million. The Company expects that, based on its current operating plan, its cash and cash equivalents will be sufficient to fund its operating expenses and capital expenditure requirements into June 2020. The future viability of the Company beyond that point is dependent on its ability to raise additional capital to finance its operations. Although the Company has been successful in raising capital in the past, there is no assurance that it will be successful in obtaining such additional financing on terms acceptable to the Company, if at all.

The Company expects that it will continue to incur significant expenses in connection with its ongoing business activities. As a result, the Company will need substantial additional funding to support its continuing operations and pursue its growth strategy. Until such time as the Company can generate significant revenue from product sales, if ever, it expects to finance its operations through the sale of equity, debt financings or other capital sources, including collaborations with other companies or other strategic transactions. The Company may be unable to raise additional funds or enter into such other agreements or arrangements when needed on favorable terms, or at all. If the Company is unable to obtain funding on a timely basis, the Company may be required to curtail, delay or discontinue one or more of its research and development programs or may be unable to expand its operations or otherwise capitalize on its business opportunities, as desired, which could materially affect the Company's business, financial condition and results of operations.

The Company has determined that its cash runway of less than twelve months, along with its accumulated deficit, history of losses and future expected losses, raises substantial doubt about the Company's ability to continue as a going concern within one year from the issuance date of these interim condensed consolidated financial statements. While the Company has plans in place to mitigate this risk, which primarily consist of raising additional capital through a combination of equity or debt financings, and, depending on the availability and level of additional financings, potentially new collaborations and reducing cash expenditures, there is no guarantee that the Company will be successful in these mitigation efforts.

2. Summary of Significant Accounting Policies

Basis of Presentation and Consolidation

The accompanying condensed consolidated financial statements and the related disclosures are unaudited and have been prepared in conformity with the accounting principles generally accepted in the United States ("GAAP") and include the accounts of Neon Therapeutics, Inc. and its wholly owned subsidiary, Neon Securities Corporation. All intercompany transactions and balances have been eliminated. The Company consolidates entities in which it has a controlling financial interest.

Additionally, certain information and footnote disclosures normally included in the Company's annual financial statements have been condensed or omitted. Accordingly, these interim condensed consolidated financial statements should be read in conjunction with the consolidated financial statements as of and for the year ended December 31, 2018, and notes thereto, which are contained in the Company's Annual Report on Form 10-K for the year ended December 31, 2018 filed with the Securities and Exchange Commission (the "SEC") on March 11, 2019 (the "Annual Report on Form 10-K").

The unaudited interim condensed consolidated financial statements have been prepared on the same basis as the audited consolidated financial statements and, in the opinion of management, reflect all normal recurring adjustments considered necessary for a fair presentation of the Company's financial position as of September 30, 2019, and the results of its operations for the three and nine months ended September 30, 2019 and 2018, and its cash flows for the nine months ended September 30, 2019 and 2018. The results of operations for the three and nine months ended September 30, 2019 are not necessarily indicative of the results that may be expected for the full year or any other subsequent interim period.

Summary of Significant Accounting Policies

The significant accounting policies and estimates used in the preparation of the condensed consolidated financial statements are described in the Company's audited financial statements as of and for the year ended December 31, 2018, and the notes thereto, which are included in the Company's Annual Report on Form 10- K. There have been no material changes in the Company's significant accounting policies during the nine months ended September 30, 2019, except as discussed below with respect to the adoption of ASU No. 2016-02, *Leases (Topic 842)* ("ASU 2016-02"), as amended.

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of expenses during the reporting periods. Significant estimates of accounting reflected in these condensed consolidated financial statements include, but are not limited to, estimates related to accrued expenses, the valuation of common stock prior to the completion of the Company's IPO, stock-based compensation, the present value of lease liabilities and the corresponding right-of-use assets and income taxes. The Company bases its estimates on historical experience and other market specific or other relevant assumptions it believes to be reasonable under the circumstances. On an ongoing basis, management evaluates its estimates, as there are changes in circumstances, facts and experience. Actual results could differ from those estimates or assumptions.

Recently Adopted Accounting Pronouncements

ASU No. 2016-02, Leases

In February 2016, the Financial Accounting Standards Board ("FASB") issuedASU 2016-02, which requires lessees to recognize most leases on their balance sheet as a right-of-use asset and a lease liability, as well as provide disclosures with respect to certain qualitative and quantitative information related to a company's leasing arrangements. Leases are classified as either operating or finance based on criteria similar to existing lease accounting, with the classification affecting the pattern and classification of expense recognition in the statement of operations. The FASB subsequently issued ASU No. 2018-11, *Leases (Topic 842): Targeted Improvements*, which includes certain amendments to ASU2016-02 intended to provide relief in implementing the new standard. Among these amendments is the option to not restate comparative periods presented in the financial statements. The Company adopted these amendments with ASU 2016-02 (collectively, the "New Leasing Standards") effective January 1, 2019.

The Company adopted the New Leasing Standards as of the effective date of January 1, 2019, with no restatement of prior periods or cumulative adjustment to retained earnings. Comparative periods in the Company's financial statements will be presented in accordance with the existing guidance under Accounting Standards Codification ("ASC") Topic 840, *Leases*. Upon adoption, the Company took advantage of the transition package of practical expedients permitted within ASU 2016-02, which allowed the Company not to reassess previous accounting conclusions around whether arrangements are, or contain, leases, as well as to carry forward both the historical classification of leases and the treatment of initial direct costs for existing leases. In addition, the Company also has made an accounting policy election to exclude leases with an initial term of twelve months or less from its balance sheet.

Under the New Leasing Standards, the Company determines whether an arrangement is or contains a lease at the inception of the contract based on the unique facts and circumstances around identified assets, if present, and control over those identified assets. Operating lease assets and liabilities are recognized at the commencement date of the lease based upon the present value of lease payments over the lease term. When determining the lease term, the Company includes options to extend or terminate the lease when it is reasonably certain that it will exercise that option. The Company uses the implicit rate when readily determinable and uses its estimated incremental borrowing rate when the implicit rate is not readily determinable based upon the information available at the commencement date in determining the present value of the lease payments. The incremental borrowing rate is determined using a secured borrowing rate for the same currency and term as the associated lease.

The Company recognizes lease costs on a straight-line basis over the lease term, and includes amounts related to short-term leases.

Adoption of the New Leasing Standards resulted in the recognition of operating leaseright-of-use assets and operating lease liabilities of approximately $8.7 million and $8.9 million, respectively, as of January 1, 2019.

Upon adoption and as of September 30, 2019, the Company did not have any finance leases. The adoption of the New Leasing Standards did not materially impact the Company's condensed consolidated statement of operations.

Refer to Note 7, Leases, for further information on the application of ASU2016-02 to the Company's current lease commitments.

ASU No. 2018-07, Improvements to Nonemployee Share-Based Payment Accounting

In June 2018, the FASB issued ASU No.2018-07, *Compensation—Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting* ("ASU 2018-07"). The standard expands the scope of ASC 718 to include all share-based payment arrangements related to the acquisition of goods and services from both nonemployees and employees. Under the amended guidance, equity-classified share-based payment awards issued to nonemployees will be measured at grant date fair value. Upon transition, the entity is required to remeasure these nonemployee awards at fair value as of the adoption date.

The Company adopted this standard as of the effective date of January 1, 2019. Prior to the adoption of ASU2018-07, for share-based awards granted to nonemployees, compensation expense was recognized over the period during which services were rendered by such nonemployees until completed. At the end of each financial reporting period prior to completion of the service, the fair value of these awards was remeasured using the then-current fair value of the Company's common shares and updated assumption inputs in the Black-Scholes option-pricing model, as applicable. After the adoption of ASU 2018-07, equity-classified share-based payment awards issued to nonemployees are measured at grant date fair value similarly to those of employees and are no longer revalued as the equity instruments vest. The new standard allows entities to use the expected term to measure nonemployee options or elect to use the contractual term as the expected term, on an award-by-award basis. The adoption of the standard did not have a material impact on the Company's condensed consolidated financial statements.

Recently Issued Accounting Pronouncements

In June 2016, the FASB issued ASU No.2016-13, *Financial Instruments-Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments* ("ASU 2016-13"). The new standard requires that expected credit losses relating to financial assets measured on an amortized cost basis and available-for-sale debt securities be recorded through an allowance for credit losses. It also limits the amount of credit losses to be recognized for available-for-sale debt securities to the amount by which carrying value exceeds fair value and also requires the reversal of previously recognized credit losses if fair value increases. ASU 2016-13 is effective for the Company on January 1, 2020. Early adoption is permitted. The Company is currently evaluating the potential impact that the adoption of this standard will have on its condensed consolidated financial statements.

In August 2018, the FASB issued ASUNo. 2018-13, *Fair Value Measurement (Topic 820): Disclosure Framework—Changes to the Disclosure Requirements for Fair Value Measurement* ("ASU 2018-13"), which modifies the disclosure requirements on fair value measurements. ASU2018-13 is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2019. Early adoption is permitted. The Company does not anticipate a material impact to the condensed consolidated financial statements as a result of the adoption of this standard.

In August 2018, the FASB issued ASUNo. 2018-15, *Intangibles—Goodwill and Other—Internal-Use Software (Subtopic 350-40): Customer's Accounting for Implementation Costs Incurred in a Cloud Computing Arrangement That Is a Service Contract* ("ASU 2018-15"), which clarifies the accounting for implementation costs in cloud computing arrangements. ASU 2018-15 is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2019. Early adoption is permitted. The Company is currently evaluating the impact that the adoption of this amendment will have on its condensed consolidated financial statements.

3. Fair Value Measurement

The following tables present information about the Company's assets that are measured at fair value on a recurring basis and indicate the level of the fair value hierarchy utilized to determine such fair values (in thousands):

		Fair Value Measurements at September 30, 2019 Using:		
	Total	Level 1	Level 2	Level 3
Cash equivalents:				
Money market funds	$ 44,010	$ 44,010	$ —	$ —
	$ 44,010	$ 44,010	$ —	$ —

		Fair Value Measurements at December 31, 2018 Using:		
	Total	Level 1	Level 2	Level 3
Cash equivalents:				
Money market funds	$ 53,188	$ 53,188	$ —	$ —
Marketable securities:				
Corporate debt securities	46,122	—	46,122	—
Commercial paper	4,489	—	4,489	—
	$ 103,799	$ 53,188	$ 50,611	$ —

There were no changes in valuation techniques or transfers between the fair value measurement levels during the three and nine months ended September 30, 2019 or 2018. There were no liabilities measured at fair value on a recurring basis as of September 30, 2019 or December 31, 2018.

4. Marketable Securities

The Company did not hold any marketable securities at September 30, 2019. Marketable securities consisted of the following at December 31, 2018 (in thousands):

	December 31, 2018			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Short-term investments:				
Corporate debt securities	$ 46,197	$ —	$ (75)	$46,122
Commercial paper	4,489	—	—	4,489
	$ 50,686	$ —	$ (75)	$50,611

As of December 31, 2018, the aggregate fair value of securities that were in an unrealized loss position for less than twelve months was $46.1 million. The Company did not intend to sell the investments, and it was not more likely than not that the Company would be required to sell the investments before recovery of their amortized cost bases. As a result, the Company determined that it did not hold any securities with any other-than-temporary impairment as of December 31, 2018.

There were no sales of available-for-sale securities during the three or nine months ended September 30, 2019 or 2018. Net unrealized holding gains or losses for the period that have been included in accumulated other comprehensive loss were not material to the Company's condensed consolidated results of operations.

5. Property and Equipment, Net

Property and equipment, net consisted of the following (in thousands):

	September 30, 2019	December 31, 2018
Software	$ 1,180	$ 1,180
Laboratory equipment	9,417	8,230
Computer equipment	102	102
Furniture and fixtures	317	371
Leasehold improvements	680	592
Assets under construction	—	511
	11,696	10,986
Less: Accumulated depreciation and amortization	(4,026)	(2,781)
	$ 7,670	$ 8,205

Depreciation and amortization expense for the three and nine months ended September 30, 2019 was $0.4 million and $1.3 million, respectively, and for three and nine months ended September 30, 2018 was $0.4 million and $1.1 million, respectively.

6. Accrued Expenses

Accrued expenses consisted of the following (in thousands):

	September 30, 2019	December 31, 2018
Accrued compensation costs	$ 3,378	$ 3,364
Accrued professional services	653	1,262
Accrued external research and manufacturing costs	2,185	3,001
Accrued additions of property and equipment	—	243
Other accrued expenses	752	552
	$ 6,968	$ 8,422

7. Leases

On January 21, 2016, the Company entered into an operating lease agreement for office and laboratory space at its current headquarters in Cambridge, Massachusetts. The lease commenced on September 28, 2016 and expires on September 27, 2024. The Company has the right to extend the lease for one additional five-year period at a market rental rate as determined by the landlord and agreed to by the Company. Per the terms of the lease agreement, the Company does not have any residual value guarantees. In connection with the lease agreement, the Company issued a letter of credit to the landlord for $0.5 million. The Company secured the letter of credit for the full amount of the letter with cash on deposit, which is reported as restricted cash, and which is classified within other long-term assets.

The Company identified and assessed the following significant assumptions in recognizing the right-of-use asset and corresponding liability related to the lease:

- *Expected lease term*—The expected lease term includes the contractual lease period. The lease agreement contains a renewal option, which was not included in the calculation of the right-of-use asset and lease liabilities as the renewal is not reasonably certain.
- *Incremental borrowing rate*—As the Company's lease does not provide a readily determinable implicit rate, nor is it available from the lessor, the Company estimated the incremental borrowing rate based on

information available at the commencement date in determining the present value of lease payments. The Company used the incremental borrowing rate on January 1, 2019 for operating leases that commenced prior to that date.

The Company recognized the right-of-use asset and corresponding lease liability on January 1, 2019 by calculating the present value of lease payments, discounted at 10%, the Company's estimated incremental borrowing rate, over the 5.7 years expected remaining lease term. Amortization of the operating lease right-of-use asset for the lease was $0.3 million and $0.9 million for the three and nine months ended September 30, 2019 and was included in operating expenses. The variable lease expense, which includes common area maintenance, utility charges and management fees was $0.2 million and $0.7 million for the three and nine months ended September 30, 2019. As of September 30, 2019 the remaining lease term was 4.90 years.

The Company also, from time to time, enters into short-term operating lease arrangements for certain laboratory and office equipment. Leases with a term of twelve months or less are not recorded on the balance sheet and the Company recognizes lease expense for these leases on a straight-line basis over the lease term. For lease agreements entered into or reassessed after the adoption of ASU 2016-02, the Company has elected to combine lease and non-lease components for all classes of underlying assets.

The components of lease expense and related cash flows were as follows (in thousands):

	Three Months Ended September 30, 2019	Nine Months Ended September 30, 2019
Lease cost		
Operating lease cost	$ 502	$ 1,506
Variable lease cost	243	720
Short-term lease cost	113	326
Total lease cost	$ 858	$ 2,552
Cash paid for amounts included in the measurement of lease liabilities	$ 469	$ 1,407

Future lease payments for the Company's operating leases as of September 30, 2019 were as follows (in thousands):

Year Ending December 31,	
2019 (remaining three months)	$ 484
2020	1,948
2021	2,006
2022	2,066
2023	2,128
Thereafter	1,632
Total future minimum lease payments	$10,264
Less: interest	(2,193)
Present value of operating lease liabilities	$ 8,071

Under the prior lease guidance, future minimum lease payments for the Company's operating leases as of December 31, 2018 were as follows (in thousands):

Year Ending December 31	
2019	$ 1,891
2020	1,948
2021	2,006
2022	2,066
2023	2,129
Thereafter	1,632
Total future minimum lease payments	$ 11,672

8. Commitments and Contingencies

Manufacturing Agreements

Peptide and Vaccine Manufacturing Agreement

In December 2015, the Company entered into a manufacturing agreement, as amended in October 2016, January 2017 and November 2018 (collectively as amended, the "Manufacturing Agreement"), with an independent third party (the "Vendor") whereby the Vendor performs manufacturing, analytical testing and quality assurance services related to the manufacture of drug product and/or peptides for use in the Company's preclinical and clinical activities. The Manufacturing Agreement provided for the development and establishment of two manufacturing suites at the Vendor's facility to be used in the manufacturing process to fill orders of peptides ordered by the Company, and requires the Company to reimburse the Vendor for specified manufacturing costs incurred in the manufacture of the peptides, plus a fixed profit margin. The Manufacturing Agreement has a five-year term and can be terminated by the Company for convenience with three-months' notice. All amounts incurred under the Manufacturing Agreement are recognized as research and development expense as incurred.

T Cell Manufacturing Agreement

In August 2019, the Company entered into a manufacturing agreement (the "NKI Agreement") with the Netherlands Cancer Institute (the "NKI") whereby the NKI performs manufacturing, analytical testing and quality assurance services related to the manufacture of the Company's autologous T cell therapy drug product for use in the Company's preclinical and clinical activities. The NKI Agreement has a three-year term, which can be extended for an additional six months at the Company's sole discretion, and can be terminated by the Company for convenience with three-months' notice. All amounts incurred under the NKI Agreement are recognized as research and development expense as incurred.

Other Agreements

License Agreement with the Broad Institute, Inc.

On November 13, 2015, the Company entered into a license agreement with the Broad Institute, Inc. (the "Broad"), a related party (see Note 12) and, in January and November 2018, the Company entered into amendments to the license agreement (as amended to date, the "Broad Agreement"). Under the Broad Agreement, the Company has been granted an exclusive worldwide license to certain intellectual property rights owned or controlled by the Broad, Dana-Farber Cancer Institute (the "DFCI") and The General Hospital Corporation d/b/a Massachusetts General Hospital ("MGH") to develop and commercialize any diagnostic, prognostic, preventative or therapeutic product for humans, including any neoantigen vaccine product. In particular, the Company has been granted both exclusive and non-exclusive licenses to a patent portfolio comprised of twelve patent families, including certain granted patents and pending patent applications in the United States and foreign jurisdictions.

Pursuant to the terms of the Broad Agreement, the Company has also been granted (i) anon-exclusive license under each institution's respective interest in certain of its patent rights to exploit the licensed products in the field in the territory during the term of the license and (ii) a non-exclusive license under each institution's licensed know-how, to exploit any diagnostic, prognostic, preventative or therapeutic product in the field in the territory during the term of the license. The Company is also entitled to sub-license the rights granted to it under the Broad Agreement. In connection with the Broad Agreement, the Company has also entered into a non-exclusive software license with the Broad under which it licenses certain object and source codes for several software programs. These licenses and rights are subject to certain limitations and retained rights, including field restrictions.

As consideration for the license, the Company paid the Broad anon-refundable license fee of $0.1 million. As additional consideration for the license, the Company must pay the Broad immaterial annual license maintenance fees. Additionally, the Company granted 60,000 shares of restricted common stock to each of the Broad, DFCI and MGH, which were determined to have an aggregate fair value of $0.2 million, and reimbursed the Broad $0.6 million for a portion of its past patent expenses related to the in-licensed patent rights. In June 2018, to align with institutional policies in place between the Broad, DFCI and MGH, DFCI and MGH transferred certain of the shares of restricted common stock that they had previously received to the Broad. Under the Broad Agreement, the Company agreed to reimburse the Broad for future patent expenses related to the patents covered by the license agreement. The Company could be obligated to make up to $12.6 million of developmental milestone payments to the Broad if certain development milestones are achieved over the term of the license agreement. Additionally, under the terms of the license agreement, the Company could be obligated to make up to an aggregate of $97.5 million of payments upon the achievement of specified sales milestones and to pay tiered royalties of low to mid single-digit percentages on net sales of products licensed under the agreement. The Company is required to pay the Broad a low double-digit percentage of any consideration received by the Company from a sublicensee in consideration for a sublicense. No developmental or commercial milestones have been achieved to date. The Company has the right to terminate the agreement for any reason, with or without cause.

License Agreement with the Dana-Farber Cancer Institute

On August 5, 2016, the Company entered into a license agreement with the DFCI to grant the Company an exclusive, royalty-free license to provide certain licensed know-how. The know-how in this agreement has particular utility in connection with the development of the licensed products referred to in the Broad Agreement. The agreement also grants a non-exclusive, royalty free right to certain clinical data being generated by the DFCI. The Company has the right to terminate the license agreement with the DFCI for any reason, with or without cause.

In consideration for the licenses, the Company granted 120,000 shares of common stock to each of the Broad and the DFCI. The shares issued to the Broad were unrestricted and fully vested. The 120,000 shares issued to the DFCI contained contingent repurchase options whereby, if the DFCI failed to achieve three specific milestones over the subsequent three-year period, the Company could repurchase the shares (one-third for each milestone) at the original purchase price, which is at zero cost. The Company has accounted for these awards consistent with equity awards with performance-based vesting conditions and, upon it being probable that the Company would not repurchase the award associated with a milestone, the associated expense would be recognized as incremental stock-based compensation expense and reflected within research and development expenses in the condensed consolidated financial statements. During the three months ended September 30, 2019, the repurchase option on the final one-third of the shares expired and the Company recognized $0.2 million of incremental stock-based compensation expense. During the nine months ended September 30, 2018 and 2017, the first and second repurchase options expired due to the achievement of the respective specified criteria and the Company recognized $0.4 million and $0.2 million of incremental stock-based compensation expense in each period, respectively. Through September 30, 2019, the repurchase option on all 120,000 of these shares has expired.

Indemnification Agreements

In the ordinary course of business, the Company may provide indemnification of varying scope and terms to vendors, lessors, business partners and other parties with respect to certain matters arising out of the relationship between the parties. In addition, the Company has entered into indemnification agreements with members of its board of directors and certain executive officers and other employees that will require the Company, among other things, to indemnify them against certain liabilities that may arise by reason of their status or service as directors, officers or employees. The maximum potential amount of future payments the Company could be required to make under these indemnification agreements is, in many cases, unlimited. To date, the Company has not incurred any material costs as a result of these indemnification obligations. The Company does not believe that the outcome of any existing claims under indemnification arrangements will have a material effect on its financial position, results of operations or cash flows, and it had not accrued any liabilities related to its obligations under these agreements in its condensed consolidated financial statements as of September 30, 2019 or December 31, 2018.

Legal Proceedings

The Company is not currently party to any material legal proceedings. At each reporting date, the Company evaluates whether or not a potential loss amount or a potential range of loss is probable and reasonably estimable under the provisions of the authoritative guidance that addresses accounting for contingencies. The Company expenses as incurred the costs related to its legal proceedings.

9. Preferred Stock and Common Stock

Preferred Stock

The Company's amended and restated certificate of incorporation authorizes the Company to issue up to 10,000,000 shares of undesignated preferred stock, $0.001 par value per share, none of which was issued or outstanding as of September 30, 2019 or December 31 2018.

Upon completion of the Company's IPO on June 29, 2018, all shares of the Company's previously issued Redeemable Convertible Preferred Stock converted into an aggregate of 18,644,462 shares of common stock. As of September 30, 2019 and December 31, 2018, there were no shares of Redeemable Convertible Preferred Stock issued or outstanding.

Common Stock

As of September 30, 2019 and December 31, 2018, the Company's certificate of incorporation, as amended and restated, authorized the Company to issue 150,000,000 shares of common stock with a par value of $0.001 per share.

Each share of common stock entitles the holder to one vote on all matters submitted to a vote of the Company's stockholders. Common stockholders are entitled to receive dividends, as may be declared by the Company's board of directors, if any. No dividends have been declared or paid during the three or nine months ended September 30, 2019 or 2018.

As of September 30, 2019 and December 31, 2018 the Company has reserved for future issuance the following number of shares of common stock:

	September 30, 2019	December 31, 2018
Shares reserved for exercise of outstanding stock options	3,541,485	2,548,073
Shares reserved for vesting of restricted stock units	540,319	—
Shares reserved for future issuance under the 2018 Stock Option and Grant Plan	334,545	760,628
Shares reserved for future issuance under the 2018 Employee Stock Purchase Plan	553,142	270,000
	4,969,491	3,578,701

At-the-market equity offering program

In July 2019, the Company filed a registration statement on Form S-3 (File No. 333-232487) with the SEC, which was declared effective on July 8, 2019, or the Shelf Registration Statement, in relation to the registration of common stock, preferred stock, warrants and/or units of any combination thereof for the purposes of selling, from time to time, its common stock, convertible securities or other equity securities in one or more offerings. Simultaneous with the Shelf Registration Statement, the Company entered into a Controlled Equity Offering℠ Sales Agreement (the "Sales Agreement") with Cantor Fitzgerald & Co. ("Cantor") to establish an at-the-market equity offering program ("ATM"). Under the Sales Agreement, Cantor may sell up to $50.0 million of the Company's common stock by any method permitted by law deemed to be an "at the market" offering as defined in Rule 415 of the Securities Act, subject to the terms of the Sales Agreement. The Company will pay to Cantor cash commissions of 3.0% of the aggregate gross proceeds of sales of common stock under the Sales Agreement. Through September 30, 2019, no shares have been sold under the ATM and no proceeds have been received.

10. Stock-Based Compensation

2015 Stock Option and Grant Plan

The Company's 2015 Stock Option and Grant Plan, as amended (the "2015 Plan"), provided for the Company to grant incentive or nonqualified stock options, restricted stock awards, unrestricted stock awards or restricted stock units to employees, directors and consultants of the Company. As of June 26, 2018, the effective date of the 2018 Stock Option and Incentive Plan, and as of September 30, 2019 and December 31, 2018, no shares remained available for future issuance under the 2015 Plan.

2018 Stock Option and Incentive Plan

On June 13, 2018, the Company's stockholders approved the 2018 Stock Option and Incentive Plan (the "2018 Plan"), which became effective on June 26, 2018. The 2018 Plan provides for the grant of incentive stock options, nonqualified stock options, stock appreciation rights, restricted stock units, restricted stock awards, unrestricted stock awards and dividend equivalent rights to the Company's officers, employees, directors and other key persons (including consultants). The number of shares initially reserved for issuance under the 2018 Plan was 1,215,000 shares, which was cumulatively increased on January 1, 2019 and which will be cumulatively increased each January 1 thereafter by 4% of the number of shares of the Company's common stock outstanding on the immediately preceding December 31 or such lesser number of shares determined by the Company's compensation committee. Effective January 1, 2019, 1,132,570 additional shares were automatically added to the shares authorized for issuance under the 2018 Plan and these shares were subsequently registered on a Registration Statement on Form S-8.

As of the effective date of the 2018 Plan, the Company will not grant any further awards under the 2015 Plan. However, the shares of common stock underlying any awards that are forfeited, canceled, held back upon

exercise or settlement of an award to satisfy the exercise price or tax withholding, reacquired by the Company prior to vesting, satisfied without the issuance of stock, expire or are otherwise terminated (other than by exercise) under the 2018 Plan and the 2015 Plan will be added back to the shares of common stock available for issuance under the 2018 Plan.

The terms of stock options and restricted stock awards, including vesting requirements, are determined by the board of directors or its delegates, subject to the provisions of the 2018 Plan.

As of September 30, 2019, there were 334,545 shares available for future issuance under the 2018 Plan.

2018 Employee Stock Purchase Plan

On June 13, 2018, the Company's stockholders approved the 2018 Employee Stock Purchase Plan (the "ESPP"), which became effective on June 26, 2018. A total of 270,000 shares of common stock were reserved for issuance under the ESPP. In addition, the number of shares of common stock that may be issued under the ESPP will automatically increase on January 1, 2019, and each January 1 thereafter through January 1, 2028, by the lesser of (i) 405,000 shares of common stock, (ii) 1% of the number of shares of the Company's common stock outstanding on the immediately preceding December 31 or (iii) such lesser number of shares determined by the administrator of the Company's ESPP. Effective January 1, 2019, 283,142 additional shares were automatically added to the shares authorized for issuance under the ESPP and these shares were subsequently registered on a Registration Statement on Form S-8.

The Company initiated its first offering period under the ESPP on July 1, 2019. Stock-based compensation expense related to the ESPP was insignificant for the three and nine months ended September 30, 2019.

Stock Options

The following table summarizes changes in stock option activity during the nine months ended September 30, 2019:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Contractual Term (in years)	Aggregate Intrinsic Value (in thousands)
Outstanding as of December 31, 2018	2,548,073	$ 7.11	8.68	$ 1,965
Granted	1,235,128	6.00		
Exercised	(44,132)	2.62		
Forfeited	(197,584)	7.36		
Outstanding as of September 30, 2019	3,541,485	$ 6.76	8.24	$ —
Options vested or expected to vest as of September 30, 2019	3,541,485	$ 6.76	8.24	$ —
Options exercisable as of September 30, 2019	1,342,524	$ 6.55	7.63	$ —

The weighted average grant-date fair value per share of stock options granted during the three and nine months ended September 30, 2019 was $1.75 per share and $4.64 per share, respectively. The weighted average grant-date fair value per share of stock options granted during the three and nine months ended September 30, 2018 was $9.85 per share and $8.99 per share, respectively.

The aggregate intrinsic value of stock options exercised during the three and nine months ended September 30, 2019 was insignificant and $0.1 million, respectively. The aggregate intrinsic value of stock options exercised during the three and nine months ended September 30, 2018 was $0.3 million and $1.1 million, respectively.

Stock Option Valuation

The assumptions that the Company used to determine the fair value of the stock options granted to employees and directors were as follows, presented on a weighted average basis:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Expected volatility	83.87%	102.45%	94.73%	101.82%
Risk-free interest rate	1.39%	2.84%	2.37%	2.63%
Expected dividend yield	— %	— %	— %	— %
Expected life (in years)	6.11	6.08	6.01	6.00

There were no stock option awards granted to nonemployees during the three or nine months ended September 30, 2019 or 2018.

Restricted Stock Units

During the nine months ended September 30, 2019, under the 2018 Plan, the Company granted restricted stock units ("RSUs"), as part of the Company's equity compensation program it provides to its employees. Pursuant to the terms of the applicable award agreements, each RSU represents the right to receive one share of the Company's common stock and the RSUs generally vest in equal annual installments over three years, provided the employee remains continuously employed with the Company through the vesting period. Upon vesting, shares of the Company's common stock are delivered to the employee, subject to the payment of applicable withholding taxes. The fair value of RSUs is based on the market value of the Company's common stock on the date of grant. Compensation expense is recognized over the applicable service period.

The following table summarizes RSU activity for the nine months ended September 30, 2019:

	Number of Shares	Weighted Average Grant-Date Fair Value per Share
Unvested as of December 31, 2018	—	$ —
Granted	594,339	$ 5.52
Vested	—	$ —
Cancelled	(54,020)	$ 6.34
Unvested as of September 30, 2019	540,319	$ 5.44

Restricted Stock Awards

Restricted stock awards originally issued under the terms of the 2015 Plan allow the Company, at its discretion, to repurchase unvested shares at the initial purchase price if the employee or nonemployee terminates his or her service relationship with the Company. No restricted stock awards were issued under the 2015 Plan during the three and nine months ended September 30, 2019 or 2018.

The 2018 Plan provides for the grant of restricted stock awards to the Company's officers, employees, directors and other key persons (including consultants). During the nine months ended September 30, 2019, the Company issued restricted stock awards for 25,000 shares of common stock to certain nonemployee founders and collaborators. The shares were granted under the terms of the 2018 Plan and the respective award agreements governing these awards. These awards vest quarterly over a one-year period.

The following table summarizes the Company's restricted common stock activity since December 31, 2018:

	Number of Shares	Weighted Average Grant-Date Fair Value per Share
Unvested restricted common stock as of December 31, 2018	383,964	$ 1.97
Granted	25,000	$ 4.64
Cancelled	(44,210)	$ 1.25
Vested	(218,460)	$ 1.89
Unvested restricted common stock as of September 30, 2019	146,294	$ 2.77

The aggregate fair value of restricted common stock awards that vested during the three and nine months ended September 30, 2019, based upon the fair values of the stock underlying the restricted stock awards on the applicable vesting dates, was $0.2 million and $1.0 million, respectively. The aggregate fair value of restricted common stock awards that vested during the three and nine months ended September 30, 2018, based upon the fair values of the stock underlying the restricted stock awards on the applicable vesting dates, was $0.9 million and $2.6 million, respectively.

Restricted Stock Awards Issued Outside of Equity Plans

From May 2015 through July 2016, the Company issued 1,510,000 shares of restricted common stock outside of the 2015 Plan to nonemployee founders and collaborators. The shares were issued under the terms of the respective restricted common stock agreements and unvested shares are subject to repurchase by the Company upon the holder's termination of their relationship with the Company. The unvested shares of restricted common stock are subject to the Company's right to repurchase at the original purchase price per share. The Company did not issue any shares of restricted common stock outside of the Company's 2015 Plan and 2018 Plan during the three or nine months ended September 30, 2019 and 2018.

Of the total shares of restricted common stock awarded to nonemployee founders and collaborators, 300,000 shares vested immediately upon grant; 910,000 shares vested quarterly over a four-year period based on each grantee's continued service relationship with the Company in varying advisory capacities; and 180,000 shares are to vest upon the achievement of specified performance milestones. Additionally, 120,000 shares were issued as fully vested awards, but were subject to repurchase options that expired upon the achievement of specified milestones. Through September 30, 2019, the repurchase options on all 120,000 of these shares have expired (see Note 8).

Of these awards, the underlying restricted common stock agreement for 180,000 shares of restricted common stock provided for a put option whereby the recipient was able to sell its vested shares back to the Company at a price per share equal to the fair value of the Company's common stock upon both (i) the termination of the consulting agreement between the recipient and the Company for any reason and (ii) the determination by the recipient's employer that the ownership of the restricted common stock was in violation of the employer's conflict of interest policy. Prior to the closing of the Company's IPO, these awards were classified in the consolidated balance sheet as contingently redeemable common stock and were presented outside of permanent equity. As of December 31, 2017, $0.4 million was recorded in temporary equity related to these awards. Upon the closing of the Company's IPO, this put option expired and the amount recorded in temporary equity was recorded to additional paid in capital.

A summary of the changes in the Company's unvested restricted common stock awards granted to founders and collaborators outside of the Company's 2015 Plan or 2018 Plan since December 31, 2018 is as follows:

	Number of Shares	Weighted Average Grant-Date Fair Value per Share
Unvested restricted common stock as of December 31, 2018	350,625	$ 1.29
Vested	(170,625)	$ 1.29
Unvested restricted common stock as of September 30, 2019	180,000	$ 1.29

The aggregate fair value of restricted common stock awards issued outside of the Company's 2015 Plan or 2018 Plan that vested during the three and nine months ended September 30, 2019, based upon the fair values of the stock underlying the restricted stock awards on the applicable vesting dates, was $0.2 million and $0.8 million, respectively. The aggregate fair value of restricted common stock awards issued outside of the Company's 2015 Plan or 2018 Plan that vested during the three and nine months ended September 30, 2018, based upon the fair values of the stock underlying the restricted stock awards on the applicable vesting dates, was $0.6 million and $1.9 million, respectively.

Stock-Based Compensation Expense

The Company recorded stock-based compensation expense related to all stock-based awards and the ESPP in the following expense categories of its condensed consolidated statements of operations and comprehensive loss (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Research and development expenses	$ 1,115	$ 896	$ 2,943	$ 3,071
General and administrative expenses	919	748	2,874	1,644
	$ 2,034	$ 1,644	$ 5,817	$ 4,715

During the three and nine months ended September 30, 2019, the Company recognized stock-based compensation expense of $0.2 million for awards with performance-based vesting conditions related to the expiration of the final repurchase option on the remaining unvested restricted common shares issued to DFCI. During the nine months ended September 30, 2018, the Company recognized stock-based compensation expense of $0.4 million for awards with performance-based vesting conditions related to the expiration of the second repurchase option on a portion of the unvested restricted common shares issued to DFCI (see Note 8).

As of September 30, 2019, the Company had an aggregate of $11.2 million of unrecognized stock-based compensation expense related to unvested stock option awards, excluding awards with performance-based vesting conditions, which is expected to be recognized over a weighted-average period of approximately 2.43 years. As of September 30, 2019, the Company also had an aggregate of $0.4 million of unrecognized stock-based compensation expense related to unvested restricted common stock awards, excluding awards with performance-based vesting conditions, which is expected to be recognized over a weighted-average period of approximately 0.89 years. Additionally as of September 30, 2019, the Company had an aggregate of $2.4 million of unrecognized stock-based compensation expense related to unvested RSUs, which is expected to be recognized over a weighted-average period of approximately 2.50 years.

11. Net Loss per Share

The Company excluded 326,294 shares of restricted common stock for the three and nine months ended September 30, 2019 and 866,119 shares of restricted common stock for the three and nine months ended September 30, 2018 from the calculation of basic net loss per share because these shares had not vested.

The Company's potential dilutive securities have been excluded from the computation of diluted net loss per share attributable to common stockholders whenever the effect of including them would be to reduce the net loss per share. In periods where there is a net loss, the weighted average number of common shares outstanding used to calculate both basic and diluted net loss per share attributable to common stockholders is the same. The following potential shares of common stock, presented based on amounts outstanding at each period end, were excluded from the calculation of diluted net loss per share attributable to common stockholders for the periods indicated because including them would have had an anti-dilutive effect:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Outstanding stock options	3,541,485	2,273,116	3,541,485	2,273,116
Unvested restricted stock units	540,319	—	540,319	—
Unvested restricted common stock	326,294	866,119	326,294	866,119
ESPP shares issuable and outstanding	49,160	—	49,160	—
	4,457,258	3,139,235	4,457,258	3,139,235

12. Related Parties

A member of the Company's board of directors is a founding director and the current president of the Broad. In November 2015, the Company entered into the Broad Agreement with the Broad (see Note 8) and, as consideration, the Company granted 60,000 shares of restricted common stock to the Broad, which were determined to have a fair value of $0.1 million. Additionally, the Company must pay the Broad immaterial annual license maintenance fees. At the time the Company entered into the Broad Agreement, the Company reimbursed the Broad $0.6 million for a portion of past patent expenses and, under the terms of the license agreement, the Company is required to reimburse Broad for future patent expenses related to patents covered by the license agreement. The Company could be obligated to make up to $12.6 million of developmental milestone payments to the Broad if certain development milestones are achieved over the term of the license agreement. Additionally, under the terms of the license agreement, the Company could be obligated to make up to an aggregate of $97.5 million of payments upon the achievement of specified sales milestones and to pay tiered royalties of low to mid single-digit percentages on net sales of products licensed under the agreement. The Company is required to pay the Broad a low double-digit percentage of any consideration received by the Company from a sublicensee in consideration for a sublicense. No developmental or commercial milestones have been achieved to date.

In August 2016, the Company entered into a license agreement with the DFCI in connection with the development of licensed products referred to in the 2015 Broad Agreement. As consideration, the Company granted 120,000 shares of restricted common stock to the Broad, which were determined to have a fair value of $0.2 million. In June 2018, to align with institutional policies in place between the Broad, the DFCI and MGH, the DFCI and MGH transferred certain of the shares of restricted common stock that they had previously received to the Broad.

The Company recorded expenses related to payments to the Broad of $0.3 million and $1.4 million during the three and nine months ended September 30, 2019, respectively, and $0.5 million and $1.0 million during the three and nine months ended September 30, 2018, respectively. At September 30, 2019 and December 31, 2018, the Company had $0.4 million and $2.0 million in accounts payable and accrued expenses due to the Broad, respectively.

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders of Neon Therapeutics, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Neon Therapeutics, Inc. and its subsidiary (the "Company") as of December 31, 2018 and 2017, and the related consolidated statements of operations and comprehensive loss, of redeemable convertible preferred stock, contingently redeemable restricted common stock and stockholders' equity (deficit) and of cash flows for each of the three years in the period ended December 31, 2018, including 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 as of December 31, 2018 and 2017, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2018 in conformity with accounting principles generally accepted in the United States of America.

Substantial Doubt About the Company's Ability to Continue as a Going Concern

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the consolidated financial statements, the Company has incurred recurring losses and negative cash flows from operations since inception, has an accumulated deficit, and will require additional financing to fund future operations that raise substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's consolidated financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (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 of these consolidated financial statements in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the consolidated 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 consolidated 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 consolidated 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 consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ PricewaterhouseCoopers LLP
Boston, Massachusetts
March 11, 2019, except with respect to the matters that raise substantial doubt about the Company's ability to continue as a going concern discussed in Note 1, as to which the date is January 27, 2020

We have served as the Company's auditor since 2016.

NEON THERAPEUTICS, INC.
CONSOLIDATED BALANCE SHEETS
(In thousands, except share and per share amounts)

	December 31,	
	2018	2017
Assets		
Current assets:		
Cash and cash equivalents	$ 52,700	$ 58,250
Marketable securities	50,611	21,475
Prepaid expenses and other current assets	2,116	1,581
Total current assets	105,427	81,306
Property and equipment, net	8,205	6,888
Deferred offering costs	—	1,567
Other long-term assets	456	732
Total assets	$ 114,088	$ 90,493
Liabilities, Redeemable Convertible Preferred Stock, Contingently Redeemable Restricted Common Stock and Stockholders' Equity (Deficit)		
Current liabilities:		
Accounts payable	$ 4,268	$ 2,166
Accrued expenses	8,422	6,601
Total current liabilities	12,690	8,767
Other liabilities	149	48
Total liabilities	12,839	8,815
Commitments and contingencies (Note 7)		
Redeemable convertible preferred stock (Series A and B), $0.001 par value; 10,000,000 shares and 93,222,418 shares authorized as of December 31, 2018 and December 31, 2017, respectively; no shares and 93,222,418 shares issued and outstanding as of December 31, 2018 and 2017, respectively	—	174,895
Contingently redeemable restricted common stock	—	355
	—	175,250
Stockholders' equity (deficit):		
Common stock, $0.001 par value; 150,000,000 shares and 130,000,000 shares authorized as of December 31, 2018 and December 31, 2017, respectively; 28,314,274 and 3,302,927 shares issued and outstanding as of December 31, 2018 and 2017, respectively	28	3
Additional paid-in capital	275,058	—
Accumulated other comprehensive loss	(75)	(13)
Accumulated deficit	(173,762)	(93,562)
Total stockholders' equity (deficit)	101,249	(93,572)
Total liabilities, redeemable convertible preferred stock, contingently redeemable restricted common stock and stockholders' equity (deficit)	$ 114,088	$ 90,493

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

NEON THERAPEUTICS, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(In thousands, except share and per share amounts)

	Year Ended December 31,		
	2018	2017	2016
Operating expenses:			
Research and development	$ 60,425	$ 37,195	$ 19,673
General and administrative	18,276	10,892	7,749
Total operating expenses	78,701	48,087	27,422
Loss from operations	(78,701)	(48,087)	(27,422)
Other income (expense), net			
Interest income	1,792	569	—
Other expense	(25)	(18)	(11)
Total other income (expense), net	1,767	551	(11)
Net loss	(76,934)	(47,536)	(27,433)
Accretion of redeemable convertible preferred stock to redemption value	(6,371)	(10,396)	(2,989)
Net loss attributable to common stockholders	$ (83,305)	$ (57,932)	$ (30,422)
Net loss per share attributable to common stockholders, basic and diluted	$ (5.54)	$ (34.32)	$ (30.72)
Weighted average common shares outstanding, basic and diluted	15,036,397	1,687,859	990,171
Comprehensive loss:			
Net loss	$ (76,934)	$ (47,536)	$ (27,433)
Other comprehensive loss:			
Unrealized losses on marketable securities	(62)	(13)	—
Total other comprehensive loss	(62)	(13)	—
Comprehensive loss	$ (76,996)	$ (47,549)	$ (27,433)

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

NEON THERAPEUTICS, INC.
CONSOLIDATED STATEMENTS OF REDEEMABLE CONVERTIBLE PREFERRED STOCK, CONTINGENTLY REDEEMABLE RESTRICTED COMMON STOCK AND STOCKHOLDERS' EQUITY (DEFICIT)
(In thousands, except share amounts)

	Redeemable Convertible Preferred Stock		Contingently Redeemable Restricted Common Stock	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount		Shares	Amount				
Balance at December 31, 2015	14,109,185	$ 14,509	$ 14	2,485,523	$ 2	$ 10	$ —	$ (9,387)	$ (9,375)
Issuance of Series A redeemable convertible preferred stock, net of issuance costs of $10	41,390,815	41,381	—	—	—	—	—	—	—
Issuance of Series B redeemable convertible preferred stock, net of issuance costs of $261	24,911,030	69,739	—	—	—	—	—	—	—
Stock-based compensation expense	—	—	81	—	—	1,288	—	—	1,288
Accretion of redeemable convertible preferred stock to redemption value	—	2,989	—	—	—	(1,314)	—	(1,675)	(2,989)
Issuance of restricted common stock	—	—	—	826,200	1	(1)	—	—	—
Cancellation of restricted common stock	—	—	—	(15,000)	—	—	—	—	—
Vesting of restricted common stock	—	—	—	—	—	17	—	—	17
Net loss	—	—	—	—	—	—	—	(27,433)	(27,433)
Balance at December 31, 2016	80,411,030	128,618	95	3,296,723	3	—	—	(38,495)	(38,492)
Issuance of Series B redeemable convertible preferred stock, net of issuance costs of $119	12,811,388	35,881	—	—	—	—	—	—	—
Stock-based compensation expense	—	—	260	—	—	2,782	—	—	2,782
Accretion of redeemable convertible preferred stock to redemption value	—	10,396	—	—	—	(2,865)	—	(7,531)	(10,396)
Exercise of stock options	—	—	—	23,734	—	56	—	—	56
Cancellation of restricted common stock	—	—	—	(17,530)	—	—	—	—	—
Vesting of restricted common stock	—	—	—	—	—	27	—	—	27
Unrealized losses on marketable securities	—	—	—	—	—	—	(13)	—	(13)
Net loss	—	—	—	—	—	—	—	(47,536)	(47,536)
Balance at December 31, 2017	93,222,418	174,895	355	3,302,927	3	—	(13)	(93,562)	(93,572)
Stock-based compensation expense	—	—	210	—	—	6,019	—	—	6,019
Accretion of redeemable convertible preferred stock to redemption value	—	6,371	—	—	—	(3,105)	—	(3,266)	(6,371)
Conversion of redeemable convertible preferred stock and contingently redeemable restricted common stock to common stock	(93,222,418)	(181,266)	(565)	18,644,462	19	181,812	—	—	181,831
Issuance of common stock upon completion of initial public offering, net of commissions, underwriting discounts and offering costs	—	—	—	6,250,000	6	89,906	—	—	89,912
Exercise of stock options	—	—	—	129,510	—	404	—	—	404
Cancellation of restricted common stock	—	—	—	(12,625)	—	—	—	—	—
Vesting of restricted common stock	—	—	—	—	—	22	—	—	22
Unrealized losses on marketable securities	—	—	—	—	—	—	(62)	—	(62)
Net loss	—	—	—	—	—	—	—	(76,934)	(76,934)
Balance at December 31, 2018	—	$ —	$ —	28,314,274	$ 28	$ 275,058	$ (75)	$ (173,762)	$ 101,249

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

NEON THERAPEUTICS, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS
(In thousands)

	Year Ended December 31,		
	2018	2017	2016
Cash flows from operating activities:			
Net loss	$ (76,934)	$ (47,536)	$ (27,433)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization expense	1,458	920	411
Net amortization of premiums and discounts on marketable securities	(4)	190	—
Stock-based compensation expense	6,229	3,042	1,370
Loss on disposal of property and equipment	25	19	38
Changes in operating assets and liabilities:			
Prepaid expenses and other current assets	(340)	(543)	15
Other long-term assets	125	717	(793)
Accounts payable	1,951	(942)	1,029
Accrued expenses and other liabilities	4,062	2,852	1,206
Net cash used in operating activities	(63,428)	(41,281)	(24,157)
Cash flows from investing activities:			
Purchases of marketable securities	(72,939)	(33,979)	—
Sales and maturities of marketable securities	43,550	12,300	—
Purchases of property and equipment	(3,222)	(3,242)	(2,396)
Cash proceeds from sales of property and equipment	—	—	39
Net cash used in investing activities	(32,611)	(24,921)	(2,357)
Cash flows from financing activities:			
Proceeds from issuance of Series A redeemable convertible preferred stock, net of issuance costs	—	—	41,381
Proceeds from issuance of Series B redeemable convertible preferred stock, net of issuance costs	—	35,881	69,739
Proceeds from initial public offering of common stock, net of commissions and underwriting discounts	93,000	—	—
Proceeds from exercise of stock options	404	55	—
Repurchase of unvested restricted common stock	(1)	(4)	—
Payment of initial public offering costs	(3,065)	(23)	—
Net cash provided by financing activities	90,338	35,909	111,120
Net (decrease) increase in cash, cash equivalents and restricted cash	(5,701)	(30,293)	84,606
Cash, cash equivalents and restricted cash, beginning of period	58,857	89,150	4,544
Cash, cash equivalents and restricted cash, end of period	$ 53,156	$ 58,857	$ 89,150
Supplemental disclosure of non-cash items:			
Accretion of redeemable convertible preferred stock to redemption value	$ 6,371	$ 10,396	$ 2,989
Conversion of redeemable convertible preferred stock and contingently redeemable restricted common stock to common stock upon closing of the initial public offering	$ 181,831	$ —	$ —
Purchases of property and equipment included in accounts payable and accrued expenses	$ 497	$ 919	$ 363
Deferred offering costs included in accounts payable and accrued expenses	$ —	$ 1,544	$ —

The following table provides a reconciliation of the cash, cash equivalents and restricted cash balances as of each of the periods shown above:

	December 31,		
	2018	2017	2016
Cash and cash equivalents	$ 52,700	$ 58,250	$ 88,493
Restricted cash included in other long-term assets	456	607	657
Total cash, cash equivalents and restricted cash	$ 53,156	$ 58,857	$ 89,150

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

NEON THERAPEUTICS, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. Nature of the Business and Basis of Presentation

Neon Therapeutics, Inc. (the "Company") is a clinical-stage immuno-oncology company and a leader in the field of neoantigen-targeted therapies, dedicated to transforming the treatment of cancer by directing the immune system towards neoantigens. The Company is leveraging its neoantigen platform and over a decade of insights from its founders to develop neoantigen-targeted therapies that use two distinct approaches, NEON / ONE and NEON / SELECT. These approaches focus on targeting a prioritized set of what the Company believes are the most therapeutically-relevant neoantigens. In NEON / ONE, these neoantigens are specific to each individual. In NEON / SELECT, these neoantigens are shared across subsets of patients or tumor types. The Company is applying these two approaches to develop neoantigen-targeted product candidates using multiple treatment modalities.

NEO-PV-01, the Company's most advanced product candidate, is a personal neoantigen vaccine that is custom-designed and manufactured based on the unique mutational fingerprint of each individual patient. The neoantigen-targeted peptides in NEO-PV-01 are intended to generate an immune response that trains each patient's immune system to target his or her individual tumor's particular neoantigens and kill the cancer cells. NEO-PV-01 is currently being evaluated in multiple Phase 1b clinical trials.

NEO-PTC-01, the Company's personal neoantigen T cell therapy, consists of multiple T cell populations targeting what we predict to be the most therapeutically-relevant neoantigens from each patient's tumor. NEO-PTC-01 is currently in preclinical development, and the Company expects to file a clinical trial application in Europe in the second half of 2019 to evaluate NEO-PTC-01 in solid tumors in patients who are refractory to checkpoint inhibitors.

NEON / SELECT is the Company's precision medicine approach to neoantigen-targeted therapies. The Company's first product candidate using this approach, NEO-SV-01, is a neoantigen vaccine for the treatment of a genetically defined subset of estrogen-receptor-positive breast cancer, for which the Company expects to file an Investigational New Drug application in the first half of 2019.

The Company is subject to risks common to early-stage companies in the biotechnology industry including, but not limited to, development by competitors of new technological innovations, protection of proprietary technology, dependence on key personnel, compliance with government regulations and the ability to obtain additional financing to fund operations. Product candidates currently under development will require significant additional research and development efforts, including extensive preclinical and clinical testing and regulatory approval, prior to commercialization. These efforts require significant amounts of additional capital, adequate personnel infrastructure and extensive compliance-reporting capabilities. Even if the Company's development efforts are successful, it is uncertain when, if ever, the Company will realize significant revenue from product sales.

Initial Public Offering

On June 29, 2018, the Company completed an initial public offering ("IPO") of its common stock, and issued and sold 6,250,000 shares of common stock at a public offering price of $16.00 per share, resulting in net proceeds of $89.9 million after deducting underwriting discounts, commissions and other offering costs. Upon the closing of the IPO in June 2018, all 93,222,418 shares of the Company's outstanding redeemable convertible preferred stock converted into an aggregate of 18,644,462 shares of common stock (see Note 8). In advance of the IPO, the board of directors and the stockholders of the Company approved a one-for-five reverse split of the Company's issued and outstanding common stock that became effective on June 13, 2018. All common share and per share amounts in these consolidated financial statements have been retroactively adjusted for all periods presented to give effect to the reverse stock split.

Liquidity

In accordance with Accounting Standards Update ("ASU") No. 2014-15,*Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern (Subtopic 205-40)*, management must evaluate whether there are conditions or events, when considered in the aggregate, that raise substantial doubt about the Company's ability to continue as a going concern within one year after the date that the financial statements are issued. This evaluation initially does not take into consideration the potential mitigating effect of management's plans that have not been fully implemented as of the date the financial statements are issued. When substantial doubt exists under this methodology, management evaluates whether the mitigating effect of its plans sufficiently alleviates substantial doubt about the company's ability to continue as a going concern. The mitigating effect of management's plans, however, is only considered if both (1) it is probable that the plans will be effectively implemented within one year after the date that the financial statements are issued, and (2) it is probable that the plans, when implemented, will mitigate the relevant conditions or events that raise substantial doubt about the entity's ability to continue as a going concern within one year after the date that the financial statements are issued. Generally, to be considered probable of being effectively implemented, the plans must have been approved before the date that the financial statements are issued.

The Company's financial statements have been prepared on the basis of continuity of operations, realization of assets and the satisfaction of liabilities in the ordinary course of business. Through December 31, 2018, the Company has funded its operations with net proceeds of $89.9 million from its IPO, as well as an aggregate of $161.1 million of net proceeds from sales of the Company's preferred stock and convertible debt. Since inception, the Company has incurred recurring losses and negative cash flows from operations in each period and on an aggregate basis. As of December 31, 2018 and 2017, the Company had an accumulated deficit of $173.8 million and $93.6 million, respectively. The Company expects its operating losses and negative operating cash flows to continue into the foreseeable future as it continues to develop, manufacture and commercialize its products.

As of January 27, 2020, the reissuance date of these consolidated financial statements, the Company expects that, based on its current operating plan, its cash, cash equivalents and marketable securities will be sufficient to fund its operating expenses and capital expenditure requirements into the third quarter of 2020. The future viability of the Company beyond that point is dependent on its ability to raise additional capital to finance its operations.

The Company expects that it will continue to incur significant expenses in connection with its ongoing business activities. As a result, the Company will need substantial additional funding to support its continuing operations and fund its growth strategy. Until such time as the Company can generate significant revenue from product sales, if ever, it expects to finance its operations through the sale of equity, debt financings or other capital sources, including collaborations with other companies or other strategic transactions. If the Company is unable to obtain funding on a timely basis, the Company may be required to curtail, delay or discontinue one or more of its research or development programs or be unable to expand its operations or otherwise capitalize on its business opportunities, as desired, which could materially affect the Company's business, financial condition and results of operations.

This raises substantial doubt about the Company's ability to continue as a going concern within one year from the reissuance of these financial statements.

2. Summary of Significant Accounting Policies

Basis of Presentation and Consolidation

The accompanying consolidated financial statements and the related disclosures have been prepared in conformity with the accounting principles generally accepted in the United States of America ("GAAP") and include the accounts of Neon Therapeutics, Inc. and its wholly owned subsidiary, Neon Securities Corporation. All intercompany transactions and balances have been eliminated. The Company consolidates entities in which it has a controlling financial interest.

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of expenses during the reporting periods. Significant estimates of accounting reflected in these consolidated financial statements include, but are not limited to, estimates related to accrued expenses, the valuation of common stock prior to the completion of the Company's IPO, stock-based compensation and income taxes. The Company bases its estimates on historical experience and other market specific or other relevant assumptions it believes to be reasonable under the circumstances. On an ongoing basis, management evaluates its estimates, as there are changes in circumstances, facts and experience. Actual results could differ from those estimates or assumptions.

Fair Value of Financial Instruments

Certain assets and liabilities are carried at fair value under GAAP. Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. Financial assets and liabilities carried at fair value are to be classified and disclosed in one of the following three levels of the fair value hierarchy, of which the first two are considered observable and the last is considered unobservable:

- Level 1—Quoted prices in active markets for identical assets or liabilities.
- Level 2—Observable inputs (other than Level 1 quoted prices), such as quoted prices in active markets for similar assets or liabilities, quoted prices in markets that are not active for identical or similar assets or liabilities, or other inputs that are observable or can be corroborated by observable market data.
- Level 3—Unobservable inputs that are supported by little or no market activity and that are significant to determining the fair value of the assets or liabilities, including pricing models, discounted cash flow methodologies and similar techniques.

The Company's cash equivalents and marketable securities are carried at fair value, determined according to the fair value hierarchy described above (see Note 3). The carrying amounts reflected in the consolidated balance sheets for prepaid expenses and other current assets, accounts payable and accrued expenses approximate their fair values, due to their short-term nature.

Cash Equivalents

Cash equivalents are highly liquid investments that are readily convertible into cash with original maturities of three months or less when purchased. Cash equivalents consisted primarily of money market funds as of December 31, 2018 and 2017.

Restricted Cash

As of December 31, 2018 and 2017, the Company had restricted cash of $0.5 million and $0.6 million, respectively, which was related to a security deposit associated with the Company's facility lease. Restricted cash accounts are classified within other long-term assets.

Marketable Securities

The Company classifies its available-for-sale investments as current assets on the balance sheet if they mature within one year from the balance sheet date.

The Company classifies all of its investments as available-for-sale securities. Available-for-sale debt securities are recorded at fair value. Unrealized gains and losses on available-for-sale debt securities are reported as accumulated other comprehensive income (loss), which is a separate component of stockholders' equity (deficit). The amortized cost of debt securities in this category is adjusted for the amortization of premiums and accretion of discounts to maturity, which are included in interest income. The cost of securities sold is determined on a specific identification basis, and realized gains and losses are included in other income (expense) within the consolidated statements of operations and comprehensive loss.

The Company evaluates its investments with unrealized losses for other-than-temporary impairment. When assessing investments for other-than-temporary declines in value, the Company considers such factors as, among other things, how significant the decline in value is as a percentage of the original cost, how long the market value of the investment has been less than its original cost, the Company's ability and intent to retain the investment for a period of time sufficient to allow for any anticipated recovery in fair value and market conditions in general. If any adjustment to fair value reflects a decline in the value of the investment that the Company considers to be "other than temporary," the Company reduces the investment to fair value through a charge to the statements of operations and comprehensive loss. No such adjustments were necessary during the periods presented.

Property and Equipment

Property and equipment, including leasehold improvements, are recorded at cost, net of accumulated depreciation and amortization. The Company capitalizes equipment that is acquired for research and development activities and that has alternative future use. Property and equipment are depreciated using the straight-line method over the estimated useful life of each asset as follows:

Asset Classification	Estimated Useful Life
Laboratory equipment	7 years
Furniture and fixtures	7 years
Software	5 years
Computer equipment	3 years
Leasehold improvements	Lesser of useful life or remaining lease term

Upon retirement or sale of assets, the cost and related accumulated depreciation and amortization are removed from the balance sheet and the resulting gain or loss is reflected within the consolidated statements of operations and comprehensive loss. Repairs and maintenance costs are expensed as incurred.

Impairment of Long-Lived Assets

Long-lived assets consist of property and equipment. Long-lived assets to be held and used are tested for recoverability whenever events or changes in business circumstances indicate that the carrying amount of the assets may not be fully recoverable. Factors that the Company considers in deciding when to perform an impairment review include significant underperformance of the business in relation to expectations, significant negative industry or economic trends and significant changes or planned changes in the use of the assets. If an impairment review is performed to evaluate a long-lived asset group for recoverability, the Company compares forecasts of undiscounted cash flows expected to result from the use and eventual disposition of the long-lived asset group to its carrying value. An impairment loss would be recognized when estimated undiscounted future cash flows expected to result from the use of an asset group are less than its carrying amount. The impairment loss would be based on the excess of the carrying value of the impaired asset group over its fair value, determined based on discounted cash flows. To date, the Company has not recorded any impairment losses on long-lived assets.

Deferred Offering Costs

The Company capitalizes certain legal, professional accounting and other third-party fees that are directly associated within-process equity financings as deferred offering costs until the equity financings are consummated. After consummation of an equity financing, these costs are recorded in stockholders' equity (deficit) as a reduction of additional paid-in capital generated as a result of the offering. Should a planned equity financing be abandoned, the deferred offering costs will be expensed immediately as a charge to operating expenses in the consolidated statement of operations and comprehensive loss.

As of December 31, 2017, the Company had capitalized $1.6 million in deferred financing costs related to its IPO. These deferred financing costs were subsequently reclassified to stockholders' equity (deficit) upon the completion of the IPO in June 2018. No deferred offering costs were capitalized as of December 31, 2018.

Research and Development Expenses

Research and development expenses include costs directly attributable to the execution of research and development programs, including personnel-related expenses such as salaries, benefits, and non-cash stock-based compensation expense; materials; supplies; depreciation on and maintenance of research equipment; manufacturing and external costs related to outside vendors engaged to conduct both preclinical studies and clinical trials; and the allocable portions of facility costs, such as rent, utilities, repairs and maintenance, depreciation, and general support services. All costs associated with research and development activities are expensed as incurred.

Research Contract Costs and Accruals

The Company has entered into various research and development contracts with research institutions and other companies. The Company records accruals for estimated ongoing research costs. When evaluating the adequacy of the accrued liabilities, the Company analyzes progress of the studies or trials, including invoices received and contracted costs. Significant judgments and estimates are made in determining the accrued balances at the end of any reporting period. Actual results could differ from the Company's estimates. The Company defers and capitalizes non-refundable advance payments made by the Company for research and development activities until the related goods are received or the related services are performed. In circumstances where amounts have been paid in excess of costs incurred, the Company records a prepaid expense.

Patent Costs

All patent-related costs incurred in connection with the filing, maintenance and prosecution of patent applications are expensed as incurred due to the uncertainty about the recovery of the expenditure. Amounts incurred are classified as general and administrative expenses in the accompanying consolidated statements of operations and comprehensive loss.

Stock-Based Compensation

The Company measures all stock-based awards granted to employees and directors based on the fair value on the date of grant. Compensation expense of those awards is recognized over the requisite service period, which is generally the vesting period of the respective award. The Company primarily issues awards with service-based vesting conditions and records the expense for these awards using the straight-line method. The Company records the expense for stock-based awards with performance-based vesting conditions over the remaining service period when management determines that achievement of the performance condition is probable. Management evaluates when the achievement of a performance condition is probable based on the expected satisfaction of the performance conditions as of the reporting date.

For share-based awards granted to non-employee consultants, compensation expense is recognized over the period during which services are rendered by such consultants until completed. At the end of each financial reporting period prior to completion of the service, the fair value of these awards is remeasured using the then-current fair value of the Company's common shares and updated assumption inputs in the Black-Scholes option-pricing model, as applicable.

The fair value of each restricted common stock award is based on the fair value of the Company's common stock, less any applicable purchase price. The fair value of each stock option is estimated using the Black-Scholes option-pricing model, which requires inputs based on certain subjective assumptions, including the expected stock price volatility, the expected term of the award, the risk-free interest rate, and expected dividends. Expected volatility is calculated based on reported volatility data for a representative group of publicly traded companies for which historical information was available. The historical volatility is calculated based on a period of time commensurate with the assumption used for the expected term. The risk-free interest rate is based on the U.S. Treasury yield curve in effect at the time of grant commensurate with the expected term assumption. The Company uses the simplified method, under which the expected term is presumed to be the midpoint between the vesting date and the end of the contractual term. The Company utilizes this method due to the lack of historical exercise data and the plain nature of its stock-based awards. The Company uses the remaining contractual term for the expected life of non-employee awards. The expected dividend yield is assumed to be zero as the Company has never paid dividends and has no current plans to pay any dividends on common stock.

Beginning with the year ended December 31, 2017, the Company adopted ASU No.2016-09, *Compensation—Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting*, and accordingly the Company accounts for stock-based compensation expense related forfeitures as the forfeiture occurs.

The Company classifies stock-based compensation expense in its consolidated statements of operations and comprehensive loss in the same manner in which the award recipient's payroll or service costs are classified.

Determination of Fair Value of Common Stock on Grant Dates prior to the Company's Initial Public Offering

Prior to the completion of the IPO, the fair value of the Company's common stock was determined by the board of directors as of the date of each option grant, with input from management, considering the Company's most recently available third-party valuations of common stock and the board of directors' assessment of additional objective and subjective factors that it believed were relevant. The board of directors determined the estimated fair value of the Company's common stock based on a number of objective and subjective factors, including the lack of an active public market for the Company's common stock and preferred stock; the prices at which the Company sold shares of its preferred stock and the superior rights and preferences of the preferred stock in relation to the Company's common stock; the progress of the Company's research and development programs, including the status of preclinical studies and current and planned clinical trials for the Company's product candidates; the Company's stage of development and commercialization and business strategy; external market conditions affecting the biotechnology industry sector; the Company's financial position; the likelihood of achieving a liquidity event, such as an IPO, or a sale of the company in light of prevailing market conditions; and the analysis of IPOs and the market performance of similar companies in the biopharmaceutical industry. The third-party valuations were performed in accordance with the guidance outlined in the American Institute of Certified Public Accountants' Accounting and Valuation Guide, *Valuation of Privately-Held-Company Equity Securities Issued as Compensation*. The methodologies included the option pricing method utilizing the back-solve method (a form of the market approach defined in the AICPA Practice Aid) and the probability-weighted expected return method based upon the probability of occurrence of certain future liquidity events such as an initial public offering or sale of the Company. Each valuation methodology included estimates and assumptions that required the Company's judgment. Significant changes to the key assumptions used in the valuations could have resulted in different fair values of the Company's common stock at each valuation date.

Income Taxes

The Company accounts for income taxes using the asset and liability method, which requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been recognized in the consolidated financial statements or in the Company's tax returns. Deferred tax assets and liabilities are determined on the basis of the differences between the financial statements and tax basis of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to reverse. Changes in deferred tax assets and liabilities are recorded in the provision for income taxes. The Company assesses the likelihood that its deferred tax assets will be recovered from future taxable income and, to the extent it believes, based upon the weight of available evidence, that it is more likely than not that all or a portion of the deferred tax assets will not be realized, a valuation allowance is established through a charge to income tax expense. Potential for recovery of deferred tax assets is evaluated by estimating the future taxable profits expected and considering prudent and feasible tax planning strategies.

The Company accounts for uncertainty in income taxes recognized in the consolidated financial statements by applying a two-step process to determine the amount of tax benefit to be recognized. First, the tax position must be evaluated to determine the likelihood that it will be sustained upon external examination by the taxing authorities. If the tax position is deemed more-likely-than-not to be sustained, the tax position is then assessed to determine the amount of benefit to recognize in the consolidated financial statements. The amount of the benefit that may be recognized is the largest amount that has a greater than 50% likelihood of being realized upon ultimate settlement. The provision for income taxes includes the effects of any resulting tax reserves, or unrecognized tax benefits, that are considered appropriate as well as the related net interest and penalties.

Comprehensive Loss

Comprehensive loss includes net loss, as well as other changes in stockholders' equity (deficit) that result from transactions and economic events other than those with stockholders. For the years ended December 31, 2018 and 2017, other comprehensive loss included unrealized losses on marketable securities. There was no difference between net loss and comprehensive loss for the year ended December 31, 2016.

Net Income (Loss) per Share

The Company follows the two-class method when computing net income (loss) per share as the Company has issued shares that meet the definition of participating securities. The two-class method determines net income (loss) per share for each class of common and participating securities according to dividends declared or accumulated and participation rights in undistributed earnings. The two-class method requires income (losses) available to common stockholders for the period to be allocated between common and participating securities based upon their respective rights to receive dividends as if all income (losses) for the period had been distributed.

Basic net income (loss) per share attributable to common stockholders is computed by dividing the net income (loss) attributable to common stockholders by the weighted average number of shares of common stock outstanding for the period, which excludes shares of restricted common stock that are not vested. Diluted net income (loss) attributable to common stockholders is computed by adjusting net income (loss) per share attributable to common stockholders to reallocate undistributed earnings based on the potential impact of dilutive securities. Diluted net income (loss) per share attributable to common stockholders is computed by dividing the diluted net income (loss) attributable to common stockholders by the weighted average number of shares of common stock outstanding for the period, including potential dilutive common shares. For purpose of this calculation, outstanding options to purchase common stock, unvested restricted common stock and shares of redeemable convertible preferred stock are considered potential dilutive common shares.

The Company's redeemable convertible preferred stock contractually entitles the holders of those shares to participate in dividends, but contractually does not require the holders of those shares to participate in losses of

the Company. Accordingly, in periods in which the Company reports a net loss attributable to common stockholders, diluted net loss per share attributable to common stockholders is the same as basic net loss per share attributable to common stockholders, since dilutive common shares are not assumed to have been issued if their effect is anti-dilutive.

Concentration of Credit Risk and Significant Suppliers

Financial instruments that potentially expose the Company to concentrations of credit risk consist primarily of cash, cash equivalents and marketable securities. The Company maintains all cash and cash equivalents at accredited financial institutions. The Company does not believe that it is subject to unusual credit risk beyond the normal credit risk associated with commercial banking relationships.

The Company is dependent on third-party manufacturers to supply products for research and development activities of its programs, including preclinical and clinical testing. In particular, the Company relies, and expects to continue to rely, on a small number of third-party manufacturers to produce and process its product candidates and to manufacture supply of its product candidates for clinical trials. These programs could be adversely affected by a significant interruption in the supply of these products.

Segment Information

The Company manages its operations as a single segment for the purposes of assessing performance and making operating decisions. All of the Company's tangible assets are held in the United States.

Recently Adopted Accounting Pronouncements

In May 2014, the Financial Accounting Standards Board ("FASB") issued ASU 2014-09, *Revenue from Contracts with Customers (Topic 606)* ("ASU 2014-09"). The standard replaced existing revenue recognition standards and significantly expands the disclosure requirements for revenue arrangements. It may be adopted either retrospectively or on a modified retrospective basis to new contracts and existing contracts with remaining performance obligations as of the effective date. The standard was effective for annual reporting periods beginning after December 15, 2017. The Company adopted the standard as of January 1, 2018 under the full retrospective method. The Company does not have and has never had any contracts that are within the scope of ASU 2014-09 or its predecessor guidance, Accounting Standard Codification ("ASC") 605, *Revenue Recognition*. Adoption of the standard did not have an impact on the Company's financial position, results of operations or cash flows as the Company does not currently have any revenue-generating arrangements; however, the adoption of this standard will impact the accounting for any future revenue transactions.

In January 2016, the FASB issued ASU No. 2016-01, *Financial Instruments—Overall (Subtopic 825-10): Recognition and Measurement of Financial Assets and Financial Liabilities* ("ASU 2016-01"). This new standard amends certain aspects of accounting and disclosure requirements for financial instruments, including the requirement that equity investments with readily determinable fair values are to be measured at fair value with any changes in fair value recognized in a company's results of operations. This new standard does not apply to investments accounted for under the equity method of accounting or those investments that result in consolidation of the investee. Equity investments that do not have readily determinable fair values may be measured at fair value or at cost minus impairment adjusted for changes in observable prices. A financial liability that is measured at fair value in accordance with the fair value option is required to be presented separately in other comprehensive income for the portion of the total change in the fair value resulting from change in the instrument-specific credit risk. In addition, a valuation allowance should be evaluated on deferred tax assets related to available-for-sale debt securities in combination with other deferred tax assets. The Company adopted the standard as of January 1, 2018. The adoption of the standard had no impact on the Company's financial position, results of operations or cash flows.

In August 2016, the FASB issued ASUNo. 2016-15, *Statement of Cash Flows (Topic 230): Classification of Certain Cash Receipts and Cash Payments* ("ASU 2016-15"), to address diversity in practice in how certain cash receipts and cash payments are presented and classified in the statement of cash flows. The Company adopted the standard as of January 1, 2018. The adoption of this standard did not have a material impact on the Company's consolidated statements of cash flows upon adoption.

In November 2016, the FASB issuedASU 2016-18, *Statement of Cash Flows (Topic 230): Restricted Cash* ("ASU 2016-18"). The amendments in this update require that amounts generally described as restricted cash and restricted cash equivalents be included within cash and cash equivalents when reconciling the beginning-of-period and end-of-period total amounts shown on the statement of cash flows. The Company adoptedASU 2016-18 as of January 1, 2018 and applied this guidance retrospectively to all periods presented in its consolidated financial statements. As a result of the adoption of ASU 2016-18, the Company no longer presents the changes within restricted cash in the Company's consolidated statements of cash flows. The reclassification was not material to the periods presented.

In May 2017, the FASB issued ASUNo. 2017-09, *Compensation—Stock Compensation (Topic 718): Scope of Modification Accounting* ("ASU 2017-09"). The new standard is intended to reduce the diversity in practice and cost and complexity when applying the guidance in Topic 718 to a change to the terms or conditions of a share-based payment award. Under the new guidance, modification accounting is required only if the fair value, the vesting conditions, or the classification of the award (as equity or liability) changes as a result of the change in terms or conditions. The Company adopted ASU 2017-09 as of January 1, 2018. The adoption of this standard did not have an impact on the Company's financial position or results of operations upon adoption or for the twelve months ended December 31, 2018.

Recently Issued Accounting Pronouncements

In February 2016, the FASB issued ASUNo. 2016-02, *Leases (Topic 842)* ("ASU 2016-02"). ASU 2016-02 requires lessees to recognize most leases on their balance sheet as a right-of-use asset and a lease liability. Leases are classified as either operating or finance based on criteria similar to existing lease accounting, with the classification affecting the pattern and classification of expense recognition in the statement of operations. This standard is effective for the Company on January 1, 2019 and requires a modified retrospective transition approach.

In July 2018, the FASB subsequently issued ASUNo. 2018-11, *Leases (Topic 842): Targeted Improvements* ("ASU 2018-11"), which includes certain amendments to ASU 2016-02 intended to provide relief in implementing the new standard. Among these amendments is the option to not restate comparative periods presented in the financial statements. The Company has elected this transition approach, using a cumulative-effect adjustment on the effective date of the standard, with comparative periods presented in accordance with the existing guidance in ASC 840. The Company adopted the standard on January 1, 2019 and has used the effective date as its date of initial application. The Company expects to take advantage of certain available expedients by electing the transition package of practical expedients permitted within ASU 2016-02, which allows the Company to not reassess previous accounting conclusions around whether arrangements are, or contain, leases, the classification of leases, and the treatment of initial direct costs. The Company also has made an accounting policy election to exclude leases with an initial term of twelve months or less from the balance sheet.

The Company is still assessing the impact of adopting the new standard, and currently expects a material impact to its consolidated balance sheet in recognizing additional lease liabilities and right-of-use assets as of January 1, 2019 related to its operating leases. The Company further expects to provide enhanced new disclosures about its leasing arrangements in its financial statements for future periods. The Company does not expect that the new standard will have a material impact on the Company's consolidated statement of operations or cash flows.

In June 2018, the FASB issued ASU No. 2018-07 (Topic 718) *Improvements to Nonemployee Share-Based Payment Accounting* ("ASU 2018-07"). This ASU is intended to simplify the accounting for share-based payments to nonemployees by aligning it with the accounting for share-based payments to employees, with certain exceptions. This guidance will be effective for annual reporting periods beginning after December 15, 2018, including interim periods within those annual reporting periods, and early adoption is permitted. The Company will adopt this standard effective January 1, 2019 and does not expect the adoption of the standard to have a material impact on the consolidated financial statements.

In August 2018, the FASB issued ASU No. 2018-13, *Fair Value Measurement (Topic 820): Disclosure Framework—Changes to the Disclosure Requirements for Fair Value Measurement* ("ASU 2018-13"), which modifies the disclosure requirements on fair value measurements. ASU 2018-13 is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2019. Early adoption is permitted. The Company does not anticipate a material impact to the consolidated financial statements as a result of the adoption of this standard.

In August 2018, the FASB issued ASU No. 2018-15, *Intangibles—Goodwill and Other—Internal-Use Software (Subtopic 350-40): Customer's Accounting for Implementation Costs Incurred in a Cloud Computing Arrangement That Is a Service Contract* ("ASU 2018-15"), which clarifies the accounting for implementation costs in cloud computing arrangements. ASU 2018-15 is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2019. Early adoption is permitted. The Company is currently evaluating the impact that the adoption of this amendment will have on its consolidated financial statements.

3. Fair Value Measurement

The following tables present information about the Company's assets that are measured at fair value on a recurring basis and indicate the level of the fair value hierarchy utilized to determine such fair values (in thousands):

	Fair Value Measurements at December 31, 2018 Using			
	Total	Level 1	Level 2	Level 3
Cash equivalents:				
Money market funds	$ 53,188	$ 53,188	$ —	$ —
Marketable securities:				
Corporate debt securities	46,122	—	46,122	—
Commercial paper	4,489	—	4,489	—
	$103,799	$ 53,188	$ 50,611	$ —

	Fair Value Measurements at December 31, 2017 Using			
	Total	Level 1	Level 2	Level 3
Cash equivalents:				
Money market funds	$ 57,750	$ 57,750	$ —	$ —
Marketable securities:				
Corporate debt securities	21,475	—	21,475	—
	$ 79,225	$ 57,750	$ 21,475	$ —

There were no changes in valuation techniques or transfers between the fair value measurement levels during the years ended December 31, 2018 or 2017. There were no liabilities measured at fair value on a recurring basis as of December 31, 2018 or 2017.

4. Marketable Securities

Marketable securities consisted of the following at December 31, 2018 and 2017 (in thousands):

	December 31, 2018			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Short-term investments:				
Corporate debt securities	$ 46,197	$ —	$ (75)	$46,122
Commercial paper	4,489	—	—	4,489
	$ 50,686	$ —	$ (75)	$50,611

	December 31, 2017			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Short-term investments:				
Corporate debt securities	$ 21,488	$ —	$ (13)	$21,475
	$ 21,488	$ —	$ (13)	$21,475

The contractual maturities of all securities held at December 31, 2018 are one year or less. As of December 31, 2018 and 2017, the aggregate fair value of securities that were in an unrealized loss position for less than twelve months was $46.1 million and $20.7 million, respectively. The Company does not intend to sell the investments, and it is not more likely than not that the Company will be required to sell the investments, before recovery of their amortized cost bases. As a result, the Company determined that it did not hold any securities with any other-than-temporary impairment as of December 31, 2018.

There were no sales of available-for-sale securities during the years ended December 31, 2018 or 2017. Net unrealized holding gains or losses for the period that have been included in accumulated other comprehensive loss were not material to the Company's consolidated results of operations.

5. Property and Equipment, Net

Property and equipment, net consisted of the following (in thousands):

	December 31,	
	2018	2017
Software	$ 1,180	$ 1,012
Laboratory equipment	8,230	6,088
Computer equipment	102	102
Furniture and fixtures	371	325
Leasehold improvements	592	335
Assets under construction	511	361
	10,986	8,223
Less: Accumulated depreciation and amortization	(2,781)	(1,335)
	$ 8,205	$ 6,888

Depreciation and amortization expense for the years ended December 31, 2018, 2017 and 2016 was $1.5 million, $0.9 million, and $0.4 million respectively.

6. Accrued Expenses

Accrued expenses consisted of the following (in thousands):

	December 31,	
	2018	2017
Accrued compensation costs	$3,364	$1,468
Accrued professional service fees	1,262	2,490
Accrued external research and manufacturing costs	3,001	1,097
Accrued additions of property and equipment	243	815
Other accrued expenses	552	731
	$8,422	$6,601

7. Commitments and Contingencies

Operating Leases

On January 21, 2016, the Company entered into a lease for office and laboratory space at its current headquarters in Cambridge, Massachusetts. The lease commenced on September 28, 2016 and expires on September 27, 2024. The Company has the right to extend the lease for one additional five-year period at a market rental rate as determined by the landlord and agreed to by the Company.

The Company also, from time to time, enters into short-term operating lease arrangements for certain laboratory equipment.

The Company records rent expense on a straight-line basis over the lease term. Rent expense during the years ended December 31, 2018, 2017 and 2016 was $2.0 million, $2.0 million and $1.0 million, respectively.

Future minimum lease payments for the Company's operating leases as of December 31, 2018 were as follows (in thousands):

Year Ending December 31	
2019	$ 1,891
2020	1,948
2021	2,006
2022	2,066
2023	2,129
Thereafter	1,632
	$ 11,672

Significant Agreements

Manufacturing Agreement

In December 2015, the Company entered into a manufacturing agreement (the "Manufacturing Agreement") with an independent third party (the "vendor") whereby the vendor performs manufacturing, analytical testing and quality assurance services related to the manufacture of drug product for use in the Company's preclinical and clinical activities. The Manufacturing Agreement included the development and establishment of a manufacturing suite (a "Cell") at the vendor's facility that would be used in the manufacturing process to fill orders of peptides ordered by the Company. All amounts incurred under the Manufacturing Agreement and subsequent amendments are recognized as research and development expense as incurred.

In October 2016, the Company and the vendor amended the Manufacturing Agreement (hereinafter the "2016 Manufacturing Agreement") to modify the payment due for the establishment of a second Cell and amend the fixed pricing for drug product produced by the vendor. The 2016 Manufacturing Agreement had a three-year term and was able to be terminated by the Company for convenience with six-months' notice.

In July 2017, the Company and the vendor further amended the 2016 Manufacturing Agreement (hereinafter the "2017 Manufacturing Agreement"). Under the 2017 Manufacturing Agreement, the Company will reimburse the vendor for specified manufacturing costs incurred in the manufacture of the peptides, plus a fixed profit margin. The 2017 Manufacturing Agreement has a five-year term and can be terminated by the Company for convenience with three-months' notice.

Other Agreements

On November 13, 2015, the Company entered into a license agreement with the Broad Institute, Inc. (the "Broad"), a related party (see Note 14), as amended in January and November 2018, pursuant to which the Company has been granted an exclusive worldwide license to certain intellectual property rights owned or controlled by Broad, Dana-Farber Cancer Institute (the "DFCI") and The General Hospital Corporation d/b/a Massachusetts General Hospital ("MGH"), (the "2015 Broad Agreement") for technology to be utilized in the Company's research and development. As consideration for the license, the Company paid the Broad a non-refundable license fee of $0.1 million. As additional consideration for the license, the Company must pay the Broad immaterial annual license maintenance fees. Additionally, the Company granted 60,000 shares of restricted common stock to each of the Broad, DFCI and MGH, which were determined to have an aggregate fair value of $0.2 million, and reimbursed the Broad $0.6 million for a portion of its past patent expenses related to the in-licensed patent rights. In June 2018, to align with institutional policies in place between the Broad, DFCI and MGH, DFCI and MGH transferred certain of the shares of restricted common stock that they had previously received to the Broad. Under the 2015 Broad Agreement, the Company agreed to reimburse the Broad for future patent expenses related to the patents covered by the license agreement. The Company could be obligated to make up to $12.6 million of developmental milestone payments to the Broad if certain development milestones are achieved over the term of the license agreement. Additionally, under the terms of the license agreement, the Company could be obligated to make up to an aggregate of $97.5 million of payments upon the achievement of specified sales milestones and to pay tiered royalties of low to mid single-digit percentages on net sales of products licensed under the agreement. The Company is required to pay the Broad a low double-digit percentage of any consideration received by the Company from a sublicensee in consideration for a sublicense. No developmental or commercial milestones have been achieved to date. The Company has the right to terminate the agreement for any reason, with or without cause.

On August 5, 2016, the Company entered into a license agreement with the DFCI to grant the Company an exclusive, royalty-free license to provide certain licensed know-how. The know-how in this agreement has particular utility in connection with the development of the licensed products referred to in the 2015 Broad Agreement. The agreement also grants a non-exclusive, royalty free right to certain clinical data being generated by the DFCI. In consideration for the licenses, the Company granted 120,000 shares of common stock to each of the Broad and DFCI. The shares issued to the Broad were unrestricted and fully vested. The 120,000 shares issued to the DFCI contained a contingent repurchase option whereby, if the DFCI failed to achieve three specific milestones, the Company could repurchase the shares (one third for each milestone) at the original purchase price, which is at zero cost. The Company has accounted for these awards consistent with equity awards with performance-based vesting conditions and, upon it being probable that the Company would not repurchase the award associated with a milestone, the expense associated with the equity grant would be recognized. During the year ended December 31, 2016, no expense was recognized as it was not probable that the DFCI would achieve the milestones. During the year ended December 31, 2017, the repurchase option associated with one-third of the shares expired due to the achievement of the specified criteria and the Company recognized $0.2 million of incremental stock-based compensation expense, which is reflected within research and development expenses in the accompanying consolidated financial statements. During the year ended December 31, 2018, the repurchase

option associated with an additional one-third of the shares expired due to the achievement of additional specified criteria and the Company recognized $0.4 million of incremental stock-based compensation expense, which is also reflected within research and development expenses in the accompanying consolidated financial statements. The Company has the right to terminate the license agreement with the DFCI for any reason, with or without cause.

Indemnification Agreements

In the ordinary course of business, the Company may provide indemnification of varying scope and terms to vendors, lessors, business partners and other parties with respect to certain matters arising out of the relationship between the parties. In addition, the Company has entered into indemnification agreements with members of its board of directors and certain executive officers and other employees that will require the Company, among other things, to indemnify them against certain liabilities that may arise by reason of their status or service as directors, officers or employees. The maximum potential amount of future payments the Company could be required to make under these indemnification agreements is, in many cases, unlimited. To date, the Company has not incurred any material costs as a result of these indemnification obligations. The Company does not believe that the outcome of any existing claims under indemnification arrangements will have a material effect on its financial position, results of operations or cash flows, and it had not accrued any liabilities related to its obligations under these agreements in its consolidated financial statements as of December 31, 2018 or 2017.

Legal Proceedings

The Company is not currently party to any material legal proceedings. At each reporting date, the Company evaluates whether or not a potential loss amount or a potential range of loss is probable and reasonably estimable under the provisions of the authoritative guidance that addresses accounting for contingencies. The Company expenses as incurred the costs related to its legal proceedings.

8. Preferred Stock

The Company's amended and restated certificate of incorporation authorizes the Company to issue up to 10,000,000 shares of undesignated preferred stock, $0.001 par value per share, none of which was issued or outstanding as of December 31, 2018.

As of December 31, 2017, the Company had 93,222,418 shares of preferred stock authorized, of which 55,500,000 shares were issued and outstanding and were designated as $0.001 par value Series A redeemable convertible preferred stock ("Series A preferred stock"), and 37,722,418 shares were issued and outstanding and were designated as $0.001 par value Series B redeemable convertible preferred stock ("Series B preferred stock").

The Company previously had issued shares of Series A and Series B preferred stock (together, the "Redeemable Convertible Preferred Stock"). The Redeemable Convertible Preferred Stock was classified outside of stockholders' equity (deficit) because the shares contained redemption features that were not solely within the control of the Company.

In August 2015, the Company entered into a Series A preferred stock purchase agreement, which, as amended, provided for the issuance and sale of up to 55,000,000 shares of Series A preferred stock at a price of $1.00 per share in up to three closings. In December 2015, the Company entered into a subscription agreement, which provided for the issuance and sale of up to an additional 500,000 shares of Series A preferred stock at a price of $1.00 per share in up to three closings. Pursuant to these agreements, the Company issued and sold a total of 14,109,185 shares during the year ended December 31, 2015 for aggregate net proceeds of $9.5 million, in addition to the conversion of then-outstanding convertible notes and accrued interest of $4.6 million. Additionally, the Company issued and sold the remaining 41,390,815 shares under these agreements during the year ended December 31, 2016 for aggregate net proceeds of $41.4 million.

In December 2016, the Company entered into a stock purchase agreement and issued and sold 24,911,030 shares of Series B preferred stock at a price of $2.81 per share for proceeds of $69.7 million, net of issuance costs of $0.3 million. In December 2017, the Company entered into a subsequent stock purchase agreement and issued and sold an additional 12,811,388 shares of Series B preferred stock at a price of $2.81 per share for proceeds of $35.9 million, net of issuance costs of $0.1 million.

Upon completion of the Company's IPO on June 29, 2018, all shares of the Redeemable Convertible Preferred Stock converted into an aggregate of 18,644,462 shares of common stock. As of December 31, 2018, there were no shares of Redeemable Convertible Preferred Stock issued or outstanding.

Redeemable Convertible Preferred Stock consisted of the following (in thousands, except share amounts):

	As of December 31, 2017				
	Preferred Shares Authorized	Preferred Shares Issued and Outstanding	Carrying Value	Liquidation Preference	Common Stock Issuable Upon Conversion
Series A preferred stock	55,500,000	55,500,000	$ 63,012	$ 63,012	11,099,994
Series B preferred stock	37,722,418	37,722,418	111,883	111,883	7,544,468
	93,222,418	93,222,418	$ 174,895	$ 174,895	18,644,462

The holders of the Redeemable Convertible Preferred Stock had the following rights and preferences prior to conversion:

Voting Rights

The holders of Redeemable Convertible Preferred Stock were entitled to vote, together with the holders of common stock, on all matters submitted to stockholders for a vote and had the right to vote the number of shares equal to the number of shares of common stock into which such Redeemable Convertible Preferred Stock could convert on the record date for determination of stockholders entitled to vote. The holders of Series A preferred stock, exclusively and as a separate class, were entitled to elect two directors of the Company.

Conversion

Each share of Redeemable Convertible Preferred Stock was convertible, at the option of the holder, at any time, and without the payment of additional consideration. In addition, the terms of the Redeemable Convertible Preferred Stock provided for automatic conversion into shares of common stock at the applicable conversion ratio then in effect (i) upon the closing of a firm commitment underwritten public offering with proceeds of at least $50.0 million after deducting underwriting discounts and commissions to the Company and the Company listing its common stock on the New York Stock Exchange or the Nasdaq Stock Market or (ii) upon the vote or written consent of the holders of at least 60% of the outstanding shares of the Redeemable Convertible Preferred Stock, voting together as a single class and, as to the conversion of the shares of Series B preferred stock, the vote of at least 60% of the outstanding shares of Series B preferred stock.

The conversion ratio of each series of Redeemable Convertible Preferred Stock was determined by dividing the Original Issue Price (as defined below) of each series of preferred stock by the Conversion Price (as defined below) of each series of preferred stock. The Original Issue Price per share was $1.00 for Series A preferred stock and $2.81 per share for Series B preferred stock, each subject to appropriate adjustment in the event of any stock dividend, stock split, combination or other similar recapitalization with respect to the Redeemable Convertible Preferred Stock. The Conversion Price was $5.00 for Series A preferred stock and $14.05 for Series B preferred stock, each subject to appropriate adjustment in the event of any stock dividend, stock split, combination or other similar recapitalization and other adjustments as set forth in the Company's certificate of incorporation, as amended and restated.

Dividends

Holders of the Series A preferred stock and Series B preferred stock were entitled to receive cumulative accruing dividends at an annual rate of $0.08 per share and $0.2248 per share, respectively (each subject to appropriate adjustment in the event of any stock split, stock dividend, combination or other similar recapitalization). Dividends were to accrue from day to day, whether or not declared and were payable only when declared by the Company's board of directors. The Company could not declare, pay or set aside any dividends on shares of any other class or series of capital stock of the Company unless the holders of the Redeemable Convertible Preferred Stock then outstanding were to first receive, or simultaneously receive, a dividend on each outstanding share of Redeemable Convertible Preferred Stock in an amount at least equal to the greater of (i) the amount of the aggregate accrued but unpaid dividends on each share of Redeemable Convertible Preferred Stock or (ii) (A) in the case of a dividend on common stock or any class or series of stock that was convertible into common stock, that dividend per share of Redeemable Convertible Preferred Stock as would equal the product of (1) the dividend payable on each share of such class or series determined, if applicable, as if all shares of such class or series had been converted into common stock and (2) the number of shares of common stock issuable upon conversion of each share of Redeemable Convertible Preferred Stock, or (B) in the case of a dividend on any class or series that was not convertible into common stock, at a rate per share of Redeemable Convertible Preferred Stock determined by (1) dividing the amount of the dividend payable on each share of such class or series of capital stock by the Original Issue Price of such class or series of capital stock (subject to appropriate adjustment in the event of any stock dividend, stock split, combination of or other similar recapitalization affecting such shares) and (2) multiplying such fraction by an amount equal to the Original Issue Price of each series of Redeemable Convertible Preferred Stock. If the Company declared, paid or sets aside, on the same date, a dividend on shares of more than one class or series of capital stock of the Company, the dividend payable to the holders of the Redeemable Convertible Preferred Stock would be calculated based upon the dividend on the class or series of capital stock that would result in the highest Redeemable Convertible Preferred Stock dividend. No dividends have been declared or paid during the years ended December 31, 2018 or 2017.

Liquidation

In the event of any liquidation event, voluntary or involuntary, dissolution or winding up of the Company or Deemed Liquidation Event (as defined below), the holders of the then-outstanding Redeemable Convertible Preferred Stock were entitled to receive, prior and in preference to any distributions to the holders of the common stock an amount per share equal to the greater of (i) the applicable Original Issue Price for each of series of Redeemable Convertible Preferred Stock, plus any accrued but unpaid dividends, or (ii) the amount that would be payable if all shares of each series had been converted into common stock.

After payments had been made in full to the holders of the Redeemable Convertible Preferred Stock, then, to the extent available, the remaining amounts would have been distributed among the holders of the shares of common stock, pro rata based on the number of shares held by each holder.

Unless 60% of the holders of the Redeemable Convertible Preferred Stock, voting together as a single class, elected otherwise, a Deemed Liquidation Event would have included a merger or consolidation (other than one in which stockholders of the Company own a majority by voting power of the outstanding shares of the surviving or acquiring corporation) or a sale, lease, transfer, exclusive license, or other disposition of substantially all of the assets of the Company.

Redemption

At the written election of the holders of at least 60% of the Redeemable Convertible Preferred Stock, voting together as a single class, the shares of Redeemable Convertible Preferred Stock outstanding were redeemable, at any time on or after December 28, 2023, in three equal annual installments commencing no more than 60 days after receipt of the required vote, in an amount equal to the Original Issue Price per share of each series of Redeemable Convertible Preferred Stock plus all accrued but unpaid dividends thereon whether or not declared.

9. Common Stock

As of December 31, 2018 and 2017, the Company's certificate of incorporation, as amended and restated, authorized the Company to issue 150,000,000 and 130,000,000 shares, respectively, of common stock with a par value of $0.001 per share.

Each share of common stock entitles the holder to one vote on all matters submitted to a vote of the Company's stockholders. Common stockholders are entitled to receive dividends, as may be declared by the Company's board of directors, if any, subject to the preferential dividend rights of the Redeemable Convertible Preferred Stock. No dividends have been declared or paid during the years ended December 31, 2018 or 2017.

As of December 31, 2018 and 2017 the Company has reserved for future issuance the following number of shares of common stock:

	As of December 31,	
	2018	2017
Shares reserved for conversion of Series A preferred stock outstanding	—	11,099,994
Shares reserved for conversion of Series B preferred stock outstanding	—	7,544,468
Shares reserved for exercise of outstanding stock options under the 2015 Stock Option and Grant Plan	2,071,013	1,587,293
Shares reserved for future issuance under the 2015 Stock Option and Grant Plan	—	1,684,952
Shares reserved for exercise of outstanding stock options under the 2018 Stock Option and Grant Plan	477,060	—
Shares reserved for future issuance under the 2018 Stock Option and Grant Plan	760,628	—
Shares reserved for future issuance under the 2018 Employee Stock Purchase Plan	270,000	—
	3,578,701	21,916,707

10. Stock-Based Compensation

2015 Stock Option and Grant Plan

The Company's 2015 Stock Option and Grant Plan, as amended (the "2015 Plan"), provided for the Company to grant incentive or nonqualified stock options, restricted stock awards, unrestricted stock awards or restricted stock units to employees, directors and consultants of the Company. The 2015 Plan was administered by the board of directors or, at the discretion of the board of directors, by a committee of the board of directors. The exercise prices, vesting and other restrictions for awards granted under the 2015 Plan were determined at the discretion of the board of directors, or their committee if so delegated, except that the exercise price per share of the stock options was not permitted to be less than 100% of the fair market value of a share of the Company's common stock on the date of grant and the term of the stock options was not permitted to be greater than ten years. Stock options granted under the 2015 Plan to employees generally vest over four years and expire after 10 years.

The total number of shares of common stock that were authorized for issuance under the 2015 Plan was 4,665,175 shares as of December 31, 2017. As of the effective date of the 2018 Stock Option and Incentive Plan, and as of December 31, 2018, no shares remained available for future issuance under the 2015 Plan.

2018 Stock Option and Incentive Plan

On June 13, 2018, the Company's stockholders approved the 2018 Stock Option and Incentive Plan (the "2018 Plan"), which became effective on June 26, 2018. The 2018 Plan provides for the grant of incentive stock options, nonqualified stock options, stock appreciation rights, restricted stock units, restricted stock awards, unrestricted stock awards and dividend equivalent rights to the Company's officers, employees, directors and

other key persons (including consultants). The number of shares initially reserved for issuance under the 2018 Plan was 1,215,000 shares, which shall be cumulatively increased on January 1, 2019 and each January 1 thereafter by 4% of the number of shares of the Company's common stock outstanding on the immediately preceding December 31 or such lesser number of shares determined by the Company's compensation committee.

As of the effective date of the 2018 Plan, the Company will not grant any further awards under the 2015 Plan. However, the shares of common stock underlying any awards that are forfeited, canceled, held back upon exercise or settlement of an award to satisfy the exercise price or tax withholding, reacquired by the Company prior to vesting, satisfied without the issuance of stock, expire or are otherwise terminated (other than by exercise) under the 2018 Plan and the 2015 Plan will be added back to the shares of common stock available for issuance under the 2018 Plan.

The terms of stock options and restricted stock awards, including vesting requirements, are determined by the board of directors or its delegates, subject to the provisions of the 2018 Plan.

As of December 31, 2018, there were 760,628 shares available for future issuance under the 2018 Plan.

2018 Employee Stock Purchase Plan

On June 13, 2018, the Company's stockholders approved the 2018 Employee Stock Purchase Plan (the "ESPP"), which became effective on June 26, 2018. A total of 270,000 shares of common stock were reserved for issuance under the ESPP. In addition, the number of shares of common stock that may be issued under the ESPP will automatically increase on January 1, 2019, and each January 1 thereafter through January 1, 2028, by the lesser of (i) 405,000 shares of common stock, (ii) 1% of the number of shares of the Company's common stock outstanding on the immediately preceding December 31 or (iii) such lesser number of shares determined by the administrator of the Company's ESPP. No offering periods under the 2018 ESPP had been initiated as of December 31, 2018.

Stock Options

The following table summarizes changes in stock option activity during the year ended December 31, 2018 (in thousands, except per share amounts):

	Number of Shares	Weighted Average Exercise Price	Weighted Average Contractual Term	Aggregate Intrinsic Value
			(in years)	*(in thousands)*
Outstanding as of December 31, 2017	1,587,293	$ 4.11	9.17	$ 8,790
Granted	1,137,083	11.01		
Exercised	(129,510)	3.13		
Forfeited	(46,793)	11.52		
Outstanding as of December 31, 2018	2,548,073	$ 7.11	8.68	$ 1,965
Options vested or expected to vest as of December 31, 2018	2,548,073	$ 7.11	8.68	$ 1,965
Options exercisable as of December 31, 2018	592,771	$ 3.81	8.09	$ 956

The weighted average grant-date fair value per share of stock options granted during the years ended December 31, 2018, 2017 and 2016 was $8.81, $5.00 and $2.10, respectively.

The aggregate intrinsic value of stock options exercised during the years ended December 31, 2018 and 2017 was $1.1 million and $0.1 million, respectively. There were no options exercised during the year ended December 31, 2016.

Stock Option Valuation

The assumptions that the Company used to determine the fair value of the stock options granted to employees and directors were as follows, presented on a weighted average basis:

	Year Ended December 31,		
	2018	2017	2016
Expected volatility	101.10%	103.28%	103.52%
Risk-free interest rate	2.69%	1.92%	1.48%
Expected dividend yield	0.00%	0.00%	0.00%
Expected life (in years)	6.00	6.04	6.04

There were no stock option awards granted tonon-employees during the year ended December 31, 2018. Stock option awards granted to non-employees during the years ended December 31, 2017 and 2016 were not significant.

Restricted Common Stock

Restricted stock awards originally issued under the terms of the 2015 Plan allow the Company, at its discretion, to repurchase unvested shares at the initial purchase price if the employees or non-employees terminate their service relationship with the Company.

No shares of restricted common stock were issued during the years ended December 31, 2018 or 2017.

The following table summarizes the Company's restricted common stock activity under the 2015 Plan since December 31, 2017:

	Number of Shares	Weighted Average Grant-Date Fair Value per Share
Unvested restricted common stock as of December 31, 2017	703,155	$ 1.93
Canceled	(12,625)	$ 1.25
Vested	(306,566)	$ 1.76
Unvested restricted common stock as of December 31, 2018	383,964	$ 1.97

The aggregate fair value of restricted common stock awards that vested during the years ended December 31, 2018, 2017 and 2016, based upon the fair values of the stock underlying the restricted stock awards on the day of vesting, was $3.1 million, $2.3 million and $0.6 million, respectively.

Founder and Collaborator Awards

From May 2015 through July 2016, the Company issued 1,510,000 shares of restricted common stock outside of the 2015 Plan tonon-employee founders and collaborators. No such shares of restricted common stock were issued during the years ended December 31, 2018 or 2017. The shares were issued under the terms of the respective restricted common stock agreements and unvested shares are subject to repurchase by the Company upon the holder's termination of their relationship with the Company. The unvested shares of restricted common stock are subject to the Company's right to repurchase at the original purchase price per share.

Of the total shares of restricted common stock awarded to the founders and collaborators, 300,000 shares vested immediately upon grant; 910,000 shares vest quarterly over a four-year period based on each grantee's continued service relationship with the Company in varying capacity as advisors; and 180,000 shares vest upon the achievement of specified performance milestones. Additionally, 120,000 shares were issued as fully vested awards, but are subject to a repurchase option, which expires upon the achievement of specified milestones. Through December 31, 2018, the repurchase option on 80,000 of these shares expired.

Of these awards, the underlying restricted common stock agreement for 180,000 shares of restricted common stock provides for a put option whereby the recipient may sell its vested shares back to the Company at a price per share equal to the fair value of the Company's common stock upon both (i) the termination of the consulting agreement between the recipient and the Company for any reason and (ii) the determination by the recipient's employer that the ownership of the restricted common stock is in violation of the employer's conflict of interest policy. Prior to the closing of the Company's IPO, these awards were classified in the consolidated balance sheet as contingently redeemable common stock and were presented outside of permanent equity. As of December 31, 2017, $0.4 million was recorded in temporary equity related to these awards. Upon the closing of the Company's IPO, this put option expired and the amount recorded in temporary equity was recorded to additional paid in capital.

A summary of the changes in the Company's unvested restricted common stock awards granted to founders and collaborators since December 31, 2017 is as follows:

	Number of Shares	Weighted Average Grant-Date Fair Value
Unvested restricted common stock as of December 31, 2017	578,123	$ 1.30
Vested	(227,498)	$ 1.29
Unvested restricted common stock as of December 31, 2018	350,625	$ 1.29

The aggregate fair value of restricted common stock awards issued outside of the 2015 Plan that vested during the years ended December 31, 2018, 2017 and 2016, based upon the fair values of the stock underlying the restricted stock awards on the day of vesting, was $2.3 million, $1.5 million and $0.9 million, respectively.

Stock-Based Compensation Expense

The Company recorded stock-based compensation expense related to all stock-based awards in the following expense categories of its consolidated statements of operations and comprehensive loss (in thousands):

	Year Ended December 31,		
	2018	2017	2016
Research and development expenses	$3,840	$2,191	$1,024
General and administrative expenses	2,389	851	346
	$6,229	$3,042	$1,370

During the year ended December 31, 2018, the Company recognized stock-based compensation expense of $0.4 million for awards with performance-based vesting conditions related to the expiration of an additional repurchase option on a portion of the unvested restricted common shares issued to the DFCI (see Note 7). During the year ended December 31, 2017, the Company recognized stock-based compensation expense of $0.2 million for awards with performance-based vesting conditions related to the expiration of a repurchase option on a portion of the unvested restricted common shares issued to the DFCI upon the achievement of a specified development milestone by the DFCI. During the year ended December 31, 2016, the Company did not recognize any stock-based compensation expense for the awards granted with performance-based vesting conditions because the performance conditions under outstanding awards were not probable of being achieved.

As of December 31, 2018, the Company had an aggregate of $10.3 million of unrecognized stock-based compensation expense related to unvested stock option awards, excluding awards with performance-based vesting conditions, which is expected to be recognized over a weighted-average period of approximately 2.6 years. Additionally, as of December 31, 2018, the Company had an aggregate of $1.4 million of unrecognized stock-based compensation expense related to unvested restricted common stock awards, excluding awards with

performance-based vesting conditions, which is expected to be recognized over a weighted-average period of approximately 1.0 years.

11. 401(k) Savings Plan

The Company has a defined-contribution savings plan under Section 401(k) of the Internal Revenue Code (the "401(k) Plan"). The 401(k) Plan covers all employees who meet defined minimum age and service requirements. Contributions are permitted up to the maximum allowed under the Internal Revenue Code of each covered employee's salary. The 401(k) Plan permits the Company to contribute at its discretion. The Company made $0.1 million in contributions to the 401(k) Plan for the year ended December 31, 2018 and did not make any contributions for the years ended December 31, 2017 and 2016, respectively.

12. Income Taxes

2017 U.S. Tax Reform

On December 22, 2017, the Tax Cuts and Jobs Act (the "Tax Reform Act") was enacted, which significantly reforms the Internal Revenue Code of 1986, as amended. The Tax Reform Act, among other things, contains significant changes to corporate taxation, including reduction of the corporate tax rate from the existing top marginal rate of 35% to a flat rate of 21%, effective as of January 1, 2018; limitation of the tax deduction for interest expense; limitation of the deduction for net operating losses to 80% of annual taxable income and elimination of net operating loss carry backs, in each case, for losses arising in taxable years beginning after December 31, 2017 (though any such tax losses may be carried forward indefinitely); and modifying or repealing many business deductions and credits, including reducing the business tax credit for certain clinical testing expenses incurred in the testing of certain drugs for rare diseases or conditions generally referred to as "orphan drugs".

As of December 31, 2017, the Company was still in the process of analyzing the impact to the Company of the Tax Reform Act. Where the Company was not able to make reasonable estimates of the effects for which its analysis was not yet complete, the Company recorded provisional amounts. During the year ended December 31, 2018, the Company finalized its analysis and filed its 2017 U.S. corporate income tax return. As a result, no material adjustments were made to the net provisional amounts recorded as of December 31, 2017 related to the Tax Reform Act.

Income Taxes

During the years ended December 31, 2018, 2017 or 2016 the Company recorded no income tax benefits for the net operating losses incurred and research and development tax credits earned in each year or interim period due to its uncertainty of realizing a benefit from those items.

A reconciliation of the U.S. federal statutory income tax rate to the Company's effective income tax rate is as follows:

	Year Ended December 31,		
	2018	2017	2016
Federal statutory income tax rate	21.0%	34.0%	34.0%
State taxes, net of federal benefit	5.9	5.0	5.3
Federal and state research and development tax credits	4.7	2.9	3.6
Other	0.3	(0.6)	2.5
Nondeductible items	(1.3)	(1.9)	(4.7)
Change in rate on deferred taxes as a result of Tax Reform Act	—	(19.9)	—
Change in valuation allowance	(30.6)	(19.5)	(40.7)
Effective income tax rate	— %	— %	— %

Net deferred taxes consisted of the following (in thousands):

	December 31,	
	2018	2017
Deferred tax assets:		
Net operating loss carryforwards	$ 32,096	$ 22,082
Capitalized research and development expenses	8,611	—
Research and development tax credit carryforwards	6,414	2,127
Stock-based compensation	150	—
Deferred rent	230	217
Accruals and reserves	866	363
Other	4	—
Total deferred tax assets	48,371	24,789
Valuation allowance	(47,536)	(23,964)
Deferred tax liabilities:		
Stock-based compensation	—	(175)
Depreciation	(835)	(650)
Net deferred tax assets	$ —	$ —

As of December 31, 2018, the Company had federal net operating loss carry forwards of approximately $117.1 million, which resulted in a deferred tax asset of $24.6 million, of which $79.1 million will begin to expire in 2034 and $38.0 million which can be carried forward indefinitely. As of December 31, 2018, the Company also had state net operating loss carry forwards of approximately $118.7 million, which resulted in deferred tax assets of $7.5 million, which begin to expire in 2034.

As of December 31, 2018, the Company had federal research and development tax credit carry forwards of approximately $5.2 million, which resulted in a deferred tax asset of $5.2 million, which begin to expire in 2034. As of December 31, 2018, the Company also had state research and development tax credit carry forwards of approximately $1.5 million, which resulted in a deferred tax asset of $1.2 million, which begin to expire in 2029.

Utilization of the net operating loss carryforwards and research and development tax credit carryforwards may be subject to an annual limitation under Section 382 of the Internal Revenue Code of 1986, and corresponding provisions of state law, due to ownership changes that have occurred previously or that could occur in the future. These ownership changes may limit the amount of carryforwards that can be utilized annually to offset future taxable income. In general, an ownership change, as defined by Section 382, results from transactions increasing the ownership of certain shareholders or public groups in the stock of a corporation by more than 50% over a three-year period. The Company has not conducted a study to assess whether a change of control has occurred or whether there have been multiple changes of control since inception due to the significant complexity and cost associated with such a study. If the Company has experienced a change of control, as defined by Section 382, at any time since inception, utilization of the net operating loss carryforwards or research and development tax credit carryforwards would be subject to an annual limitation under Section 382, which is determined by first multiplying the value of the Company's stock at the time of the ownership change by the applicable long-term tax-exempt rate, and then could be subject to additional adjustments, as required. Any limitation may result in expiration of a portion of the net operating loss carryforwards or research and development tax credit carryforwards before utilization. Further, until a study is completed and any limitation is known, no amounts are being presented as an uncertain tax position.

The Company has evaluated the positive and negative evidence bearing upon its ability to realize the deferred tax assets. Management has considered the Company's cumulative net losses and its lack of commercialization of any products or generation of any revenue from product sales since inception and has concluded that it is more likely than not that the Company will not realize the benefits of the deferred tax assets.

Accordingly, a full valuation allowance has been established against the net deferred tax assets as of December 31, 2018 and 2017. Management reevaluates the positive and negative evidence at each reporting period.

Changes in the valuation allowance for deferred tax assets during the years ended December 31, 2018 and 2017 were primarily due to the increase in net operating loss carryforwards, and were as follows:

	Year Ended December 31,		
	2018	2017	2016
Valuation allowance as of beginning of year	$23,964	$14,706	$ 3,537
Increases recorded to income tax provision	23,765	9,832	11,760
Decreases recorded as a benefit to income tax provision	(193)	(574)	(591)
Valuation allowance as of end of year	$47,536	$23,964	$ 14,706

The Company has not recorded any amounts for unrecognized tax benefits as of December 31, 2018, 2017 or 2016.

The Company files tax returns as prescribed by the tax laws of the jurisdictions in which it operates. In the normal course of business, the Company is subject to examination by federal and state jurisdictions, where applicable. There are currently no pending tax examinations. As of December 31, 2018 and 2017, the Company's tax years are still open under statute from 2014 to the present. Earlier years may be examined to the extent that tax credit or net operating loss carry forwards are used in future periods. It is the Company's policy to include penalties and interest expense related to income taxes as a component of other income (expense) and interest expense, respectively, as necessary. As of December 31, 2018 and 2017, the Company had no accrued interest or penalties related to uncertain tax positions and no amounts have been recognized in the Company's consolidated statements of operations and comprehensive loss.

13. Net Loss per Share

Basic and diluted net loss per share attributable to common stockholders was calculated as follows (in thousands, except share and per share amounts):

	Year Ended December 31,		
	2018	2017	2016
Numerator:			
Net loss	$ (76,934)	$ (47,536)	$ (27,433)
Accretion of redeemable convertible preferred stock to redemption value	(6,371)	(10,396)	(2,989)
Net loss attributable to common stockholders	$ (83,305)	$ (57,932)	$ (30,422)
Denominator:			
Weighted average common shares outstanding, basic and diluted	15,036,397	1,687,859	990,171
Net loss per share attributable to common stockholders, basic and diluted	$ (5.54)	$ (34.32)	$ (30.72)

The Company excluded 734,589, 1,281,278 and 1,874,023 shares of restricted common stock for the years ended December 31, 2018, 2017 and 2016, respectively, from the calculation of basic net loss per share because these shares had not vested.

The Company's potential dilutive securities, which include stock options, unvested restricted common stock and redeemable convertible preferred stock, have been excluded from the computation of diluted net loss per

share attributable to common stockholders whenever the effect of including them would be to reduce the net loss per share. In periods where there is a net loss, the weighted average number of common shares outstanding used to calculate both basic and diluted net loss per share attributable to common stockholders is the same. The following potential common shares, presented based on amounts outstanding at each period end, were excluded from the calculation of diluted net loss per share attributable to common stockholders for the periods indicated because including them would have had an anti-dilutive effect:

	Year Ended December 31,		
	2018	2017	2016
Series A preferred stock (as converted to common stock)	—	11,099,994	11,099,994
Series B preferred stock (as converted to common stock)	—	7,544,468	4,982,201
Outstanding stock options	2,548,073	1,587,293	986,113
Unvested restricted common stock	734,589	1,281,278	1,874,023
	3,282,662	21,513,033	18,942,331

14. Related Parties

During the years ended December 31, 2018, 2017 and 2016, the Company paid fees to Third Rock Ventures, LLC ("TRV"), an affiliate of one of the Company's principal stockholders, in exchange for consulting services. These services included services as the Company's interim Chief Executive Officer and interim Chief Scientific Officer during the year ended December 31, 2016. The Company recorded expenses related to such fees of an insignificant amount, $0.1 million and $1.0 million during the years ended December 31, 2018, 2017 and 2016, respectively. At December 31, 2018 and 2017, the Company had no such amounts and an insignificant amount, respectively, in accounts payable and accrued expenses due to TRV.

A member of the Company's board of directors is a founding director and the current president of the Broad. In November 2015, the Company entered into the 2015 Broad Agreement with the Broad (see Note 7) and, as consideration, the Company granted 60,000 shares of restricted common stock to the Broad, which were determined to have a fair value of $0.1 million. Additionally, the Company must pay the Broad immaterial annual license maintenance fees. At the time the Company entered into the 2015 Broad Agreement, the Company reimbursed the Broad $0.6 million for a portion of past patent expenses and, under the terms of the license agreement, the Company is required to reimburse Broad for future patent expenses related to patents licensed to the Company. The Company could be obligated to make up to $12.6 million of developmental milestone payments to the Broad if certain development milestones are achieved over the term of the license agreement. Additionally, under the terms of the license agreement, the Company could be obligated to make up to an aggregate of $97.5 million of payments upon the achievement of specified sales milestones and to pay tiered royalties of low to mid single-digit percentages on net sales of products licensed under the agreement. The Company is required to pay the Broad a low double-digit percentage of any consideration received by the Company from a sublicensee in consideration for a sublicense. No developmental or commercial milestones have been achieved to date.

In August 2016, the Company entered into a license agreement with the DFCI in connection with the development of licensed products referred to in the 2015 Broad Agreement. As consideration, the Company granted 120,000 shares of restricted common stock to the Broad, which were determined to have a fair value of $0.2 million. In June 2018, to align with institutional policies in place between the Broad, DFCI and MGH, the DFCI and MGH transferred certain of the shares of restricted common stock that they had previously received to the Broad. The Company recorded expenses related to payments to the Broad of $2.0 million, $0.8 million and $0.7 million during the years ended December 31, 2018, 2017 and 2016, respectively. At December 31, 2018 and 2017, the Company had $2.0 million and $0.2 million in accounts payable and accrued expenses due to the Broad, respectively.

15. Selected Quarterly Financial Data (Unaudited)

The following table contains selected quarterly financial information for 2018 and 2017. The Company believes that the following information reflects all normal recurring adjustments necessary for a fair statement of the information for the periods presented. The operating results for any quarter are not necessarily indicative of results for any future period.

	2018			
	First Quarter	Second Quarter	Third Quarter	Fourth Quarter
	(in thousands, except per share data)			
Total operating expenses	$ 16,757	$ 19,117	$ 19,053	$ 23,774
Total other income (expense), net	237	218	662	650
Net loss	(16,520)	(18,899)	(18,391)	(23,124)
Accretion of redeemable convertible preferred stock to redemption value	(3,186)	(3,185)	—	—
Net loss attributable to common stockholders	$ (19,706)	$ (22,084)	$ (18,391)	$ (23,124)
Net loss per share attributable to common stockholders, basic and diluted	$ (9.47)	$ (7.84)	$ (0.67)	$ (0.84)

	2017			
	First Quarter	Second Quarter	Third Quarter	Fourth Quarter
	(in thousands, except per share data)			
Total operating expenses	$ 9,548	$ 9,764	$ 14,142	$ 14,633
Total other income (expense), net	79	162	153	157
Net loss	(9,469)	(9,602)	(13,989)	(14,476)
Accretion of redeemable convertible preferred stock to redemption value	(2,476)	(2,503)	(2,530)	(2,887)
Net loss attributable to common stockholders	$ (11,945)	$ (12,105)	$ (16,519)	$ (17,363)
Net loss per share attributable to common stockholders, basic and diluted	$ (8.10)	$ (7.55)	$ (9.59)	$ (8.93)

16. Subsequent Events

The Company considers events or transactions that have occurred after the balance sheet date of December 31, 2018, but prior to the filing of the financial statements with the SEC to provide additional evidence relative to certain estimates or to identify matters that require additional recognition or disclosure.

Subsequent events have been evaluated through March 11, 2019, the date at which the consolidated financial statements for the year ended December 31, 2018 were issued.

17. Subsequent Events (Unaudited)

On November 20, 2019, the Company issued a press release announcing that, as part of a new strategic focus, it was reducing its workforce by approximately 24% of its current headcount. This workforce reduction took place during the fourth quarter of 2019. At this time, the Company ceased undertaking new additional spending commitments related to its cancer vaccine programs, NEO-PV-01 and NEO-SV-01. The Company will continue to conduct follow-up from its NT-002 clinical trial of NEO-PV-01 in first-line patients with untreated advanced or metastatic non-small cell lung cancer, with plans to report clinical data from this trial in the third

quarter of 2020. The Company also plans to cease future enrollment in its NT-003 trial in metastatic melanoma. The Company believes these actions will improve its potential to bring value to patients, employees and shareholders.

On January 15, 2020, the Company entered into an Agreement and Plan of Merger (the "Merger Agreement") with BioNTech SE, a Societas Europaea organized and existing under the laws of Germany ("Parent"), and Endor Lights, Inc., a Delaware corporation and a direct, wholly-owned subsidiary of Parent ("Merger Sub" and, together with Parent, the "Acquiring Parties"), pursuant to which, subject to the satisfaction or waiver of the conditions therein, Merger Sub will merge with and into the Company (the "Merger"), with the Company surviving as a wholly-owned subsidiary of Parent. The Merger Agreement was unanimously approved by the members of the board of directors of the Company (the "Board") and the Board resolved to recommend approval of the Merger Agreement to the Company's shareholders.

Subject to the terms of the Merger Agreement, at the effective time of the Merger (the "Effective Time"), each share of the Company's common stock issued and outstanding immediately prior to the Effective Time shall automatically be cancelled and converted into the right to receive 0.063 of an American Depositary Share of Parent ("Parent ADS"), with each Parent ADS representing one ordinary share of Parent, without interest but subject to any withholding required under applicable law (the "Merger Consideration").

American Depositary Shares

Representing Ordinary Shares

PRELIMINARY PROSPECTUS

, 2020

Through and including , 2020 (the 25th day after the date of this prospectus), all dealers effecting transactions in these securities, whether or not participating in this offering, may be required to deliver a prospectus. This is in addition to the dealers' obligation to deliver a prospectus when acting as underwriters and with respect to their unsold allotments or subscriptions.

PART II

INFORMATION NOT REQUIRED IN THE PROSPECTUS

Item 6. Indemnification of Directors and Officers

As a German European public company with limited liability, we are—insofar as applicable pursuant to the SE Regulation and the German law on the implementation of the SE (SEAG)—subject to the German Stock Corporation Act (*Aktiengesetz*), as amended. Under German law, we may not indemnify members of our Management Board and Supervisory Board to the extent the relevant claim or loss has arisen as a result of the breach by the member of his or her duties owed to us. Otherwise we are required under the law to indemnify our Management Board and Supervisory Board members from and against any liabilities arising out of or in connection with their services to us.

We provide directors' and officers' liability insurance for the members of our Management and Supervisory Boards against civil liabilities, which they may incur in connection with their activities on behalf of our company.

In the underwriting agreement, the form of which is filed as Exhibit 1.1 to this Registration Statement, the underwriters will agree to indemnify, under certain conditions, us, the members of our Supervisory Board, Management Board and persons who control our company within the meaning of the Securities Act, against certain liabilities, but only to the extent that such liabilities are caused by information relating to the underwriters furnished to us in writing expressly for use in this registration statement and certain other disclosure documents.

Insofar as indemnification of liabilities arising under the Securities Act may be permitted to our board, executive officers, or persons controlling us pursuant to the foregoing provisions, we have been informed that, in the opinion of the SEC, such indemnification is against public policy as expressed in the Securities Act and is therefore unenforceable.

Item 7. Recent Sales of Unregistered Securities

Set forth below is information regarding all securities issued by us without registration under the Securities Act since January 1, 2016. We believe that each of such issuances was exempt from registration under the Securities Act in reliance on Section 4(a)(2) of the Securities Act or Rule 506 promulgated thereunder as transactions by an issuer not involving a public offering. The recipients of securities in each of these transactions acquired the securities for investment only and not with a view to or for sale in connection with any distribution thereof, and appropriate legends were affixed to the securities issued in these transactions. Each of the recipients of securities in these transactions was either an accredited investor within the meaning of Rule 501 of Regulation D under the Securities Act or was our employee, director or consultant and received the securities under our equity incentive plans. None of these transactions involved any underwriters, underwriting discounts or commissions or any public offering. All recipients had adequate access, through their relationships with us to information about us. The sales of these securities were made without any general solicitation or advertising.

- In February 2018 we issued 22,587,912 ordinary shares in private placements to a group of existing and new investors for aggregate proceeds received of $270.9 million, which we refer to as our Series A financing.
- In September 2018 we issued 582,714 ordinary shares as part of our Stock Appreciation Rights program for aggregate consideration of €5.9 million ($6.5 million).
- In October 2018 we issued 3,360,870 ordinary shares in private placements to Pfizer, Fidelity and an existing investor for aggregate proceeds received of $55.0 million.
- In January 2019 we issued 5,088,204 ordinary shares in private placements to Sanofi and an existing investor for aggregate proceeds received of $92.1 million.

- In April 2019 we issued 2,374,794 ordinary shares in a private placement to Eli Lilly. The shares were subscribed for by Eli Lilly against contribution in kind of shares in BioNTech Cell & Gene Therapies GmbH, which were valued at $43.0 million.
- In June and August 2019 we issued an aggregate of 12,465,288 ordinary shares in private placements to a group of existing and new investors for aggregate proceeds received of $225.6 million, which we refer to as our Series B financing.

  We also issued 5,524,506 shares for anticipated proceeds of €89.3 million to a Hong Kong-based investor in connection with the Series B private placement. Under the terms of the Series B investment agreement, the investor agreed to fund the closing of such shares by August 23, 2019, but was unable to do so. The shares were transferred to us for no consideration and are held in treasury.
- In August 2019 we agreed to issue up to 3,038,674 ordinary shares in a private placement to BMGF for aggregate consideration of €49.9 million ($55.0 million). Such issuance occurred upon registration of the shares in the commercial register (*Handelsregister*).

Item 8. Exhibits

(a) The following documents are filed as part of this registration statement:

Exhibit No.	Exhibit
1.1*	Form of Underwriting Agreement
2.1**†	Agreement and Plan of Merger by and among the Registrant, Endor Lights, Inc. and Neon Therapeutics, Inc., dated January 15, 2020
3.1**	Articles of Association of the Registrant
4.1	Form of Specimen American Depositary Receipt (included in Exhibit 4.3)
4.2	Registrant's Specimen Certificate for Ordinary Shares (incorporated herein by reference to Exhibit 4.2 to the Registrant's Registration Statement on Form F-1 (File No. 333-233688), filed with the SEC on September 9, 2019)
4.3	Form of Deposit Agreement among the Registrant, the depositary and holders and beneficial owners of the American Depositary Shares (incorporated herein by reference to Exhibit 1 to the Registration Statement on Form F-6 (File No. 333-233898), filed with the SEC on September 23, 2019)
5.1**	Opinion of Freshfields Bruckhaus Deringer LLP regarding the validity of the Ordinary Shares being registered
10.1†	Master Agreement for Research Services by and among the Registrant, BioNTech RNA Pharmaceuticals GmbH, BioNTech Diagnostics GmbH, BioNTech Protein Therapeutics GmbH, BioNTech Cell & Gene Therapies GmbH, Eufets GmbH, JPT Peptide Technologies GmbH and TRON-Translationale Onkologie an der Universitätsmedizin der Johannes Gutenberg Universität Mainz gemeinnützige GmbH, dated January 1, 2015 (incorporated herein by reference to Exhibit 10.1 to the Registrant's Registration Statement on Form F-1 (File No. 333-233688), filed with the SEC on September 9, 2019)
10.2†	Confirmation Letter by and among the Registrant, BioNTech RNA Pharmaceuticals GmbH and TRON-Translationale Onkologie an der Universitätsmedizin der Johannes Gutenberg Universität Mainz gemeinnützige GmbH dated September 15, 2016 (incorporated herein by reference to Exhibit 10.2 to the Registrant's Registration Statement on Form F-1 (File No. 333-233688), filed with the SEC on September 9, 2019)

Exhibit No.	Exhibit
10.3†	Supplementary Agreement for IVAC Developments to the Master Agreement for Research Services by and among the Registrant, BioNTech RNA Pharmaceuticals GmbH, BioNTech Diagnostics GmbH, BioNTech Protein Therapeutics GmbH, BioNTech Cell & Gene Therapies GmbH, BioNTech Innovative Manufacturing Services GmbH (f/k/a Eufets GmbH), JPT Peptide Technologies GmbH and TRON-Translationale Onkologie an der Universitätsmedizin der Johannes Gutenberg Universität Mainz gemeinnützige GmbH, dated November 28, 2017 (incorporated herein by reference to Exhibit 10.3 to the Registrant's Registration Statement on Form F-1 (File No. 333-233688), filed with the SEC on September 9, 2019)
10.4†	License Agreement by and among the Registrant, TRON-Translationale Onkologie an der Universitätsmedizin der Johannes Gutenberg Universität Mainz gemeinnützige GmbH, Johannes Gutenberg-Universität Mainz, Universitätsmedizin der Johannes Gutenberg-Universität and Ganymed Pharmaceuticals AG, dated January 1, 2015 (incorporated herein by reference to Exhibit 10.4 to the Registrant's Registration Statement on Form F-1 (File No. 333-233688), filed with the SEC on September 9, 2019)
10.5†	Framework Collaboration Agreement by and among the Registrant, BioNTech RNA Pharmaceuticals GmbH, BioNTech Diagnostics GmbH, BioNTech Protein Therapeutics GmbH, BioNTech Cell & Gene Therapies GmbH, BioNTech Innovative Manufacturing Services GmbH, JPT Peptide Technologies GmbH and TRON-Translationale Onkologie an der Universitätsmedizin der Johannes Gutenberg Universität Mainz gemeinnützige GmbH, dated August 29, 2019 (incorporated herein by reference to Exhibit 10.5 to the Registrant's Registration Statement on Form F-1 (File No. 333-233688), filed with the SEC on September 9, 2019)
10.6†	Amended Patent License Agreement by and among the Registrant, the Board of Supervisors of Louisiana State University and Agricultural and Mechanical College and Uniwersytet Warszawski, dated May 12, 2015 (incorporated herein by reference to Exhibit 10.6 to the Registrant's Registration Statement on Form F-1 (File No. 333-233688), filed with the SEC on September 9, 2019)
10.7†	License and Collaboration Agreement by and between the Registrant and Genmab A/S, dated May 19, 2015 (incorporated herein by reference to Exhibit 10.7 to the Registrant's Registration Statement on Form F-1 (File No. 333-233688), filed with the SEC on September 9, 2019)
10.8†	Amendment No. 1 to License and Collaboration Agreement by and between the Registrant and Genmab A/S, dated May 18, 2017 (incorporated herein by reference to Exhibit 10.8 to the Registrant's Registration Statement on Form F-1 (File No. 333-233688), filed with the SEC on September 9, 2019)
10.9†	Amendment No. 2 to License and Collaboration Agreement by and between the Registrant and Genmab A/S, dated August 4, 2017 (incorporated herein by reference to Exhibit 10.9 to the Registrant's Registration Statement on Form F-1 (File No. 333-233688), filed with the SEC on September 9, 2019)
10.10†	Amendment No. 3 to License and Collaboration Agreement by and between the Registrant and Genmab A/S, dated May 18, 2018 (incorporated herein by reference to Exhibit 10.10 to the Registrant's Registration Statement on Form F-1 (File No. 333-233688), filed with the SEC on September 9, 2019)
10.11†	Collaboration and License Agreement by and between Sanofi S.A. and BioNTech RNA Pharmaceuticals GmbH, dated November 2, 2015 (incorporated herein by reference to Exhibit 10.11 to the Registrant's Registration Statement on Form F-1 (File No. 333-233688), filed with the SEC on September 9, 2019)

Exhibit No.	Exhibit
10.12†	Amendment to Collaboration and License Agreement by and between Sanofi S.A. and BioNTech RNA Pharmaceuticals GmbH, dated December 22, 2018 (incorporated herein by reference to Exhibit 10.12 to the Registrant's Registration Statement on Form F-1 (File No. 333-233688), filed with the SEC on September 9, 2019)
10.13†	Development Agreement by and between Sanofi S.A. and BioNTech RNA Pharmaceuticals GmbH, dated March 29, 2018 (incorporated herein by reference to Exhibit 10.13 to the Registrant's Registration Statement on Form F-1 (File No. 333-233688), filed with the SEC on September 9, 2019)
10.14†	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)
10.15**†	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
10.16**†	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
10.17†	Patent Sublicense Agreement by and between CellScript, LLC and BioNTech RNA Pharmaceuticals GmbH, dated July 14, 2017 (incorporated herein by reference to Exhibit 10.15 to the Registrant's Registration Statement on Form F-1 (File No. 333-233688), filed with the SEC on September 9,2019)
10.18†	Patent Sublicense Agreement by and between mRNA RiboTherapeutics, Inc. and BioNTech RNA Pharmaceuticals GmbH, dated July 14, 2017 (incorporated herein by reference to Exhibit 10.16 to the Registrant's Registration Statement on Form F-1 (File No. 333-233688), filed with the SEC on September 9, 2019)
10.19†	License and Co-Development Agreement by and between Genevant Sciences GmbH and BioNTech RNA Pharmaceuticals GmbH, dated July 4, 2018 (incorporated herein by reference to Exhibit 10.17 to the Registrant's Registration Statement on Form F-1 (File No. 333-233688), filed with the SEC on September 9, 2019)
10.20†	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)
10.21†	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)
10.22†	Sublease Agreement by and among the Registrant and Universitätsmedizin der Johannes Gutenberg-Universität Mainz, dated January 14, 2013 (incorporated herein by reference to Exhibit 10.20 to the Registrant's Registration Statement on Form F-1 (File No. 333-233688), filed with the SEC on September 9, 2019)
10.23†	Amendment to Sublease Agreement by and among the Registrant and Universitätsmedizin der Johannes Gutenberg-Universität Mainz, dated July 5, 2014 (incorporated herein by reference to Exhibit 10.21 to the Registrant's Registration Statement on Form F-1 (File No. 333-233688), filed with the SEC on September 9, 2019)

Exhibit No.	Exhibit
10.24†	Amendment to Sublease Agreement by and among the Registrant and Universitätsmedizin der Johannes Gutenberg-Universität Mainz, dated June 8, 2015 (incorporated herein by reference to Exhibit 10.22 to the Registrant's Registration Statement on Form F-1 (File No. 333-233688), filed with the SEC on September 9, 2019)
10.25†	Amendment to Sublease Agreement by and among the Registrant and Universitätsmedizin der Johannes Gutenberg-Universität Mainz, dated January 18, 2017 (incorporated herein by reference to Exhibit 10.23 to the Registrant's Registration Statement on Form F-1 (File No. 333-233688), filed with the SEC on September 9, 2019)
10.26†	Lease Agreement by and among the Registrant and Wolfram Richter, dated August 17, 2011 (incorporated herein by reference to Exhibit 10.24 to the Registrant's Registration Statement on Form F-1 (File No. 333-233688), filed with the SEC on September 9, 2019)
10.27†	Amendment No. 1 to Lease Agreement by and among the Registrant and Wolfram Richter, dated February 17, 2012 (incorporated herein by reference to Exhibit 10.25 to the Registrant's Registration Statement on Form F-1 (File No. 333-233688), filed with the SEC on September 9, 2019)
10.28†	Amendment No. 2 to Lease Agreement by and among the Registrant and Wolfram Richter, dated February 1, 2013 (incorporated herein by reference to Exhibit 10.26 to the Registrant's Registration Statement on Form F-1 (File No. 333-233688), filed with the SEC on September 9, 2019)
10.29†	Amendment No. 3 to Lease Agreement by and among the Registrant and Wolfram Richter, dated March 6, 2013 (incorporated herein by reference to Exhibit 10.27 to the Registrant's Registration Statement on Form F-1 (File No. 333-233688), filed with the SEC on September 9, 2019)
10.30†	Amendment No. 4 to Lease Agreement by and among the Registrant and Wolfram Richter, dated December 10, 2013 (incorporated herein by reference to Exhibit 10.28 to the Registrant's Registration Statement on Form F-1 (File No. 333-233688), filed with the SEC on September 9, 2019)
10.31†	Amendment No. 5 to Lease Agreement by and among the Registrant and Wolfram Richter, dated March 29, 2016 (incorporated herein by reference to Exhibit 10.29 to the Registrant's Registration Statement on Form F-1 (File No. 333-233688), filed with the SEC on September 9, 2019)
10.32†	Amendment No. 6 to Lease Agreement by and among the Registrant and Wolfram Richter, dated October 6, 2017 (incorporated herein by reference to Exhibit 10.30 to the Registrant's Registration Statement on Form F-1 (File No. 333-233688), filed with the SEC on September 9,2019)
10.33†	Lease Agreement by and among the Registrant and Wista-Management GmbH, dated April 12, 2005 (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)
10.34†	Amendment to Lease Agreement by and among the Registrant and Wista-Management GmbH, dated December 27, 2018 (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)
10.35†	Loan Agreement by and between BioNTech Innovative Manufacturing Services GmbH and Deutsche Bank AG dated November 21, 2017 (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)
10.36†	Loan Agreement by and between JPT Peptides Technologies GmbH and Deutsche Bank AG dated July 18, 2018 (incorporated herein by reference to Exhibit 10.34 to the Registrant's Registration Statement on Form F-1 (File No. 333-233688), filed with the SEC on September 9, 2019)

Exhibit No.	Exhibit
10.37†	Investment Agreement by and between the Registrant and the Bill & Melinda Gates Foundation, dated August 30, 2019 (incorporated herein by reference to Exhibit 10.35 to the Registrant's Registration Statement on Form F-1 (File No. 333-233688), filed with the SEC on September 9, 2019)
10.38†	Letter Agreement by and between the Registrant and the Bill & Melinda Gates Foundation, dated August 30, 2019 (incorporated herein by reference to Exhibit 10.36 to the Registrant's Registration Statement on Form F-1 (File No. 333-233688), filed with the SEC on September 9, 2019)
10.39†	Drug Discovery Research, Development and Commercialization Agreement by and between the Registrant and Eli Lilly and Company, dated May 11, 2015 (incorporated herein by reference to Exhibit 10.37 to the Registrant's Registration Statement on Form F-1 (File No. 333-233688), filed with the SEC on September 9, 2019)
10.40**†	Finance Contract by and between the Registrant and the European Investment Bank, dated December 12, 2019
10.41**†	Finance Fee Letter by and between the Registrant and the European Investment Bank, dated December 12, 2019
21.1**	List of Subsidiaries of the Registrant
23.1*	Consent of Ernst & Young GmbH Wirtschaftsprüfungsgesellschaft, Independent Registered Public Accounting Firm
23.2*	Consent of PricewaterhouseCoopers LLP, Independent Registered Public Accounting Firm
23.3**	Consent of Freshfields Bruckhaus Deringer LLP (included in Exhibit 5.1)
24.1	Powers of Attorney (included on signature page)

* To be filed by amendment.
** Filed herewith.
† Certain information has been excluded from the exhibit because it both (i) is not material and (ii) would likely cause competitive harm to the Registrant if publicly disclosed.

Item 9. Undertakings

The undersigned hereby undertakes:

(a) The undersigned registrant hereby undertakes to provide to the underwriter at the closing specified in the underwriting agreements certificates in such denominations and registered in such names as required by the underwriter to permit prompt delivery to each purchaser.

(b) Insofar as indemnification for liabilities arising under the Securities Act of 1933 may be permitted to directors, officers and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question of whether such indemnification by it is against public policy as expressed in the Act and will be governed by the final adjudication of such issue.

(c) The undersigned registrant hereby undertakes that:

(1) For purposes of determining any liability under the Securities Act of 1933, the information omitted from the form of prospectus filed as part of this registration statement in reliance upon Rule 430A and contained in a form of prospectus filed by the Registrant pursuant to Rule 424(b)(1) or (4) or 497(h) under the Securities Act shall be deemed to be part of this registration statement as of the time it was declared effective.

(2) For the purpose of determining any liability under the Securities Act of 1933, each post-effective amendment that contains a form of prospectus shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, the registrant certifies that it has reasonable grounds to believe that it meets all of the requirements for filing on Form F-1 and has duly caused this registration statement to be signed on its behalf by the undersigned, thereunto duly authorized, in Mainz, Germany on , 2020.

BIONTECH SE
By: _____
Name: Prof. Ugur Sahin, M.D.
Title: Chief Executive Officer

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below hereby constitutes and appoints Prof. Ugur Sahin, M.D., Özlem Türeci, Sean Marett, Sierk Poetting and Ryan Richardson and each of them, individually, as his true and lawful attorneys-in-fact and agents, with full power of substitution and resubstitution, for him and in his name, place and stead in any and all capacities, in connection with this registration statement, including to sign in the name and on behalf of the undersigned, this registration statement and any and all amendments hereto, including post-effective amendments and registration statements filed pursuant to Rule 462 under the Securities Act of 1933, as amended, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the U.S. Securities and Exchange Commission, granting unto such attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done in and about the premises, as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, or his substitute, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Act of 1933, as amended, this registration statement has been signed by the following persons on , 2020 in the capacities indicated:

Name	Title	Date
Prof. Ugur Sahin, M.D.	Chief Executive Officer (principal executive officer)	
Dr. Sierk Poetting, Ph.D.	Chief Financial Officer (principal accounting officer)	
Helmut Jeggle	Chair of the Supervisory Board	
Michael Motschmann	Director	
Prof. Christoph Huber, M.D.	Director	
Dr. Ulrich Wandschneider	Director	

SIGNATURE OF AUTHORIZED U.S. REPRESENTATIVE OF REGISTRANT

Pursuant to the requirements of the Securities Act of 1933, as amended, the undersigned, the duly authorized representative in the United States of BioNTech SE has signed this registration statement on , 2020.

BIONTECH USA HOLDING, LLC

Name: Jacob Willemsen
Title: Corporate Secretary

Exhibit 2.1

Execution Version

AGREEMENT AND PLAN OF MERGER

by and among:

Neon Therapeutics, Inc.,
a Delaware corporation;

BioNTech SE,
a *Societas Europaea* organized and existing under the laws of Germany; and

Endor Lights, Inc.,
a Delaware corporation

Dated as of January 15, 2020

TABLE OF CONTENTS

EXHIBITS AND SCHEDULES

AGREEMENT AND PLAN OF MERGER

THIS AGREEMENT AND PLAN OF MERGER ("**Agreement**") is made and entered into as of January 15, 2020, by and among: BioNTech SE, a *Societas Europaea* organized and existing under the laws of Germany, having its registered office at An der Goldgrube 12, 55131 Mainz, Germany and being registered with the commercial register of the local court of Mainz under HRB 48720 ("**Parent**"); Endor Lights, Inc., a Delaware corporation and a direct, wholly-owned subsidiary of Parent ("**Merger Sub**"); and Neon Therapeutics, Inc., a Delaware corporation (the "**Company**"). Certain capitalized terms used in this Agreement are defined in Exhibit A attached hereto.

RECITALS

A. The Board of Directors of the Company (the "**Company Board**"), has unanimously (i) determined that it is in the best interests of the Company and the holders of shares of the Company's common stock, $0.001 par value per share (the "**Shares**"), to enter into this Agreement providing for, among other things, the merger of Merger Sub with and into the Company (the "**Merger**"), with the Company continuing as a wholly-owned Subsidiary of Parent in accordance with the DGCL, (ii) approved this Agreement and the consummation of the Contemplated Transactions in accordance with the DGCL and (iii) adopted a resolution recommending that this Agreement and the Contemplated Transactions be approved and adopted by the holders of Shares.

B The board of directors of Merger Sub (the "**Merger Sub Board**") has unanimously: (i) determined that it is in the best interests of Merger Sub and its stockholder, and declared it advisable, to enter into this Agreement; and (ii) approved the execution, delivery, and performance of this Agreement and the consummation of the Contemplated Transactions in accordance with the DGCL.

C Parent has a stated share capital in the amount of EUR 232,304,250, divided into 232,304,250 ordinary nopar-value registered shares with a calculative nominal value of EUR 1.00 each ("**Parent Ordinary Shares**"). Pursuant to section 4 para. (5) lit. c) of Parent's articles of association (*Satzung* - "**Parent's Articles of Association**"), Parent's management board (*Vorstand* - "**Parent's Management Board**") is authorized, subject to approval by the Parent's supervisory board (*Aufsichtsrat* - the "**Parent's Supervisory Board**"), to increase Parent's share capital by up to EUR 105,818,002 by issuing up to 105,818,002 new ordinary no par-value registered shares against cash or contribution in kind (the "**Parent Authorized Capital**"), whereby the Parent's Management Board is authorized, subject to approval by the Parent's Supervisory Board to exclude any preemptive rights (*Bezugsrechte*) for one or several capital increases under the Parent Authorized Capital in an aggregate amount of up to 20% of the share capital of Parent, either at the time this authorization became effective or, if lower, at the time it is utilized against contribution in kind.

D As a condition and inducement to the willingness of Parent and Merger Sub to enter into this Agreement, certain stockholders of the Company are entering into voting agreements with Parent, substantially in the form of Exhibit B attached hereto (the "**Voting Agreements**"), simultaneously with the execution and delivery of this Agreement.

E For U.S. federal income Tax purposes, Parent, Merger Sub and the Company intend that (1) the Merger satisfy the definition of a "reorganization" set forth in Section 368(a) of the Code, (2) the Merger not result in the recognition of gain under Section 367(a)(1) of the Code by any holder of Company Common Stock (other than any holder of Company Common Stock that is a "five-percent transferee shareholder" (within the meaning of Treasury Regulations Section 1.367(a)-3(c)(5)(ii)) of Parent immediately following the Merger (a "**Five-Percent Shareholder**") or that held Parent Ordinary Shares or Parent ADSs immediately prior to the Merger) (clauses (1) and (2) collectively the "**Intended Tax Treatment**"), and (3) that this Agreement will constitute a "plan of reorganization" within the meaning of Treasury Regulation Section 1.368-2(g), and that Parent, Merger Sub and the Company will each be a "party to the reorganization" within the meaning of Section 368(b) of the Code.

AGREEMENT

The parties to this Agreement, intending to be legally bound, agree as follows:

ARTICLE I

MERGER TRANSACTION

Section 1.1 Merger of Merger Sub into the Company.

(a) As promptly as practicable following the date hereof, Parent shall appoint a bank or trust company or other independent financial institution (the "**Trust Company**"), which shall be reasonably acceptable to the Company, to act as (i) contribution agent in connection with the formation of Merger Sub and the Share Exchange (in such function, the "**Contribution Agent**"), pursuant to a contribution agreement between Parent and the Contribution Agent, which shall be reasonably acceptable to the Company (the "**Contribution Agreement**"), and (ii) exchange agent in connection with the Share Exchange (in such function, the "**Exchange Agent**"). Parent shall enter into an exchange agent agreement with the Exchange Agent, in form and substance reasonably satisfactory to the Company, which agreement shall set forth the duties, responsibilities and obligations of the Exchange Agent consistent with the terms of this Agreement. Parent may appoint one or more substitute persons, reasonably acceptable to the Company, to perform any of the functions of the Trust Company described herein. Solely to accommodate the transactions described in this Article I and Article II and subject to the terms and conditions of the Contribution Agreement, one business day prior to the Effective Time, Parent shall cause the Contribution Agent to be registered as Parent's fiduciary (for the period prior to the Effective Time only), as the record holder of all of the issued and outstanding shares of common stock, $0.01 par value per share, of Merger Sub (the "**Merger Sub Common Stock**"); provided, however, that it is understood and agreed that the Contribution Agent shall act as a fiduciary of the former holders of Company Common Stock after the Effective Time. In the Contribution Agreement (inter alia), the Contribution Agent shall take on the obligation to the holders of Company Common Stock to execute a subscription certificate (*Zeichnungsschein*) following the Effective Time pursuant to Section 2.2.

(b) Upon the terms and subject to the conditions set forth in this Agreement, and in accordance with the DGCL, Merger Sub shall be merged with and into the Company at the Effective Time. Following the Effective Time, the separate corporate existence of Merger Sub shall cease, and the Company shall be the surviving corporation in the Merger (with respect to all post-Closing periods, the "**Surviving Corporation**") and shall succeed to and assume all the rights and obligations of Merger Sub in accordance with this Agreement and the applicable provisions of the DGCL.

(c) The consummation of the Merger (the "**Closing**") shall take place at the offices of Covington & Burling LLP, The New York Times Building, 620 Eighth Avenue, New York, NY 10018, at 9:00 a.m. local time no later than the second business day following the day on which the last to be satisfied of the conditions set forth in Article VII (other than those conditions that by their nature must be satisfied or waived at the Closing, but subject to the fulfillment or waiver of such conditions) shall be satisfied or waived in accordance with this Agreement, or at such other place, time and date as the parties hereto shall agree. The date on which the Closing occurs is referred to as the "**Closing Date**".

(d) Subject to the provisions of this Agreement, contemporaneous with the Closing, the parties hereto shall cause the Merger to be consummated by filing with the Secretary of State of the State of Delaware a certificate of merger with respect to the Merger (the "**Certificate of Merger**"), executed in accordance with the relevant provisions of the DGCL and shall promptly make all other filings or recordings required under the DGCL with respect to the Merger. The Merger shall become effective at such time as the Certificate of Merger is duly filed with the Secretary of State of the State of Delaware, or at such other time or date as Parent and the Company shall agree and specify in the Certificate of Merger (the time at which the Merger becomes effective, the "**Effective Time**").

Section 1.2 Organizational Documents; Directors and Officers of the Surviving Corporation. Unless otherwise agreed to by the Company and Parent prior to the Effective Time:

(a) At the Effective Time, the certificate of incorporation of the Surviving Corporation shall be amended and restated in its entirety to be the same as the certificate of incorporation of Merger Sub, as in effect immediately prior to the Effective Time, except that such certificate of incorporation shall (i) be amended to change the name of the Surviving Corporation to "BioNTech Boston, Inc." and (ii) comply with Section 6.4. Thereafter, the certificate of incorporation of the Surviving Corporation may only be amended in accordance with its terms, Section 6.4 and as provided by Law.

(b) At the Effective Time, the bylaws of Merger Sub as in effect immediately prior to the Effective Time shall be the bylaws of the Surviving Corporation (except that (i) all references to Merger Sub in the bylaws of the Surviving Corporation shall be amended to refer to "BioNTech Boston, Inc." and (ii) such bylaws shall comply with Section 6.4). Thereafter, the bylaws of the Surviving Corporation may only be amended or repealed in accordance with their terms and the certificate of incorporation of the Surviving Corporation and as provided by Law.

(c) The Company shall cause to be delivered to Parent, at the Closing, resignations of all the directors of the Company to be effective upon the Effective Time. At the Effective Time, the directors and officers of Merger Sub shall continue in office as the directors and officers, respectively, of the Surviving Corporation, and such directors and officers shall hold office in accordance with and subject to the certificate of incorporation and bylaws of the Surviving Corporation.

ARTICLE II

CONVERSION OF SHARES AND DELIVERY OF MERGER CONSIDERATION

Section 2.1 Conversion of Capital Stock. At the Effective Time, as a result of the Merger and without any action on the part of the Company, Parent, Merger Sub or the holder of any capital stock of Parent, Merger Sub or the Company:

(a) Each Parent Ordinary Share issued and outstanding immediately prior to the Effective Time shall remain issued and outstanding and shall not be affected by the Merger.

(b) All Shares that are owned or held in treasury by the Company or owned by Parent or Merger Sub (other than Shares held in trust accounts, managed accounts and the like, or otherwise held in a fiduciary or agency capacity, that are beneficially owned by Third Parties) shall be cancelled and shall cease to exist and no stock of Parent or other consideration shall be delivered in exchange therefor.

(c) Except as provided in Section 2.1(b), each Share issued and outstanding immediately prior to the Effective Time (including the shares held in the Company Trust), and subject to Section 2.1(e) and Section 2.2, shall automatically be cancelled and converted into the right to receive 0.063 of an American Depositary Share of Parent ("**Parent ADS**") (such number of Parent ADSs, the "**Exchange Ratio**"), with each Parent ADS representing one Parent Ordinary Share, pursuant to the terms of the deposit agreement between Parent and The Bank of New York Mellon (the "**Depositary**") (such agreement, the "**Deposit Agreement**"). The Parent ADSs issued hereunder, subject to adjustment as provided in Section 2.1(f) shall be referred to herein as the "**Merger Consideration**", without interest, but subject to any withholding required under applicable Tax Law, plus the right, if any, to receive pursuant to Section 2.8, cash in lieu of fractional shares of Parent ADSs into which such Shares would have been converted pursuant to this Section 2.1(c) (the "**Fractional Share Consideration**").

(d) Each share of Merger Sub Common Stock issued and outstanding immediately prior to the Effective Time shall be converted into and become one newly issued, fully paid, and non-assessable share of common stock, par value $0.001 per share, of the Surviving Corporation with the same rights, powers, and privileges as the shares so converted and shall constitute the only outstanding shares of capital stock of the Surviving Corporation. From and after the Effective Time, all certificates representing shares of Merger Sub Common Stock shall be deemed for all purposes to represent the number of shares of common stock of the Surviving Corporation into which they were converted in accordance with the immediately preceding sentence.

(e) All of the Shares converted into the right to receive the Merger Consideration pursuant to this Article II shall no longer be outstanding and shall automatically be cancelled and shall cease to exist as of the Effective Time, and each certificate previously representing any such Shares (each, a "**Certificate**") or any book-entry share which immediately prior to the Effective Time represented such Shares (each, a "**Book-Entry Share**") shall thereafter represent only the right to receive the Merger Consideration and any applicable Fractional Share Consideration, as well as any dividends to which holders of Shares become entitled in accordance with Section 2.3(d).

(f) If, between the date of this Agreement and the Effective Time, the outstanding Parent Ordinary Shares shall have been increased, decreased, changed into or exchanged for a different number or kind of shares or securities as a result of a reorganization, recapitalization, reclassification, stock dividend, stock split, reverse stock split, or other similar change in capitalization, an appropriate and proportionate adjustment shall be made to the Exchange Ratio.

Section 2.2 Share Capital Increase and Share Exchange. As soon as possible following the Effective Time and in accordance with Sections 202 *et seq*. (including Sections 185 and 187 *et seq.*) of the German Stock Corporation Act (*Aktiengesetz*, the "**GSCA**"), Parent shall: (i) effect the increase of its stated share capital by (A) passing a resolution of the Parent's Management Board with the approval of the Parent's Supervisory Board, both in accordance with section 4 para. (5) lit. c) of Parent's Articles of Association and conditional only upon the Merger becoming effective, to use the authorized share capital (*genehmigtes Kapital*) of Parent under exclusion of any preemptive rights (*Bezugsrechte*) in the meaning of Sec. 186 par. 3 and 4, Sec. 203 par. 2 GSCA to issue new Parent Ordinary Shares underlying the Merger Consideration to the Contribution Agent for the benefit of the former holders of shares of the Company Common Stock against the prior contribution by the Contribution Agent to Parent of all of the issued and outstanding shares of common stock of the Surviving Corporation by contribution-in-kind, (B) apply with the competent local court (*Amtsgericht*) of Parent to have a German accounting firm, determine the adequacy of the contribution-in-kind as consideration for the new Parent Ordinary Shares in accordance with Sections 205 in conjunction with Section 33 GSCA, (C) allowing the Contribution Agent to execute a subscription certificate (*Zeichnungsschein*) with the contents and in the form stipulated by the GSCA and the Contribution Agreement, (D) seeing to the effectuation of the contribution-in-kind through a transfer of all of the issued and outstanding shares of Surviving Corporation Common Stock to Parent by the Contribution Agent, (E) registering the implementation of such increase of Parent's stated capital with the commercial register of Parent (the "**Commercial Register**" such registration, the "**Share Capital Increase**"), and (F) issuing the new Parent Ordinary Shares underlying the Merger Consideration to the Contribution Agent for the benefit of the former holders of shares of the Company Common Stock (the "**Share Issuance**") (whereby it is understood that steps (A) to (F) are to be effected at the respective times set forth in the following sentence); and (ii) cause (A) the Contribution Agent to deposit with the Depositary, for the benefit of the holders of shares of Company Common Stock, the Parent Ordinary Shares underlying the Merger Consideration, (B) the Depositary to issue to the Exchange Agent the Parent ADSs comprising the Merger Consideration and (C) the Exchange Agent to deliver in accordance with this Section 2.2 the Parent ADSs reflecting the Merger Consideration to the former holders of shares of Company Common Stock (such Parent ADSs, together with any dividends or distributions with respect thereto, being referred to as the "**Exchange Fund**") and any cash in lieu of fractional Parent ADSs (the actions described in clauses (i) and (ii) above, collectively, the "**Share Exchange**"). Parent shall approve the resolutions described in clause (i)(A) above prior to Closing; the appointment of the German accounting firm by the competent local court (*Amtsgericht*) of Parent (clause (i)(B) above) shall be requested by Parent as soon as practicable after the execution of this Agreement, and a draft of the determination of the adequacy of the contribution-in-kind shall be delivered by the accounting firm to the parties at Closing; the subscription certificate (clause (i)(C) above) shall be executed by the Contribution Agent on the business day following the day of the Effective Time; the transfer of all issued and outstanding Surviving Corporation Common Stock by the Contribution Agent to Parent (clause (i)(D) above) shall be effected on the business day following the day of the Effective Time; and the Share Capital Increase and the Share Issuance shall be effected as soon as reasonably practicable thereafter. Parent shall cause the Exchange Agent to, pursuant to irrevocable instructions, deliver the Parent ADSs contemplated to be issued pursuant to this Article II out of the Exchange Fund in accordance with this Section 2.2. The Exchange Fund shall not be used for any other purpose. At the Effective Time, Parent's obligation to effect the Share Exchange shall become unconditional, subject only to the completion of the contribution-in-kind by the Contribution Agent described in this Section 2.2.

Section 2.3 Exchange of Shares.

(a) Transfer Books. At the Effective Time, the share transfer books of the Company shall be closed, and thereafter there shall be no further registration of transfers of Shares. From and after the Effective Time, Persons who held Shares immediately prior to the Effective Time shall cease to have rights with respect to such Shares, except as otherwise provided for herein. On or after the Effective Time, any Certificates presented to the Exchange Agent or the Surviving Corporation for any reason shall be exchanged for the Merger Consideration with respect to the Shares, formerly represented thereby.

(b) Exchange Procedures. As promptly as practicable following the Effective Time (but in no event later than five business days thereafter), Parent shall cause the Exchange Agent to mail to each holder of record of a Certificate or Certificates that immediately prior to the Effective Time represented outstanding Shares whose shares were converted into the right to receive the Merger Consideration pursuant to Section 2.1(c): (i) a letter of transmittal (a "**Letter of Transmittal**") which shall specify that delivery shall be effected, and risk of loss and title to the Certificates shall pass to the Exchange Agent only upon proper delivery of the Certificate or Certificates to the Exchange Agent, which Letter of Transmittal shall be in such form and have such other customary provisions as Parent and the Company may reasonably agree upon, and (ii) instructions for use in effecting the surrender of the Certificates in exchange for the Merger Consideration into which the number of Shares previously represented by such Certificate shall have been converted pursuant to this Agreement, together with any amounts payable in respect of the Fractional Share Consideration in accordance with Section 2.8 and dividends or other distributions on Parent ADSs in accordance with Section 2.3(d). Upon surrender of a Certificate to the Exchange Agent, or to such other agent or agents reasonably satisfactory to the Company as may be appointed by Parent, together with such Letter of Transmittal duly completed and validly executed in accordance with the instructions thereto, and such other documents as may reasonably be required by the Exchange Agent, the holder of such Certificate shall be entitled to receive in exchange therefor the Merger Consideration payable in respect of the Shares previously represented by such Certificate pursuant to the provisions of this Article II, plus any Fractional Share Consideration that such holder has the right to receive pursuant to the provisions of Section 2.8 and any amounts that such holder has the right to receive in respect of dividends or other distributions on Parent ADSs in accordance with Section 2.3(d) to be mailed or delivered by wire transfer, within five business days following the later to occur of (A) the Effective Time or (B) the Exchange Agent's receipt of such Certificate (or affidavit of loss in lieu thereof), and the Certificate so surrendered shall be forthwith cancelled. The Exchange Agent shall accept such Certificates upon compliance with such reasonable terms and conditions as the Exchange Agent may impose to effect an orderly exchange thereof in accordance with customary exchange practices. In the event of a transfer of ownership of Shares that is not registered in the transfer records of the Company, payment may be made to a Person other than the Person in whose name the Certificate so surrendered is registered, if such Certificate shall be properly endorsed or otherwise be in proper form for transfer, or any Book-Entry Share shall be properly transferred, and the Person requesting such payment shall pay any transfer or other Taxes required by reason of the payment to a Person other than the registered holder of such Certificate or Book-Entry Share or establish to the reasonable satisfaction of Parent that such Tax has been paid or is not applicable. Until surrendered as contemplated by this Section 2.2, each Certificate shall be deemed, at any time after the Effective Time, to represent only the right to receive, upon such surrender, the Merger Consideration as contemplated by this Article II. No interest shall be paid or accrue on any cash payable upon surrender of any Certificate or in respect of Book- Entry Shares or on the Merger Consideration or the Fractional Share Consideration payable upon the surrender of the Certificates or Book-Entry Shares or on any distributions to which holders of such Certificates or Book-Entry Shares are entitled pursuant to Section 2.3(d).

(c) Book-Entry Shares. Any holder of Book-Entry Shares shall not be required to deliver a Certificate or an executed Letter of Transmittal to the Exchange Agent to receive the Merger Consideration (or any amounts payable in respect of the Fractional Share Consideration in accordance with Section 2.1(c)) or distribution to which such holder is entitled pursuant to Section 2.3(d) that such holder is entitled to receive pursuant to this Article II. In lieu thereof, each registered holder of one or more Book-Entry Shares shall automatically upon the Effective Time be entitled to receive, and Parent shall cause the Exchange Agent to pay and deliver as soon as reasonably practicable after the Effective Time (but in no event more than five business days thereafter), the Merger Consideration, together with any amounts payable in respect of the Fractional Share Consideration in accordance with Section 2.1(c) and any distribution to which such holder is entitled pursuant to Section 2.3(d) (less required withholdings as provided in Section 2.5) for each Book-Entry Share. Payment of the Merger Consideration, Fractional Share Consideration and distributions with respect to Book-Entry Shares shall only be made to the person in whose name such Book-Entry Shares are registered.

(d) Dividends with Respect to Parent ADSs. No dividends or other distributions with respect to Parent ADSs or Parent Ordinary Shares with a record date after the Effective Time shall be paid to the holder of any unsurrendered Certificate or Book-Entry Share with respect to the Parent ADSs or Parent Ordinary Shares issuable hereunder, and all such dividends and other distributions shall be paid by Parent to the Exchange Agent and shall be included in the Exchange Fund, in each case until the surrender of such Certificate (or affidavit of loss in lieu thereof) in accordance with this Agreement. Following surrender of any such Certificate (or affidavit of loss in lieu thereof) there shall be paid to the holder thereof in addition to the other amounts payable hereunder (i) promptly after the time of such surrender, the amount of dividends or other distributions with a record date after the Effective Time theretofore paid with respect to such whole Parent ADSs to which such holder is entitled pursuant to this Agreement and (ii) at the appropriate payment date, the amount of dividends or other distributions with a record date after the Effective Time but prior to such surrender and with a payment date subsequent to such surrender payable with respect to such whole Parent ADSs.

(e) Termination of Exchange Fund. Any portion of the Exchange Fund (including any Fractional Share Consideration, any applicable dividends or other distributions with respect to Parent ADSs or Parent Ordinary Shares and any interest and other income received with respect thereto) which remains undistributed to the former holders of Shares on the first anniversary of the Effective Time shall be delivered to Parent, upon demand, and any former holders of Shares who have not theretofore received any Merger Consideration to which they are entitled under this Article II shall thereafter look only to the Surviving Corporation for payment of their claims with respect thereto.

(f) No Liability. None of Parent, Merger Sub, the Company, the Surviving Corporation or the Exchange Agent, or any employee, officer, director, agent or Affiliate of any of them, shall be liable to any holder of Shares in respect of any part of the Merger Consideration delivered to a public official pursuant to any applicable abandoned property, escheat or similar Law. Any amounts remaining unclaimed by holders of any such Shares immediately prior to the time at which such amounts would otherwise escheat to, or become property of, any Governmental Entity shall, to the extent permitted by applicable Law, become the property of the Surviving Corporation, free and clear of any claims or interest of any such holders or their successors, assigns or personal representatives previously entitled thereto.

(g) Investment of Exchange Fund. The Exchange Agent shall invest any cash included in the Exchange Fund as directed by Parent or, after the Effective Time, the Surviving Corporation; provided, however, that (i) no such investment shall relieve Parent or the Exchange Agent from making the payments required by this Article II and, to the extent that there are losses with respect to such investments, or the Exchange Fund diminishes for other reasons below the level required to make prompt payments of the Merger Consideration as contemplated hereby, Parent shall promptly replace or restore the portion of the Exchange Fund lost through investments or other events, without interest, so as to ensure that the Exchange Fund is, at all times, maintained at a level sufficient to make such payments, (ii) no such investment shall have maturities that could prevent or delay payments to be made pursuant to this Agreement, and (iii) such investments shall be in short-term obligations of the United States of America with maturities of no more than 30 days or guaranteed by the United States of America and backed by the full faith and credit of the United States of America. Any net profit resulting from, or interest or income produced by, such investments, shall be property of, and paid to, Parent.

Section 2.4 Company Compensatory Awards. All of the provisions of this Section 2.4 shall be effectuated without any action on the part of the holder of any Company Compensatory Award.

(a) Treatment of Company Options. At the Effective Time, each Company Option which is outstanding immediately prior to the Effective Time (whether or not then vested or exercisable) shall be cancelled and converted automatically into the right to receive, as soon as reasonably practicable after the Effective Time (but no later than ten business days thereafter), a cash payment in an amount equal to the product of (i) the total number of Shares subject to such Company Option immediately prior to such cancellation and (ii) the excess, if any, of the Cash Merger Consideration over the exercise price per share subject to such Company Option immediately prior to such cancellation. Each Company Option that, as of immediately prior to such cancellation, has an exercise price per share that is equal to or greater than the Cash Merger Consideration shall be cancelled for no consideration being paid to the holder of such Company Option. "**Cash Merger Consideration**" shall mean the product of the VWAP of Parent ADS multiplied by the Exchange Ratio.

(b) Company Restricted Stock. At the Effective Time, (i) each Share of Company Restricted Stock that is outstanding as of immediately prior to the Effective Time shall vest in full and (ii) each such Share of Company Restricted Stock shall be cancelled and converted automatically into the right to receive the Merger Consideration in accordance with the terms of Article II in the same manner as other outstanding Shares.

(c) Company RSUs. Prior to the Effective Time, the Company shall establish a trust (which shall not be affiliated with either Parent or the Company), the purpose of which shall be to hold shares of Company Common Stock (prior to the Merger and Parent ADSs thereafter) that will become issuable to Company employees holding Company RSUs which are outstanding as of immediately prior to the Effective Time (the "**Company Trust**"). Prior to the Effective Time, the Company shall issue and deliver to the Company Trust such number of shares of Company Common Stock as shall be necessary to satisfy the obligations under all such Company RSUs, in each case outstanding as of immediately prior to the Effective Time. The parties agree to reasonably cooperate with respect to the establishment and operation of the Company Trust in furtherance of the provisions hereunder, including with respect to satisfying any applicable tax withholding obligations. At the Effective Time, (i) each Company RSU that is held by any current Company employee and is outstanding as of immediately prior to the Effective Time shall vest in full and (ii) each such Company RSU shall be cancelled and converted automatically into the right to receive from the Company Trust, as soon as reasonably practicable after the Effective Time (but no later than five business days thereafter), the Merger Consideration in respect of each Share underlying the unsettled portion of the Company RSU.

(d) ESPP. As soon as practicable following the date hereof, the Company Board (or, if appropriate, any committee administering the ESPP) shall adopt such resolutions and take such other actions as may be required (including providing notice to the ESPP participants) to provide that, with respect to the ESPP: (i) no new offering periods will commence, nor will any existing offering periods be extended, following the date hereof, (ii) no individuals will be permitted to enroll in the ESPP following the date hereof, and (iii) no existing participants will be permitted to increase their respective rates of deductions and purchases following the date hereof. If the Effective Time occurs during the offering period in effect as of the date hereof, such offering period will be terminated no later than three business days prior to the Effective Time and be the final offering period under the ESPP and the accumulated payroll deductions of each participant under the ESPP will be returned to the participant by the Surviving Corporation pursuant to the terms of the ESPP, without the issuance of any Shares.

(e) As soon as reasonably practicable following the date hereof and in any event prior to the Effective Time, the Company Board (or, if appropriate, any committee(s) administering the Company Equity Plans or the ESPP) shall adopt such resolutions and take such other actions as are necessary for the treatment of the Company Compensatory Awards and the ESPP pursuant to this Section 2.4 (e), which resolutions will also provide that such Company Compensatory Awards and the Company Equity Plans and ESPP shall terminate conditioned upon, and effective immediately after, the Effective Time.

(f) Manner of Effecting. Prior to the Effective Time, the Company and Parent agree that the Company shall, and shall be permitted under this Agreement to, take all corporate action necessary to effectuate the provisions of this Section 2.4.

Section 2.5 Withholding Rights. Parent, the Surviving Corporation, the Exchange Agent or any other applicable withholding agent, as applicable, shall be entitled to deduct and withhold from the Merger Consideration and any amounts otherwise payable pursuant to this Agreement to any holder of Shares and Company Compensatory Awards, such amounts as Parent, the Surviving Corporation or the Exchange Agent is required to deduct and withhold with respect to the making of such payment under the Code, and the rules and regulations promulgated thereunder, or any provision of applicable Tax Law. To the extent that amounts are so deducted or withheld and paid over to the appropriate Governmental Entity by Parent, the Surviving Corporation or the Exchange Agent, as applicable, such withheld amounts shall be treated for all purposes of this Agreement as having been paid to the Person in respect of which such deduction and withholding was made by Parent, the Surviving Corporation or the Exchange Agent, as applicable.

Section 2.6 Lost Certificates. If any Certificate shall have been lost, stolen or destroyed, then upon the making of an affidavit of that fact by the Person claiming such Certificate to be lost, stolen or destroyed and, if required by Parent or the Exchange Agent, the posting by such Person of a bond in a reasonable customary amount, as indemnity against any claim that may be made against it with respect to such Certificate, the Exchange Agent will issue in exchange for such lost, stolen or destroyed Certificate the Merger Consideration, Fractional Share Consideration, if any, and any distributions to which the holder thereof is entitled pursuant to this Article II.

Section 2.7 Dissenters' Rights. No dissenters' or appraisal rights shall be available with respect to the Merger or the other Contemplated Transactions, so long as the provisions of Section 262 of the DGCL are applicable to the transaction.

Section 2.8 Fractional Shares. No certificate or scrip representing fractional Parent ADSs shall be issued upon the surrender for exchange of Certificates or with respect to Book-Entry Shares, and such fractional share interests shall not entitle the owner thereof to vote or to any other rights of a stockholder of Parent. Notwithstanding any other provision of this Agreement, each holder of Shares converted pursuant to the Merger who would otherwise have been entitled to receive a fraction of a Parent ADS shall receive, in lieu thereof, cash (rounded to the nearest whole cent), without interest, in an amount equal to such fractional part of a Parent ADS multiplied by the VWAP of Parent ADS.

ARTICLE III

REPRESENTATIONS AND WARRANTIES OF THE COMPANY

Except (a) as disclosed in the Company SEC Documents filed prior to the date hereof (but only to the extent that it is reasonably apparent from such disclosure in the Company SEC Documents that it is applicable to one or more specified sections of the Company Disclosure Schedule, and excluding any disclosures set forth under the headings "Forward-Looking Statements," "Risk Factors," or any similar section and any disclosures therein that are predictive, cautionary or forward-looking in nature); or (b) as set forth in the Company Disclosure Schedule delivered by the Company to Parent and Merger Sub prior to or simultaneously with the execution of this Agreement; provided, that clause (a) shall not apply to Sections 3.3 (Capitalization), 3.5 (Absence of Changes), 3.6 (Intellectual Property), 3.9 (Compliance, Permits; Restrictions), 3.18 (Authority; Binding Nature of Agreement) or 3.20 (Non-Contravention; Consents), the Company hereby represents and warrants to Parent and Merger Sub as follows:

Section 3.1 Due Organization; Subsidiaries.

(a) The Company (i) is a corporation that is duly organized, validly existing and in good standing under the Law of its jurisdiction of incorporation, (ii) has corporate power and authority to own, lease and operate its properties and assets and to conduct its business as presently conducted and (iii) is duly qualified or licensed to do business as a foreign corporation and is in good standing (with respect to jurisdictions that recognize such concept) in each jurisdiction where the character of the properties owned, leased or operated by it or the nature of its business makes such qualification or licensing necessary, except, with respect to clause (iii), where the failure to be so qualified or licensed would not reasonably be expected to have, individually or in the aggregate, a Company Material Adverse Effect.

(b) Section 3.1(b) of the Company Disclosure Schedule identifies each Subsidiary of the Company and indicates its jurisdiction of organization. Each such Subsidiary (i) is a corporation or other entity that is duly organized, validly existing and in good standing (with respect to jurisdictions that recognize such concept) under the Law of its jurisdiction of incorporation or organization, as applicable, (ii) has corporate (or, in the case of any Subsidiary that is not a corporation, other) power and authority to own, lease and operate its properties and assets and to conduct its business as presently conducted and (iii) is duly qualified or licensed to do business as a foreign corporation or company and is in good standing (with respect to jurisdictions that recognize such concept) in each jurisdiction where the character of the properties owned, leased or operated by it or the nature of its business makes such qualification or licensing necessary, except, with respect to clause (iii), where the failure to be so qualified or licensed would not reasonably be expected to have, individually or in the aggregate, a Company Material Adverse Effect. All of the outstanding shares of capital stock or other equity interests of each Subsidiary of the Company are owned by the Company or a wholly owned Subsidiary of the Company, free and clear of any Encumbrances (other than transfer restrictions arising under applicable Law).

(c) None of the Acquired Companies owns any capital stock of, or any equity interest of, or any equity interest of any nature in, any other Entity, other than in the Acquired Companies or short-term investments. None of the Acquired Companies has agreed or is obligated to make, or is bound by any Contract under which it may become obligated to make, any future investment in or capital contribution to any other Entity.

Section 3.2 Organizational Documents. The Company has made available to Parent accurate and complete copies of the certificate of incorporation, bylaws and other charter and organizational documents of each of the Acquired Companies, including all amendments thereto, as in effect on the date hereof. The Acquired Companies' certificates of incorporation, bylaws or other charter and organizational documents so delivered are in full force and effect. None of the Acquired Companies is in material violation of any of the provisions of its respective certificate of incorporation, bylaws and other charter and organizational documents.

Section 3.3 Capitalization.

(a) The authorized capital stock of the Company consists of (i) 150,000,000 Shares and (ii) 10,000,000 shares of undesignated preferred stock, par value $0.001 per share (the "**Company Preferred Stock**"). At the close of business on January 14, 2020 (the "**Capitalization Date**"): (A) 28,729,725 Shares were issued and outstanding (including 2,847,358 shares of Company Restricted Stock, of which 285,538 remain unvested as of the date hereof); (B) 3,356,003 Shares were subject to issuance pursuant to Company Options, all of which were granted and outstanding under the Company Equity Plans; (C) 2,053,270 Shares were subject to issuance pursuant to Company RSUs, all of which were granted or committed to be granted and outstanding under the Company Equity Plans; (D) 156,265 Shares were reserved for issuance in respect of future awards under the Company Equity Plans; (E) 777,512 Shares were available for issuance under the ESPP, including a maximum of 154,660 Shares available for issuance pursuant to the offering period in effect as of the date hereof, assuming employees participating in the current offering as of the Capitalization Date continue to contribute at their current contribution rate through the last day of the offering period and assuming a per share purchase price based upon the closing price as of the first day of the current offering period; and (F) no shares of Company Preferred Stock were issued and outstanding. All of the outstanding Shares have been duly authorized and validly issued, and are fully paid, nonassessable and free of preemptive rights.

(b) Section 3.3(b) of the Company Disclosure Schedule sets forth, as of the Capitalization Date, a list of (i) all outstanding Company Options, including the name of the holder, the holder's country of residence, whether such award was issued in respect of employment, the grant date, the expiration date, the number of Shares subject to each such award, the exercise price per Share, the vesting schedule, whether such award is intended to be an "incentive stock option" under Section 422 of the Code, and the Company Equity Plan under which such award was granted, (ii) all outstanding Company RSUs, including the name of the holder, the holder's country of residence, whether such award was issued in respect of employment, the grant date, the number of Shares subject to each such award, the vesting schedule, and the Company Equity Plan under which such award was granted, and (iii) all outstanding Company Restricted Stock, including the name of the holder, the holder's country of residence, whether such award was issued in respect of employment, the grant date, the number of Shares subject to each such award, the purchase price per Share (if any), the vesting schedule, whether a valid 83(b) election has been filed with respect to such award, and the Company Equity Plan under which such award was granted. No portion of any Company Option may be "early exercised" (*i.e*., exercised prior to becoming vested). Except as set forth onSection 3.3(b) of the Company Disclosure Schedule, the Company has not made any additional equity grants, whether Company Options, Company RSUs or any other form of security, at any time after the Capitalization Date.

(c) Except as set forth in the Company's Certificate of Incorporation, (i) none of the outstanding Shares is entitled or subject to any preemptive right, antidilutive right, right of repurchase or forfeiture, right of participation, right of maintenance, conversion right, redemption right or any similar right; (ii) none of the outstanding Shares is subject to any right of first refusal in favor of any of the Acquired Companies; and (iii) there is no contract to which any of the Acquired Companies is a party relating to the voting or registration of, or restricting any Person from purchasing, selling, pledging or otherwise disposing of (or from granting any option or similar right with respect to), any Shares. None of the Acquired Companies is under any obligation, nor is any of the Acquired Companies bound by any contract pursuant to which it will become obligated, to repurchase, redeem or otherwise acquire any outstanding Shares or other securities.

(d) There are no bonds, debentures, notes or other Indebtedness of the Acquired Companies issued and outstanding having the right to vote (or convertible or exercisable or exchangeable for securities having the right to vote) on any matters on which stockholders of the Company may vote.

(e) As of the Capitalization Date, and except as set forth in Sections 3.3(a) and (b), there was no: (i) outstanding subscription, option, call, warrant or other right (whether or not currently exercisable) to acquire any shares of the capital stock, restricted stock unit, stock-based performance unit, shares of phantom stock, stock appreciation right, profit participation right or any other right that is linked to, or the value of which is based on or derived from, the value of any shares of capital stock of the Company; (ii) outstanding security, instrument, bond, debenture or note that is or may become convertible into or exchangeable for any shares of the capital stock or other securities of any of the Acquired Companies; or (iii) stockholder rights plan (or similar plan commonly referred to as a "poison pill") or Contract under which any Acquired Company is or may become obligated to sell or otherwise issue any shares of its capital stock or any other securities.

(f) All Company Options (i) have been granted and administered in accordance with the terms of the applicable Company Equity Plan or other applicable Contract governing the terms of such award, (ii) have an exercise price that is no less than the fair market value of the underlying Shares on the date of grant, as determined in accordance with Section 409A of the Code, and (iii) are otherwise exempt from Section 409A of the Code. The Company has made available to Parent, accurate and complete copies of (i) each Company Equity Plan and (ii) the forms of standard award agreement under the Company Equity Plans. The treatment of the Company Options, Company RSUs and Company Restricted Stock under this Agreement does not violate the terms of the Company Equity Plans or any Contract governing the terms of such awards and will not cause adverse tax consequences under Section 409A of the Code. At all times, the ESPP has qualified as an "employee stock purchase plan" under Section 423 of the Code, and all options to purchase shares under the ESPP (now outstanding or previously exercised or forfeited) have satisfied the requirements of Section 423 of the Code.

Section 3.4 SEC Filings; Financial Statements.

(a) All reports, schedules, forms, statements and other documents (including exhibits and all other information incorporated therein) required to be filed or furnished by the Company with the SEC since May 31, 2018 (the "**Company SEC Documents**") have been filed or furnished with the SEC on a timely basis. As of the time it was filed or furnished with the SEC (or, if amended or superseded by a filing prior to the date hereof, then on the date of such filing): (i) each of the Company SEC Documents complied as to form in all material respects with the applicable requirements of the Securities Act, the Exchange Act, the Sarbanes-Oxley Act and NASDAQ (as the case may be) and the rules and regulations of the SEC promulgated thereunder applicable to such Company SEC Documents; and (ii) none of the Company SEC Documents contained when filed or furnished (and, in the case of registration statements and proxy statements, on the dates of effectiveness and the dates of mailing, respectively) any untrue statement of a material fact or omitted, as the case may be, to state a material fact required to be stated or incorporated by reference therein or necessary in order to make the statements therein, in the light of the circumstances under which they were made, not misleading. None of the Company's Subsidiaries is required to file or furnish any forms, reports, or other documents with the SEC.

(b) The financial statements (including any related notes or schedules thereto) contained or incorporated by reference in the Company SEC Documents: (i) complied as to form in all material respects with the published rules and regulations of the SEC applicable thereto; (ii) were prepared in accordance with GAAP applied on a consistent basis throughout the periods covered (except as may be indicated in the notes to such financial statements or, in the case of unaudited statements, as permitted by Form 10-Q, Form 8-K or any successor form under the Exchange Act, and recognize that unaudited financial statements are subject to normal and recurring year-end adjustments); and (iii) fairly present, in all material respects, the financial position of the Company as of the respective dates thereof and the results of operations, stockholders' equity and cash flows of the Company for the periods covered thereby. No financial statements of any Person other than the Acquired Companies are required by GAAP to be included in the consolidated financial statements of the Company.

(c) The Company has established and maintains a system of internal control over financial reporting (as such terms are defined by Rule 13a-15(f) or 15d-15(f) under the Exchange Act) that is sufficient in all material respects to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with GAAP including policies and procedures that: (i) require the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of the assets of the Company and its Subsidiaries; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with GAAP and that receipts and expenditures of the Company and its Subsidiaries are being made only in accordance with appropriate authorizations of the Company's management and the Company Board; and (iii) provide assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of assets of the Company and its Subsidiaries.

(d) The Company's "disclosure controls and procedures" (as defined by Rules13a-15(e) and 15d-15(e) under the Exchange Act) are designed to ensure that all information (both financial and non-financial) required to be disclosed by the Company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in the rules and forms of the SEC, and that all such information is accumulated and communicated to the Company's management as appropriate to allow timely decisions regarding required disclosure and to make the certifications of the chief executive officer and chief financial officer of the Company required under the Exchange Act with respect to such reports. Neither the Company nor, to the Knowledge of the Company, the Company's independent registered public accounting firm has identified or been made aware of: (i) any "significant deficiency" or "material weakness" (each as defined by Rule 12b-2 of the Exchange Act) in the system of internal control over financial reporting utilized by the Company and its Subsidiaries that has not been subsequently remediated; or (ii) any fraud that involves the Company's management or other employees who have a role in the preparation of financial statements or the internal control over financial reporting utilized by the Company and its Subsidiaries. Since January 1, 2018, the principal executive officer and the principal financial officer of the Company have made all certifications required by the Sarbanes-Oxley Act. The Company is in compliance in all material respects with all current listing and corporate governance requirements of NASDAQ, and is in compliance in all material respects with all rules, regulations and requirements of the Sarbanes-Oxley Act and the SEC.

(e) None of the Acquired Companies has effected, entered into, created, is a party to, or has any commitment to become a party to, any joint venture, off-balance sheet partnership or any similar Contract or arrangement (including any Contract or arrangement related to any transaction or relationship between or among the Acquired Companies, on the one hand, and any unconsolidated Affiliate, including any structured finance, special purpose or limited purpose entity or Person, on the other hand), or any securitization transaction or "off-balance sheet arrangement" (as defined in Item 303(a) of Regulation S-K under the Exchange Act).

(f) As of the date hereof, there are no outstanding or unresolved comments in comment letters received from the SEC with respect to the Company SEC Documents.

(g) Except as permitted by the Exchange Act, including Sections 13(k)(2) and (3), since January 1, 2017, none of the Acquired Companies has made or permitted to remain outstanding any "extensions of credit" (within the meaning of Section 402 of the Sarbanes-Oxley Act) or prohibited loans to any executive officer (as defined in Rule 3b-7 under the Exchange Act) or director of the Company.

(h) The Company has conducted an assessment and determined that it does not produce, design, test, manufacture, fabricate or develop "critical technologies" as defined pursuant to 31 CFR § 801.204 and in turn is not a "pilot program U.S. business" within the meaning of 31 CFR § 801.213.

Section 3.5 Absence of Changes. Since June 30, 2019 through the date hereof, the Acquired Companies have conducted their businesses in the ordinary course consistent with past practice and, since and through such dates, there has not been or occurred (i) any Company Material Adverse Effect or (ii) any event, condition, action, or effect that, if taken during the period from the date of this Agreement through the Effective Time without Parent's consent, would constitute a breach of clause (vii), (ix), (x), (xi), (xiv), (xvi), (xvii), (xviii), (xix), (xx), (xxv) or (xxvi) of Section 5.2(a).

Section 3.6 Intellectual Property.

(a) Section 3.6(a) of the Company Disclosure Schedule lists all United States and non-United States patents and patent applications, trademark registrations and applications therefor and registered copyrights and applications therefor owned, co-owned, or in-licensed by the Company (such registrations and applications, the "**Company Registered IP**"), including, with respect to each such registration and application, (i) the jurisdiction of application/registration, (ii) the application or registration number and (iii) the date of filing or issuance for each such item, and, for in-licensed Intellectual Property, (iv) the registered owner of the Intellectual Property; (v) the relevant license agreement by which rights are conveyed; and (vi) whether the in-license is exclusive or non-exclusive. To the Knowledge of the Company, no Company Registered IP is invalid or unenforceable, except for such exceptions are not and would not reasonably be expected to be material to the Acquired Companies.

(b) All founders, key employees and any other employees, consultants, inventors or contributors involved in the development of owned or co-owned Company Registered IP, and, to the Knowledge of the Company, of in-licensed Company Registered IP, that specifically covers or claims a Company product or otherwise provides material value in support of the business of the Acquired Companies as currently conducted or proposed to be conducted as described in any of the Company SEC Documents have signed confidentiality and invention assignment agreements or similar agreements for the transfer, assignment, or licensing of such owned or co-owned Company Registered IP to the Acquired Companies pursuant to which the Acquired Companies either (i) have obtained ownership of and are the exclusive owners of or (ii) have obtained a valid and unrestricted right to exploit, sufficient for the operation of the business of the Acquired Companies as currently conducted or proposed to be conducted as described in any of the Company SEC Documents, such Company Registered IP.

(c) The owned, co-owned, and, to the Knowledge of the Company, without requiring the Company to have conducted searches therefor, the in-licensed Company Registered IP, of the Acquired Companies are free and clear of any Encumbrance, other than Permitted Encumbrances.

(d) Section 3.6(d) of the Company Disclosure Schedule identifies, as of the date of this Agreement, (i) each Company Inbound License and (ii) each Company Outbound License.

(e) To the Knowledge of the Company, the operation of the business of the Acquired Companies as currently conducted and proposed to be conducted as described in any of the Company SEC Documents does not infringe or misappropriate any Intellectual Property owned by another Person, except as is not and would not reasonably be expected to be material to the Acquired Companies. There is no Legal Proceeding pending or, to the Knowledge of the Company, threatened in writing, against any of the Acquired Companies relating to any infringement or misappropriation of any Intellectual Property of another Person by any of the Acquired Companies.

(f) None of the Acquired Companies is subject to any judgment, order, writ, injunction or decree of any court or any Governmental Entity or any arbitrator, nor has any of the Acquired Companies entered into or is a party to any agreement made in settlement of any pending or threatened litigation, which materially restricts or impairs the use of any Company Intellectual Property.

(g) To the Knowledge of the Company, no other Person is infringing or misappropriating any Company Registered IP that is owned, co-owned or exclusively licensed to the Acquired Companies under any Company Inbound License, except as would not, individually, or in the aggregate, be material to the Acquired Companies.

(h) The Acquired Companies have taken commercially reasonable steps necessary to maintain the confidentiality of the material trade secret rights held by any of the Acquired Companies, or purported to be held by any of the Acquired Companies, as a trade secret.

Section 3.7 Title to Assets; Real Property.

(a) Except as is not, and would not reasonably be expected to be, material to the Acquired Companies, the Acquired Companies have good, valid and marketable title to, or in the case of assets purported to be leased by the Acquired Companies, valid leasehold interests in, each of the tangible assets reflected as owned or leased by the Acquired Companies on the Most Recent Balance Sheet (except for tangible assets sold or disposed of since the date of the Most Recent Balance Sheet and except for tangible assets being leased to the Acquired Companies with respect to which the lease has expired since such date), free of any liens or Encumbrances (other than Permitted Encumbrances). All material items of equipment and other tangible assets owned by or leased to the Acquired Companies are adequate for the uses to which they are being put, and are in good and safe operating condition and repair (ordinary wear and tear and routine ongoing maintenance excepted).

(b) None of the Acquired Companies owns, or has ever owned, any real property.

(c) Section 3.7(c) of the Company Disclosure Schedule sets forth the address of each lease, sublease or license or any other instrument (each a **"Lease"**) under which the Company leases, subleases or licenses any real property (each **"Leased Real Property"**) and the applicable Acquired Company that holds a leasehold interest in such Leased Real Property. The Company has made available to Parent an accurate and correct and complete copies of each Lease (including all amendments, extensions, renewals, guaranties, and other agreements with respect thereto) with respect to each Leased Real Property and each such Lease for a Leased Real Property is legal, valid and binding on the Acquired Companies, as the case may be, and, to the Knowledge of the Company, each other party thereto (including any assignee thereof), as applicable, and in full force and effect, except as may be limited by bankruptcy, insolvency, moratorium and other similar applicable Law affecting creditors' rights generally and by general principles of equity (the **"Enforceability Exceptions"**). No Acquired Company has received any notice of any pending or threatened condemnation proceeding with respect to any Leased Real Property, and neither the whole or any material portion of the Leased Real Property has been damaged or destroyed by fire or other casualty, which damage remains unrepaired. To the Knowledge of the Company, the Leased Real Property and its continued use, occupancy and operation as currently used, occupied and operated, does not constitute a nonconforming use under any applicable building, zoning, subdivision or similar Law applicable to the Leased Real Property, or under the applicable Lease or any restrictive covenant affecting the Leased Real Property. No Person leases, subleases, licenses or otherwise has the right to use or occupy any of the Leased Real Property or is in possession of any Leased Real Property other than the applicable Acquired Company that holds a leasehold interest in such Leased Real Property.

Section 3.8 Company Material Contracts.

(a) Except as set forth on Section 3.8 of the Company Disclosure Schedule, and except for this Agreement, as of the date hereof, none of the Acquired Companies is a party to or is bound by any Contract:

(i) that is a "material contract" (as such term is defined in Item 601(b)(10) of Regulation S-K of the Exchange Act);

(ii) requiring or otherwise involving the payment by or to any of the Acquired Companies of more than an aggregate of $100,000 on an annual basis;

(iii) evidencing a capital expenditure in excess of $100,000;

(iv) (A) provides for annual compensation in excess of $100,000 in exchange for the employment of, or the performance of services by, any director, officer, employee or consultant (other than any employment offer letter (in such form as previously provided to Parent) that is terminable "at will" without any contractual obligation on the part of any Acquired Company to make any severance, termination, change in control, or similar payment), (B) contains terms obligating or which may in the future obligate any of the Acquired Companies to make any severance, termination or similar payment to any current or former employee or (C) pursuant to which any of the Acquired Companies may be obligated to make any bonus or similar payment to any current or former employee or director;

(v) (A) limiting the ability or right of any Acquired Company (or, after the Effective Time, Parent or any of its Affiliates) to compete or engage in any line of business or to compete with any Person in any geographic area, (B) containing any "most favored nations" terms and conditions (including with respect to pricing) or exclusivity obligations, (C) granting any right of first refusal, right of first offer, rights of negotiation or similar right, or (D) containing any other term, condition or clause that individually or in the aggregate, limits or purports to limit in any material respect the ability of any Acquired Company (or, after the Effective Time, Parent or its Affiliates) to own, operate, manufacture, sell, distribute, transfer, pledge or otherwise dispose of any material assets or business of any Acquired Company (or, after the Effective Time, Parent or its Affiliates);

(vi) providing for indemnification (or reimbursement or advancement of legal fees or expenses) of any current or former officer, director or employee of any Acquired Company;

(vii) relating to or evidencing Indebtedness for borrowed money or any guarantee of Indebtedness for borrowed money by any Acquired Company which, together with all other such Contracts relating to or evidencing Indebtedness for borrowed money or any guarantee of Indebtedness for borrowed money by any Acquired Company (if any), do not exceed $50,000 in the aggregate (excluding loans to wholly-owned Subsidiaries in the ordinary course of business consistent with past practice);

(viii) relating to any joint venture, partnership, strategic alliance, research and development project or similar arrangement that is material to the business of the Acquired Companies;

(ix) under which any Acquired Company leases, subleases or licenses any real property;

(x) under which any Acquired Company leases personal property (not relating primarily to real property), pursuant to which any Acquired Company is required to make rental payments in excess of $100,000 per year;

(xi) (A) in which any Acquired Company has agreed to purchase a minimum quantity of goods or has agreed to purchase goods or services from a sole-source or (B) pursuant to which any Acquired Company has continuing obligations or interests involving the payment of royalties, milestones or other amounts calculated based upon the revenues or income of such Acquired Company, in each case that is not terminable by the applicable Acquired Company without cost or penalty upon less than 30 days' notice;

(xii) for (A) the disposition of any significant portion of the assets or business of any Acquired Company, (B) the acquisition, directly or indirectly, of a material portion of the assets or business of any other Person (whether by merger, sale of stock or assets or otherwise), or (C) related to any disposition or acquisition that contains continuing representations, covenants, indemnities or other obligations (including "earn out" or other contingent payment obligations);

(xiii) relating to the research, development, supply, distribution, marketing, promotion, commercialization, manufacturing or license of any product or product candidate of any Acquired Company that is material to the business of any Acquired Company;

(xiv) containing a standstill or similar obligation of any Acquired Company to a Third Party or of a Third Party to the Acquired Company that does not terminate in accordance with its terms in connection with the execution of this Agreement;

(xv) (A) requires or permits any Acquired Company (or any successor), or an acquirer of any Acquired Company, to make any payment to another Person as a result of a change of control of the Company, (B) gives another Person a right to receive or elect to receive such payment or (C) is subject to modification or termination as a result of a change of control of any Acquired Company;

(xvi) containing any agreement by any Acquired Company to indemnify any Person against any infringement, violation or misappropriation of the Intellectual Property rights of a Third Party, other than Contracts entered into in the ordinary course of business consistent with past practice;

(xvii) with any Governmental Entity;

(xviii) which would prohibit or materially delay the consummation of the Contemplated Transactions or otherwise materially impair the ability of the Company to perform its obligations hereunder;

(xix) that is a Company Inbound License or Company Outbound License; and

(xx) that is the type of Contract that would be required to be disclosed under Item 404 of Regulation S-K of the Exchange Act.

(b) Each Contract of the type described above in this Section 3.8(b), whether or not set forth in Section 3.8 of the Company Disclosure Schedule, is referred to herein as a **"Company Material Contract"**. Except Company Material Contracts that have expired or terminated by their terms with no continuing obligations thereunder, all of the Company Material Contracts are valid and binding on the Acquired Companies, as the case may be, and, to the Knowledge of the Company, each other party thereto, as applicable, and in full force and effect, except as may be limited by the Enforceability Exceptions. No Acquired Company has, and to the Knowledge of the Company, none of the other parties thereto have, violated in any material respect any provision of, or committed or failed to perform any act, and no event or condition exists, which with or without notice, lapse of time or both would constitute a material default under the provisions of any Company Material Contract, and, no Acquired Company has received or given any notice of any violation or breach of, default under, or intention to cancel, terminate, adversely modify or not renew, any Company Material Contract. The Company has made available to Parent accurate and complete copies of all Company Material Contracts in effect as of the date hereof.

Section 3.9 Compliance; Permits; Restrictions.

(a) The Company and its Subsidiaries are and, since January 1, 2017, have been in compliance in all material respects with all Laws applicable to the Acquired Companies, and, since January 1, 2017, have not received any written notice alleging any violation with respect to any applicable Laws.

(b) Each of the current product candidates of the Acquired Companies is being, and at all times has been, developed, and has been since January 1, 2017, tested, manufactured, labeled, distributed and stored, as applicable, in compliance in all material respects with the FDC Act, as amended, and applicable regulations enforced by the U.S. Food and Drug Administration (the **"FDA"**) and comparable applicable Laws outside of the United States, including those requirements relating to current good manufacturing practices, good laboratory practices and good clinical practices, as applicable. To the extent the foregoing representation and warranty is made with respect to activities conducted by Third Parties, such representation and warranty is made solely to the Knowledge of the Company.

(c) The Company and its Subsidiaries are and, since January 1, 2017, have been in compliance in all material respects with all Healthcare Laws that are applicable to the Company and its Subsidiaries. The Company is not subject to any enforcement, regulatory or administrative proceedings relating to any Healthcare Laws, and to the Knowledge of the Company, no such proceeding has been threatened in writing.

(d) No current employee of the Acquired Companies, nor to the Knowledge of the Company, any former employee or Third Party conducting or monitoring studies on behalf of the Company has been debarred by the FDA. To the Knowledge of the Company, the Company has not made any false statements to the FDA.

Section 3.10 Certain Business Practices. Each of the Acquired Companies is in compliance in all material respects with the Foreign Corrupt Practices Act of 1977, as amended, the U.K. Bribery Act and any other U.S. or foreign Law concerning bribery or corrupt payments applicable to any Acquired Company. Since January 1, 2017, none of the Acquired Companies has, to the Knowledge of the Company, been investigated by any Governmental Entity with respect to, and none of the Acquired Companies has been given written notice by a Governmental Entity of, any violation by any of the Acquired Companies of the Foreign Corrupt Practices Act of 1977, as amended, the U.K. Bribery Act, or any other U.S. or foreign Law concerning corrupt payments. None of the Acquired Companies nor any Company Associate authorized to act, and acting, on behalf of an Acquired Company has unlawfully paid or given, offered or promised to pay or give, or authorized or ratified the payment or giving, directly or indirectly, of any monies or anything else of value to any national, provincial, municipal or other government official or employee or any political party or candidate for political office or Governmental Entity for the direct or indirect purpose of improperly influencing any act or decision of such Person or of the Governmental Entity to obtain or retain business, or direct business to any Person or to secure any other improper benefit or advantage. For purposes of this provision, an "official or employee" includes any known official or employee of any directly or indirectly government-owned or controlled entity, and any known officer or employee of a public international organization, as well as any Person known to be acting in an official capacity for or on behalf of any such government or department, agency, or instrumentality, or for or on behalf of any such public international organization.

Section 3.11 Tax Matters.

(a) Each of the Company and its Subsidiaries (i) has filed (taking into account any extension of time within which to file) all income and other material Tax Returns required to have been filed by or with respect to the Company or any of its Subsidiaries, and all such Tax Returns are accurate and complete in all material respects and were prepared in substantial compliance with all applicable Laws, (ii) has paid all Taxes required to have been paid, whether or not shown as due on such Tax Returns and (iii) has not received written notice of any proposed or assessed deficiencies for any Tax from any taxing authority, against the Company or any of its Subsidiaries.

(b) Neither the Company nor any of its Subsidiaries is the subject of any currently ongoing Tax audit or other proceeding with respect to Taxes nor has any Tax audit or other proceeding with respect to Taxes been proposed against any of them in writing. No issues relating to material Taxes of the Company or any of its Subsidiaries were raised by the relevant Tax authority in any completed audit or examination. Neither the Company nor any of its Subsidiaries has waived any statute of limitations in respect of Taxes or agreed to any extension of time with respect to a Tax assessment or deficiency (other than pursuant to extensions of time to file Tax Returns obtained in the ordinary course of business consistent with past practice) in either case that is still outstanding.

(c) The Company and each of its Subsidiaries has timely withheld and paid all Taxes required to have been withheld and paid in connection with amounts paid or owing to any employee, independent contractor, creditor, stockholder or other Third Party.

(d) There are no Encumbrances for Taxes (other than Taxes not yet due and payable) on any of the assets of the Company or any of its Subsidiaries.

(e) Neither the Company nor any of its Subsidiaries is a party to or bound by any written Tax allocation, indemnification (including indemnification of Taxes with respect to service-providers) or sharing agreement (other than an agreement with the Company or any of its Subsidiaries and other than customary indemnifications for Taxes contained in credit or other commercial agreements the primary purposes of which do not relate to Taxes). Neither the Company nor any of its Subsidiaries is or has been a member of an affiliated group (other than a group the common parent of which is the Company) filing a consolidated U.S. federal income Tax Return. Neither the Company nor any of its Subsidiaries is liable under Treasury Regulations Section 1.1502-6 (or any similar provision of the Tax laws of any state, local or foreign jurisdiction), or as a transferee or successor, by contract, or otherwise, for any Tax of any Person other than the Company and its Subsidiaries.

(f) Neither the Company nor any of its Subsidiaries was a "distributing corporation" or "controlled corporation" in a transaction intended to qualify under Section 355 of the Code within the past two years or otherwise as part of a "plan" or "series of related transactions" (within the meaning of Section 355(e) of the Code) that includes the Merger.

(g) The Company has not been a United States real property holding corporation within the meaning of Section 897(c)(2) of the Code during the period specified in Section 897(c)(1)(A)(ii) of the Code.

(h) Neither the Company nor any of its Subsidiaries has entered into any transaction identified as a "listed transaction" within the meaning of Sections 1.6011-4(b)(2) or 301.6111-2(b)(2) of the Treasury Regulations or any similar provision of state, local, or foreign law.

(i) Neither the Company nor any of its Subsidiaries has taken or agreed to take any action nor to the Knowledge of the Company is there any fact or circumstance that would reasonably be expected to prevent or impede the Merger from qualifying for the Intended Tax Treatment.

Section 3.12 Employee Matters; Benefit Plans

(a) Section 3.12(a) of the Company Disclosure Schedule sets forth an accurate and complete list of each material Company Benefit Plan. With respect to each material Company Benefit Plan, the Company has made available to Parent an accurate and complete copy of: (i) each plan document, including all amendments thereto, and all related trusts; (ii) the current summary plan description, including any material modifications; (iii) the most recent determination letter (or if applicable, advisory or opinion letter) from the IRS, if any, and any pending applications for a determination or opinion letter; and (iv) all material notices or other non-routine material written correspondence regarding such Company Benefit Plan between a plan fiduciary, any Acquired Company, or any ERISA Affiliate and the IRS, Department of Labor, Pension Benefit Guarantee Corporation, or other Governmental Entity.

(b) None of the Acquired Companies nor any ERISA Affiliate thereof sponsors, maintains or contributes or is obligated to contribute to, or has ever sponsored, maintained, contributed or been obligated to contribute to, or incurred any liability with respect to: (i) any plan subject to Title IV of ERISA or Section 412 of the Code, (ii) any "multiemployer plan" within the meaning of Section 4001(a)(3) or 3(37) of ERISA, (iii) any "multiple employer plan" within the meaning of Section 4063 or 4064 of ERISA, (iv) any "multiple employer welfare arrangement" within the meaning of Section 3(40) of ERISA or (v) any health or other welfare arrangement that is self-insured. No Company Benefit Plan is or has ever been, or currently funds or has ever been funded by, a "voluntary employees' beneficiary association" within the meaning of Section 501(c)(9) of the Code or other funding arrangement for the provision of welfare benefits.

(c) Each Company Benefit Plan intended to be qualified under Section 401(a) of the Code is entitled to rely upon a favorable determination or opinion letter from the IRS. To the Knowledge of the Company, no event has occurred and no condition, facts or circumstances exist that would reasonably be expected to cause the loss of such qualification or the imposition of material liability, penalty or Tax under ERISA, the Code or other applicable Laws. All assets of the Company Benefit Plans consist of cash or actively traded securities. No assets of any Company Benefit Plan consist of capital stock of the Company, other than with respect to the Company Equity Plans and ESPP.

(d) (i) Each Company Benefit Plan has been established, operated, administered and maintained in compliance in all material respects with its terms and with the requirements prescribed by applicable Laws, including ERISA and the Code; (ii) no litigation has commenced with respect to any Company Benefit Plan (other than routine claims for benefits) and, to the Knowledge of the Company, no such litigation is threatened; (iii) there are no material governmental audits or investigations pending or, to the Knowledge of the Company, threatened in connection with any Company Benefit Plan; and (iv) to the Knowledge of the Company, there are no facts or circumstances that reasonably would be expected to give rise to any litigation, audits, investigations, actions, or claims against any Company Benefit Plan, any fiduciary with respect to a Company Benefit Plan or the assets of a Company Benefit Plan. Except as would not reasonably be expected to be material to the Acquired Companies, (i) none of the Acquired Companies have engaged in any non-exempt prohibited transaction (within the meaning of Section 4975 of the Code or Section 406 of ERISA) and, to the Knowledge of the Company, no such prohibited transaction has occurred with respect to any Company Benefit Plan and (ii) no fiduciary (within the meaning of Section 3(21) of ERISA) that is an Acquired Company or a committee or employee of an Acquired Company, and, to the Knowledge of the Company, no fiduciary who is not an Acquired Company or a committee or employee of an Acquired Company, has breached such fiduciary's fiduciary duty under ERISA with respect to a Company Benefit Plan or otherwise has any liability in connection with any acts taken (or failed to be taken) with respect to the administration or investment of the assets of any Company Benefit Plan.

(e) Except as provided in Section 2.4, neither the execution and delivery of this Agreement nor the consummation of the Contemplated Transactions will (either alone or together with any other event) (i) result in, or cause the accelerated vesting, payment, funding or delivery of, or increase the amount or value of, any payment or benefit to any current or former employee, officer, director or other service provider of any Acquired Company, (ii) result in any "parachute payment" (as defined in Section 280G(b)(2) of the Code) or (iii) result in the triggering or imposition of any restrictions or limitations on the rights of the Acquired Companies to amend or terminate any Company Benefit Plan. No Company Benefit Plan provides, and no Acquired Company has any obligation to provide, a tax "gross-up" or similar "make-whole" payment to any current or former employee, officer, director, or other service provider of any Acquired Company, and no such obligation will arise as a result of the execution and delivery of this Agreement or the consummation of the Contemplated Transactions (either alone or together with any other event) or otherwise.

(f) No Company Benefit Plan provides for, and none of the Acquired Companies has any obligation to provide, any post-retirement or post-termination health, life insurance or other welfare benefits, except as required under Part 6 of Subtitle B of Title I of ERISA or Section 4980B of the Code or similar state Law for which the individual pays for the full cost of coverage. Each Company Benefit Plan that is a health plan is in compliance in all material respects with the Patient Protection and Affordable Care Act and the Health Care and Education Reconciliation Act of 2010, and the Acquired Companies have offered all full-time employees the ability to elect minimum essential coverage that provides minimum value for themselves and their dependents in accordance with such Laws.

(g) Each Company Benefit Plan that is a "non-qualified deferred compensation plan" (as such term is defined in Section 409A(d)(1) of the Code) has been operated and maintained in compliance with the requirements of Section 409A of the Code and applicable guidance issued thereunder and in compliance in all material respects with the terms of such Company Benefit Plan.

(h) No Company Benefit Plan is subject to any Laws other than those of the United States or any state, county, or municipality in the United States, nor is any Company Benefit Plan maintained for the benefit of employees, officers, directors, consultants or other service providers located outside of the United States. No Acquired Company contributes to or has any obligation to contribute to any scheme, plan or arrangement mandated by a government other than the United States federal government. Except as set forth on Section 3.12(h) of the Company Disclosure Schedule, there has been no amendment to, or written interpretation of or announcement by any Acquired Company relating to, or change in employee participation or coverage under, any Company Benefit Plan that would materially increase the expense of maintaining such Company Benefit Plan above the level of expense incurred in respect thereof for the most recent fiscal year ending prior to the Closing Date. For each Company Benefit Plan, all contributions, premiums and payments that have become due through the date hereof have been made within the time periods prescribed by the terms of such plan and applicable Laws.

Section 3.13 Labor Matters.

(a) The Company has made available to Parent an accurate and complete list of each employee of the Acquired Companies as of the date hereof, together with each such person's name, job title, date of hire, exempt classification status under the Fair Labor Standards Act, full-time or part-time status, immigration status, work location, annual base salary or wages, annual target incentive or bonus compensation with respect to such person for the current fiscal year, and accrued vacation. The Company has made available to Parent an accurate and complete list of each natural person who serves as an independent contractor or consultant of the Acquired Companies as of the date hereof or who served in such capacity within the prior 12 months, together with each such person's name, description of services, consulting or contracting term and consulting or contracting fee. Independent contractors and consultants of the Acquired Companies are collectively referred to in this Agreement as "**Contractors**".

(b) The Acquired Companies are in compliance in all material respects with all applicable Law and Orders governing labor and employment, including those relating to wages, hours, benefits, worker classification, immigration, affirmative action, collective bargaining, discrimination, reductions in force, civil rights, paid sick leave, protected leave (including family, medical and parental leave), disability rights and accommodations, safety and health, workers' compensation, and the collection and payment of withholding or Social Security Taxes and similar Taxes. The Acquired Companies have, or will have no later than the Closing Date, paid all accrued salaries, bonuses, commissions, wages, and severance of the employees of the Acquired Companies due to be paid through the Closing Date.

(c) The employees of the Acquired Companies are not now, and have never been, represented by a labor union or works council and there is not, to the Knowledge of the Company, any attempt to organize any employees of the Acquired Companies for the purpose of forming or joining a labor union or works council. There is no pending, and, to the Knowledge of the Company, there is no threatened strike, slowdown, picketing, work stoppage or other material labor dispute by the employees of the Acquired Companies. To the Knowledge of the Company, each employee of the Acquired Companies is (i) a United States citizen or lawful permanent resident of the United States or (ii) an alien authorized to work in the United States either specifically for the applicable Acquired Company or for any United States employer. Each Acquired Company has completed a Form I-9 (Employment Eligibility Verification) for each of its employees, and each such Form I-9 has since been updated to the extent required by applicable Laws and is accurate and complete in all material respects as of the date hereof. No Acquired Company is or has been a government contractor. All employees of the Acquired Companies are employed in the United States, and all of the terms and conditions of their employment are governed exclusively by Laws of the United States or a state, county, or municipality in the United States.

(d) There are no Legal Proceedings pending or, to the Knowledge of the Company, threatened between an Acquired Company, on the one hand, and any of its current or former employees, officers, directors or consultants, on the other, including with respect to (i) unpaid wages, bonuses, commissions, unpaid overtime, child labor, record keeping violations, wrongful discharge, retaliation, libel, or slander or (ii) any claim under the Fair Labor Standards Act, the Davis-Bacon Act of 1931, the Walsh-Healey Act of 1936 or the McNamara-O'Hara Service Contract Act of 1965, the 1964 Civil Rights Acts, the Equal Pay Act of 1963, the Age Discrimination in Employment Act, the Americans with Disabilities Act, the Family and Medical Leave Act, the Fair Labor Standards Act, or any other federal labor or employment Law or comparable state fair employment practices act. No review, investigation or other proceeding by any Governmental Entity with respect to any current or former employee or independent contractor of the Acquired Companies is pending or, to the Knowledge of the Company, threatened.

(e) None of the Acquired Companies has experienced a "plant closing" or "mass layoff" as defined in the WARN Act, and, except as set forth on Section 3.13(e) of the Company Disclosure Schedule, during the 90- day period preceding the date hereof, no employee of an Acquired Company has suffered an "employment loss," with respect to such Acquired Company as defined in the WARN Act. The Acquired Companies have complied with all requirements under the WARN Act with respect to any "plant closing" or "mass layoff" as defined in the WARN Act, and have provided to Parent copies of all WARN notices issued within the prior 12 months, if any.

(f) Each current Contractor can be terminated by the Acquired Companies within 30 days' notice for any reason without any amounts being owed to such individual, other than with respect to compensation or payments accrued before the notice of termination. Except as set forth on Section 3.13(f) of the Company Disclosure Schedule, the Acquired Companies have properly classified, pursuant to the Code and any other applicable Laws, all Contractors used by the Acquired Companies within the last 12 months; none of the Acquired Companies have or would reasonably be expected to have any liability for unpaid Taxes with respect to any Contractor within the last 12 months; and no Contractor within the last 12 months has or would reasonably be expected to have a claim for eligibility to participate in, or benefits under, any Company Benefit Plan if such individual is later reclassified as an employee of the Acquired Companies. None of the Acquired Companies have any "leased employees" within the meaning of Section 414(n) of the Code. To the Knowledge of the Company, no employee of the Acquired Companies or any current Contractor is a party to, or is otherwise bound by, any agreement or arrangement with any Third Party (including any confidentiality or non-competition agreement) that in any way prohibits, adversely effects or restricts the performance of such employee's or such Contractor's duties to the Acquired Companies. Each current employee and current Contractor of the Acquired Companies and each former employee and former Contractor of the Acquired Companies has executed a binding and enforceable nondisclosure and assignment-of-rights agreement for the benefit of the Acquired Companies vesting all rights in work product created by the employee or Contractor during the employee's employment or the Contractor's affiliation with the Acquired Companies.

(g) No written, or to the Knowledge of the Company, oral allegations of sexual harassment have been made against any officer or employee of the Acquired Companies. No Acquired Company has entered into any settlement agreement related to allegations of sexual harassment or misconduct by an officer or employee of the Acquired Companies.

(h) The representations and warranties set forth in this Section 3.13 shall constitute the only representations and warranties of the Company with respect to labor matters.

Section 3.14 Environmental Matters. Except as would not reasonably be expected to result in a material liability: (i) each of the Acquired Companies is, and for the past five years has been, in compliance with all applicable Environmental Laws and possesses and is in compliance with all Environmental Permits; (ii) there are no, and for the past five years have not been any, Environmental Claims, requests for information, notices, administrative inquiries, or complaints pending or, to the Knowledge of the Company, threatened against the Acquired Companies; (iii) none of the Acquired Companies, and to the Knowledge of the Company, no other Person, has released any Hazardous Substance at, on, under or from any property currently or formerly owned or leased by the Acquired Companies in an amount or manner which would reasonably be expected to result in material liability to any Acquired Company under Environmental Law and (iv) there are no material liabilities of any Acquired Company of any kind whatsoever, whether accrued, retained, assumed, contingent, absolute, determined, determinable or otherwise arising under or relating to any Environmental Law or any Hazardous Substance, including liabilities arising by Contract or by operation of Law, and there is no condition, situation or set of circumstances that would reasonably be expected to result in or be the basis for any such liability. The Company has provided Parent with accurate and complete copies of all material reports relating to Environmental Law, Hazardous Substances, and occupational health and safety in its possession or reasonable control, including Phase I and Phase II reports, remedial and investigation reports, and industrial hygiene records and assessments. The representations and warranties set forth in this Section 3.14 shall constitute the only representations and warranties of the Company with respect to environmental matters.

Section 3.15 Insurance. Section 3.15 of the Company Disclosure Schedule sets forth an accurate and complete list of all material insurance policies of the Acquired Companies (including the names of the insurer and insured, the policy number, the amount of the premium and the period, type and amounts of coverage provided thereunder) as of the date hereof (the "**Insurance Policies**"), all of which are in full force and effect. None of the Acquired Companies has received any written communication notifying any Acquired Company of any (a) premature cancellation or invalidation of any Insurance Policy (except with respect to policies that have been replaced with similar policies), (b) written denial of any material claim under any Insurance Policy or (c) material increase in the amount of the premiums payable with respect to any Insurance Policy. As of the date hereof, there is no pending material claim by any Acquired Company against any insurance carrier under any insurance policy held by any Acquired Company or under policies that were previously in effect. The Acquired Companies are in compliance in all material respects with all of its obligations under the Insurance Policies. None of the Acquired Companies is in material breach or default, and none of the Acquired Companies has taken any action or failed to take any action which, with notice or the lapse of time, would reasonably be expected to constitute such a breach or default under, or permit rescission or termination of, any of such Insurance Policies.

Section 3.16 Legal Proceedings; Orders.

(a) There is no Legal Proceeding pending (or, to the Knowledge of the Company, threatened in writing) against the Acquired Companies, or any of its present or former directors, officers or employees in their capacity as such, that would reasonably be expected to be material to the Acquired Companies, taken as a whole.

(b) There is no material Order applicable to, imposed against, or binding upon the Acquired Companies.

(c) There are no internal investigations or other internal inquiries conducted at the direction of the Company Board, and, to the Knowledge of the Company, there is no pending or threatened (in writing) investigation by any Governmental Entity, with respect to the Acquired Companies.

Section 3.17 Privacy and Data Security.

(a) Each of the Acquired Companies is currently complying and has, since January 1, 2017 complied in all material respects with all applicable Privacy and Information Security Laws, including Laws relating to the privacy of Personal Information regarding clinical trial participants, patients, patient family members, caregivers or advocates, physicians and other health care professionals, clinical trial investigators, researchers and pharmacists that interact with any of the Acquired Companies in connection with the operation of the Acquired Companies' business. To the Knowledge of the Company, no investigations, claims or complaints are pending or have been threatened against the Acquired Companies by any Person regarding a violation of Privacy and Information Security Laws, and/or other information security policies. None of the Acquired Companies is a "covered entity" or "business associate" for purposes of HIPAA. The Acquired Companies have provided all requisite notices, obtained all required consents, and satisfied all other material requirements for their processing of Personal Information for the conduct of business as currently conducted and in connection with the consummation of the Contemplated Transactions.

(b) The Acquired Companies have adopted reasonable and appropriate, organizational, physical, administrative and technical measures consistent with industry practices to protect Personal Information and protect against Security Incidents (as defined below). Without limitation to the generality of the foregoing, such measures are appropriate to protect the Personal Information collected, stored, or otherwise processed by or on behalf of the Acquired Companies, the confidential or proprietary information of or related to their businesses, and the Company IT Systems from unauthorized access, acquisition, interruption, alteration, modification, use or other processing, or any other compromise of their confidentiality, integrity or availability (any such incident a "**Security Incident**"). Except as expressly disclosed pursuant to Section 3.17 of the Company Disclosure Schedule, since January 1, 2017, none of the Acquired Companies (nor, to the Knowledge of the Company, any Third Parties acting on their behalf) have experienced any actual or alleged Security Incident, and none of the Acquired Companies (nor, to the Knowledge of the Company, any Third Parties acting on their behalf) have notified, or been required to notify, any person of any Security Incident or other event involving Personal Information that is in the custody, possession or control of any of the Acquired Companies. In addition, to the Knowledge of the Company, no individuals or Third Parties (including any threat actors described in Section 3.17 of the Company Disclosure Schedule) have ongoing unauthorized access to Company IT Systems, and to the Knowledge of the Company, none of the Acquired Companies or Company IT Systems have any information security vulnerabilities that would reasonably be expected to materially adversely impact the operation of relevant Company IT Systems or cause a Security Incident.

Section 3.18 Authority; Binding Nature of Agreement.

(a) The Company has all requisite corporate power and authority to enter into this Agreement, to perform its obligations hereunder and, subject to the Company Stockholder Approval, to consummate the Contemplated Transactions. The execution, delivery and performance by the Company of this Agreement and the consummation by the Company of the Contemplated Transactions, except for obtaining the Company Stockholder Approval, have been duly authorized by all necessary corporate action on the part of the Company. The affirmative vote of the holders of a majority of the outstanding Shares voting to approve and adopt this Agreement (the "**Company Stockholder Approval**") is the only vote of the holders of any of the Company's capital stock necessary for the consummation of the Contemplated Transactions.

(b) The Company Board (at a meeting duly called and held) has unanimously: (i) determined that this Agreement and the Contemplated Transactions, including the Merger, upon the terms and subject to the conditions set forth herein, are in the best interests of the Company's stockholders, (ii) approved and declared advisable this Agreement and the Contemplated Transactions in accordance with the requirements of the DGCL, (iii) resolved to recommend that the stockholders of the Company approve and adopt this Agreement at the Company Stockholders' Meeting (the "**Company Board Recommendation**") and (iv) to the extent necessary, adopted a resolution having the effect of causing the Merger, this Agreement and the Contemplated Transactions not to be subject to any Takeover Statute or similar Law that might otherwise apply to the Merger or any of the other Contemplated Transactions, which actions have not, as of the date hereof, been subsequently rescinded, modified or withdrawn. This Agreement has been duly executed and delivered by the Company and constitutes the legal, valid and binding obligation of the Company and, assuming due authorization, execution and delivery by Parent and Merger Sub, is enforceable against the Company in accordance with its terms, subject to the Enforceability Exceptions.

Section 3.19 Takeover Statutes. Assuming the accuracy of Parent and Merger Sub's representations and warranties set forth inSection 4.11, the Company Board has taken all action necessary to render inapplicable to the Merger the restrictions on business combinations contained in Section 203 of the DGCL. No other "business combination," "control share acquisition," "fair price," "moratorium" or other takeover or anti-takeover statute or similar federal or state Law (together with Section 203 of the DGCL, "**Takeover Statutes**") are applicable to this Agreement, the Voting Agreements, or the Contemplated Transactions.

Section 3.20 Non-Contravention; Consents.

(a) Assuming compliance with the applicable provisions of the DGCL and the listing requirements of NASDAQ, the filing of the registration statement on Form F-4 to be filed with the SEC by Parent in connection with the Merger (the "**Form F-4**") (and the proxy statement to be filed with the SEC and sent to the Company's stockholders in connection with the Merger (including any amendments or supplements thereto, the "**Proxy Statement**")) and obtaining the Company Stockholder Approval, the execution, delivery and performance of this Agreement by the Company and the consummation by the Company of the Contemplated Transactions do not and will not: (i) result in a breach or violation of, or default under, any of the provisions of the Company Charter Documents or the comparable governing instruments of any of the other Acquired Companies; (ii) with or without notice or lapse of time or both, result in a breach or violation of, a termination (or right of termination) or default under, any change in or acceleration or creation of any obligations, or loss of rights pursuant to any Company Material Contract or the creation of any Encumbrance (other than Permitted Encumbrances) on any assets of any Acquired Company, in each case that would be binding upon any Acquired Company; or (iii) result in a breach or violation of any Law or Order applicable to any Acquired Company, except in each case in clauses (ii) and (iii), as, individually or in the aggregate, would not reasonably be expected to have a Company Material Adverse Effect.

(b) Except as may be required by the Exchange Act or Takeover Statutes, the DGCL, and the rules and regulations of NASDAQ, and assuming the filing of the Proxy Statement and obtaining the Company Stockholder Approval, neither the Company nor any of its Affiliates is required to give notice to, deliver any report to, make any filing with, or obtain any consent or waiver from any Person at any time prior to the Closing in connection with the execution, delivery and performance of this Agreement, or the consummation by the Company of the Contemplated Transactions, except those that the failure to give, deliver, make or obtain would not, individually or in the aggregate, reasonably be expected to have a Company Material Adverse Effect.

Section 3.21 Liabilities. Except as set forth on Section 3.21 of the Company Disclosure Schedule, the Acquired Companies have no liabilities or obligations, whether or not accrued, contingent or otherwise and whether or not required to be disclosed, except for: (i) liabilities and obligations reflected on the balance sheet in the Company 10-Q (including any related notes); (ii) liabilities and obligations incurred in the ordinary course of business consistent with past practice since the date of the Most Recent Balance Sheet, and which would not reasonably be expected to have, individually or in the aggregate, a Company Material Adverse Effect; and (iii) liabilities and obligations incurred in connection with the Contemplated Transactions.

Section 3.22 Information Supplied. None of the information supplied or to be supplied by or on behalf of the Company for inclusion or incorporation by reference in the Form F-4 will, at the time the FormF-4 is filed with the SEC, and at any time it is amended or supplemented or at the time it becomes effective under the Securities Act, contain any untrue statement of a material fact or omit to state any material fact required to be stated therein or necessary to make the statements therein, in light of the circumstances under which they were made, not misleading. The Proxy Statement will not, on the date it is first mailed to the Company's stockholders, or at the time of the Company Stockholders' Meeting or at the time of any amendment or supplement thereof, contain any untrue statement of a material fact or omit to state any material fact necessary in order to make the statements made therein, in light of the circumstances under which they were made, not misleading. The Proxy Statement will comply as to form in all material respects with the requirements of the Exchange Act. Notwithstanding the foregoing, no representation or warranty is made by the Company with respect to statements made or incorporated by reference therein based on information supplied in writing by Parent, Merger Sub or any Affiliate of Parent or Merger Sub expressly for inclusion therein.

Section 3.23 Fairness Opinion. The Company Board has received the written opinion of Duff & Phelps, LLC to the effect that as of the date of such opinion and subject to the assumptions and limitations set forth therein, the Exchange Ratio is fair, from a financial point, of view to the holders of Shares. As of the date of this Agreement, such opinion has not been withdrawn, revoked or modified. The Company shall provide an accurate and complete copy of such opinion for informational purposes to Parent on or as soon as possible following the date of this Agreement.

Section 3.24 Financial Advisor. No agent, broker, finder, financial advisor or investment banker (other than Ondra Partners and Duff & Phelps, LLC) is entitled to any brokerage, finder's, financial advisor's or other fee or commission in connection with this Agreement or the Merger based upon arrangements made by or on behalf of the Acquired Companies.

ARTICLE IV

REPRESENTATIONS AND WARRANTIES OF PARENT AND MERGER SUB

Except (a) as disclosed with reasonable specificity in the Parent SEC Documents which are publicly available at least three business days prior to the date of this Agreement (other than information that is (i) contained solely in the risk factors sections of such Parent SEC Documents and (ii) in any forward-looking statements in such Parent SEC Documents that are of a nature that they speculate about future developments), Parent and Merger Sub hereby represent and warrant to the Company as follows:

Section 4.1 Due Organization; Subsidiaries.

(a) Each of Parent and Merger Sub is a corporation that is (i) duly organized, validly existing and in good standing under the Law of its jurisdiction of incorporation, (ii) has corporate power and authority to own, lease and operate its properties and assets and to conduct its business as presently conducted and (iii) is duly qualified or licensed to do business as a foreign corporation and is in good standing (with respect to jurisdictions that recognize such concept) in each jurisdiction where the character of the properties owned, leased or operated by it or the nature of its business makes such qualification or licensing necessary, except, with respect to clause (iii), where the failure to be so qualified or licensed would not reasonably be expected to have, individually or in the aggregate, a Parent Material Adverse Effect.

Section 4.2 Organizational Documents. Parent has made available to the Company accurate and complete copies of the certificate of incorporation, bylaws and other charter and organizational documents of each of Parent and Merger Sub, including all amendments thereto, as in effect on the date hereof. Parent and Merger Sub's certificates of incorporation, bylaws or other charter and organizational documents so delivered are in full force and effect.

Section 4.3 Capitalization.

(a) As of January 14, 2020, Parent's share capital registered in the commercial register*(Handelsregister)* totals €232,304,250, which is divided into 232,304,250 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. Under § 4(5) of Parent's Articles of Association *(Satzung)*, through August 18, 2024, the Parent's Management Board is authorized to increase its share capital, on one or more occasions, by a total of up to €105,818,002 by issuing, on one or more occasions, up to 105,818,002 new, registered shares with no par value *(Genehmigtes Kapital)*, in each case with the consent of Parent's Supervisory Board. In addition, pursuant to § 4(6) of Parent's Articles of Association, Parent's share capital is conditionally increased by €21,874,806 through issuance of new, registered shares with no par value *(Bedingtes Kapital ESOP 2017/2019)*, which conditional capital may only be used to issue shares to the holders of option rights granted under Parent's Employee Stock Ownership Plan to members of the Parent's Management Board and to certain of Parent's employees. Pursuant to § 4(7) of Parent's Articles of Association, Parent's share capital is conditionally increased by €87,499,260 through issuance of new, registered shares with no par value *(Bedingtes Kapital WSV 2019)*, which conditional capital may only be used to issue shares to the holders or creditors of option rights or conversion rights or if 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 Parent exercises a right to choose to grant its 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.

Section 4.4 SEC Filings; Financial Statements.

(a) All reports, schedules, forms, statements and other documents (including exhibits and all other information incorporated therein) required to be filed or furnished by the Company with the SEC since October 9, 2019 (the "**Parent SEC Documents**") have been filed or furnished with the SEC on a timely basis. As of the time it was filed or furnished with the SEC (or, if amended or superseded by a filing prior to the date hereof, then on the date of such filing): (i) each of the Parent SEC Documents complied as to form in all material respects with the requirements of the Securities Act, the Exchange Act, the Sarbanes-Oxley Act and NASDAQ (as the case may be) and the rules and regulations of the SEC promulgated thereunder applicable to such Parent SEC Documents; and (ii) none of the Parent SEC Documents contained when filed or furnished (and, in the case of registration statements and proxy statements, on the dates of effectiveness and the dates of mailing, respectively), and each Parent SEC Document filed or furnished subsequent to the date hereof will not contain, any untrue statement of a material fact or omitted, as the case may be, to state a material fact required to be stated or incorporated by reference therein or necessary in order to make the statements therein, in the light of the circumstances under which they were made, not misleading.

(b) The financial statements (including any related notes or schedules thereto) contained or incorporated by reference in the Parent SEC Documents: (i) complied as to form in all material respects with the published rules and regulations of the SEC applicable thereto applicable to Parent; and (ii) fairly present, in all material respects, the financial position of Parent as of the respective dates thereof and the results of operations, changes in equity and cash flows of Parent for the periods covered thereby.

Section 4.5 Absence of Changes. Since December 31, 2018 through the date hereof, to the Knowledge of Parent, there has not been any event, condition, change, occurrence or development that has had or would reasonably be expected to have a Parent Material Adverse Effect.

Section 4.6 Compliance; Permits; Restrictions.

(a) Parent and its Subsidiaries are and, since January 1, 2017, have been in compliance in all material respects with all Laws applicable to Parent and its Subsidiaries, and, since January 1, 2017, have not received any written notice alleging any violation with respect to any applicable Laws.

(b) Each of the current products and product candidates of Parent and its Subsidiaries is being, and at all times has been, developed, and has been since January 1, 2017, tested, manufactured, labeled, distributed and stored, as applicable, in compliance in all material respects with the laws of the applicable jurisdiction, including those requirements relating to current good manufacturing practices, good laboratory practices and good clinical practices, as applicable. To the extent the foregoing representation and warranty is made with respect to activities conducted by Third Parties, such representation and warranty is made solely to the Knowledge of Parent.

(c) Parent and its Subsidiaries are and, since January 1, 2017, have been in compliance in all material respects with all Healthcare Laws that are applicable to Parent and its Subsidiaries. Parent is not subject to any enforcement, regulatory or administrative proceedings relating to any Healthcare Laws, and to the Knowledge of Parent, no such proceeding has been threatened in writing.

(d) No current employee of Parent and its Subsidiaries, nor to the Knowledge of Parent, any former employee or Third Party conducting or monitoring studies on behalf of the Parent or its Subsidiaries has been debarred by any Governmental Entity. To the Knowledge of Parent, Parent has not made any false statements to any Governmental Entity.

Section 4.7 Sufficiency of Funds. Parent and Merger Sub expressly acknowledge and agree that their obligations under this Agreement, including their obligations to consummate the Contemplated Transactions, are not subject to, or conditioned on, the receipt or availability of any funds or financing.

Section 4.8 Legal Proceedings; Orders.

(a) There is no Legal Proceeding pending (or, to the Knowledge of Parent, threatened in writing) against Parent or its Subsidiaries, or any of its present or former directors, officers or employees in their capacity as such, that would reasonably be expected to be material to Parent and its Subsidiaries taken as a whole.

(b) There is no material Order applicable to, imposed against, or binding upon Parent or its Subsidiaries.

(c) There are no internal investigations or other internal inquiries conducted at the direction of the Parent's Management Board or Parent's Supervisory Board, and, to the Knowledge of Parent, there is no pending or threatened (in writing) investigation by any Governmental Entity, with respect to Parent or its Subsidiaries.

Section 4.9 Authority; Binding Nature of Agreement.

(a) Each of Parent and Merger Sub has all requisite corporate power and authority to enter into this Agreement, and subject to approval by the Parent's Supervisory Board, to consummate the Contemplated Transactions. The execution, delivery and performance by Parent and Merger of this Agreement and the consummation by Parent and Merger Sub of the Contemplated Transactions, except for obtaining Parent's Management Board and Parent's Supervisory Board approval in respect of the Share Issuance, have been duly authorized by all necessary corporate action on the part of Parent and Merger Sub. The affirmative vote of the Parent's Management Board and Parent's Supervisory Board to approve the Share Issuance is the only vote necessary for the consummation of the Contemplated Transactions.

(b) The Parent's Management Board by resolutions duly adopted by a unanimous vote of all directors of Parent duly called and held and not subsequently rescinded or modified in any way has (A) determined that this Agreement and the Contemplated Transactions, including the Merger, upon the terms and subject to the conditions set forth herein, are fair to, and in the best interests of, Parent and Parent's stockholders, (B) approved and declared advisable this Agreement and the Contemplated Transactions, including the Merger, upon the terms and subject to the conditions set forth herein and (C) directed that the Share Issuance by submitted to a formal resolutions of Parent's Management Board and Parent's Supervisory Board.

(c) The Merger Sub Board, by resolutions duly adopted by a unanimous vote at a meeting of all directors of Merger Sub duly called and held and not subsequently rescinded or modified in any way, has (A) determined that this Agreement and the Contemplated Transactions, including the Merger, upon the terms and subject to the conditions set forth herein, are in the best interests of, Merger Sub and Parent, as the sole stockholder of Merger Sub, (B) approved and declared advisable this Agreement, and the Contemplated Transactions, including the Merger, upon the terms and subject to the conditions set forth herein, (C) directed that this Agreement be submitted to a vote by Parent, and (D) resolved to recommend that Parent approve and adopt this Agreement.

Section 4.10 Non-Contravention; Consents.

(a) Assuming compliance with the applicable provisions of the DGCL, and the listing requirements of NASDAQ, the filing of theForm F-4 (and the Proxy Statement) the execution, delivery and performance of this Agreement by Parent and Merger Sub and the consummation by Parent and Merger Sub of the Contemplated Transactions do not and will not: (i) result in a breach or violation of, or default under, any of the provisions of the Parent Charter Documents or the comparable governing instruments of any of Parent's Subsidiaries; (ii) with or without notice or lapse of time or both, result in a breach or violation of, a termination (or right of termination) or default under, any change in or acceleration or creation of any obligations, or loss of rights pursuant to any Parent material Contract or the creation of any Encumbrance (other than Permitted Encumbrances) on any assets of Parent or its Subsidiaries, in each case that would be binding upon Parent or any of its Subsidiaries; or (iii) result in a breach or violation of any Law or Order applicable to Parent or any of its Subsidiaries, except in each case in clauses (i), (ii) and (iii), as, individually or in the aggregate, would not reasonably be expected to have a Parent Material Adverse Effect.

(b) Except (i) as may be required by the Exchange Act and Takeover Statutes, the DGCL, state securities and "blue sky" Laws, and the rules and regulations of NASDAQ, (ii) the registration of the capital increase with the Commercial Register for the Share Capital Increase, (iii) as contemplated by Section 6.8, and (iv) confirmation by the court-appointed accounting firm of the determination of adequacy of thecontribution-in-kind, as required by Section 7.1(g), and assuming the filing of the Proxy Statement, neither Parent nor any of its Affiliates is required to give notice to, deliver any report to, make any filing with, or obtain any consent or waiver from any Person at any time prior to the Closing in connection with the execution, delivery and performance of this Agreement, or the consummation by Parent of the Contemplated Transactions, except those that the failure to give, deliver, make or obtain would not, individually or in the aggregate, reasonably be expected to have a Parent Material Adverse Effect.

Section 4.11 Information Supplied. None of the information supplied or to be supplied by or on behalf of Parent or Merger Sub for inclusion or incorporation by reference in the Form F-4 will, at the time the FormF-4 is filed with the SEC, and at any time it is amended or supplemented or at the time it becomes effective under the Securities Act, contain any untrue statement of a material fact or omit to state any material fact required to be stated therein or necessary to make the statements therein, in light of the circumstances under which they were made, not misleading. Notwithstanding the foregoing, no representation or warranty is made by Parent or Merger Sub with respect to statements made or incorporated by reference therein based on information supplied in writing by the Acquired Companies or any of their Affiliates expressly for inclusion therein.

Section 4.12 Ownership of Shares. None of Parent, Merger Sub or any other Subsidiary of Parent is, nor at any time during the last three years has been, an "interested stockholder" of the Company as defined in Section 203 of the DGCL.

Section 4.13 Merger Sub. The authorized capital stock of Merger Sub consists of 100 shares of common stock, par value $0.01 per share, all of which are validly issued and outstanding. Merger Sub was formed solely for the purpose of engaging in the Contemplated Transactions and has not engaged in any business activities or conducted any operations other than in connection with the Contemplated Transactions. Parent is the sole stockholder and owns all of the interests of Merger Sub.

Section 4.14 Financial Advisor. No agent, broker, finder, financial advisor or investment banker is entitled to any brokerage, finder's, financial advisor's or other fee or commission in connection with this Agreement or the Merger based upon arrangements made by or on behalf of Parent or any of its Subsidiaries.

Section 4.15 Reorganization. Neither Parent nor Merger Sub has taken or agreed to take any action nor to the Knowledge of Parent is there any fact or circumstance that would reasonably be expected to prevent or impede the Merger from qualifying for the Intended Tax Treatment.

ARTICLE V

CERTAIN COVENANTS OF THE PARTIES

Section 5.1 Access and Investigation. Subject to Section 6.1, during the period commencing on the date of this Agreement and ending at the earlier of the termination of this Agreement pursuant to Article VIII and the Effective Time (the "**Pre-Closing Period**"), upon reasonable notice, the Acquired Companies shall, and shall use commercially reasonable efforts to cause their Representatives to: (a) provide Parent, Merger Sub and their respective Representatives with reasonable access during normal business hours to the Acquired Companies' Representatives, personnel and assets and to all existing books, records, Tax Returns, work papers and other documents and information relating to the Acquired Companies; (b) provide Parent, Merger Sub and their respective Representatives with such copies of the existing books, records, Tax Returns, work papers, product data, and other documents and information relating to the Acquired Companies, and with such additional financial, operating and other data and information regarding the Acquired Companies as Parent, Merger Sub and their respective Representatives may reasonably request; and (c) permit Parent and Merger Sub's officers and other employees to meet, upon reasonable notice and during normal business hours, with the chief financial officer and other officers and managers of the Acquired Companies responsible for the Acquired Companies' financial statements and the internal controls of the Acquired Companies to discuss such matters as Parent or Merger Sub may deem necessary or appropriate in order to enable Parent and Merger Sub to satisfy their respective obligations under the Sarbanes-Oxley Act and the rules and regulations relating thereto. Notwithstanding the foregoing, the Acquired Companies may restrict the foregoing access to the extent that any Law applicable to the Acquired Companies requires the Acquired Companies to restrict or prohibit access to any such properties or information or as may be necessary to preserve the attorney-client privilege under any circumstances in which such privilege may be jeopardized by such disclosure or access. The Acquired Companies and Parent and Merger Sub will each use their commercially reasonable efforts to make appropriate substitute arrangements to permit reasonable disclosure under circumstances in which the restrictions of the preceding sentence apply.

Section 5.2 Conduct of the Parties.

(a) Operation of the Company's Business. During the Pre-Closing Period: except: (i) as required under this Agreement, (ii) with the written consent of Parent (not to be unreasonably withheld, conditioned or delayed, solely with respect to Sections 5.2(a)(ix), (xvii), (xix) and (xxi) or (xxvii) as it relates to any of the foregoing actions described in clauses (ix), (xvii), (xix) and (xxi) of Section 5.2(a)) or (iii) as required by applicable Law or (iv) as set forth in Section 5.2(a) of the Company Disclosure Schedule, the Company shall, and shall cause each of its Subsidiaries to (A) conduct its business and operations in the ordinary course of business consistent with past practice, (B) use its commercially reasonable efforts to: (1) preserve intact its business organization and material assets, (2) keep available the services of its officers and employees who are integral to the operation of the business as presently conducted and as presently contemplated in the Company SEC Documents to be conducted, (3) maintain in effect all of its Governmental Authorizations, and (4) maintain satisfactory relationships with customers, lenders, suppliers, licensors, licensees, distributors and others having material business relationships with the Company and (C) not, directly or indirectly:

(i) declare, set aside or pay any dividends on, or make any other distributions (whether in cash, stock or property or any combination thereof) in respect of, any of its capital stock;

(ii) redeem, repurchase or otherwise acquire, or offer to redeem, repurchase or otherwise acquire, directly or indirectly, any of its capital stock or any of its other securities;

(iii) sell, issue, grant or authorize the issuance or grant of (A) any capital stock or other security of the Company, (B) any option, call, warrant, share of phantom stock or phantom stock right, stock purchase or stock appreciation right, restricted stock unit, performance stock unit or right to acquire any capital stock or other security of the Company, or (C) any instrument convertible into or exchangeable for any capital stock or other security of the Company, in each of clauses (A) through (C) other than: (x) the issuance of Shares upon the exercise of Company Options, pursuant to the terms of the award agreements that are outstanding on the date of this Agreement or in accordance with the terms of the ESPP, in each case in accordance with the applicable equity award's terms as in effect on the date of this Agreement, and (y) grants or awards of Shares (including Company Restricted Stock and Company RSUs) or Company Options required to be made under the ESPP pursuant to the existing offering period in effect as of the date hereof or pursuant to the terms of existing employment or other written compensation agreements in effect as of the date of this Agreement and listed on Section 3.12(a) of the Company Disclosure Schedule;

(iv) split, combine or reclassify its outstanding shares of capital stock of the Company or enter into any agreement with respect to voting of any of the capital stock of any of the Acquired Companies or any securities convertible into or exchangeable for such capital stock;

(v) except (1) as contemplated by Section 6.2 or (2) to the extent required by applicable Law or as required pursuant to a Company Benefit Plan in effect prior to the date of this Agreement and set forth in Section 3.12(a) of the Company Disclosure Schedule, (A) (i) increase the salary, wages, benefits, bonuses or other compensation payable or to become payable of any current or former employee, officer, director, consultant or other service provider of the Acquired Companies or (ii) grant or increase any severance, change of control, retention, termination or similar pay to any such individual; (B) enter into, establish, adopt, modify, amend or terminate any Company Benefit Plan (or any arrangement that would constitute a Company Benefit Plan if in effect on the date hereof); (C) accelerate the time of payment or vesting of, or the lapsing of restrictions with respect to, or fund or otherwise secure the payment of, any compensation or benefits under any Company Benefit Plan; (D) terminate the employment or services of any employee, officer, director or consultant of any Acquired Company, other than terminations for cause in the ordinary course of business consistent with past practice; (E) hire, or engage any new employee, officer, director or consultant of any Acquired Company; (F) recognize any new union, works council or similar employee representative with respect to any employee of the Acquired Companies; or (G) implement or announce any plant closing or employee layoff that would or would reasonably be expected to implicate the WARN Act;

(vi) commence any offering or offering period under the ESPP or extend any offering period under the ESPP in effect as of the date hereof;

(vii) amend, modify, waive, rescind or otherwise change any provision of or permit the adoption of any amendment to the Company Charter Documents;

(viii) incur or assume any long-term or short-term Indebtedness except in respect of Indebtedness owing by any wholly owned Subsidiary of the Company to the Company or another wholly owned Subsidiary of the Company;

(ix) make any capital expenditures in an amount in excess of $100,000 individually or $250,000 in the aggregate;

(x) acquire, lease, license or sublicense any right or other asset, including Intellectual Property, or any securities, interests or businesses from any other Person or sell, assign, abandon, permit to lapse or otherwise transfer or dispose of, incur any Encumbrance on, or lease, license or sublicense, any right or other asset, including Intellectual Property, or any securities, interests or businesses to any other Person, or waive or relinquish, abandon, allow to lapse or encumber (except for any Permitted Encumbrance) any right or asset, including Intellectual Property, or any securities, interests or businesses, in each case of the foregoing, other than sales of inventory or dispositions of obsolete or worthless equipment in the ordinary course of business consistent with past practice;

(xi) change any of its methods of accounting or accounting practices in any material respect unless required by GAAP or applicable Law, except for such changes that are required by GAAP or Regulation S-X promulgated under the Exchange Act or as otherwise expressly disclosed in the Company SEC Documents filed prior to the date of this Agreement;

(xii) enter into any collective bargaining, agreement to form a work council or other union or similar agreement or commit to enter into any such agreements;

(xiii) issue or forgive any loans, advances or capital contributions to any other Person; other than routine travel, relocation and business advances to employees in the ordinary course of business consistent with past practice;

(xiv) enter into any transactions or Contracts with any Affiliates or other Persons that would be required to be disclosed by the Company under Item 404 or Regulation S-K of the SEC;

(xv) form any Subsidiary;

(xvi) merge or consolidate with any Person or adopt a plan of complete or partial liquidation or resolutions providing for a complete or partial liquidation, dissolution, restructuring, recapitalization or other reorganization (other than this Agreement and the Merger);

(xvii) settle or compromise any material Tax liability, agree to any extension or waiver regarding the application of the statute of limitations with respect to any material Taxes or material Tax Returns or make any material election with respect to its Taxes, in each case other than in the ordinary course of business consistent with past practice or in compliance with applicable Law (including Tax Laws);

(xviii) write up, write down, or write off the book value of any assets, except in accordance with GAAP consistently applied;

(xix) compromise, settle, or offer or propose to settle, any Legal Proceeding or other claim (except with respect to immaterial routine matters in the ordinary course of business consistent with past practice that involve the payment of monetary damages in aggregate not in excess of $50,000 and do not (A) include any other obligation to be performed by, or limitation upon, the Acquired Companies, Parent, Merger Sub or their Affiliates that is material to the Acquired Companies, Parent, Merger Sub or their Affiliates; or (B) result in any (1) imposition of equitable relief on, or the admission of wrongdoing by, any Acquired Company or (2) actual or potential violation of any criminal Law);

(xx) initiate or settle any disputes related to any Company Registered IP or any Third Party Intellectual Property or Intellectual Property rights;

(xxi) (A) terminate, cancel, assign, renew or agree to any material amendment of, change in, or waiver under, any Company Material Contract, (B) enter into any Contract that, if existing on the date of this Agreement, would be a Company Material Contract or (C) amend or modify any Contract in existence on the date hereof that, after giving effect to such amendment or modification, would be a Company Material Contract;

(xxii) convene any regular or special meeting (or any adjournment or postponement thereof) of the Company's stockholders other than the Company Stockholders' Meeting;

(xxiii) fail to keep in full force and effect the Insurance Policies or replacement or revised provisions providing insurance coverage in a manner consistent with past practice with respect to the assets, operations and activities of the Acquired Companies as are currently in effect;

(xxiv) take any action that would reasonably be expected to prevent or materially impede, interfere with, hinder or delay the consummation by Parent or any of its Subsidiaries of the Contemplated Transactions;

(xxv) implement or announce any material employee layoffs;

(xxvi) (1) commence any clinical study of which Parent has not been informed prior to the date of this Agreement, (2) unless mandated by any Governmental Entity or necessary to protect the health and well-being of clinical study subjects, discontinue, terminate or suspend any ongoing clinical study or (3) discontinue, terminate or suspend any ongoing IND-enabling preclinical study without first consulting Parent in good faith; or

(xxvii) agree, resolve or commit to take any of the foregoing actions described in clauses (i) through (xxvi) of this Section 5.2(a).

Notwithstanding the foregoing, (i) nothing contained in this Agreement shall give to Parent or Merger Sub, directly or indirectly, rights to control or direct the operations of the Acquired Companies prior to the Effective Time and (ii) nothing in this Section 5.2(a) shall restrict the Acquired Companies from, or require the consent of Parent prior to, engaging in any transaction or entering into any agreement exclusively among the Acquired Companies.

(b) Operation of Parent's Business. During the Pre-Closing Period: except: (i) as required under this Agreement, (ii) with the written consent of the Company (not to be unreasonably withheld, conditioned or delayed) or (iii) as required by applicable Law, Parent shall use its commercially reasonable efforts to not, directly or indirectly:

(i) declare, set aside or pay any dividends on, or make any other distributions (whether in cash, stock or property or any combination thereof) in respect of, any of its capital stock;

(ii) amend, or propose or agree to amend, Parent's or its Subsidiaries' certificate of incorporation or bylaws in any manner that would adversely affect the consummation of the Merger or affect the holders of Shares whose shares are converted into Parent ADSs at the Effective Time in a manner different from holders of Parent ADSs prior to the Effective Time;

(iii) take or omit to take any action to cause the Parent ADSs to cease to be eligible for listing on NASDAQ; or

(iv) agree, resolve or commit to take any of the foregoing actions described in clauses (i) through (iii) of this Section 5.2(b).

Section 5.3 Unsolicited Proposals.

(a) Subject to Section 5.4(b) and except as permitted by this Section 5.3, during the Pre-Closing Period:

(i) the Company shall not, nor shall the Company permit any of its Subsidiaries to, nor shall the Company authorize or knowingly permit any of its Representatives or any of its Subsidiaries' Representatives to, directly or indirectly (other than with respect to the Contemplated Transactions), (A) solicit, initiate, propose, knowingly facilitate or knowingly encourage any inquiries, proposals or offers that constitute, or that could reasonably be expected to lead to, an Acquisition Proposal, (B) enter into, engage in, continue or otherwise participate in any discussions or negotiations with any Third Party regarding an Acquisition Proposal, or furnish to any Third Party information or data or provide to any Third Party access to the businesses, properties, assets, books or records, or personnel of the Company or any of its Subsidiaries, in each case with respect to any Acquisition Proposal or any inquiry, proposal or offer that could reasonably be expected to lead to an Acquisition Proposal, (C) grant any waiver, amendment or release of or under, or fail to enforce, any confidentiality, standstill or similar agreement (or any confidentiality, standstill or similar provision of any other Contract), (D) approve, endorse or recommend any proposal that constitutes or could reasonably be expected to lead to any Acquisition Proposal, (E) enter into any letter of intent, agreement, contract, commitment or agreement in principle (other than an Acceptable Confidentiality Agreement) with respect to an Acquisition Proposal or enter into any agreement, contract or commitment requiring the Company to abandon, terminate or fail to consummate the Contemplated Transactions or that could otherwise materially impede the ability of Parent and Merger Sub to consummate the Contemplated Transactions or (F) propose, resolve or agree to do any of the foregoing; and

(ii) the Company shall, and shall cause its Subsidiaries to, and shall direct its and their respective Representatives to, (A) immediately cease and terminate any existing solicitations, encouragements, facilitations, discussions or negotiations with any Third Party, theretofore conducted by the Company, its Subsidiaries or their respective Representatives with respect to an Acquisition Proposal, or that would reasonably be expected to lead to an Acquisition Proposal and (B) promptly following the date hereof terminate any physical or electronic data room access and use commercially reasonable efforts to cause all non-public information previously provided by or on behalf of it or any of its Subsidiaries to any such Third Party or Representative to be returned or destroyed in accordance with the applicable Acceptable Confidentiality Agreement.

(b) Notwithstanding anything to the contrary contained in this Agreement, if, at any time on or after the date hereof and prior to obtaining the Company Stockholder Approval, (i) the Company receives an unsolicited written bona fide Acquisition Proposal from a Third Party, (ii) such Acquisition Proposal did not result from a breach of this Section 5.3 or Section 5.4 and (iii) the Company Board, determines in good faith, after consultation with its financial advisor and outside legal counsel, that such Acquisition Proposal constitutes, or would reasonably be expected to lead to, a Superior Proposal, and that the failure to take the actions described in clauses (A) and (B) below would be inconsistent with its fiduciary duties under applicable Law, then the Company may (A) furnish information and data with respect to the Company and its Subsidiaries to the Third Party making such Acquisition Proposal and afford such Third Party access to the businesses, properties, assets and personnel of the Company and its Subsidiaries and (B) enter into, maintain and participate in discussions or negotiations with the Third Party making such Acquisition Proposal regarding such Acquisition Proposal or otherwise cooperate with or assist or participate in, or facilitate, any such discussions or negotiations (including by entering into a customary confidentiality agreement with such Third Party for the purpose of receiving non-public information relating to such Third Party); provided, however, that the Company (1) will not, and will not permit its Subsidiaries or its or their Representatives to, furnish any non-public information except pursuant to an Acceptable Confidentiality Agreement and (2) will concurrently provide to Parent any information concerning the Company or its Subsidiaries provided to such Third Party which was not previously provided to Parent. Notwithstanding anything to the contrary contained in this Agreement, the Company and its Representatives may (x) following the receipt of an unsolicited written bona fide Acquisition Proposal from a Third Party, contact such Third Party solely in order to clarify and understand the terms and conditions of such Acquisition Proposal made by such Third Party in order to permit the Company Board to determine in good faith, after consultation with its financial advisor and outside legal counsel, whether such Acquisition Proposal constitutes, or would reasonably be expected to lead to, a Superior Proposal and (y) direct any Persons to this Agreement, including the specific provisions of this Section 5.3.

(c) The Company shall as promptly as practicable (and in any event within 48 hours) notify Parent, orally and in writing, of the Company's receipt of any Acquisition Proposal or any inquiry, proposal or offer that could reasonably be expected to lead to an Acquisition Proposal, which notification shall include a copy of the applicable written Acquisition Proposal, inquiry, proposal or offer (or, if oral, the material terms and conditions of such Acquisition Proposal, inquiry, proposal or offer) and the identity of the Third Party making such Acquisition Proposal, inquiry, proposal or offer. The Company shall thereafter keep Parent reasonably informed on a reasonably current basis of the status of any material developments, discussions or negotiations regarding any such Acquisition Proposal, and the material terms and conditions thereof (including any change in price or form of consideration or other material amendment thereto), including by providing a copy of material documentation (which shall include any proposals or offers) relating thereto that is exchanged between the Third Party (or its Representatives) making such Acquisition Proposal, inquiry, proposal or offer and the Company (or its Representatives) within 48 hours after receipt thereof.

(d) The Company agrees not to release or permit the release of any Person from, or to waive or permit the waiver or termination of any provision of, any standstill or similar agreement to which the Company or any of its Subsidiaries is a party, other than to the extent the Company Board determines in good faith, after consultation with outside legal counsel, that failure to provide such waiver, release or termination would reasonably be expected to be inconsistent with its fiduciary duties under applicable Law.

Section 5.4 Adverse Recommendation Change.

(a) Subject to Section 5.4(b) and Section 5.4(c), the Company Board shall not effect a Company Adverse Recommendation Change.

(b) Notwithstanding anything in this Agreement to the contrary, including Section 5.4(a), at any time prior to obtaining the Company Stockholder Approval, the Company Board may, if it determines in good faith (after consultation with its financial advisor and outside legal counsel), that the failure to do so would be inconsistent with its fiduciary duties under applicable Law, make a Company Adverse Recommendation Change; provided, however, that the Company Board may not effect a Company Adverse Recommendation Change pursuant to this Section 5.4(b) unless:

(i) the Company shall have provided at least four business days' prior written notice to Parent advising Parent that the Company Board intends to make a Company Adverse Recommendation Change (a "Notice of Superior Proposal") and specifying the reasons therefor, including, the material terms and conditions of, and the identity of the Third Party making, such Superior Proposal, and a copy of any other relevant transaction documents (it being understood and agreed that any amendment to the financial terms or any other material term of such Superior Proposal shall require a new Notice of Superior Proposal, which shall require a new notice period of two business days, and compliance with this Section 5.4(b) with respect to such new notice);

(ii) during such four business day notice period as provided in Section 5.4(b)(i) (or two business day notice period following an amended Superior Proposal as provided in Section 5.4(b)(i)), the Company shall, and shall cause its Representatives to, to the extent requested by Parent, negotiate with Parent in good faith to make such adjustments to the terms and conditions of this Agreement as would enable the Company Board to maintain the Company Board Recommendation; and

(iii) taking into account all adjustments to the terms of this Agreement that may be irrevocably offered in writing by Parent pursuant to this Section 5.4(b) as described above, the Company Board (no earlier than the end of the four business day notice period as provided in Section 5.4(b)(i) (or two business day period, if following an amended Superior Proposal as provided in Section 5.4(b)(i))) determines in good faith after consultation with its financial advisor and outside legal counsel that such Acquisition Proposal constitutes a Superior Proposal and the failure to effect a Company Adverse Recommendation Change would be inconsistent with its fiduciary duties under applicable Law.

Nothing in this Section 5.4(b) shall be deemed to modify or otherwise affect the obligation of the Company to submit the adoption of this Agreement and the approval of the Merger to the holders of Shares and to seek the Company Stockholder Approval at the Company Stockholders' Meeting in accordance with Section 5.6.

(c) Notwithstanding anything in this Agreement to the contrary, including Section 5.4(a), at any time prior to obtaining the Company Stockholder Approval, the Company Board may take any of the actions described in clauses (a), (b) or (e) of the definition of "Company Adverse Recommendation Change," following the occurrence of an Intervening Event, if the Company Board determines in good faith after consultation with its financial advisor and outside legal counsel, that the failure to do so would be inconsistent with its fiduciary duties under applicable Law; provided, however, that the Company Board may not effect a Company Adverse Recommendation Change pursuant to this Section 5.4(c) unless:

(i) the Company shall have provided prior written notice of at least four business days to Parent advising Parent that the Company Board intends to effect such a Company Adverse Recommendation Change and specifying the material facts underlying the determination by the Company Board that an Intervening Event has occurred and the reason for such Company Adverse Recommendation Change, in reasonable detail (a "Notice of Intervening Event") (it being understood and agreed that any material change to the facts and circumstances relating to an Intervening Event shall require a new Notice of Intervening Event, which shall require a new notice period of two business days, and compliance with this Section 5.4(c) with respect to such new notice);

(ii) during such four business day notice period as provided in Section 5.4(c)(i) (or two business day notice period following an amended Notice of Intervening Event as provided in Section 5.4(c)(i)), the Company shall, and shall cause its Representatives to, to the extent requested by Parent, negotiate with Parent in good faith to make such adjustments to the terms and conditions of this Agreement as would enable the Company Board to maintain the Company Board Recommendation; and

(iii) taking into account all adjustments to the terms of this Agreement that may be irrevocably offered in writing by Parent pursuant to this Section 5.4(c) as described above, the Company Board (no earlier than the end of the four business day notice period as provided in Section 5.4(c)(i) (or two business day period, if following an amended Notice of Intervening Event as provided in Section 5.4(c)(i))) determines in good faith after consultation with its financial advisor and outside legal counsel that the failure to effect such a Company Adverse Recommendation Change would be inconsistent with its fiduciary duties under applicable Law.

(d) Nothing contained in Section 5.3 or this Section 5.4 or elsewhere in this Agreement shall prohibit the Company or the Company Board from taking and disclosing a position contemplated by Rule 14d-9, Rule 14e-2(a) or Item 1012(a) of Regulation M-A promulgated under the Exchange Act or making any disclosure that constitutes a "stop, look and listen" communication or similar communication of the type contemplated by Rule 14d-9 promulgated under the Exchange Act; provided that any such disclosure shall be deemed to constitute a Company Adverse Recommendation Change if the Company fails to expressly and publicly reaffirm the Company Board Recommendation in such disclosure or similar communication. For the avoidance of doubt, in no event shall the issuance of a "stop, look and listen" communication pursuant to Rule 14d-9 of the Exchange Act (or similar statement pursuant to any requirement of applicable Law), without more, constitute a Company Adverse Recommendation Change.

Section 5.5 Preparation of Proxy Statement and Form F-4.

(a) In connection with the Company Stockholders' Meeting, as soon as reasonably practicable following the date of this Agreement, the Company shall prepare and file with the SEC the Proxy Statement, and Parent shall prepare and file with the SEC the Form F-4 (which shall include a prospectus with respect to the Parent ADSs issuable in the Merger and the Proxy Statement to be sent to the stockholders of the Company). The Company and Parent shall each use its reasonable best efforts to: (i) cause the Form F-4 to be declared effective under the Securities Act as promptly as practicable after its filing; (ii) ensure that the Form F-4 complies in all material respects with the applicable provisions of the Securities Act and the Exchange Act; and (iii) keep the Form F-4 effective for so long as necessary to complete the Merger. Parent shall notify the Company promptly of the time when the Form F-4 has become effective or any supplement or amendment to the Form F-4 has been filed, and of the issuance of any stop order or suspension of the qualification of the Parent ADSs issuable in connection with the Merger for offering or sale in any jurisdiction. The Company shall use its reasonable best efforts to: (A) cause the Proxy Statement to be mailed to the Company's stockholders as promptly as practicable after the Form F-4 is declared effective under the Securities Act and (B) ensure that the Proxy Statement complies in all material respects with the applicable provisions of the Securities Act and Exchange Act. Parent shall also take any other action required to be taken under the Securities Act, the Exchange Act, any applicable foreign or state securities or "blue sky" Laws, and the rules and regulations thereunder in connection with the issuance of Parent ADSs in the Merger, and the Company shall furnish to Parent all information concerning the Company as may be reasonably requested in connection with any such actions.

(b) Parent and the Company shall furnish to the other party all information concerning such Person and its Affiliates required by the Securities Act or the Exchange Act to be set forth in the Form F-4 or the Proxy Statement. Each of Parent and the Company shall promptly correct any information provided by it for use in the Form F-4 or the Proxy Statement if and to the extent that such information shall have become false or misleading in any material respect. Each of Parent and the Company shall take all steps necessary to amend or supplement the Form F-4 or the Proxy Statement, as applicable, and to cause the Form F-4 or Proxy Statement, as so amended or supplemented, to be filed with the SEC and disseminated to the holders of Shares, in each case as and to the extent required by applicable Law.

(c) Parent and the Company shall promptly provide the other party and their counsel with any comments or other communications, whether written or oral, that Parent or the Company, or their counsel may receive from the SEC or its staff with respect to the Form F-4 or the Proxy Statement promptly after the receipt of such comments. Prior to the filing of the Form F-4 or the Proxy Statement with the SEC (including in each case any amendment or supplement thereto, except with respect to any amendments filed in connection with a Company Adverse Recommendation Change or in connection with any disclosures made in compliance with Section 5.4) or the dissemination thereof to the holders of Shares, or responding to any comments of the SEC with respect to the Form F-4 or Proxy Statement, each of Parent and the Company shall provide the other party and their counsel a reasonable opportunity to review and comment on such Form F-4, Proxy Statement, or response (including the proposed final version thereof), and each of Parent and the Company shall give reasonable and good faith consideration to any comments made by the other party or their counsel.

Section 5.6 Company Stockholders' Meeting. The Company shall take all action necessary to duly call, give notice of, convene, and hold the Company Stockholders' Meeting as soon as reasonably practicable after the Form F-4 is declared effective, and, in connection therewith, the Company shall mail the Proxy Statement to the holders of Shares in advance of such meeting. Except to the extent that the Company Board shall have effected a Company Adverse Recommendation Change as permitted by Section 5.4, the Proxy Statement shall include the Company Board Recommendation. Subject to Section 5.4, the Company shall use reasonable best efforts to: (a) solicit from the holders of Shares proxies in favor of the adoption of this Agreement and approval of the Merger; and (b) take all other actions necessary or advisable to secure the vote or consent of the holders of Shares required by applicable Law to obtain such approval. The Company shall keep Parent and Merger Sub updated with respect to proxy solicitation results as reasonably requested Parent or Merger Sub. Once the Company Stockholders' Meeting has been called and noticed, the Company shall not postpone or adjourn the Company Stockholders' Meeting without the consent of Parent (other than: (i) in order to obtain a quorum of its stockholders; (ii) as reasonably determined by the Company to comply with applicable Law) or (iii) after consultation with Parent and outside legal counsel, to ensure that any necessary supplement or amendment to the Proxy Statement is provided to the holders of Shares within a reasonable amount of time in advance of the Company Stockholders' Meeting. The Company shall use its reasonable best efforts to hold the Company Stockholders' Meeting as soon as reasonably practicable after the date of this Agreement, and to set the same record date for each such meeting. If the Company Board makes a Company Adverse Recommendation Change, it will not alter the obligation of the Company to submit the adoption of this Agreement and the approval of the Merger to the holders of Shares at the Company Stockholders' Meeting to consider and vote upon, unless this Agreement shall have been terminated in accordance with its terms prior to the Company Stockholders' Meeting; provided, that such obligation shall not be affected by the commencement, proposal, disclosure, announcement, submission or communication to the Company of any Acquisition Proposal (whether or not a Superior Proposal).

Section 5.7 Approval by Sole Stockholder of Merger Sub. Immediately following the execution and delivery of this Agreement, Parent, as sole stockholder of Merger Sub, shall adopt this Agreement and approve the Merger, in accordance with the DGCL.

ARTICLE VI

ADDITIONAL COVENANTS OF THE PARTIES

Section 6.1 Filings, Approvals and Cooperation.

(a) Upon the terms and subject to the conditions set forth in this Agreement, each of the parties hereto will use all reasonable best efforts to take, or cause to be taken, all actions, and to do, or cause to be done, all things reasonably necessary, proper or advisable (including making any requisite filings or giving any requisite notices) under applicable Laws to consummate and make effective the Contemplated Transactions as expeditiously as practicable and to ensure that the conditions set forth in Article VII are satisfied, insofar as such matters are within the control of any of them. Without limiting the generality of the foregoing and subject to Section 5.1, the Company, on the one hand, and Parent and Merger Sub, on the other hand, shall each furnish to the other such necessary information and reasonable assistance as the other party may reasonably request in connection with the foregoing.

(b) In case at any time after the Effective Time any further action is necessary to carry out the purposes of this Agreement, each of the parties to this Agreement shall take or cause to be taken all such necessary action, including the execution and delivery of such further instruments and documents, as may be reasonably requested by any party hereto for such purposes or otherwise to consummate the Contemplated Transactions.

(c) Other than in connection with the matters contemplated bySection 5.5, interactions between any of the parties with any Governmental Entity in the ordinary course of business or following initial engagement by a Governmental Entity with any of the parties relating to the Contemplated Transactions, any contact by a party with any Governmental Entity or the staff or regulators of any Governmental Entity relating to the Contemplated Transactions shall only be made with the prior written consent of the other parties. Subject to the limitations of applicable Law and the instructions of any Governmental Entity (and other than in connection with the matters contemplated by Section 5.5, interactions between the Company or Parent and any Governmental Entity in the ordinary course of business, or any disclosure containing confidential information), (i) the parties shall promptly inform the other parties of any material communication received from any Governmental Entity regarding the Contemplated Transactions and (ii) each party shall, to the extent reasonably practicable, provide the other parties with the opportunity to (A) participate in any appearance, meeting and material discussion with, and (B) review and comment on (which comments shall be considered in good faith by the other parties) any presentation, memoranda, brief, filing, proposal or other material communication to, any Governmental Entity or the staff or regulators of any Governmental Entity regarding the Contemplated Transactions.

Section 6.2 Employee Compensation and Benefits. For a period commencing upon the Effective Time and continuing through the first anniversary of the Effective Time, Parent shall provide, or shall cause to be provided, to each employee of the Acquired Companies who continues to be employed by Parent or the Surviving Corporation (or any Subsidiary thereof) following the Effective Time (the "**Continuing Employees**"): (i) total cash compensation (including base salary or base hourly rate, as applicable, and bonus opportunities that are at least equal to the cash compensation (excluding equity-based compensation and retention benefits)) provided to such Continuing Employees immediately prior to the Effective Time and (ii) retirement benefits and health and welfare benefits at levels which are, in the aggregate, substantially comparable in the aggregate to those benefits received by such Continuing Employees immediately prior to the Effective Time (excluding any defined benefit retirement benefits or post-employment welfare benefits). Without limiting the foregoing:

(a) With respect to any accrued but unused personal, sick or vacation time to which any Continuing Employee is entitled pursuant to the personal, sick or vacation policies applicable to such Continuing Employee immediately prior to the Effective Time, Parent shall, or shall cause the Surviving Corporation to and instruct its Subsidiaries to, as applicable, assume the liability for such accrued personal, sick or vacation time and allow such Continuing Employee to use such accrued personal, sick or vacation time in accordance with the written policies of the applicable Acquired Company.

(b) Parent agrees that all Continuing Employees shall be eligible to continue to participate in the Surviving Corporation's health benefit plans to the extent that they were eligible to participate in such plans prior to the Closing; provided, however, that (i) nothing in this Section 6.2 or elsewhere in this Agreement shall limit the right of Parent or the Surviving Corporation to amend or terminate any such health benefit plan at any time, and (ii) if Parent or the Surviving Corporation terminates any such health benefit plan, then (upon expiration of any appropriate transition period) Parent shall use reasonable best efforts to cause the Continuing Employees to be eligible to participate in the corresponding Parent Benefit Plan to substantially the same extent as similarly situated employees of Parent (taking into account job location). To the extent that service is relevant for eligibility, vesting or allowances (including paid time off) under any benefit plan of Parent and/or the Surviving Corporation, then Parent shall cause such benefit plan to (to the extent that it would not result in any duplication of benefits), for purposes of eligibility, vesting and allowances (including paid time off) but not for purposes of benefit accrual, credit Continuing Employees for service prior to the Effective Time with the Acquired Companies to the same extent that such service was recognized prior to the Effective Time under the corresponding benefit plan of the Company.

(c) With respect to all employees, the Acquired Companies shall be responsible for providing any notices required to be given, which notices shall be in a form that is compliant with applicable regulations and subject to advance review and approval of Parent (such approval not to be unreasonably withheld) and otherwise complying with the WARN Act caused by the Acquired Companies prior to the Effective Time. If Parent determines that an event would trigger WARN obligations after the Effective Time, Parent shall be responsible for providing notices to all employees as are required to be provided notice under the WARN Act in a form that is compliant with applicable regulations. On the Closing Date, the Company shall provide Parent with a list of employees of the Acquired Companies who have suffered an "employment loss" (as defined in the WARN Act) in the ninety days preceding the Closing Date, each identified by date of employment loss, employing entity and work location.

(d) Nothing in this Section 6.2 or elsewhere in this Agreement is intended nor shall be construed to (i) be treated as an amendment to any particular employee benefit or retirement plan, including any Company Benefit Plan or Parent Benefit Plan, (ii) prevent Parent from amending or terminating any of its benefit plans (or any Company Benefit Plan following the Effective Time) in accordance with their terms, (iii) create a right in any employee to employment with Parent, the Surviving Corporation or any other Subsidiary of the Surviving Corporation and the employment of each Continuing Employee shall be "at will" employment or (iv) create any third-party beneficiary rights in any employee of the Acquired Companies or the Surviving Corporation, any beneficiary or dependent thereof, or any collective bargaining representative thereof, including with respect to the compensation, terms and conditions of employment and/or benefits that may be provided to any Continuing Employee by Parent or the Company or under any benefit plan which Parent, any Acquired Company or the Surviving Corporation may maintain.

(e) From and after the Closing Date, Parent shall cause the Surviving Corporation to honor, in accordance with its terms, each existing (as of the date hereof) employment, change in control, retention or severance agreement and certain other obligations, in each case as set forth in Section 6.2(e) of the Company Disclosure Schedule.

Section 6.3 Certain Tax Matters

(a) The Company, Merger Sub and Parent shall use their respective commercially reasonable efforts to cause the Merger to qualify, and agree not to, and not to permit or cause any affiliate or any subsidiary to, take any actions or cause any action to be taken that which would reasonably be expected to prevent the Merger from qualifying for the Intended Tax Treatment.

(b) The Company, Merger Sub and Parent shall treat, and shall not take any Tax reporting position inconsistent with the Intended Tax Treatment, unless otherwise required pursuant to a "determination" within the meaning of Section 1313(a) of the Code.

(c) The parties shall cooperate and use their commercially reasonable efforts in order for the Company to obtain the opinion of Goodwin Procter LLP ("**Company's Counsel**"), in form and substance reasonably acceptable to Parent, dated as of the Closing (the "**Company Counsel's Opinion**"), and Parent to obtain the opinion of Covington & Burling LLP ("**Parent's Counsel**"), in form and substance reasonably acceptable to the Company, dated as of the Closing (the "**Parent Counsel's Opinion**") to the effect that, on the basis of the facts, representations and assumptions set forth or referred to in such opinions, for U.S. federal income tax purposes, the Merger will qualify for the Intended Tax Treatment. The issuance of each of the Company Counsel's Opinion and Parent Counsel's Opinion shall be conditioned upon the receipt by each counsel of customary representation letters from each of the Company and Merger Sub, on the one hand, and Parent, on the other hand, in each case, in form and substance reasonably satisfactory to such counsel. Each such representation letter shall be dated on or before the date of such opinion and shall not have been withdrawn or modified in any material respect.

Section 6.4 Indemnification of Officers and Directors.

(a) For six years after the Effective Time, Parent shall cause the Surviving Corporation to maintain officers' and directors' liability insurance in respect of acts or omissions occurring prior to the Effective Time covering each Person currently covered by the Company's officers' and directors' liability insurance policy on terms with respect to coverage and amount no less favorable than those of such policy in effect on the date hereof; provided, however, that in satisfying its obligation under this Section 6.4(a), neither Parent nor the Surviving Corporation shall be obligated to pay annual premiums in excess of 300% of the amount per annum the Company paid in its last full fiscal year prior to the date of this Agreement (the "**Current Premium**") and if such premiums for such insurance would at any time exceed 300% of the Current Premium, then the Surviving Corporation shall cause to be maintained policies of insurance that, in the Surviving Corporation's good faith judgment, provide the maximum coverage available at an annual premium equal to 300% of the Current Premium. The provisions of the immediately preceding sentence shall be deemed to have been satisfied if prepaid "tail" or "runoff" policies have been obtained by the Company prior to the Effective Time, which policies provide such Persons currently covered by such policies with coverage for an aggregate period of six years from the Effective Time with respect to claims arising from facts or events that occurred on or before the Effective Time, including, in respect of the Contemplated Transactions; provided, however, that the amount paid for such prepaid policies does not exceed 300% of the Current Premium. If such prepaid policies have been obtained prior to the Effective Time, the Surviving Corporation shall (and Parent shall cause the Surviving Corporation to) maintain such policies in full force and effect for their full term, and continue to honor the obligations thereunder.

(b) From and after the Effective Time, Parent shall cause the Surviving Corporation to: (i) indemnify and hold harmless each individual who at the Effective Time is, or at any time prior to the Effective Time was, a director or officer of the Company or of a Subsidiary of the Company (each, an "**Indemnified Party**") for any and all costs and reasonable expenses (including fees and reasonable expenses of legal counsel, which shall be advanced as they are incurred, provided that the Indemnified Party shall have made an undertaking to repay such expenses if it is ultimately determined that such Indemnified Party was not entitled to indemnification under this Section 6.4(b)), judgments, fines, penalties or liabilities (including amounts paid in settlements or compromises) imposed upon or reasonably incurred by such Indemnified Party in connection with or arising out of any Legal Proceeding (whether civil or criminal, and including any proceeding before any administrative or legislative body or agency) in which such Indemnified Party may be involved or with which he or she may be threatened (regardless of whether as a named party or as a participant other than as a named party, including as a witness) (an "**Indemnified Party Proceeding**") (A) by reason of such Indemnified Party's being or having been such director or officer or an employee or agent of the Company or any Subsidiary of the Company or otherwise in connection with any action taken or not taken at the request of the Company or any Subsidiary of the Company or (B) arising out of such Indemnified Party's service in connection with any other corporation or organization for which he or she serves or has served as director, officer, employee, agent, trustee or fiduciary at the request of the Company or any Subsidiary of the Company (including in any capacity with respect to any employee benefit plan), in each of clause (A) or (B) whether or not the Indemnified Party continues in such position at the time such Indemnified Party Proceeding is brought or threatened and at, or at any time prior to, the Effective Time (including any Indemnified Party Proceeding relating in whole or in part to the Contemplated Transactions or relating to the enforcement of this provision or any other indemnification or advancement right of any Indemnified Party), to the fullest extent permitted under applicable Law; and (ii) fulfill and honor in all respects the obligations of the Company and its Subsidiaries pursuant to: (x) each indemnification agreement in effect between the Company or any of its Subsidiaries and any Indemnified Party as of the date of this Agreement; and (y) any indemnification provision (including advancement of reasonable expenses) and any exculpation provision set forth in the certificate of incorporation or bylaws of the Company as in effect on the date of this Agreement. Parent shall cause the Surviving Corporation to pay all reasonable expenses, including reasonable attorneys' fees, that may be incurred by Indemnified Parties in connection with their enforcement of their rights provided under this Section 6.4. Parent's and the Surviving Corporation's obligations under the foregoing clauses (i) and (ii) shall continue in full force and effect for a period of six years from the Effective Time; provided, however, that all rights to indemnification, exculpation and advancement of reasonable expenses in respect of any claim asserted or made within such period shall continue until the final disposition of such claim.

(c) If Parent, the Surviving Corporation or any of its successors or assigns (i) consolidates with or merges into any other Person and shall not be the continuing or Surviving Corporation or entity of such consolidation or merger or (ii) transfers or conveys all or substantially all of its properties and assets to any Person, then, and in each such case proper provision shall be made so that the successors and assigns of Parent or the Surviving Corporation, as the case may be, shall assume the obligations set forth in this Section 6.4.

(d) The provisions of this Section 6.4 are (i) intended to be for the benefit of, and shall be enforceable by, each Indemnified Party, his or her heirs and his or her Representatives and (ii) in addition to, and not in substitution for, any other rights to indemnification or contribution that any such individual may have under any certificate of incorporation or bylaws, by contract or otherwise. The obligations of Parent and the Surviving Corporation under this Section 6.4 shall not be terminated or modified in such a manner as to adversely affect the rights of any Indemnified Party unless (x) such termination or modification is required by applicable Law or (y) the affected Indemnified Party shall have consented in writing to such termination or modification (it being expressly agreed that the Indemnified Parties shall be Third Party beneficiaries of this Section 6.4).

Section 6.5 Transaction Litigation. The Company shall (i) as promptly as reasonably practicable (and in any event within two business days) notify Parent in writing of any Transaction Litigation and thereafter keep Parent informed on a reasonably current basis with respect to the status thereof (including by promptly furnishing to Parent and its Representatives such information related to such Transaction Litigation as such Persons may reasonably request), (ii) give Parent the opportunity to participate in the defense of any Transaction Litigation, (iii) give Parent the right to review and comment on all material filings or responses to be made by the Company in connection with any such Transaction Litigation (and the Company will give reasonable consideration to such comments) and (iv) not cease to defend, consent to the entry of any judgment, offer to settle, enter into any settlement with respect to any such Transaction Litigation without the prior written consent of Parent, which such consent shall not be unreasonably withheld, conditioned or delayed. Without otherwise limiting the Indemnified Parties' rights with regard to the right to counsel, following the Effective Time, the Indemnified Parties shall be entitled to continue to retain Goodwin Procter LLP or such other counsel selected by such Indemnified Parties prior to the Effective Time to defend any Transaction Litigation.

Section 6.6 Disclosure. During the Pre-Closing Period, Parent and the Company shall consult with each other before issuing any press release or making any other public statement, or scheduling a press conference or conference call with investors or analysts, with respect to this Agreement or the Contemplated Transactions and shall not issue any such press release or make any such other public statement without the consent of the other party, which shall not be unreasonably withheld, delayed or conditioned, except as such release or announcement may be required by applicable Law, in which case the party required to make the release or announcement shall consult with the other party about, and allow the other party reasonable time (taking into account the circumstances) to comment on, such release or announcement in advance of such issuance, and the party will consider such comments in good faith; provided, however, that notwithstanding the foregoing, (i) neither the Company nor Parent will be obligated to engage in such consultation with respect to communications that are principally directed to employees, customers, partners or vendors so long as such communications are consistent with previous releases, public disclosures or public statements made jointly by the parties (or individually, if approved by the other party) and (ii) the Company shall not be required to consult with Parent before issuing any press release or making any other public statement with respect to a Company Adverse Recommendation Change effected in accordance with Section 5.4 or with respect to the receipt and consideration of any Acquisition Proposal.

Section 6.7 Takeover Laws; Advice of Changes.

(a) If any Takeover Statute may become, or may purport to be, applicable to the Contemplated Transactions, each of Parent and the Company and the members of its respective board of directors, to the extent permissible under applicable Law, shall grant such approvals and take such actions, in accordance with the terms of this Agreement, as are necessary so that the Contemplated Transactions may be consummated as promptly as practicable, and in any event prior to the End Date, on the terms and conditions contemplated hereby and otherwise, to the extent permissible under applicable Law, act to eliminate the effect of any Takeover Statute on any of the Contemplated Transactions.

(b) Each of the Company and Parent will give prompt notice to the other (and will subsequently keep the other informed on a reasonably current basis of any material developments related to such notice) upon its becoming aware of the occurrence or existence of any fact, event or circumstance that (i) has, (x) with respect to the Company, had or would reasonably be expected to result in any Company Material Adverse Effect and (y) with respect to Parent or Merger Sub, had or would reasonably be expected to have a Parent Material Adverse Effect or (ii) is reasonably likely to result in any of the conditions set forth in Article VII not being able to be satisfied prior to the End Date.

Section 6.8 Section 16 Matters. Promptly after the date hereof and prior to the Effective Time, the board of directors of each of the Company and Parent (or, in each case, a duly authorized committee thereof) shall take all such actions within its control as may be necessary or appropriate to cause any dispositions of equity securities of the Company and acquisitions of equity securities of Parent (including derivative securities) in connection with the Contemplated Transactions by each individual who is a director or executive officer of the Company or is or may become a director or executive officer of Parent in connection with the Contemplated Transactions to be exempt under Rule 16b-3 promulgated under the Exchange Act.

Section 6.9 Confidentiality. Parent and the Company hereby acknowledge and agree to continue to be bound by (i) the letter agreement, dated as of December 3, 2019, between Parent and the Company and (ii) the Confidentiality Agreement, dated as of January 3, 2020, between Parent and the Company ((i) and (ii) collectively the "**Confidentiality Agreements**"). All information provided by or on behalf of the Company or its Subsidiaries, on the one hand, and Parent, on the other hand, pursuant to this Agreement will be kept confidential in accordance with the Confidentiality Agreements.

Section 6.10 Stock Exchange Delisting; Deregistration. Prior to the Closing Date, the Company shall cooperate with Parent and use reasonable best efforts to take, or cause to be taken, all actions, and do or cause to be done all things, reasonably necessary, proper or advisable on its part under applicable Law and rules and policies of NASDAQ to enable the delisting by the Surviving Corporation of the Shares from NASDAQ and the deregistration of the Shares under the Exchange Act as promptly as practicable after the Effective Time, and in any event no more than ten days after the Closing Date. The Company shall cause the Shares not to be delisted from NASDAQ prior to the Effective Time.

Section 6.11

Listing of Parent ADSs. Parent shall use its reasonable best efforts to cause the Parent ADSs to be issued as part of the Merger Consideration to be listed on NASDAQ, subject to official notice of issuance.

Section 6.12 License Agreements. Parent agrees that, prior to Closing, Parent, its affiliates and agents will cease their participation in any opposition or appeal of the grant of any letters patent within the Company Registered IP in any legal or administrative proceedings, including, without limitation, in a court of law, before the United States Patent and Trademark Office, before the European Patent Office, or any other agency or tribunal in any jurisdiction, or in arbitration, that have been filed or are ongoing at any time prior to Closing, including, without limitation, reexamination, inter partes review, opposition, interference, post-grant review, nullity proceeding, pre-issuance submission, third party submission, derivation proceeding or declaratory judgment action.

ARTICLE VII

CONDITIONS PRECEDENT TO THE MERGER

Section 7.1 Conditions to Each Party's Obligation to Effect the Merger. The respective obligation of each party to effect the Merger shall be subject to the satisfaction at or prior to the Closing of each of the following conditions (which may be waived in whole or in part by such party):

(a) Company Stockholder Approval. The Company Stockholder Approval shall have been obtained.

(b) Statutes. No Law shall have been enacted or promulgated by any federal or state Governmental Entity of competent jurisdiction and remain in effect that precludes, restrains, enjoins or prohibits the consummation of the Merger.

(c) Injunctions. There shall be no Order (whether temporary, preliminary or permanent) of a Governmental Entity or a court of competent jurisdiction in effect precluding, restraining, enjoining, prohibiting, suspending or making illegal the consummation of the Merger.

(d) Form F-4. The Form F-4 shall have been declared effective by the SEC under the Securities Act and no stop order suspending the effectiveness of the Form F-4 shall have been issued by the SEC and remain in effect, and no proceeding for that purpose shall have been initiated by the SEC and not subsequently withdrawn.

(e) Listing of Parent ADSs. The Parent ADSs to be issued in the Merger shall have been approved for listing on NASDAQ, subject to official notice of issuance.

(f) Determination of Adequacy. A draft of the determination of adequacy of the contribution-in-kind by the court-appointed accounting firm as provided for in Section 2.2(i)(B) shall confirm such adequacy.

Section 7.2

Additional Conditions to Obligation of Parent and Merger Sub to Effect the Merger. The obligations of Parent and Merger Sub to effect the Merger are also subject to the satisfaction or waiver by Parent at or prior to the Effective Time of the following conditions:

(a) Representations and Warranties. (i) The representations and warranties of the Company set forth in this Agreement (without giving effect to any references to any Company Material Adverse Effect or materiality qualifications and other qualifications based upon the concept of materiality or similar phrases contained therein), other than the representations and warranties set forth in clauses (ii) and (iii) of this Section 7.2(a), shall be true and correct in all respects as of the date of this Agreement and as of the Closing Date as though made on and as of such date and time (except to the extent that any such representation and warranty expressly speaks as of an earlier date, in which case such representation and warranty shall have been true and correct as of such earlier date), unless the failure of such representations and warranties of the Company to be so true and correct, individually or in the aggregate, has not had and would not reasonably be expected to have a Company Material Adverse Effect; (ii) the representations and warranties set forth in Section 3.3(a) (Capitalization) shall be true and correct in all respects (except to a de minimis extent) as of the date of this Agreement and as of the Closing Date as though made on and as of such date and time and (iii) the representations and warranties set forth in Section 3.1(a) (Due Organization), Section 3.5(i) (Absence of Changes), Section 3.18 (Authority; Binding Nature of Agreement), Section 3.19 (Takeover Statutes), Section 3.23 (Fairness Opinion) and Section 3.24 (Financial Advisor) shall be true and correct in all material respects as of the date of this Agreement and as of the Closing Date as though made on and as of such date and time (except to the extent that any such representation and warranty expressly speaks as of an earlier date, in which case such representation and warranty shall have been true and correct in all material respects as of such earlier date).

(b) Performance of Obligations of the Company. The Company shall have performed or complied in all material respects with all of the obligations, agreements and covenants contained in this Agreement to be performed or complied with by the Company at or prior to the Closing pursuant to the terms of this Agreement.

(c) Closing Certificate. Parent shall have received a certificate signed by an authorized executive officer of the Company, dated the Closing Date, to the effect that the conditions set forth in Section 7.2(a), Section 7.2(b) and Section 7.2(d) have been satisfied.

(d) No Company Material Adverse Effect. Since the date of this Agreement, there shall not have occurred and be continuing any event, change, effect or development that, individually or in the aggregate, has had or would reasonably be expected to have a Company Material Adverse Effect.

(e) FIRPTA Certificate. On or no more than 30 days prior to the Closing Date, the Company shall deliver to Parent a certificate (in form and substance reasonably satisfactory to Parent) pursuant to Treasury Regulations Section 1.1445-2(c)(3), stating that the Company is not and has not been a United States real property holding corporation (as defined in Section 897(c)(2) of the Code) during the applicable period specified in Section 897(c)(1)(A)(ii) of the Code.

(f) Tax Opinion. Parent shall have received the Parent Counsel's Opinion dated as of the Closing Date and addressed to Parent (or if Parent's Counsel is unable to issue such an opinion, either Company's Counsel or another nationally recognized law firm proposed by the Company that is reasonably acceptable to Parent) ("**Parent's Replacement Counsel**"). The condition set forth in thisSection 7.2(f) shall not be waivable by Parent after receipt of the Company Stockholder Approval unless further stockholder approvals are obtained with appropriate disclosure.

Section 7.3 Additional Conditions to Obligation of the Company to Effect the Merger. The obligations of the Company to effect the Merger are also subject to the satisfaction or waiver by the Company at or prior to the Effective Time of the following conditions:

(a) Representations and Warranties. (i) The representations and warranties of Parent and Merger Sub set forth in this Agreement (without giving effect to any references to any Parent Material Adverse Effect or materiality qualifications and other qualifications based upon the concept of materiality or similar phrases contained therein), other than the representations and warranties set forth in clauses (ii) and (iii) of this Section 7.3(a), shall be true and correct in all respects as of the date of this Agreement and as of the Closing Date as though made on and as of such date and time (except to the extent that any such representation and warranty expressly speaks as of an earlier date, in which case such representation and warranty shall have been true and correct as of such earlier date), unless the failure of such representations and warranties of Parent and Merger Sub to be so true and correct, individually or in the aggregate, has not had and would not reasonably be expected to have a Parent Material Adverse Effect; (ii) the representations and warranties set forth in Section 4.3(a) (Capitalization) shall be true and correct in all respects (except to a de minimis extent) as of the date of this Agreement and as of the Closing Date as though made on and as of such date and time, and (iii) the representations and warranties set forth in Section 4.1 (Due Organization; Subsidiaries), Section 4.4 (SEC Filings; Financial Statements), Section 4.5 (Absence of Changes), Section 4.9 (Authority; Binding Nature of Agreement), and Section 4.14 (Financial Advisor) shall be true and correct in all material respects as of the date of this Agreement and as of the Closing Date as though made on and as of such date and time (except to the extent that any such representation and warranty expressly speaks as of an earlier date, in which case such representation and warranty shall have been true and correct in all material respects as of such earlier date).

(b) Performance of Obligations of Parent. Parent and Merger Sub each shall have performed or complied in all material respects with all of the obligations, agreements and covenants contained in this Agreement to be performed or complied with by Parent and Merger Sub, respectively, at or prior to the Closing pursuant to the terms of this Agreement.

(c) Closing Certificate. The Company shall have received a certificate signed by an authorized executive officer of Parent, dated the Closing Date, to the effect that the conditions set forth in Section 7.3(a) and Section 7.3(b) have been satisfied.

(d) Tax Opinion. The Company shall have received the Company Counsel's Opinion dated as of the Closing Date and addressed to the Company (or if Company's Counsel is unable to issue such an opinion, either Parent's Counsel or another nationally recognized law firm proposed by Parent that is reasonably acceptable to the Company ("**Company's Replacement Counsel**")). The condition set forth in this Section 7.3(e) shall not be waivable by the Company after receipt of the Company Stockholder Approval unless further stockholder approvals are obtained with appropriate disclosure.

ARTICLE VIII

TERMINATION

Section 8.1 Termination By Mutual Consent. This Agreement may be terminated at any time prior to the Effective Time (whether before or after the receipt of the Company Stockholder Approval) by the mutual written consent of Parent and the Company.

Section 8.2 Termination By Either Parent or the Company. This Agreement may be terminated by either Parent or the Company at any time prior to the Effective Time (whether before or after the receipt of the Company Stockholder Approval):

(a) if the Merger has not been consummated by 11:59 p.m. Eastern time on October 15, 2020 (the "End Date"); provided, however, that the right to terminate this Agreement pursuant to this Section 8.2(a) shall not be available to any party whose breach of any representation, warranty, covenant, or agreement set forth in this Agreement has been the cause of, or resulted in, the failure of the Merger to be consummated on or before the End Date;

(b) if any Governmental Entity of competent jurisdiction shall have enacted, issued, promulgated, enforced, or entered any Law or Order making illegal, permanently enjoining, or otherwise permanently prohibiting the consummation of the Contemplated Transactions and such Law or Order shall have become final and nonappealable; provided, however, that the right to terminate this Agreement pursuant to this Section 8.2(b) shall not be available to any party whose breach of any representation, warranty, covenant, or agreement set forth in this Agreement has been the cause of, or resulted in, the issuance, promulgation, enforcement, or entry of any such Law or Order; or

(c) if this Agreement has been submitted to the stockholders of the Company for adoption at a duly convened Company Stockholders' Meeting and the Company Stockholder Approval shall not have been obtained at such meeting (unless such Company Stockholders' Meeting has been adjourned or postponed, in which case at the final adjournment or postponement thereof).

Section 8.3 Termination By Parent. This Agreement may be terminated by Parent at any time prior to the Effective Time:

(a) (i) if a Company Adverse Recommendation Change shall have occurred or (ii) the Company shall have materially breached its obligations under Section 5.3 or Section 5.4; or

(b) if there shall have been a breach by the Company of any representation, warranty, covenant, or agreement on the part of the Company set forth in this Agreement such that the conditions to the Closing of the Merger set forth in Section 7.2(a) or Section 7.2(b), as applicable, would not be satisfied and, in either such case, such breach is incapable of being cured by the End Date, or if curable prior to the End Date, has not been cured within the earlier of (i) 30 calendar days after the receipt of written notice thereof from Parent stating Parent's intention to terminate this Agreement pursuant to this Section 8.3(b) and (ii) three business days before the End Date.

Section 8.4 Termination By the Company. This Agreement may be terminated by the Company at any time prior to the Effective Time: if there shall have been a breach by Parent or Merger Sub of any representation, warranty, covenant or agreement on the part of Parent or Merger Sub set forth in this Agreement such that the conditions to the Closing of the Merger set forth in Section 7.3(a) or Section 7.3(b), as applicable, would not be satisfied and, in either such case, such breach is incapable of being cured by the End Date, or if curable prior to the End Date, has not been cured within the earlier of (i) 30 calendar days after the receipt of written notice thereof from the Company stating the Company's intention to terminate this Agreement pursuant to this Section 8.4 and (ii) three business days before the End Date.

Section 8.5 Notice of Termination; Effect of Termination(a). The party desiring to terminate this Agreement pursuant to this Article VIII (other than pursuant to Section 8.1) shall deliver written notice of such termination to each other party hereto specifying with particularity the reason for such termination, and any such termination in accordance with this Section 8.5 shall be effective immediately upon delivery of such written notice to the other party or at such date as specified in such termination notice. If this Agreement is terminated pursuant to Article VIII, this Agreement shall be of no further force or effect without liability of any party (or any Representative of such party) to each other party hereto; provided, however, that the provisions of this Section 8.5, Section 6.9, Section 8.6, Article IX and the applicable definitions in Exhibit A or elsewhere in this Agreement shall survive any termination hereof pursuant to this Article VIII. Notwithstanding the foregoing or any other provision of this Agreement to the contrary, none of Parent, Merger Sub or the Company shall be relieved or released from any liabilities or damages arising out of its knowing or intentional material breach of any provision of this Agreement or any other agreement delivered in connection herewith or any fraud; provided, however, that the failure of any party to consummate the Merger by the time specified in Section 1.1 (b) after all conditions (other than those conditions that by their nature are to be satisfied by actions taken at the Closing) have been satisfied or waived shall constitute an intentional material breach by such party, and such party shall be liable to the other parties for such breach as provided herein notwithstanding any termination of this Agreement. The Confidentiality Agreements shall survive the termination of this Agreement and shall remain in full force and effect in accordance with its terms.

Section 8.6 Fees and Expenses Following Termination.

(a) If this Agreement is terminated by Parent pursuant to Section 8.3(a), then the Company shall pay to Parent (by wire transfer of immediately available funds), within two business days after such termination, the Termination Fee.

(b) If (i) this Agreement is terminated by (A) Parent pursuant to Section 8.3(b) or (B) Parent or the Company pursuant to Section 8.2(c), (ii) an Acquisition Proposal is made or communicated to the Company or is publicly disclosed and not withdrawn, (x) before such termination, in the case of a termination pursuant to Section 8.3(b) or (y) before the Company Stockholders' Meeting, in the case of a termination pursuant to Section 8.2(c), and (iii) during the period commencing as of immediately following the date of this Agreement and ending within twelve months after the date of such termination, the Company consummates an Acquisition Proposal or enters into a definitive agreement in respect of an Acquisition Proposal, which Acquisition Proposal is subsequently consummated (whether during such twelve month period or thereafter), then in any such event the Company shall pay to Parent (by wire transfer of immediately available funds), substantially concurrently with the consummation of the Acquisition Proposal, the Termination Fee (it being understood for all purposes of this Section 8.6(b), all references in the definition of Acquisition Proposal to "15% or more" shall be deemed to be references to "more than 50%" instead).

(c) In the event that Parent receives full payment of the Termination Fee pursuant to Section 8.6, the receipt of such Termination Fee shall be deemed to be liquated damages for any and all losses or damages suffered or incurred by Parent and any of its Affiliates or any other Person in connection with this Agreement (and the termination hereof), the Contemplated Transactions (and the abandonment thereof) or any matter forming the basis for such termination, and, except in the case of the Company's fraud, (i) the Company shall have no further liability, whether pursuant to a claim at law or in equity, to Parent or any of its Affiliates in connection with this Agreement (and the termination hereof), the Contemplated Transactions (and the abandonment thereof) or any matter forming the basis for such termination, and (ii) except as provided in Section 9.6 hereof, none of Parent and its respective Affiliates or any other Person shall be entitled to bring or maintain any Legal Proceeding against the Company or its Affiliates for damages or any equitable relief arising out of or in connection with this Agreement, any of the Contemplated Transactions or any matters forming the basis for such termination (other than equitable relief to require payment of such Termination Fee). For the avoidance of doubt, any payment of the Termination Fee made by the Company under this Section 8.6 shall be payable only once with respect to this Section 8.6 and not in duplication, even though such payment may be payable under one or more provisions hereof.

(d) The parties acknowledge and hereby agree that the provisions of this Section 8.6 are an integral part of the Contemplated Transactions, and that, without such provisions, the parties would not have entered into this Agreement. If the Company shall fail to pay in a timely manner the amounts due pursuant to this Section 8.6, and, in order to obtain such payment, Parent makes a claim against the Company that results in a judgment, the Company shall pay to Parent the reasonable costs and expenses (including Parent's reasonable attorneys' fees and expenses) incurred or accrued in connection with such suit, together with interest on the amounts set forth in this Section 8.6 at the prime lending rate prevailing during such period as published in *The Wall Street Journal*. Any interest payable hereunder shall be calculated on a daily basis from the date such amounts were required to be paid until (but excluding) the date of actual payment, and on the basis of a 360-day year.

(e) Except as otherwise provided in this Agreement, all expenses incurred in connection with this Agreement and the Contemplated Transactions will be paid by the party incurring such expenses.

ARTICLE IX

MISCELLANEOUS PROVISIONS

Section 9.1 Amendment. Any provision of this Agreement may be amended or waived prior to the Effective Time if, but only if, such amendment or waiver is in writing and is signed, in the case of an amendment, by each party to this Agreement or, in the case of a waiver, by each party against whom the waiver is to be effective; provided, however, that following the receipt of the Company Stockholder Approval, there shall be no amendment or supplement to the provisions of this Agreement which by Law or in accordance with the rules of any relevant self-regulatory organization would require further approval by the holders of Shares without such approval.

Section 9.2 Waiver. No failure on the part of any party to exercise any power, right, privilege or remedy under this Agreement, and no delay on the part of any party in exercising any power, right, privilege or remedy under this Agreement, shall operate as a waiver of such power, right, privilege or remedy; and no single or partial exercise of any such power, right, privilege or remedy shall preclude any other or further exercise thereof or of any other power, right, privilege or remedy. No party shall be deemed to have waived any claim arising out of this Agreement, or any power, right, privilege or remedy under this Agreement, unless the waiver of such claim, power, right, privilege or remedy is expressly set forth in a written instrument duly executed and delivered on behalf of such party; and any such waiver shall not be applicable or have any effect except in the specific instance in which it is given.

Section 9.3 No Survival of Representations and Warranties. None of the representations and warranties contained in this Agreement or in any certificate or schedule or other document delivered pursuant to this Agreement shall survive the Merger.

Section 9.4 Entire Agreement; No Reliance; Counterparts.

(a) This Agreement, the Voting Agreements and the Confidentiality Agreements and the other agreements referred to herein constitute the entire agreement and supersede all prior agreements and understandings, both written and oral, among or between any of the parties with respect to the subject matter hereof and thereof; provided, however, that the Confidentiality Agreements shall not be superseded and shall remain in full force and effect pursuant to their respective terms.

(b) Each party hereto agrees that, except for the representations and warranties contained in Article III (including the Company Disclosure Schedule), and Article IV of this Agreement, or contained in any certificate required to be delivered by a party pursuant to this Agreement, neither the Company, Parent or Merger Sub makes any other representations or warranties and each hereby disclaims any other representations or warranties made by itself or any of its Representatives, with respect to the execution and delivery of this Agreement or the Contemplated Transactions, notwithstanding the delivery or disclosure to any other party or any other party's Representatives of any document or other information with respect to any one or more of the foregoing. Without limiting the generality of the foregoing, and notwithstanding any otherwise express representations and warranties made by the parties in this Agreement, each party agrees that none of the other parties makes or has made any representation or warranty with respect to (i) any projections, forecasts, estimates, plans or budgets or future revenues, expenses or expenditures, future results of operations (or any component thereof), future cash flows (or any component thereof) or future financial condition (or any component thereof) of the future business, operations or affairs of such other party or any of its Subsidiaries heretofore or hereafter delivered to or made available to the other parties, or (ii) any other information, statements or documents heretofore or hereafter delivered to or made available to such other parties, including the information in the electronic data room of such party, with respect to such party or any of its Subsidiaries or the business, operations or affairs of such party or any of its Subsidiaries, except to the extent and as expressly covered by a representation and warranty made by such party in this Agreement.

(c) This Agreement may be executed in several counterparts, each of which shall be deemed an original and all of which shall constitute one and the same instrument. The exchange of a fully executed Agreement (in counterparts or otherwise) by facsimile or electronic transmission (including PDF or similar format) shall be sufficient to bind the parties to the terms and conditions of this Agreement.

Section 9.5 Applicable Law; Jurisdiction; Waiver of Jury Trial

(a) This Agreement, and all claims or causes of action (whether at Law, in contract or in tort or otherwise) that may be based upon, arise out of or relate to this Agreement or the negotiation, execution or performance hereof, shall be governed by and construed in accordance with the internal laws of the State of Delaware applicable to agreements made and to be performed entirely within the State of Delaware, without giving effect to any choice or conflict of law provision or rule (whether of the State of Delaware or any other jurisdiction) that would cause the application of the Laws of any jurisdiction other than the State of Delaware. The parties hereto hereby agree and consent to be subject to the exclusive jurisdiction of the Court of Chancery of the State of Delaware in New Castle County, Delaware (or, if (and only if) the Court of Chancery of the State of Delaware shall be unavailable, any other court of the State of Delaware or, in the case of claims to which the federal courts have exclusive subject matter jurisdiction, any federal court of the United States of America sitting in the State of Delaware) and hereby waive the right to assert the lack of personal or subject matter jurisdiction or improper venue in connection with any such suit, action, or other proceeding. In furtherance of the foregoing, each of the parties (i) waives the defense of inconvenient forum, (ii) agrees not to commence any suit, action or other proceeding arising out of this Agreement or the Contemplated Transactions other than in any such court, and (iii) agrees that a final judgment in any such suit, action, or other proceeding shall be conclusive and may be enforced in other jurisdictions by suit or judgment or in any other manner provided by Law. Each of the parties hereto irrevocably consents to the service of any summons and complaint and any other process in any other action relating to the Merger, on behalf of itself or its property, by the personal delivery of copies of such process to such party. Nothing in this Section 9.5(a) shall affect the right of any party hereto to serve legal process in any other manner permitted by Law.

(b) EACH OF THE PARTIES HERETO HEREBY IRREVOCABLY WAIVES ANY AND ALL RIGHT TO TRIAL BY JURY IN ANY LEGAL PROCEEDING ARISING OUT OF OR RELATED TO THIS AGREEMENT OR THE CONTEMPLATED TRANSACTIONS.

Section 9.6 Specific Performance. The parties agree that irreparable damage would occur and that the parties would not have any adequate remedy at law in the event that any of the provisions of this Agreement were not performed in accordance with their specific terms or were otherwise breached, except as expressly provided in the following sentence. It is accordingly agreed that, prior to valid termination of this Agreement in accordance with Article VIII, the parties shall be entitled to an injunction or injunctions to prevent breaches or threatened breaches of this Agreement and to enforce specifically the terms and provisions of this Agreement in a court of competent jurisdiction as set forth in Section 9.5 and, in any action for specific performance, each party waives the defense of adequacy of a remedy at law and waives any requirement for the securing or posting of any bond in connection with such remedy, this being in addition to any other remedy to which they are entitled at law or in equity (subject to the limitations set forth in this Agreement). The parties hereto further agree that (i) by seeking the remedies provided for in this Section 9.6, a party shall not in any respect waive its right to seek any other form of relief that may be available to a party under this Agreement (including monetary damages) for breach of any of the provisions of this Agreement or in the event that this Agreement has been terminated or in the event that the remedies provided for in this Section 9.6 are not available or otherwise are not granted, and (ii) nothing set forth in this Section 9.6 shall require any party hereto to institute any Legal Proceeding for (or limit any party's right to institute any Legal Proceeding for) specific performance under this Section 9.6 prior or as a condition to exercising any termination right under Article VIII (and pursuing damages after such termination), nor shall the commencement of any Legal Proceeding pursuant to this Section 9.6 or anything set forth in this Section 9.6 restrict or limit any party's right to terminate this Agreement in accordance with the terms of Article VIII or pursue any other remedies under this Agreement that may be available at any time.

Section 9.7 Assignability. Neither this Agreement nor any of the rights, interests or obligations hereunder shall be assigned by any of the parties hereto, in whole or in part (whether by operation of law or otherwise), without the prior written consent of the other parties, and any attempt to make any such assignment without such consent shall be null and void; provided, however, that each of Parent and Merger Sub may assign any of their rights and obligations hereunder to (i) one or more of their Affiliates at any time (including any Person who acquires control of Parent at any time following the date of this Agreement) and (ii) after the Effective Time, to any Person; provided, further, that such transfer or assignment shall not relieve Parent or Merger Sub of its obligations hereunder.

Section 9.8 Third Party Beneficiaries. Notwithstanding anything contained in this Agreement to the contrary, nothing in this Agreement, express or implied, is intended to confer on any Person other than the parties hereto or their respective heirs, successors, executors, administrators and assigns any rights, remedies, obligations or liabilities under or by reason of this Agreement, except, after the Effective Time, for the provisions of Article II concerning payment of the Merger Consideration and Section 6.4, which provisions shall inure to the benefit of the Persons or entities benefiting therefrom who shall be third-party beneficiaries thereof and who may enforce the covenants contained therein.

Section 9.9 Notices. Any notices or other communications required or permitted under, or otherwise given in connection with, this Agreement shall be in writing and shall be deemed to have been duly given (i) when delivered or sent if delivered in person or sent by facsimile transmission (provided confirmation of facsimile transmission is obtained), (ii) on the fifth business day after dispatch by registered or certified mail, (iii) on the next business day if transmitted by national overnight courier or (iv) on the date delivered if sent by e-mail (provided confirmation of email receipt is obtained), in each case as follows:

if to Parent or Merger Sub:

BioNTech SE
An der Goldgrube 12
55131 Mainz
Germany
Attention: James Ryan, Vice President, Legal and IP
Facsimile No. 49 6131 9084-390
Email: legal@biontech.de

with a copy to (which shall not constitute notice):

Covington & Burling LLP
265 Strand
London WC2R 1BH
Attention: Paul Claydon
Facsimile No. 44-20-7025-0875
Email: pclaydon@cov.com

and

Covington & Burling LLP
The New York Times Building
620 Eighth Avenue
New York, NY 10018
Attention: Jack S. Bodner
Facsimile No. 646-441-9079
Email: jbodner@cov.com

if to the Company:

Neon Therapeutics, Inc.
40 Erie Street, Suite 110
Cambridge, MA 02139
Attention: Jolie M. Siegel, VP, General Counsel and Secretary
Email: jsiegel@neontherapeutics.com

with a copy to (which shall not constitute notice):

Goodwin Procter LLP
100 Northern Avenue
Boston, Massachusetts 02210
Attention: Mitchell S. Bloom
James A. Matarese
Lillian Kim
Facsimile No.: (617) 523-1231

E-Mail: mbloom@goodwinlaw.com;
jmatarese@goodwinlaw.com; and
lkim@goodwinlaw.com

Section 9.10 Cooperation. The Company agrees to reasonably cooperate with Parent and to execute and deliver such further documents, certificates, agreements and instruments and to take such other actions as may be reasonably requested by Parent to evidence or reflect the Contemplated Transactions and to carry out the intent and purposes of this Agreement, in each case to the extent not inconsistent with any other provision of this Agreement.

Section 9.11 Severability. If any term or other provision of this Agreement is invalid, illegal or incapable of being enforced by any rule of law or public policy, all other conditions and provisions of this Agreement shall nevertheless remain in full force and effect so long as the economic or legal substance of the Contemplated Transactions is not affected in any manner materially adverse to any party. Upon such determination that any term or other provision is invalid, illegal or incapable of being enforced, the parties hereto shall negotiate in good faith to modify this Agreement so as to effect the original intent of the parties as closely as possible in a mutually acceptable manner to the end that the Contemplated Transactions are fulfilled to the extent possible.

Section 9.12 Obligation of Parent. Parent shall cause Merger Sub to comply in all respects with each of the representations, warranties, covenants, obligations, agreements and undertakings made or required to be performed by Merger Sub in accordance with the terms of this Agreement and the Contemplated Transactions.

Section 9.13 Construction.

(a) For purposes of this Agreement, whenever the context requires: the singular number shall include the plural, and vice versa; the masculine gender shall include the feminine and neuter genders; the feminine gender shall include the masculine and neuter genders; and the neuter gender shall include masculine and feminine genders.

(b) Any rule of construction to the effect that ambiguities are to be resolved against the drafting party shall not be applied in the construction or interpretation of this Agreement.

(c) As used in this Agreement, the words “include” and “including,” and variations thereof, shall not be deemed to be terms of limitation, but rather shall be deemed to be followed by the words “without limitation.”

(d) Except as otherwise indicated, all references in this Agreement to “Sections,” “Exhibits,” “Annexes” and “Schedules” are intended to refer to Sections of this Agreement and Exhibits, Annexes or Schedules to this Agreement.

(e) The phrases “provided to,” “furnished to,” “made available” and phrases of similar import when used herein, unless the context otherwise requires, means that a copy of the information or material referred to has been provided to the party to which such information or material is to be provided in the virtual data room set up by the providing party in connection with this Agreement at least 24 hours prior to the date hereof.

(f) The term “party” or “parties” shall refer to a party hereto or parties hereto, as applicable, unless the context otherwise requires.

(g) The bold-faced or underlined headings contained in this Agreement are for convenience of reference only, shall not be deemed to be a part of this Agreement and shall not be referred to in connection with the construction or interpretation of this Agreement.

[Signature page follows]

IN WITNESS WHEREOF, the parties have caused this Agreement to be executed as of the date first above written.

Neon Therapeutics, Inc.

By: /s/ Hugh O'Dowd
Name: Hugh O'Dowd
Title: President and CEO

[Signature Page to Agreement and Plan of Merger]

IN WITNESS WHEREOF, the parties have caused this Agreement to be executed as of the date first above written.

BioNTech SE

By: /s/ Dr. Sierk Poetting
Name: Dr. Sierk Poetting
Title: Managing Director

By: /s/ Sean Marett
Name: Sean Marett
Title: Managing Director

IN WITNESS WHEREOF, the parties have caused this Agreement to be executed as of the date first above written.

Endor Lights, Inc.

By: /s/ Sean Marett
Name: Sean Marett
Title: Director

By: /s/ Dr. Sierk Poetting
Name: Dr. Sierk Poetting
Title: Director

EXHIBIT A

CERTAIN DEFINITIONS

For purposes of this Agreement (including this Exhibit A):

"**Acceptable Confidentiality Agreement**" means a customary confidentiality agreement (a) containing terms not less favorable in the aggregate to the Company than the terms of the Confidentiality Agreement and (b) that does not prohibit the Company from providing any information to Parent in accordance with Section 5.3 or Section 5.4 or otherwise prohibit the Company from complying with its obligations in Section 5.3 or Section 5.4. Notwithstanding the foregoing, a Person who has previously entered into a confidentiality agreement with the Company relating to a potential acquisition of, or business combination with, the Company shall not be required to enter into a new or revised confidentiality agreement, and such existing confidentiality agreement shall be deemed to be an Acceptable Confidentiality Agreement for all purposes of this Agreement.

"**Acquired Company**" means the Company and its Subsidiary, collectively.

"**Acquisition Proposal**" means with respect to the Company, any offer or proposal from any Third Party relating to any transaction or series of related transactions involving (i) any acquisition or purchase by any Third Party, directly or indirectly, of 15% or more of any class of outstanding voting or equity securities of the Company, or any tender offer or exchange offer that, if consummated, would result in any Third Party beneficially owning 15% or more of any class of outstanding voting or equity securities of the Company, (ii) any merger, amalgamation, consolidation, share exchange, asset acquisitions, business combination, joint venture, license, collaboration, research and development or other similar transaction involving the Company or any of its Subsidiaries, the business of which constitutes 15% or more of the net revenues, net income or assets of the Company and its Subsidiaries, taken as a whole, (iii) any liquidation, dissolution, recapitalization, extraordinary dividend or other significant corporate reorganization of the Company or any of its Subsidiaries, the business of which constitutes 15% or more of the net revenues, net income or assets of the Company and its Subsidiaries, taken as a whole, or (iv) any combination of the foregoing.

"**Affiliate**" means, as to any Person, any other Person that, directly or indirectly, controls, or is controlled by, or is under common control with, such Person. For this purpose, "control" (including, with its correlative meanings, "controlled by" and "under common control with") means the possession, directly or indirectly, of the power to direct or cause the direction of management or policies of a Person, whether through the ownership of securities or partnership or other ownership interests, by contract or otherwise. Notwithstanding the foregoing, for purposes of this Agreement, AT Impf GmbH, having its place of business at Rosenheimer Platz 6, 81669 Munich, Germany ("**AT Impf**") and any Person or Entity that directly or indirectly, through one or more intermediaries, controls, is controlled by, or is under common control with AT Impf (other than Parent, or any Person or Entity that is directly or indirectly controlled by Parent) shall not be considered an Affiliate of Parent.

"**Agreement**" is defined in the Preamble to this Agreement.

"**Book-Entry Share**" is defined in Section 2.1(e) of this Agreement.

"**business day**" means a day, other than Saturday, Sunday or other day on which commercial banks in New York, New York or Mainz, Germany are authorized or required by applicable Law to close.

"**Capitalization Date**" is defined in Section 3.3(a) of this Agreement.

"**Cash Merger Consideration**" is defined in Section 2.4(a) of this Agreement.

"**Certificate**" is defined in Section 2.1(e) of this Agreement.

"**Certificate of Merger**" is defined in Section 1.1(d) of this Agreement.

"**Class A Agreements**" means the agreements set forth in Schedule 1.1(b) of the Company Disclosure Schedule.

"**Closing**" is defined in Section 1.1(c) of this Agreement.

"**Closing Date**" is defined in Section 1.1(c) of this Agreement.

"**Code**" means the Internal Revenue Code of 1986, as amended.

"**Commercial Register**" is defined in Section 2.2 of this Agreement.

"**Company**" is defined in the Preamble to this Agreement.

"**Company 10-Q**" means the Company's Quarterly Report on Form 10-Q for the fiscal quarter ended September 30, 2019.

"**Company Adverse Recommendation Change**" means the Company Board: (a) failing to make, withdraw, amend, modify, or materially qualify, in a manner adverse to Parent or Merger Sub, or otherwise making any statement or proposal inconsistent with, the Company Board Recommendation; (b) failing to include the Company Board Recommendation in the Proxy Statement that is mailed to the Company's stockholders; (c) adopting, approving, endorsing, recommending or otherwise declaring advisable an Acquisition Proposal; (d) failing to recommend against acceptance of any tender offer or exchange offer for the Shares within ten business days after the commencement of such offer; (e) failing to reaffirm (publicly, if so requested by Parent) the Company Board Recommendation within ten business days after the date any Acquisition Proposal (or material modification thereto) is first publicly disclosed by the Company or the Person making such Acquisition Proposal; or (f) resolving or agreeing to take any of the foregoing actions.

"**Company Associate**" means any current or former employee (including officers) and any other individual who is a director, in each case, of any Acquired Company.

"**Company Benefit Plan**" means each "employee benefit plan," as defined in Section 3(3) of ERISA (whether or not subject to ERISA), and each other stock bonus, stock purchase, stock option, restricted stock, restricted stock unit, stock appreciation right or other equity or equity-based, deferred-compensation, employment, retirement, welfare-benefit, bonus, incentive, commission, change in control, retention, severance, separation, paid time off, or fringe benefit or other benefit or compensation plan, policy, program, contract, arrangement or agreement other than any employment offer letter (in such form as previously provided to Parent) that is terminable "at will" without any contractual obligation on the part of any Acquired Company to make any severance, termination, change in control, or similar payment, which, in each case, is sponsored, maintained or contributed by the Acquired Companies or with respect to which any Acquired Company has or would reasonably be expected to have any liability.

"**Company Board**" is defined in the Recitals to this Agreement.

"**Company Board Recommendation**" is defined in Section 3.18(b) of this Agreement.

"**Company Charter Documents**" means the Company's certificate of incorporation and bylaws, each as amended and as in effect on the date hereof.

"**Company Common Stock**" means all of the issued and outstanding shares of common stock, $0.001 par value per share, of the Company.

"**Company Compensatory Award**" means each Company Option, Company RSU and Company Restricted Stock.

"**Company Contract**" means any Contract to which any of the Acquired Companies is a party.

"**Company's Counsel**" is defined in Section 6.3(c) of this Agreement.

"**Company Counsel's Opinion**" is defined in Section 6.3(c) of this Agreement.

"**Company Disclosure Schedule**" means the disclosure schedule that has been prepared by the Company in accordance with the requirements of this Agreement and that has been delivered by the Company to Parent immediately prior to or concurrently with the execution of this Agreement.

"**Company Equity Plans**" means the Company's 2015 Stock Option and Grant Plan and the Company's 2018 Stock Option and Incentive Plan.

"**Company Inbound License**" means any Company Contract pursuant to which any Intellectual Property of another Person (other than an Affiliate of the Company) that is material to the business of the Acquired Companies, is licensed to any Acquired Company, in each case, other than (i) agreements between any Acquired Company and its employees or consultants, and (ii) agreements for any third-party commercially available services or non-customized commercially available software.

"**Company IT Systems**" means all information technology and computer systems (including software, information technology infrastructure and assets and telecommunication hardware and other equipment) used by or for the benefit of the Acquired Companies, including those relating to the transmission, storage, maintenance, organization, presentation, generation, processing or analysis of Personal Information or confidential or proprietary information of or related to their businesses.

"**Company Material Adverse Effect**" means any event, condition, change, occurrence or development, individually or in the aggregate with all other events, conditions, changes, occurrences or developments, that has or would reasonably be expected to have a material adverse effect (i) on the business, assets, liabilities (contingent or otherwise), condition (financial or otherwise) or results of operations of the Company and its Subsidiaries, taken as a whole, or (ii) on the ability of the Company to consummate the Merger or any of the Contemplated Transactions prior to the End Date; provided, that, for purposes of clause (i), no effects resulting from or arising out of the following shall be taken into account in determining whether there has been a Company Material Adverse Effect: (A) the execution, announcement, pendency or consummation of the Contemplated Transactions (including any litigation or any loss of or adverse change in the relationship of the Company and its Subsidiaries with their respective employees, contractors, lenders, customers, partners, suppliers, vendors or other Third Parties related thereto, other than termination of the Class A Agreements, or the Company having received formal written notification of termination from any of the parties to the Class A Agreements) (provided that this clause (A) shall not apply with respect to any representation or warranty the purpose of which is to address the consequences resulting from the execution and delivery of this Agreement or the consummation of the Contemplated Transactions or the performance of obligations under this Agreement); (B) the identity of Parent or any of its Affiliates as the acquirer of the Company; (C) general business, economic or political conditions, or the capital, banking, debt, financial or currency markets, or changes therein; (D) general conditions in an industry in which the Company and its Subsidiaries operate or in any specific jurisdiction or geographical area in the United States or elsewhere in the world where the Acquired Companies operate, or changes therein; (E) any changes in GAAP (or the enforcement or interpretation thereof); (F) any changes in applicable Law (or the enforcement or interpretation thereof), including the adoption, implementation, repeal, modification or reinterpretation of any Law, regulation or policy (or interpretations thereof) by any Governmental Entity; (G) the taking of any action, or refraining from taking any action, in each case at the written direction of Parent or Merger Sub; (H) any outbreak or escalation of acts of terrorism, hostilities, sabotage or war, or any weather-related event, fire or natural or man-made disaster or act of God, or any escalation of any of the foregoing; (I) any Transaction Litigation; or (J) any failure by the Company to meet internal or analysts' estimates, projections, expectations, budgets or forecasts of operating statistics, revenue, earnings or any other financial or performance measures (whether made by the Company or any Third Parties), or any decline in the price or change in trading volume of Shares (it being understood that the underlying causes of such failures or changes in this clause (J) may be taken into account in determining whether a Company Material Adverse Effect has occurred, unless such underlying cause would otherwise be excepted by this definition); or (K) the matters expressly set forth in the Company Disclosure Schedule (excluding (i) any material worsening with respect to any matter disclosed therein and (ii) other than matters included in the Company Disclosure Schedule in response to listing requirements); provided that in the case of clauses (C), (D), (E), (F) and (H), such effect may be taken into account in determining whether or not there has been a Company Material Adverse Effect to the extent such effect has a materially disproportionate effect on the Company and its Subsidiaries, taken as a whole, as compared to other participants in the industry in which the Company and its Subsidiaries operate, in which case only the incremental materially disproportionate impact or impacts may be taken into account in determining whether or not there has been a Company Material Adverse Effect.

"**Company Material Contract**" is defined in Section 3.8(b) of this Agreement.

"**Company Options**" means all options to purchase Shares granted by the Company under the Company Equity Plans.

"**Company Outbound License**" means any Company Contract pursuant to which any Intellectual Property that is material to the business of the Acquired Companies taken as a whole is licensed to another Person (other than an Affiliate of the Company), in each case, other than any outbound agreements entered into in the ordinary course of business consistent with past practice.

"**Company Preferred Stock**" is defined in Section 3.3(a) of this Agreement.

"**Company Registered IP**" is defined in Section 3.6(a) of this Agreement.

"**Company's Replacement Counsel**" is defined in Section 7.3(d) of this Agreement.

"**Company Restricted Stock**" means each award with respect to a Share that is, at the time of determination, subject to a risk of forfeiture or repurchase by the Company, whether subject to time- or performance-based vesting and whether granted by the Company pursuant to the Company Equity Plans or otherwise issued or granted.

"**Company RSU**" means any issued and outstanding restricted stock units, whether payable in cash, shares or otherwise, granted under a Company Equity Plan.

"**Company SEC Documents**" is defined in Section 3.4(a) of this Agreement.

"**Company Stockholder Approval**" is defined in Section 3.18(a) of this Agreement.

"**Company Stockholders' Meeting**" means a special meeting of holders of Shares to consider and vote upon the approval and adoption of this Agreement and the Merger.

"**Company Trust**" is defined in Section 2.4(c).

"**Confidentiality Agreements**" is defined in Section 6.9 of this Agreement.

"**Contemplated Transactions**" means the Merger, and the other transactions and actions contemplated to be consummated by each of this Agreement and the Voting Agreements.

"**Continuing Employees**" is defined in Section 6.2 of this Agreement.

"**Contract**" means any legally binding contract, agreement, note, bond, indenture, mortgage, guarantee, option, lease (or sublease), license, sales or purchase order, warranty, commitment, or other instrument, obligation, arrangement or understanding of any kind, including all amendments, supplements or modifications thereto.

"**Contractors**" is defined in Section 3.13 of this Agreement.

"**Contribution Agent**" is defined in Section 1.1(a) of this Agreement.

"**Contribution Agreement**" is defined in Section 1.1(a) of this Agreement.

"**Current Premium**" is defined in Section 6.4(a) of this Agreement.

"**Deposit Agreement**" is defined in Section 2.1(c) of this Agreement.

"**Depositary**" is defined in Section 2.1(c) of this Agreement.

"**DGCL**" means the Delaware General Corporation Law, Title 8, Chapter 1 of the Delaware Code.

"**Effective Time**" is defined in Section 1.1(d) of this Agreement.

"**Encumbrance**" means any lien, pledge, hypothecation, charge, mortgage, security interest, encumbrance, option, right of first refusal, preemptive right, community property interest or restriction of any kind or nature (including any restriction on the voting of any security, any restriction on the transfer of any security or other asset, any restriction on the receipt of any income derived from any asset, any restriction on the use of any asset and any restriction on the possession, exercise or transfer of any other attribute of ownership of any asset).

"**End Date**" is defined in Section 8.2(a) of this Agreement.

"**Enforceability Exceptions**" is defined in Section 3.7(c) of this Agreement.

"**Entity**" means any corporation (including any non-profit corporation), general partnership, limited partnership, limited liability partnership, joint venture, estate, trust, company (including any company limited by shares, limited liability company or joint stock company), firm, society or other enterprise, association, organization or entity.

"**Environmental Claims**" means any and all claims or Orders by any Governmental Entity or other Person alleging that any Acquired Company is in violation of, or has liability under, any Environmental Law.

"**Environmental Law**" means any applicable Law, permit, Order or any agreement with any Governmental Entity or other Person, in each case relating to pollution, human health and safety, natural resources, the environment or any Hazardous Substance.

"**Environmental Permits**" means, with respect to any Person, all permits, licenses, franchises, certificates, approvals and other similar authorizations relating to or required by Environmental Law and affecting, or relating in any way to, the business of a Person or any of its Subsidiaries.

"**ERISA**" means the Employee Retirement Income Security Act of 1974, as amended.

"**ERISA Affiliate**" means any employers, whether or not incorporated, that would be treated together with any Acquired Company as a single employer within the meaning of Section 414 of the Code.

"**ESPP**" means the Company's 2018 Employee Stock Purchase Plan.

"**Exchange Act**" means the Securities Exchange Act of 1934, as amended, and the rules and regulations promulgated thereunder.

"**Exchange Agent**" is defined in Section 1.1(a) of this Agreement.

"**Exchange Fund**" is defined in Section 2.2 of this Agreement.

"**Exchange Ratio**" is defined in Section 2.1(c) of this Agreement.

"**FDA**" is defined in Section 3.9(b) of this Agreement.

"**FDC Act**" means the U.S. Federal Food, Drug, and Cosmetic Act, as amended.

"**Five-Percent Shareholder**" is defined in the Recitals of this Agreement.

"**Form F-4**" is defined in Section 3.20(a) of this Agreement.

"**Fractional Share Consideration**" is defined in Section 2.1(c) of this Agreement.

"**GAAP**" means United States generally accepted accounting principles.

"**Governmental Authorization**" means, with respect to any Person, all licenses, permits, certificates, waivers, consents, franchises (including similar authorizations or permits), exemptions, variances, expirations and terminations of any waiting period requirements and other authorizations and approvals issued to such Person by or obtained by such Person from any Governmental Entity, or of which such Person has the benefit under any applicable Law.

"**Governmental Entity**" means (i) any government or any state, department, local authority or other political subdivision thereof, or (ii) any governmental or quasi-governmental body, agency, authority (including any central bank, taxing authority or transgovernmental or supranational entity or authority), minister or instrumentality (including any court or tribunal) exercising executive, legislative, judicial, regulatory or administrative functions of or pertaining to government.

"**GSCA**" is defined in Section 2.2 of this Agreement.

"**Hazardous Substance**" means any pollutant, contaminant, waste or chemical or any toxic, radioactive, ignitable, corrosive, reactive or otherwise hazardous substance, waste or material, or any substance, waste or material having any constituent elements displaying any of the foregoing characteristics, including any medical or biological waste, reagent, petroleum product or byproduct, asbestos, led, polychlorinated biphenyls, or any substance, waste or material regulated under any Environmental Law or that is capable of causing harm or injury to human health, natural resources or the environment or would reasonably be expected to give rise to liability or any obligation to remediate under any applicable Law.

"**Healthcare Laws**" means (i) the FDC Act including 21 U.S.C. § 351(a)(2)(B), as applicable; the Public Health Service Act; and applicable regulations issued by the FDA, including 21 CFR parts 50, 56, and 312; (ii) the exclusion laws (42 U.S.C. § 1320a-7), and the regulations promulgated pursuant to such statutes; and (iii) all applicable comparable state, federal, non-U.S. or other Laws relating to any of the foregoing.

"**HIPAA**" means the Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Economic and Clinical Health Act, and their implementing regulations.

"**Indebtedness**" means, with respect to any Person, all obligations (including all obligations in respect of principal, accrued interest, penalties, fees and premiums) of such Person: (i) for borrowed money (including obligations in respect of drawings under overdraft facilities), (ii) evidenced by notes, bonds, debentures, mortgages, indentures or similar contracts or agreements, (iii) for the deferred purchase price of property, goods or services (other than trade payables or accruals incurred in the ordinary course of business consistent with past practice), (iv) under capital leases (in accordance with GAAP), (v) in respect of outstanding letters of credit and bankers' acceptances, (vi) for contracts or agreements relating to interest rate or currency rate protection, swap agreements, collar agreements and similar hedging agreements or (vii) guaranteeing any obligations of any other Person of the type described in the foregoing.

"**Indemnified Party**" is defined in Section 6.4(b) of this Agreement.

"**Indemnified Party Proceeding**" is defined in Section 6.4(b) of this Agreement.

"**Insurance Policies"** is defined in Section 3.15 of this Agreement.

"**Intellectual Property**" means any intellectual property or similar proprietary right including all patents, patent applications, inventions (whether or not patentable), copyrighted works, trade secrets, know-how, data, trademarks, trademark registrations and applications, domain names, website addresses, URLs, customer lists and related information, software and licenses of any of the foregoing.

"**Intended Tax Treatmen**t" is defined in the Recitals to this Agreement.

"**Intervening Event**" means, with respect to the Company, any material event, circumstance, change, effect, occurrence, development, or condition occurring or arising after the date hereof that was not known to, nor reasonably foreseeable by, the Company Board, as of or prior to the date of this Agreement, affecting the business, assets or operations of the Acquired Companies, taken as a whole, and not relating to any Acquisition Proposal, which material fact, circumstance, change, effect, occurrence, development or condition becomes known to the Company Board after the date hereof and prior to the time of obtaining the Company Stockholder Approval, other than (i) the receipt, existence of or terms of an Acquisition Proposal, (ii) any inquiry, indication of interest, proposal or offer that could reasonably be expected to lead to an Acquisition Proposal, or the consequences thereof, (iii) any change, in and of itself, in the market price or trading volume of the Shares, (iv) any change, in and of itself, in the market price or trading volume of the Parent ADSs, (v) the fact that the Company exceeds any internal or published industry analyst projections or forecasts or estimates of revenues or earnings (it being understood that the underlying causes of such changes in this clause (v) may be taken into account in determining whether there has been an Intervening Event, unless such underlying cause would otherwise be excepted by this definition), or (vi) any result from the announcement or pendency of, or any actions required to be taken by the Company (or to be refrained from being taken by the Company) pursuant to, this Agreement.

"**IRS**" means the Internal Revenue Service.

"**Knowledge of Parent**" means the actual knowledge of each of the individuals identified on Section 1.1(a) of the Parent Disclosure Schedule.

"**Knowledge of the Company**" means the actual knowledge of each of the individuals identified in Section 1.1(a) of the Company Disclosure Schedule. For purposes of Sections 3.12, 3.13 and 3.17 only, the Company shall be deemed to have "Knowledge" of a particular fact or other matter if the Company's General Counsel has actual knowledge or would reasonably be expected to possess such knowledge after reasonable inquiry of such fact or matter.

"**Law**" means any international, national, federal, state or local law (statutory, common or otherwise), constitution, treaty, convention, ordinance, code, rule, regulation or other similar requirement enacted, adopted, promulgated or applied by a Governmental Entity, as amended unless expressly specified otherwise.

"**Lease**" is defined in Section 3.7(c) of this Agreement.

"**Leased Real Property**" is defined in Section 3.7(c) of this Agreement.

"**Legal Proceeding**" means any action, suit, litigation, arbitration, proceeding (including any civil, criminal, administrative, investigative or appellate proceeding), hearing, inquiry, audit, examination or investigation commenced, brought, conducted or heard by or before, or otherwise involving, any court or other Governmental Entity or any arbitrator or arbitration panel.

"**Letter of Transmittal**" is defined in Section 2.3(b) of this Agreement.

"**Merger**" is defined in the Recitals to this Agreement.

"**Merger Consideration**" is defined in Section 2.1(c) of this Agreement.

"**Merger Sub**" is defined in the Preamble to this Agreement.

"**Merger Sub Board**" is defined in the Recitals to this Agreement.

"**Merger Sub Common Stock**" is defined in Section 1.1(a) of this Agreement.

"**Most Recent Balance Sheet**" means the balance sheet of the Company as of September 30, 2019 set forth in the Company 10-Q.

"**NASDAQ**" means The NASDAQ Global Select Market, or any successor thereto.

"**Notice of Intervening Event**" is defined in Section 5.4(c)(i) of this Agreement.

"**Notice of Superior Proposal**" is defined in Section 5.4(b)(i) of this Agreement.

"**Order**" means any binding order, injunction, judgment, decree, ruling, award or other similar requirement enacted, adopted, promulgated or applied by a Governmental Entity or arbitrator.

"**Parent**" is defined in the Preamble to this Agreement.

"**Parent ADS**" is defined in Section 2.1(c) of this Agreement.

"**Parent's Articles of Association**" is defined in the Recitals to this Agreement.

"**Parent Authorized Capital**" is defined in the Recitals to this Agreement.

"**Parent Benefit Plan**" means each "employee benefit plan," as defined in Section 3(3) of ERISA (whether or not subject to ERISA), and each other stock bonus, stock purchase, stock option, restricted stock, restricted stock unit, stock appreciation right or other equity or equity-based, deferred-compensation, employment, retirement, welfare-benefit, bonus, incentive, commission, change in control, retention, severance, separation, paid time off, or fringe benefit or other benefit or compensation plan, policy, program, contract, arrangement or agreement other than any employment offer letter that is terminable "at will" without any contractual obligation on the part of Parent or any of its Subsidiaries to make any severance, termination, change in control, or similar payment, which, in each case, is sponsored, maintained or contributed by Parent or any of its Subsidiaries or with respect to which Parent or any of its Subsidiaries has or would reasonably be expected to have any liability.

"**Parent Charter Documents**" means Parent Articles of Association and rules of procedure for Parent's Management Board and Parent's Supervisory Board *(Geschäftsordnungen für den Vorstand und für den Aufsichtsrat)*, each as amended and as in effect on the date hereof.

"**Parent's Counsel**" is defined in Section 6.3(c) of this Agreement.

"**Parent Counsel's Opinion**" is defined in Section 6.3(c) of this Agreement.

"**Parent Disclosure Schedule**" means the disclosure schedule that has been prepared by Parent in accordance with the requirements of this Agreement and that has been delivered by Parent to the Company immediately prior to or concurrently with the execution of this Agreement.

"**Parent's Management Board**" is defined in the Recitals to this Agreement.

"**Parent Material Adverse Effect**" means any event, condition, change, occurrence or development, individually or in the aggregate with all other events, conditions, changes, occurrences or developments, that has had a material adverse effect on the ability of Parent or Merger Sub to consummate the Merger or any of the Contemplated Transactions prior to the End Date.

"**Parent Ordinary Shares**" is defined in the Recitals to this Agreement.

"**Parent's Replacement Counsel**" is defined in Section 7.2(f) of this Agreement.

"**Parent SEC Documents**" is defined in Section 4.4(a) of this Agreement.

"**Parent's Supervisory Board**" is defined in the Recitals to this Agreement.

"**Permitted Encumbrance**" means any Encumbrance that (a) arises out of Taxes not yet due and payable or the validity of which is being contested in good faith by appropriate proceedings and for which adequate reserves have been established on financial statements in accordance with GAAP, (b) represents the rights of customers, suppliers and subcontractors in the ordinary course of business consistent with past practice under the terms of any Contracts to which the relevant party is a party or under general principles of commercial or government contract Law not in default and payable without penalty or interest or the validity of which is being contested in good faith by appropriate proceedings or (c) in the case of any Contract, are restrictions against the transfer or assignment thereof that are included in the terms of such Contract.

"**Person**" means any individual, Entity or Governmental Entity.

"**Personal Information**" means data and information concerning an identifiable natural person or that is otherwise regulated under Privacy and Information Security Laws.

"**Pre-Closing Period**" is defined in Section 5.1 of this Agreement.

"**Privacy and Information Security Laws**" means (i) applicable Laws relating to privacy, security and/or collection and use of personal information, and/or (ii) any other applicable Laws relating to information security, in each case as applicable to the Company.

"**Proxy Statement**" is defined in Section 3.20(a) of this Agreement.

"**Representatives**" means with respect to any Person, the directors, officers, employees, agents, financial advisors, attorneys, accountants, consultants and other authorized representatives of such Person, acting in such capacity.

"**SEC**" means the United States Securities and Exchange Commission.

"**Securities Act**" means the Securities Act of 1933, as amended.

"**Security Incident**" is defined in Section 3.17(b) of this Agreement.

"**Share Capital Increase**" is defined in Section 2.2 of this Agreement.

"**Share Exchange**" is defined in Section 2.2 of this Agreement.

"**Share Issuance**" is defined in Section 2.2 of this Agreement.

"**Shares**" is defined in the Recitals to this Agreement.

"**Subsidiary**" means, when used with respect to another Entity, any Person that directly or indirectly owns or purports to own, beneficially or of record, (a) an amount of voting securities or other interests in such Entity that is sufficient to enable such Person to elect at least a majority of the members of such Entity's board of directors or other governing body, or (b) at least 50% of the outstanding equity or economic interests of such Entity. Notwithstanding the foregoing, for purposes of this Agreement, Parent shall not be considered a Subsidiary of AT Impf or and any Person or Entity that directly or indirectly, through one or more intermediaries, controls, is controlled by, or is under common control with AT Impf (other than Parent, or any Person or Entity that is directly or indirectly controlled by Parent).

"**Superior Proposal**" means any *bona fide* written Acquisition Proposal made after the date hereof that the Company Board, determines in good faith (after consultation with its financial advisor and outside legal counsel), taking into account, among other things, all legal, financial, regulatory, and other aspects of the Acquisition Proposal and the Third Party making the Acquisition Proposal, including the form of consideration, financing terms (and certainty of financing) thereof and the likelihood of consummation, any applicable termination fees, as well as any adjustment to the terms and conditions offered in writing by Parent in response to such proposal pursuant to Section 5.4(b), which (a) would, if consummated, result in a transaction that is more favorable from a financial point of view to the Company's stockholders than the Merger and (b) is reasonably capable of being consummated in accordance with its terms; provided, however, that, for purposes of this definition of "Superior Proposal," references in the term "Acquisition Proposal" to "15%" shall be deemed to be references to "50%".

"**Surviving Corporation**" is defined in Section 1.1(b) of this Agreement.

"**Surviving Corporation Common Stock**" means all of the issued and outstanding shares of common stock, $0.001 par value per share, of the Surviving Corporation.

"**Takeover Statutes**" is defined in Section 3.19 of this Agreement.

"**Tax**" means any and all federal, state, local, or non-U.S. income, gross receipts, license, payroll, employment, excise, severance, stamp, occupation, premium, windfall profits, customs, duties, capital stock, franchise, profits, withholding, social security (or similar, including FICA), unemployment, disability, real property, personal property, escheat, unclaimed property, sales, use, transfer, registration, value added, alternative or add-on minimum, estimated, or other tax of any kind or any charge of any kind in the nature of (or similar to) taxes, including any interest, penalty, or addition thereto, in each case whether disputed or not.

"**Tax Return**" means any return (including any information return), report, statement, declaration, estimate, schedule, notice, notification, form, election, certificate or other document or information filed with or submitted to, or required to be filed with or submitted to, any Governmental Entity in connection with the determination, assessment, collection or payment of any Tax or in connection with the administration, implementation or enforcement of or compliance with any Law relating to any Tax, including any amendment thereof or attachment thereto.

"**Termination Fee**" means $3,200,000.

"**Third Party**" means any Person or "group" (as defined under Section 13(d) of the Exchange Act) of Persons, other than, as applicable, Parent or any of its Affiliates or Representatives, or the Company or any of its Affiliates or Representatives.

"**Transaction Litigation**" means any claim or Legal Proceeding (including any class action or derivative litigation) asserted or commenced by, on behalf of or in the name of, against or otherwise involving the Company, the Company Board, any committee thereof and/or any of the Company's directors or officers relating directly or indirectly to this Agreement, the Merger, the Contemplated Transactions or any related transaction (including any such claim or Legal Proceeding based on allegations that the Company's entry into this Agreement or the terms and conditions of this Agreement or any related transaction constituted a breach of the fiduciary duties of any member of the Company Board, any member of the board of directors of any of the Company's Subsidiaries or any officer of the Company or any of its Subsidiaries).

"**Trust Company**" is defined in Section 1.1 of this Agreement.

"**Voting Agreements**" is defined in Recitals to this Agreement.

"**VWAP of Parent ADS**" means the volume weighted average price of one Parent ADS for the ten trading days immediately prior to the second business day prior to the Closing Date, starting with the opening of trading on the first trading day to the closing of the second to last trading day prior to the Closing Date, as reported by Bloomberg.

"**WARN**" or "**WARN Act**" means the United States Worker Adjustment and Retraining Notification Act, as amended, or any state or local Mini-WARN Law.

Exhibit 3.1

Convenience Translation! The German version is authoritative!

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 seat in Mainz, Germany.

(3) The financial year is the calendar year.

§ 2 Purpose of enterprise

(1) The purpose of the company is to research and develop, as well as to manufacture and market immunological andRNA-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 entitled 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 232,304,250.00 and is divided across 232,304,250no-par value shares.

(2) Any entitlement of shareholders to the right of issuance of share certificates is excluded, to the extent permitted by law or unless certification is required under the rules applicable at a stock exchange 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 sharing of new shares may be determined in deviation from Section 60(2) Sentence 3 German Stock Corporation Act (*AktG*).

(5) The Management Board is authorized, subject to the consent of the Supervisory Board, to increase the company's share capital in the period up to 18 August 2024 on one occasion or on multiple occasions by up to a total of EUR 105,818,002.00 by issuing up to 105,818,002 new, no-par value registered shares against contributions in cash or in kind (Authorized Capital). In principle, the shareholders are to be granted a right of subscription. The shares may also be assumed by one or more banking institution(s) or one or more companies operating according to Section 53(1) sentence 1 Banking Act (*Kreditwesengesetz*; *KWG*) or Section 53b(1) sentence 1 or (7) KWG with the requirement that the shares are offered to the company's shareholders for purchase (so-called indirect right to subscription). The Management Board is authorized to exclude the subscription right of shareholders in one or more instance(s) of a capital increase as part of the Authorized Capital, subject to Supervisory Board approval,

(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 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;

(c) 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;

(d) 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;

(e) to implement an election dividend (*scrip dividend*/share dividend) by which shareholders are given the option to contribute their dividend entitlements to the company (either in whole or part) as a contribution in kind against issuance of new shares in the company;

(f) if shares are issued to one or more investors on one or more occasions or in connection therewith to shareholders by way of co-investments (within the meaning of the **Annex to Section 4(5))** on the basis of agreements concluded by 30 June 2020 at an issue price (including any further payment agreed under the law of obligations) of at least USD 18.10 (to this extent, the more detailed provisions of the Annex to Section 4(5) shall apply) and, in doing so, the provisions of the Annex to Section 4(5) are complied with. However, this authority to exclude the subscription right pursuant to this letter f) shall lapse if the shares of the Company or the rights or certificates representing them have been admitted to trading on a stock exchange or any other multilateral trading system,

(g) in case shares are to be issued to a member of the Management Board of the Company or to another person who is employed by the company or one of its 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 the company or one of its 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,

(h) in a capital increase effected after introduction of the Company's shares or certificates representing them to trading on a stock exchange or a multilateral trading system, if excluding subscription rights, according to the written declaration of an internationally renowned investment bank, 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 authorised capital, according to such declaration, does not exceed the extent necessary for a successful placement, and

(i) in order to be able to satisfy an option to acquire additional shares or American Depositary Shares that has been agreed with the issuing banks in connection with a public offering of shares in the Company 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 sentence 4 lit. a) to c) and h) above may not exceed 20% of the share capital, either at the time this authorization becomes effective or – if lower – at the time it is utilized. 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 (ii) treasury shares that have been disposed under exclusion of subscription rights during the term of this authorization (except in the case of lit. b) para (v), (vi) or (vii) of the resolution to item no. 8 of the General Meeting of 19 August 2019).

The new shares participate in the profits as of the beginning of the first 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. The Management Board shall be authorized, with the consent of the Supervisory Board, to determine further details of the capital increase and its implementation.

(6) The share capital is conditionally increased by up to EUR 21,874,806.00 by issuing up to 21,874,806 new registeredno-par value shares each representing a notional value of EUR 1.00 of the share capital (Conditional Capital ESOP 2017/2019). The sole purpose of the Conditional Capital ESOP 2017/2019 is the grant of rights to holders of stock options issued by the Company under the authorisation granted by the General Meeting of 18 August 2017 under agenda item5.a), also in the version of such authorisation as amended by resolution of the General Meeting of 19 August 2019 on agenda item 6.a) (together the "Authorisation 2017/2019"). The shares shall be issued at the strike price determined in accordance with the provisions of the Authorisation 2017/2019 in the version applicable at the time of its exercise. The conditional capital increase shall only be implemented to the extent that the holders of the stock options issued by the Company under the Authorisation 2017/2019 exercise their subscription rights and the Company does not service the stock options by delivering treasury shares or by a cash payment. The new shares 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.

(7) The share capital is conditionally increased by up to EUR 87,499,260.00 by issuing up to 87,499,260 new registeredno-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 said 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 for 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 shall be authorised, subject to Supervisory Board approval, to determine the remaining details for implementing the conditional capital increase.

(8) 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.

(3) The appointment of deputy members of the Management Board is permissible.

§ 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 has a quorum 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 telefax or by means of electronic media.

(2) The resolutions of the Management Board are passed by a majority of the votes cast, unless otherwise stipulated by mandatory law with abstentions not to 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 four members.

(2) 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 at the longest until 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.

(3) 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.

(4) 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.

(5) 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.

(6) In addition to reimbursement of their expenses, the members of the Supervisory Board receive an annual remuneration of EUR 50,000, the chairperson three times this amount and the deputy chairperson one and a half times this amount. The chairperson of the Audit Committee receives an additional annual remuneration of EUR 20,000. The members of the Supervisory Board who are only members of the Supervisory Board for part of the fiscal year or who chair or deputy chair the Supervisory Board or the Audit Committee receive the respective remuneration pro rata temporis. The same shall apply if this provision or a specific version of this provision is only in force for part of the financial year. If the reimbursement of out-of-pocket expenses or the remuneration is subject to value-added tax, value-added tax shall be payable in addition.

§ 10 Chairperson and deputy

(1) The Supervisory Board shall elect a chairperson and a deputy chairperson from among its members for the duration of its term of office. In these elections 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.

(2) 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 constitutes a quorum if at least three members participate in the adoption of the resolution. A member shall also participate 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.

§ 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 registered are entitled to participation and the exercising of their voting rights in the General Meeting if they are registered with the Company for participation. 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 the said 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. 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 present, except where at least half of the share capital is present.

(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, the potential Management Report of the Management Board, the Consolidated Financial Statements and any Group Management Report and the proposal for the appropriation of net profits and 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 resolves 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 judiciary 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 leave unaffected any exclusive international jurisdiction under German or European law of the court seated at the venue of the Company's statutory seat.

IX. XIV. 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 the BioNTech SE by conversion of BioNTech AG into a European company (SE) in the amount of up to EUR 100,000.

Annex to Section 4(5) of the Articles of Association

Stipulations which are to be fulfilled in the event of an exclusion of the subscription right pursuant to Section 4(5) Sentence 4 Subsection (f) (the 'new investor clause')

(i) The portion of shares issued on the basis of the respective Management Board resolution on the utilization of the authorized capital (including the shares issued to shareholders on the basis of co-investments pursuant to item (iv)) should not exceed one tenth of the share capital existing at the time of the resolution. In the event that shares have already been issued previously using the authorization to exclude subscription rights in accordance with the new investor clause, said tenth shall be replaced by the aforementioned tenth less the fractions which the shares issued in each case represented in relation to the share capital existing at the time of the respective resolution of the Management Board.

(ii) The issue price in US dollars (including any further payment agreed under the law of obligations) shall be converted into euros for the purpose of determining an issue price in euros on the basis of an exchange rate that is determined by the Management Board in its dutiful discretion and that is current at the time of the resolution on the issuance or, in the case of further payments agreed under the law of obligations, at the time of the request for further payment.

(iii) Shareholders who hold a total of 60 % of the company's shares and among whom are Medine GmbH, the AT Impf GmbH, at least one Fidelity fund and at least one Redmile fund, have to approve the issuance of shares by declaration in text form. "Fidelity fund" or "Redmile fund" means any investment fund managed or advised by Fidelity Management & Research Company or any of its affiliates or, respectively, by Redmile Group LLC or any of its affiliates on the basis of a contract.

(iv) In connection with any capital increase under exclusion of subscription rights pursuant to the new investor clause either (x) no shareholder nor any company affiliated with a shareholder will be given the opportunity to participate in the envisaged share issue, or (y) the company will announce the envisaged share issue to each shareholder by email notifying the number of shares that the respective new investor intends to subscribe for, the issue price per share (including any further payment agreed under the law of obligations) and the total issue price to be paid by the respective investor (including, if applicable, the further payment), will request each shareholder, with a deadline of at least one week, to make a binding declaration in text form as to the extent to which he/she

himself/herself wishes to subscribe for shares in the context of the relevant capital increase ("co-investment"), and offer those who have submitted the declaration in due time to conclude a corresponding subscription agreement by submitting a proper draft subscription form. Each shareholder may transfer or assign his or her right to co-invest to companies affiliated with him or, in the case of an investment fund, to another investment fund advised directly or indirectly by the same investment advisor or by an investment advisor affiliated to the same. The invitation and the offer shall be restricted (in the cases set out in letters b and c below in the event that a determination of the relevant content is made) to the extent that;

a. the pro rata amount of the share capital represented by the total shares to be subscribed for by way of co-investments in the context of the capital increase in question may not exceed the fraction set out in item (i) with the proviso that existing subscription requests are initially taken into account in proportion to the pro rata shareholdings and are otherwise disregarded to the extent that this amount would otherwise be exceeded,

b. the pro rata amount of the share capital represented by the total number of shares to be subscribed for by way of co-investments within the framework of the capital increase in question may not exceed the amount determined in the invitation and the offer (which amounts to at least half of the total envisaged amount of the capital increase); in such a case, the provisions of letter a shall apply mutatis mutandis, and

c. the co-investment is subject to the condition that, upon penalty of exclusion from theco-investment, within a period of at least five banking days to be determined by the company, starting from the date of availability of the proper draft of the subscription form corresponding to the declaration (x) the company receives the duly signed subscription form in two originals , and (y) that the issue amount (in whole or the part claimed by the company) is fully paid.

Exhibit 5.1

Hamburg
Freshfields Bruckhaus Deringer LLP
Hohe Bleichen 7
20354 Hamburg
T +49 40 36 90 60 (Zentrale)
+49 40 36 90 62 06 (Durchwahl)
F +49 40 36 90 61 55
E peter.versteegen@freshfields.com
www.freshfields.com

Doc ID
DAC31877923

Our Ref
162745-0015

Draft for SEC filing purposes – subject to final documentation.

Confidential

BioNTech SE
An der Goldgrube 12
55131 Mainz
Germany

, 2020

BioNTech SE – Form F-1 Registration Statement

Ladies and Gentlemen

We are acting as legal advisers to BioNTech SE, a European stock corporation (SE) with its business address at An der Goldgrube 12, 55131 Mainz, Germany and registered with the commercial register (*Handelsregister*) of the local court (*Amtsgericht*) of Mainz, Germany, (the ***Commercial Register***) under number HRB 48720 (the ***Company***) as to matters of German law in connection with the public offering and sale of up to American Depository Receipts (the ***ADS***), with each ADS representing one no par value registered share of the Company (the ***New Shares***), each such share having a notional par value of EUR 1.00 per Share.

In this opinion, "Germany" means the Federal Republic of Germany.

1. Documents Reviewed

For the purpose of rendering this legal opinion, we have examined the following documents (together, the ***Opinion Documents***):

(a) A copy of the Company's articles of association (*Satzung*), as in effect as of the date of this opinion (the ***Articles of Association***);

(b) A copy of an electronic excerpt (*Handelsregisterauszug*) from the Commercial Register relating to the Company dated , 2020 (the ***Register Excerpt***);

(c) A copy of the registration statement (as amended) the ***Registration Statement***) on Form F-1 (File No. 333-) filed by the Company with the Securities and Exchange Commission on , 2020 pursuant to the Securities Act of 1933, as amended; and

(d) Draft copies of the minutes of the resolutions of the management board (*Vorstand*) of the Company and the supervisory board (*Aufsichtsrat*) of the Company, resolving upon the increase of the Company's share capital from the Company's authorized capital by issuing up to new no par value registered shares at an issuance price of EUR 1.00 per share (together the ***Capital Increase Resolutions***, with said capital increase being referred to as the ***Authorized Capital Increase***);

(e) any such certificates, corporate records and other documents, and such matters of law, as we have deemed necessary or appropriate for the purposes of this opinion. We have not reviewed any other documents for the purposes of this opinion.

2. Assumptions

As to questions of fact material to this opinion that we did not independently establish or verify, we have relied on certificates or comparable documents of public officials and of officers and representatives of the Company.

In considering the Opinion Documents and rendering this opinion we have assumed without further inquiry:

(a) the conformity of all copies of documents supplied to us with the relevant originals and the authenticity and completeness of all documents submitted to us whether as originals or as copies;

(b) that all signatures on Opinion Documents are genuine signatures of those individuals from whom they purport to stem;

(c) that Opinion Documents examined by us in draft form have been or, as the case may be, will be executed in the form of the draft examined by us by the party that in the respective draft is envisaged to so execute the respective Opinion Document;

(d) that all individuals who have executed and delivered or will execute and deliver any of the Opinion Documents had or will have, at the relevant times, (i) full legal capacity (*Geschäftsfähigkeit*) and (ii) power to validly represent (*Vertretungsmacht*) the respective party (other than individuals executing, passing or delivering on behalf of the Company), in executing and delivering the relevant Opinion Document;

(e) that none of the Opinion Documents has been or, as the case may be, will be revoked, rescinded, repealed, terminated (whether in whole or in part), amended or supplemented;

(f) the correctness and completeness of all factual matters expressed in the Opinion Documents;

(g) that the Register Excerpt is accurate and complete as at its date and that no changes to the facts related therein have occurred between the date the Register Excerpt was issued and the date hereof;

(h) that the Articles of Association are true and accurate as of the date of this opinion;

(i) that the Capital Increase Resolutions are not affected by any factual circumstance not apparent from the Opinion Documents (unless known to us); and

(j) that no other arrangements between any of the parties to the Capital Increase Resolutions in respect of the transaction contemplated thereby or other declaration or act which modifies or supersedes any of the terms of a Capital Increase Resolution exist (unless known by us).

3. Laws Considered

The undersigned is admitted to the bar association (*Rechtsanwaltskammer*) in Hamburg, Germany, and licensed as attorney (*Rechtsanwalt*) in Germany. This opinion is, therefore, limited to matters of German law as presently in effect and applied by the German courts (including the law of the European Union to the extent it is directly applicable in Germany). We have not investigated and do not express or imply any opinion with respect to the laws of any other jurisdiction.

4. Opinion Statements

Based upon and subject to the foregoing and the qualifications set out below, we are of the opinion that:

(a) The Company is a European stock corporation (SE) duly established and validly existing under the laws of Germany and registered with the Commercial Register under number HRB 48720.

(b) Following the due execution of the Capital Increase Resolutions, the due execution and delivery of a subscription form by the relevant subscriber, the payment to the Company of the issuance price of EUR 1.00 per New Share and the registration of the implementation of the Authorized Capital Increase with the Commercial Register, the relevant New Shares will be validly issued to the relevant subscriber and fully paid (subject to the payment of the difference between the nominal amount and the final offer price).

5. Qualifications

The foregoing opinion statements are subject to the following qualifications:

In this opinion, concepts of German law are addressed in the English language and not in the original German terms, which may differ in their exact legal meaning. This opinion may only be relied upon under the express condition that this opinion and any issues of interpretation arising hereunder are exclusively governed by German law.

This opinion speaks of its date only, and we do not assume any obligation to update this opinion or to inform you of any changes to any of the facts or laws of other matters referred to herein. This opinion is limited to the matters addressed herein and should not be read as opinion in respect to any other matter.

We hereby consent to the filing of this opinion letter as an exhibit to the Registration Statement and to the references to this firm under the caption “Legal Matters” contained in the prospectus included in the Registration Statement. In giving such consent, we do not admit that we are in the category of persons whose consent is required under Section 7 of the Securities Act or the rules and regulations promulgated thereunder.

This opinion is for your benefit in connection with the Registration Statement and may be relied upon by you and by persons entitled to rely upon it pursuant to the applicable provisions of the Securities Act.

Very truly yours,

Dr. Peter Versteegen
Freshfields Bruckhaus Deringer LLP

Exhibit 10.15

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

FIRST AMENDMENT TO THE COLLABORATION AGREEMENT

THIS FIRST AMENDMENT TO THE COLLABORATION AGREEMENT**("First Amendment")** is made and entered into, effective as of June 1, 2018 **("Amendment Effective Date"),** by and between BioNTech RNA Pharmaceuticals GmbH, a limited liability company organized under the laws of Germany **("RNP")** and BioNTech AG, a stock corporation organized under the laws of Germany**("BNT")** (RNP and BNT collectively, **"BioNTech"),** and Genentech, Inc., a corporation organized under the laws of the State of Delaware **("GNE")** and F. Hoffmann-La Roche Ltd, a corporation organized under the laws of Switzerland **("Roche")** (GNE and Roche, collectively, **"Genentech").** BioNTech and Genentech are sometimes referred to herein individually as a **"Party"** and collectively as the **"Parties ."**

BACKGROUND

WHEREAS, the Parties entered into a Collaboration Agreement dated as of September 20, 2016 pursuant to which BioNTech and Genentech agreed to collaborate in the research, development, and commercialization of Collaboration Products (the **"Agreement");**

WHEREAS, the Parties have agreed to amend the Agreement to add a patent to the list of BioNTech Core Patents as set forth herein.

NOW THEREFORE, for good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the Parties agree as follows:

I . **Schedule 1.20 BioNTech Core Patents.** Schedule 1.20 shall be deleted and replaced in its entirety with the revised Schedule 1.20 attached hereto.

2. **Survival of Agreement Terms.** All terms and conditions of the Agreement not modified by this First Amendment shall continue in full force and effect in accordance with their terms. All capitalized terms not otherwise defined herein shall have the same definition as in the Agreement. In the event of any conflict between the terms and conditions of this First Amendment and the Agreement, the terms and conditions set forth in this First Amendment shall control with respect to the subject matter hereof.

[Signature page follows - the rest of this page intentionally left blank]

IN WITNESS WHEREOF, the Parties have executed this First Amendment by their respective officers hereunto duly authorized, on the Amendment Effective Date.

GENENTECH, INC.

By: /s/ Redacted
Name:
Title:

BIONTECH RNA PHARMACEUTICALS GMBH

By: /s/ Redacted
Name:
Title:

F. HOFFMANN-LA ROCHE LTD

By: /s/ Redacted
Name:
Title:

BIONTECH SE

By: /s/ Redacted
Name:
Title:

F. HOFFMANN-LA ROCHE LTD

By: /s/ Redacted
Name:
Title:

BioNTech Core Patents

No.	Solely owned BioNTech Core Patents	In-Licensed BioNTech Core Patents
[***]	**[***]**	**[***]**

Neoepitope Prediction Algorithm	
[***]	**[***]**

[***]

Exhibit 10.16

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

SECOND AMENDMENT TO THE COLLABORATION AGREEMENT

This SECOND AMENDMENT (the "**Second Amendment**") is made and entered into, effective as of December 6, 2019 (the "**Second Amendment Effective Date**"), by and between BioNTech RNA Pharmaceuticals GmbH, a limited liability company organized under the laws of Germany ("**RNP**") and BioNTech SE, a European stock corporation ("**BNT**") (RNP and BNT collectively, "**BioNTech**"), and Genentech, Inc., a corporation organized under the laws of the State of Delaware ("**GNE**") and F. Hoffmann-La Roche Ltd, a corporation organized under the laws of Switzerland ("**Roche**") (GNE and Roche, collectively, "**Genentech**").

WHEREAS, the Parties entered into a Collaboration Agreement, dated as of September 20, 2016, as amended on June 1, 2018, pursuant to which BioNTech and Genentech agreed to collaborate in the research, development, and commercialization of Collaboration Products (the "**Agreement**").

WHEREAS, BioNTech and Genentech wish to modify certain terms of the Agreement with respect to [***] (i) certain RNA manufacturing projects within the CMC Development Plan and (ii) development of the commercial upstream manufacturing process.

NOW, THEREFORE, for good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the Parties agree as follows:

1. **Defined Terms**.

   a. Section 1.20 is hereby deleted in its entirety and replaced with the following:

      "'**BioNTech Core Patents**' means (a) the Patents listed on Schedule 1.20, (b) [***] and (c) all Patents claiming priority to any of the Patents described in clauses (a) or (b), or claiming priority to a priority document thereof."

   b. Section 1.27 is hereby amended by adding the following sentence to the end of the Section:

      "For clarity, BioNTech Know-How [***]."

   c. Section 1.59 is hereby amended by adding the following clause to the end of the Section:

      "; *provided*, however, that, notwithstanding anything to the contrary in this Agreement or the MDSA, CollaborationKnow-How [***]"

d. The following definition is hereby added to the Agreement as Section 1.331:

"'**External Sequencing Party**' means an entity other than BioNTech or Genentech that is selected by Genentech to conduct some or all of the Sequencing Manufacturing Project."

e. The following definition is hereby added to the Agreement as Section 1.332:

"'**RNA Manufacturing Know-How**' means all Know-How that is discovered, generated, conceived or reduced to practice by a Party (or any authorized Third Party acting on a Party's behalf) solely or jointly in the course of conducting the RNA Manufacturing Projects."

f. The following definition is hereby added to the Agreement as Section 1.333:

"'**RNA Manufacturing Projects**' means the work packages for the Collaboration Products concerning RNA manufacturing process, [***] set forth in Schedule 1.333."

g. The following definition is hereby added to the Agreement as Section 1.334:

"'**Sequencing Manufacturing IP**' means the Sequencing Manufacturing Know-How and all Patents that claim any such Sequencing Manufacturing Know-How."

h. The following definition is hereby added to the Agreement as Section 1.335:

"'**Sequencing Manufacturing Know-How**' means all Know-How that is discovered, generated, conceived or reduced to practice by Genentech or by the External Sequencing Party on a Party's behalf (whether solely or jointly with a Party) in the course of conducting any activities in connection with the Sequencing Manufacturing Project."

i. The following definition is hereby added to the Agreement as Section 1.336:

"'**Sequencing Manufacturing Project**' means the development of the upstream portion of the Manufacturing Process for Commercial Manufacturing [***]."

2. **Exhibits**. The schedule attached hereto as Exhibit A is hereby incorporated into the Agreement as Schedule 1.333.

3. **Amendment of the CMC Development Plan**. For each RNA Manufacturing Project, the Parties hereby agree that they will (a) agree upon a written project plan for such RNA Manufacturing Project, which will set forth the scope of work to be performed by each Party, deliverables, time schedule and budget (including required FTEs, equipment and other resources), (b) promptly amend the CMC Development Plan to include such agreed-upon project plan for such RNA Manufacturing Project, and (c) conduct such RNA Manufacturing Project in accordance with such project plan.

Notwithstanding the foregoing, in the event that the Parties are unable to agree on such written project plan [***].

4. **Decision-Making**. Section 2.8.2(g) is hereby amended by adding the following clause to the end of the Section:

"[***]"

5. **Sequencing Manufacturing by the External Sequencing Party**. The following provision is hereby added to the Agreement as Section 7.4:

"Sequencing Manufacturing by the External Sequencing Party.

7.4.1 Sequencing Manufacturing Project. Notwithstanding anything to the contrary in this Agreement (including Sections 7.1 and 7.2) or the MDSA, Genentech shall have the sole right and responsibility for the performance of the Sequencing Manufacturing Project, at its discretion (subject to Sections 7.4.2 and 10.2.5), and may use the External Sequencing Party to conduct some or all of the Sequencing Manufacturing Project. Genentech shall ensure that the Sequencing Manufacturing Project is designed to deliver, and shall use commercially reasonable efforts to deliver, [***].

7.4.2 Use of External Sequencing Party by BioNTech. If in connection with BioNTech's Development of a BioNTech Indication or BioNTech's Development or Commercialization of Reversion Products pursuant to Section 14.5.4, in each case, in accordance with (and subject to the terms and conditions of) this Agreement, BioNTech desires to use the External Sequencing Party that Genentech is using to perform the sequencing for the upstream portion of the Manufacturing Process for Commercial Manufacturing [***], Genentech will [***] in the case of BioNTech Indications, or [***] in the case of Reversion Products.'

6. **Costs**.

a. The following provision is hereby added to the Agreement as Section 8.2.8:

"**RNA Manufacturing Project Costs**. BioNTech shall be solely responsible for, and shall bear, all CMC Development Costs incurred by or on behalf of BioNTech or Genentech in the performance of activities pursuant to a RNA Manufacturing Project. In the event that Genentech incurs CMC Development Costs in connection with an RNA Manufacturing Project, such costs shall be reported to, and reimbursed by, BioNTech as part of the reconciliation process set forth in Sections 8.2.6 and 8.2.7. Genentech may offset the amounts of any invoices for such reconciled costs not paid in accordance with Section 8.2.7 from any payments due to BioNTech pursuant to Sections 8.4.1 and 8.7. Notwithstanding the foregoing, for any portion of such CMC Development Costs that both (a) are incurred by or on behalf of Genentech in excess of [***] percent ([***]%) of the budget set forth

in the CMC Development Plan for activities allocated to Genentech pursuant to such RNA Manufacturing Project, and (b) have not been approved by BioNTech in advance, Genentech shall bear such portion of the CMC Development Costs. For clarity, the costs of implementing any processes or developments made under an RNA Manufacturing Project into the Manufacturing Process for a Collaboration Product shall be Shared Development Costs."

b. The following provision is hereby added to the Agreement as Section 8.2.9:

"**Sequencing Manufacturing Project**. Genentech shall be solely responsible for, and shall bear, all Development Costs incurred by it and its Affiliates for the performance of the Sequencing Manufacturing Project by Genentech, its Affiliates or the External Sequencing Party."

7. **Intellectual Property**.

a. The following is provision is hereby added to Section 10.2.1 as subsection (d):

"[***]"

b. The following provision is hereby added to the Agreement as Section 10.2.5:

"[***]"

8. **Survival of Agreement Terms**. All terms and conditions of the Agreement not modified by this Second Amendment shall continue in full force and effect in accordance with their terms. All capitalized terms not otherwise defined herein shall have the same definition as in the Agreement. In the event of any conflict between the terms and conditions of this Second Amendment and the Agreement, the terms and conditions set forth in this Second Amendment shall control with respect to the subject matter hereof.

[Remainder of the page intentionally left blank; signature page follows.]

IN WITNESS WHEREOF, the Parties have each caused this Second Amendment to be executed by their duly authorized representatives.

GENENTECH, INC.

By: /s/ Redacted
Name:
Title:

BIONTECH RNA PHARMACEUTICALS GMBH

By: /s/ Redacted
Name:
Title:

F. HOFFMANN-LA ROCHE LTD

By: /s/ Redacted
Name:
Title:

BIONTECH SE

By: /s/ Redacted
Name:
Title:

F. HOFFMANN-LA ROCHE LTD

By: /s/ Redacted
Name:
Title:

Exhibit A

Work Package	Objective	Key Deliverables	Target Completion Date	Target Implementation Date
[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]

Exhibit 10.40

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

Contract number (FI No):
[***]

Contract number (FI No):
[***]

Serapis No: [***]

Personalised Immunotherapies (EGFF)

Finance Contract

between the

European Investment Bank

and

BioNTech SE

THIS CONTRACT IS MADE ON _12 DECEMBER 2019 BETWEEN:

The European Investment Bank having its seat at 100 blvd Konrad Adenauer, Luxembourg, L-2950 Luxembourg, represented by Hristo Stoykov, Head of Division and Stefan Becker, Senior Counsel (the "**Bank**")

and

BioNTech SE a European public limited-liability company (*Europäische Gesellschaft*) incorporated in Germany, having its registered office at An der Goldgrube 12, D-55131 Mainz, Germany, registered with the commercial register (*Handelsregister*) of the local court (*Amtsgericht*) of Mainz under HRB 48720, represented by Dr. Sierk Poetting, CFO & COO (*Vorstand*) (the "**Borrower**")

WHEREAS:

(A) The Borrower has stated that it is implementing an investment programme relating to R&D investments for the development of patient-tailored therapeutic vaccines for cancer in Germany as more particularly described in the technical description (the "**Technical Description"**) set out in Schedule A (*Investment Specification and Reporting*) (the "**Investment**"). The total cost of the Investment, as estimated by the Bank, is EUR [***].

(B) The Bank, considering that the financing of the Investment falls within the scope of its functions, agreed to provide the Borrower with a credit (including a profit participation credit (*partiarisches Darlehen*)) in an amount of EUR 50,000,000 (fifty million euro) under this finance contract (the "**Contract**") to partially finance the Investment;**provided that** the amount of the loan hereunder shall not, in any case, exceed 50% (fifty per cent.) of the cost of the Investment. The Parties being aware of the differences between a profit participation credit (*partiarisches Darlehen*) and a silent partnership (*stille Gesellschaft*), have consciously decided to enter into this Contract.

(C) This operation benefits from a guarantee from the European Union under the European Fund for Strategic Investments ('**EFSI**").

(D) The statute of the Bank provides that the Bank shall ensure that its funds are used as rationally as possible in the interests of the European Union; and, accordingly, the terms and conditions of the Bank's loan operations must be consistent with relevant policies of the European Union.

(E) The Bank considers that access to information plays an essential role in the reduction of environmental and social risks, including human rights violations, linked to the projects it finances and has therefore established its transparency policy, the purpose of which is to enhance the accountability of the Bank's group towards its stakeholders and the citizens of the European Union in general.

(F) The processing of personal data shall be carried out by the Bank in accordance with applicable European Union legislation on the protection of individuals with regard to the processing of personal data by the European Union institutions and bodies and on the free movement of such data.

(G) The Bank places great emphasis on integrity and good governance and has therefore established policies and procedures to avoid misuse of its funds for purposes of tax fraud, tax evasion, money laundering and financing of terrorism, and with a view to protect against its operations financing artificial arrangements aimed at tax avoidance. Such policies and procedures are designed to be in line with the principles and standards of applicable EU Law, and European Union or internationally agreed tax standards on transparency and exchange of information.

It is hereby agreed as follows:

ARTICLE 1

Interpretation and definitions

1.1 Interpretation

In this Contract:

(a) references to Articles, Recitals, Schedules and (Sub-)Paragraphs are, save if explicitly stipulated otherwise, references respectively to articles of, and recitals, schedules and (sub-)paragraphs of schedules to, this Contract. All Recitals and Schedules form part of this Contract;

(b) references to "law" or "laws" mean (i) any applicable law and any applicable treaty, constitution, statute, legislation, decree, normative act, rule, regulation, judgement, order, writ, injunction, determination, award or other legislative or administrative measure or judicial or arbitral decision in any jurisdiction which is binding or applicable case law, and (ii) EU Law;

(c) references to applicable law, applicable laws or applicable jurisdiction means (i) a law or jurisdiction applicable to the Borrower or any other Obligor (as the context requires), its respective rights and/or obligations (in each case arising out of or in connection with the Finance Documents), its capacity and/or assets and/or the Investment; and/or, as applicable, (ii) a law or jurisdiction (including in each case the Bank's Statute) applicable to the Bank, its rights, obligations, capacity and/or assets;

(d) references to a provision of law are references to that provision as amended or re-enacted;

(e) references to any Finance Document or other agreement or instrument are references to that Finance Document or other agreement or instrument as amended, novated, supplemented, extended or restated;

(f) words and expressions in plural shall include singular and vice versa;

(g) "promptly" is to be construed as *unverzüglich* (without undue delay) within the meaning of Section 121 para. 11 of the BGB; and

(h) a Default (other than an Event of Default) is "continuing" if it has not been remedied or waived and an Event of Default is "continuing" if it has not been waived.

This Contract is made in the English language. For the avoidance of doubt, the English language version of this Contract shall prevail over any translation of this Contract. However, where a German translation of a word or phrase appears in the text of this Contract, the German translation of such word or phrase shall prevail.

1.2 Definitions

In this Contract:

"**Accepted Tranche**" means a Tranche in respect of a Disbursement Offer which has been duly accepted by the Borrower in accordance with its terms on or before the Disbursement Acceptance Deadline.

"**acting in concert**" means acting together pursuant to an agreement or understanding (whether formal or informal).

"**AktG**" means the German stock corporation act (*Aktiengesetz*).

"**Approved Financial Statements**" has the meaning given to that term in Paragraph 2.(a)(i) of Schedule I (*Information and Visits*).

"**Authorisation**" means an authorisation, permit, consent, approval, resolution, licence, exemption, filing, notarisation or registration.

"**Authorised Signatory**" means a person authorised to sign individually or jointly (as the case may be) Disbursement Acceptances on behalf of the Borrower and named in the most recent List of Authorised Signatories and Accounts received by the Bank prior to the receipt of the relevant Disbursement Acceptance.

"**BGB**" means the German Civil Code (*Bürgerliches Gesetzbuch*).

"**Business Day**" means a day (other than a Saturday or Sunday) on which the Bank and commercial banks are open for general business in Luxembourg and Mainz, Germany.

"**Cancellation Fee**" has the meaning given to such term in Article 1.2 (*Definitions*) of the Finance Fee Letter.

"**Cash Interest Fixed Rate**" means (i) in relation to Credit A a fixed rate of 1% (100 basis points) per annum and (ii) in relation to Credit B a fixed rate of 2% (200 basis points) per annum.

"**Change-of-Control Event**" means:

(a) any person or group of persons acting in concert gains Control of the Borrower or of any entity directly or indirectly Controlling the Borrower; or

(b) the Borrower ceases to Control any Guarantor; or

(c) a Delisting of the Borrower.

"**Change-of-Law Event**" means the enactment, promulgation, execution or ratification of or any change in or amendment to any law, rule or regulation (or in the application or official interpretation of any law, rule or regulation) that occurs after the date of this Contract and which, in the opinion of the Bank, would materially impair an Obligor's ability to perform its obligations under the Finance Documents.

"**Compliance Certificate**" means a certificate substantially in the form set out in Schedule E (*Form of Compliance Certificate*).

"**Contract Number**" shall mean each Bank generated number identifying this Contract and indicated on the cover page of this Contract after the letters "FI No".

"**Control**" means (i) owning (directly or indirectly) more than 50% (fifty per cent) of the shares in an entity, (ii) the power to cast, or to control the casting of, more than 50% (fifty per cent) of the maximum number of votes that might be cast at a shareholder or general meeting of an entity, (iii) the power to appoint or remove all, or the majority, of the directors of an entity, and/or (iv) the power to direct the management and policies of an entity, whether through the ownership of voting capital, by contract or otherwise, and "**Controlling**" and "**Controlled**" has the corresponding meaning.

"**Credit**" has the meaning given to it in Article 2.1 (*Amount of Credit*).

"**Credit A**" has the meaning given to it in Article 2.1(a) (*Amount of Credit*).

"**Credit A Milestone Events**" has the meaning given to such term in Part A (*Initial Documentary Conditions Precedent and Credit A Conditions Precedents*) of Schedule F.

"**Credit B**" has the meaning given to it in Article 2.1(b) (*Amount of Credit*).

"**Credit B Milestone Events**" has the meaning given to such term in Part B (*Credit B – Conditions Precedent*) of Schedule F.

"**Default**" means an Event of Default or any event or circumstance specified in Article 9 (*Events of Default*) which would (with the expiry of a grace period, the giving of notice, the making of any determination under this Contract or any combination of any of the foregoing) be an Event of Default.

"**Deferred Interest Fixed Rate**" means in relation to Credit A a fixed rate of 5% (500 basis points) per annum.

"**Delisting**" means voluntary or involuntary removal of listed shares from a regulated market or revocation of admission to trading of shares on a regulated market.

"**Disbursement Acceptance**" means a copy of the Disbursement Offer duly countersigned by the Borrower.

"**Disbursement Acceptance Deadline**" means the date and time of expiry of a Disbursement Offer as specified therein.

"**Disbursement Account**" means, in respect of each Tranche, the bank account set out in the most recent List of Authorised Signatories and Accounts.

"**Disbursement Date**" means the date on which disbursement of a Tranche is made by the Bank.

"**Disbursement Offer**" means a letter substantially in the form set out in Schedule C (*Form of Disbursement Offer/Acceptance*).

"**Dispute**" has the meaning given to it in Article 10.2 (*Jurisdiction*).

"**Disruption Event**" means either or both of:

(a) a material disruption to those payment or communications systems or to those financial markets which are, in each case, required to operate in order for payments to be made in connection with this Contract; or

(b) the occurrence of any other event which results in a disruption (of a technical or systems-related nature) to the treasury or payments operations of either the Bank or the Borrower, preventing that party from:

(i) performing its payment obligations under this Contract; or

(ii) communicating with other parties in accordance with the terms of this Contract,

and which disruption (in either such case as per Paragraph (a) or (b) above) is not caused by, and is beyond the control of, the party whose operations are disrupted.

"**Drug Product Revenues**" means the amount of the consolidated revenues resulting from drug product sales (including royalties) of the Group Companies, calculated on the basis of the Approved Financial Statements for the respective financial year, excluding milestone and upfront payments as well as revenues associated with peptides, diagnostics and contract development and manufacturing businesses of JPT Peptide Technologies GmbH, BioNTech Diagnostics GmbH and BioNTech Innovative Manufacturing Services GmbH. In the case that Intellectual Property Rights related to drug assets that are either fully or partly-owned by the Borrower or any other Group Company as at the date of this Contract or in the future are out-licensed or partnered in a co-development deal, the total drug revenues generated on the market shall be considered for the calculation of Drug Product Revenues (rather than the percentage of revenues due to the Borrower or the respective other Group Company).

"**EBITDA**" means, in respect of any Relevant Period, the consolidated operating profit of the Group before taxation (excluding the results from discontinued operations):

(a) after deducting own work capitalised;

(b) before deducting any interest, commission, fees, discounts, prepayment fees, premiums or charges and other finance payments whether paid, payable or capitalised by any Group Company (calculated on a consolidated basis) in respect of that Relevant Period;

(c) not including any accrued interest owing to any Group Company;

(d) after adding back any amount attributable to the amortisation or depreciation of assets of members of the Group;

(e) before taking into account any Exceptional Items;

(f) after deducting the amount of any profit (or adding back the amount of any loss) of any Group Company which is attributable to minority interests;

(g) plus or minus the Group's share of the profits or losses (after finance costs and tax) of entities which are not Group Companies;

(h) before taking into account any unrealised gains or losses on any financial instrument (other than any derivative instrument which is accounted for on a hedge accounting basis); and

(i) before taking into account any gain arising from an upward revaluation of any other asset,

in each case, to the extent added, deducted or taken into account, as the case may be, for the purposes of determining operating profits of the Group before taxation.

"**EIB Fee Letter**" means the letter from the Bank to the Borrower dated 31 October 2018.

"**EFSI**" has the meaning given in Recital (C).

"**EFSI Regulation**" means the Regulation 2015/1017 of the European Parliament and of the Council of 25 June 2015 on the European Fund for Strategic Investments, as amended, supplemented or restated.

"**Environment**" means the following, in so far as they affect human health or social well-being:

(a) fauna and flora;

(b) soil, water, air, climate and the landscape; and

(c) cultural heritage and the built environment,

and includes, without limitation, occupational and community health and safety.

"**Environmental Approval**" means any Authorisation required by Environmental Law.

"**Environmental Claim**" means any claim, proceeding, formal notice or investigation by any person in respect of any Environmental Law.

"**Environmental Law**" means EU Law including principles and standards, and national laws and regulations, of which a principal objective is the preservation, protection or improvement of the Environment.

"**Expert Determination**" has the meaning given to it in Article 4.3(d) (*Profit Participation*).

"**Existing Indebtedness**" means any Indebtedness of members of the Group arising under any arrangement listed in Schedule J (*Existing Indebtedness*).

"**Existing Security**" means any Security granted by members of the Group which are listed in Schedule K (*Existing Security*).

"**EU Directives**" means the directives of the European Union.

"**EU Law**" means the acquis communautaire of the European Union as expressed through the Treaties of the European Union, the regulations, the EU Directives, delegated acts, implementing acts, and the case law of the Court of Justice of the European Union.

"**EUR**" or "**euro**" means the lawful currency of the Member States of the European Union which adopt or have adopted it as their currency in accordance with the relevant provisions of the Treaty on European Union and the Treaty on the Functioning of the European Union or their succeeding treaties.

"**EURIBOR**" has the meaning given to it in Schedule B (*Definition of EURIBOR*).

"**Event of Default**" means any of the circumstances, events or occurrences specified in Article 9 (*Events of Default*).

"**Exceptional Items**" means any material items of an unusual or non-recurring nature which represent gains or losses including those arising on:

(a) the restructuring of the activities of an entity and reversals of any provisions for the cost of restructuring;

(b) disposals, revaluations, write downs or impairment of non-current assets or any reversal of any write down or impairment;

(c) disposals of assets associated with discontinued operations; and

(d) any other examples of "exceptional items" (as such term has the meaning attributed to it in IFRS).

"**Fee Letters**" means the EIB Finance Letter and the Finance Fee Letter.

"**Finance Fee Letter**" means the Luxembourg law governed finance fee letter from the Bank to the Borrower dated on or about the date hereof.

"**Final Availability Date**" means the day falling [***] months after the date of this Contract.

"**Finance Documents**" means this Contract, any Guarantee Agreement, the Security Documents, the Fee Letters and any other document designated a "Finance Document" by the Borrower and the Bank.

"**Finance Lease**" means any lease or hire purchase contract which would, in accordance with IFRS in force prior to 1 January 2019, be treated as a finance or capital lease; it is understood between the parties to this Contract that the definition of "Finance Lease" does not include operational lease.

"**GAAP**" means generally accepted accounting principles (*Grundsätze ordnungsgemäßer Buchführung*) in Germany, including IFRS.

"**Germany**" means the Federal Republic of Germany.

"**Group**" means the Group Companies, taken together as a whole.

"**Group Company**" means the Borrower and its Subsidiaries.

"**Guarantee Agreement**" means a guarantee and indemnity agreement in form and substance satisfactory to the Bank (to be) entered into by a Guarantor as guarantor and the Bank as beneficiary.

"**Guarantor**" means BioNTech RNA Pharmaceuticals GmbH and each Material Subsidiary which enters into a Guarantee Agreement in accordance with Sub-Paragraph (b) of Paragraph 16 (*Guarantees*) of Schedule H (*General Undertakings*).

"**IFRS**" means international accounting standards within the meaning of IAS Regulation 1606/2002 to the extent applicable to the relevant financial statements.

"**Illegal Activities**" means any of the following illegal activities or activities carried out for illegal purposes: tax evasion, tax fraud, fraud, corruption, coercion, collusion, obstruction, money laundering, financing of terrorism or any illegal activity that may affect the financial interests of the EU, according to applicable laws.

"**Indebtedness**" means any:

(a) obligations for borrowed money;

(b) indebtedness under any acceptance credit;

(c) indebtedness under any bond, debenture, note or similar instrument;

(d) instrument under any bill of exchange;

(e) indebtedness in respect of any interest rate or currency swap or forward currency sale or purchase or other form of interest or currency hedging transaction (including without limit caps, collars and floors);

(f) indebtedness under any Finance Lease;

(g) indebtedness (actual or contingent) under any guarantee, bond security, indemnity or other agreement;

(h) indebtedness (actual or contingent) under any instrument entered into for the purpose of raising finance;

(i) indebtedness in respect of a liability to reimburse a purchaser of any receivables sold or discounted in the event that any amount of those receivables is not paid;

(j) indebtedness arising under a securitisation; or

(k) other transaction which has the commercial effect of borrowing.

"**Independent Expert**" means an investment bank or consultancy firm of international standing and repute, appointed by the Borrower and accepted by the Bank.

"**Initial Ownership Stake**" has the meaning given to that term in Paragraph 13 (b)(i) of Schedule H (*General Undertakings*).

"**InsO**" means the German Insolvency Code (*Insolvenzordnung*).

"**Intellectual Property Rights**" means intellectual property rights (*gewerbliche Schutzrechte; Immaterialgüterrechte*) of every designation (including, without limitation, patents, utility patents, copyrights, design rights, trademarks, software, service marks and know how) whether capable of registration or not.

"**Investment**" has the meaning given to that term in Recital (A).

"**Land Charge**" means the first ranking land charge without certificate (*Buchgrundschuld*) in the amount of EUR 50,000,000 (plus [***]) created under the Land Charge Creation Deed with which the Borrower will encumber its Property and certain of its assets falling within the statutory scope of the Land Charge (*Grundschuldhaftungsverband*) in favour of the Bank.

"**Land Charge Creation Deed**" means any document by means of which the Land Charge is created and which includes, *inter alia*, an abstract acknowledgement of debt of the Borrower in the amount of the Land Charge (in each case subject to the submission to the immediate enforcement (*sofortige Zwangsvollstreckungsunterwerfung*) *in personam* and *in rem* for the full Land Charge amount), the Borrower's approval for registration (*Eintragungsbewilligung*) of the Land Charge in the land register, regardless of whether such document will be officially certified (*öffentlich beglaubigt*) or notarially recorded (*notariell beurkundet*).

"**Lead Organisation**" means the European Union, the United Nations and international standard setting organisations including the International Monetary Fund, the Financial Stability Board, the Financial Action Task Force, the Organisation for Economic Cooperation and Development and the Global Forum on Transparency and Exchange of Information for Tax Purposes and any successor organisations.

"**List of Authorised Signatories and Accounts**" means a list (signed by Authorised Signatories), in form and substance satisfactory to the Bank, setting out: (i) the Authorised Signatories, accompanied by evidence of signing authority of the persons named on the list and specifying if they have individual or joint signing authority, (ii) the specimen signatures of such persons, and (iii) the bank account(s) to which disbursements may be made under this Contract (specified by IBAN code if the country is included in the IBAN Registry published by SWIFT, or in the appropriate account format in line with the local banking practice), BIC/SWIFT code of the bank and the name of the bank account(s) beneficiary.

"**Loan**" means the aggregate of the amounts disbursed from time to time by the Bank under this Contract.

"**Loan Outstanding**" means the aggregate of the amounts disbursed from time to time by the Bank under this Contract that remains outstanding.

"**Material Adverse Change**" means, any event or change of condition, which, in the reasonable opinion of the Bank has a material adverse effect on:

(a) the ability of any Obligor to perform its respective obligations under the Finance Documents;

(b) the business, operations, property or condition (financial or otherwise) of any Obligor or the Group as a whole; or

(c) the legality, validity or enforceability of, or the effectiveness or ranking of, or the value of any Security granted to the Bank, or the rights or remedies of the Bank under the Finance Documents.

"**Material Subsidiary**" means BioNTech RNA Pharmaceuticals GmbH and any Subsidiary from time to time, whose gross revenues, total assets or EBITDA represents more than 5% of (i) the consolidated gross revenues of the Group or, (ii) the Total Assets, or, (iii) as the case may be, the consolidated EBITDA of the Group, as calculated based on the then latest consolidated audited accounts of the Group.

"**Maturity Date**" means, for each Tranche, the last Repayment Date of that Tranche as specified in the relevant Disbursement Offer, being the date falling 6 (six) years from the respective Disbursement Date of the relevant Tranche.

"**Milestone Events**" means collectively the Credit A Milestone Events and the Credit B Milestone Events.

"**Non-EIB Financing**" includes any loan (save for the Loan and any other direct loans from the Bank to the Borrower (or any other Group Company) or a Guarantor), credit bond or other form of financial indebtedness or any obligation for the payment or repayment of money originally granted to the Borrower (or any other Group Company) or a Guarantor) for a term of more than 3 (three) years.

"**Obligor**" means the Borrower and each Guarantor.

"**Payment Date**" means the quarterly dates specified in the Disbursement Offer until and including the Maturity Date, save that, in case any such date is not a Relevant Business Day, it means the following Relevant Business Day, without adjustment to the interest due under Article 4 (*Interest*), except for those cases where a payment is made as a single instalment in accordance with Article 5.1 (*Normal Repayment*), and to the final interest payment only, when it shall mean the preceding Relevant Business Day, with adjustment to the interest due under Article 4 (*Interest*).

"**Permitted Disposal**" means each disposal permitted in accordance with Paragraph 7(b) (*Disposal of assets*) of Schedule H (*General Undertakings*).

"**Permitted Guarantees**" means each and every guarantee permitted in accordance with Paragraph 16 (*Guarantees*) of Schedule H (*General Undertakings*).

"**Permitted Hedging**" has the meaning given to such term in Paragraph 17 (*Hedging*) of Schedule H (*General Undertakings*).

"**Permitted Indebtedness**" means Indebtedness of the Borrower and/or any Group Company which is permitted in accordance with Paragraph 15 (*Indebtedness*) of Schedule H (*General Undertakings*).

"**Permitted Security**" means Security of the Borrower and/or any Group Company which is permitted in accordance withSub-Paragraph (c) Paragraph 23 (*Negative pledge*) of Schedule H (*General Undertakings*).

"**Prepayment Amount**" means the amount of a Tranche to be prepaid by the Borrower in accordance with Articles 5.2 (*Voluntary prepayment*), 5.3 (*Compulsory prepayment*) or 9.1 (*Right to demand repayment*).

"**Prepayment Date**" means the date on which the Borrower proposes or is requested by the Bank, as applicable, to effect prepayment of a Prepayment Amount.

"**Prepayment Event**" means any of the events described in Article 5.3 (*Compulsory Prepayment*).

"**Prepayment Fee**" means, in relation to a Prepayment Amount in respect of a Tranche, a fee as follows:

(a) a fee of 4% (400 basis points) of the Prepayment Amount if the Prepayment Date is after the relevant Disbursement Date but before or on the first anniversary of such Disbursement Date;

(b) a fee of 3% (300 basis points) of the Prepayment Amount if the Prepayment Date is after the first anniversary of the relevant Disbursement Date but before or on the second anniversary of such Disbursement Date;

(c) a fee of 2% (200 basis points) of the Prepayment Amount if the Prepayment Date is after the second anniversary of the relevant Disbursement Date but before or on the third anniversary of such Disbursement Date;

(d) a fee of 1% (100 basis points) of the Prepayment Amount if the Prepayment Date is after the third anniversary of the relevant Disbursement Date but before or on the fourth anniversary of such Disbursement Date; or

(e) a fee of 0.5% (50 basis points) of the Prepayment Amount if the Prepayment Date is after the fourth anniversary of the relevant Disbursement Date but before the Maturity Date,

with such fee being payable on the applicable Prepayment Date.

"**Prepayment Notice**" means a written notice from the Bank to the Borrower in accordance with Article 5.2.3 (*Prepayment mechanics*).

"**Prepayment Request**" means a written request from the Borrower to the Bank to prepay all or part of the Loan Outstanding, in accordance with Article 5.2.1 (*Prepayment option*).

"**Profit Participation Cap**" means, at any time, an amount of EUR 15,000,000 (fifteen million euro) or any other amount agreed between the Bank and the Borrower in writing.

"**Profit Participation Payments**" has the meaning given to it in Article 4.3 (*Profit Participation*).

"**Property**" means the property of BioNTech Real Estate GmbH & Co. KG at Hechtsheimer Straße, Mainz-Weisenau, Rheinland-Pfalz, Germany, consisting of building and land, registered with the land register (*Grundbuch*) of the local court (*Amtsgericht*) of Mainz, folio 6393, district of Weisenau, plot (Flur) 2, parcels (Flurstück) 35/67.

"**Relevant Business Day**" means a day on which the Trans-European Automated Real-time Gross Settlement Express Transfer payment system which utilises a single shared platform and which was launched on 19 November 2007 (TARGET2) is open for the settlement of payments in EUR.

"**Relevant Period**" means each period of 12 (twelve) months ending on or about the last day of the financial year.

"**Repayment Date**" shall mean the sole Payment Date specified in the Disbursement Offer for the repayment of a Tranche in accordance with Article 5.1 (*Normal repayment*).

"**Repeating Representations**" means each of the representations set out in Schedule G (*Representations and Warranties*) other than those Paragraphs thereof which are identified with the words "*(Non-repeating)*" at the end of the Paragraphs.

"**Security**" means any mortgage, land charge (*Grundschuld*), pledge, lien, charge, assignment, security transfer (*Sicherungsübereignung*), retention of title arrangements, hypothecation, or other security interest securing any obligation of any person or any other agreement or arrangement having a similar effect.

"**Security Purpose Agreement**" means the security purpose agreement (*Sicherungszweckvereinbarung*) to be entered into by the Borrower as security grantor and the Bank as beneficiary in relation to the Land Charge.

"**Security Documents**" means the Land Charge Creation Deed, the Security Purpose Agreement, each Guarantee Agreement and any other document entered into by any person creating or expressed to create any Security over all or any part of its assets in respect of the obligations of any of the Obligors under any of the Finance Documents.

"**Semi-Annual Date**" means each of 30 June and 31 December.

"**Standby Fee**" has the meaning given to such term in Article 2. (*Standby fee*) of the Finance Fee Letter.

"**Subsidiary**" means a subsidiary within the meaning of Sections 15 to 17 AktG and an entity of which the Borrower has direct or indirect Control.

"**Tax**" means any tax, levy, impost, duty or other charge or withholding of a similar nature (including any penalty or interest payable in connection with any failure to pay or any delay in paying any of the same).

"**Technical Description**" has the meaning given to it in Recital (A).

"**Total Assets**" means the total consolidated assets of the Group, as shown in the Borrower's latest consolidated financial statements, as at the end of any Relevant Period.

"**Tranche**" means each disbursement made or to be made under this Contract. In the event that no Disbursement Acceptance has been received, Tranche shall mean a Tranche as offered under Article 2.2.2 (*Disbursement Offer*).

"**Voluntary Non EIB Prepayment**" means a voluntary prepayment by any Group Company or any Guarantor (for the avoidance of doubt, prepayment shall include a repurchase, redemption or cancellation where applicable) of a part or the whole of any Non-EIB Financing where:

(a) such prepayment is not made within a revolving credit facility (save for the cancellation of a revolving credit facility); or

(b) such prepayment is not made out of the proceeds of a loan or other indebtedness having a term at least equal to the unexpired term of the Non-EIB Financing prepaid.

ARTICLE 2

Credit and Disbursements

2.1 Amount of Credit

By this Contract, the Bank establishes in favour of the Borrower, and the Borrower accepts, a credit (including a profit participation credit (*partiarisches Darlehen*)) in an aggregate amount of EUR 50,000,000 (fifty million euro) for the financing of the Investment (the "**Credit**"), consisting of:

(a) a term loan in an amount of EUR 25,000,000 (twenty five million euro) ("**Credit A**"); and

(b) a term loan in an amount of EUR 25,000,000 (twenty five million euro) ("**Credit B**").

2.2 Disbursement procedure

2.2.1 Tranches

The Bank shall disburse the Credit in Euros in up to five Tranches. Credit A can only be drawn in full, in an amount of EUR 25,000,000 (twenty five million euro). The amount of each Tranche under Credit B, shall be in a minimum amount of EUR 5,000,000 (five million euro) or (if less) the entire undrawn balance of the Credit B.

2.2.2 Disbursement Offer

Upon request by the Borrower and subject to Article 2.5 (*Conditions of Disbursement*), provided that no event mentioned in Sub-Paragraph (b) of Article 2.6 (*Cancellation*) has occurred and is continuing, the Bank shall send to the Borrower a Disbursement Offer for the disbursement of a Tranche. The latest time for receipt by the Borrower of a Disbursement Offer is [***] days before the Final Availability Date. The Disbursement Offer shall specify:

(a) the amount of the Tranche;

(b) the Disbursement Date, which shall be a Relevant Business Day, falling at least [***] days after the date of the Disbursement Offer and on or before the Final Availability Date;

(c) the interest rate basis of the Tranche, namely:

  (i) the Cash Interest Fixed Rate applicable to such Tranche;

  (ii) if relevant, the Deferred Interest Fixed Rate; and

  (iii) the Payment Dates;

(d) the terms and frequency for repayment of principal (bullet);

(e) the Maturity Date; and

(f) the Disbursement Acceptance Deadline.

2.2.3 Disbursement Acceptance

(a) The Borrower may accept a Disbursement Offer by delivering a Disbursement Acceptance to the Bank no later than the Disbursement Acceptance Deadline. The Disbursement Acceptance shall be signed by an Authorised Signatory with individual representation right or 2 (two) or more Authorised Signatories with joint representation rights and shall specify the Disbursement Account to which disbursement of the Tranche should be made in accordance with Article 2.3 (*Disbursement Account*).

(b) If a Disbursement Offer is duly accepted by the Borrower in accordance with its terms on or before the Disbursement Acceptance Deadline, and provided the conditions in Article 2.5.4 (*All Tranches – Other Conditions*) are met, the Bank shall make the Accepted Tranche available to the Borrower in accordance with the relevant Disbursement Offer and subject to the terms and conditions of this Contract.

(c) The Borrower shall be deemed to have refused any Disbursement Offer which has not been duly accepted in accordance with its terms on or before the Disbursement Acceptance Deadline, in which case the Tranche shall not be made available to the Borrower by the Bank, and the Credit shall not be affected.

2.3 Disbursement Account

(a) Disbursement shall be made to the Disbursement Account specified in the relevant Disbursement Acceptance, provided that such Disbursement Account is acceptable to the Bank in accordance with Article 6.2(d) (*Time and place of payment*).

(b) Only one Disbursement Account may be specified for each Tranche.

2.4 Currency of disbursement

The Bank shall disburse each Tranche in EUR.

2.5 Conditions of Disbursement

2.5.1 Initial Documentary Conditions Precedent

Without prejudice to Article 2.5.2 below, no Disbursement Offer will be provided by the Bank under this Contract unless the Bank has received all of the documents and other evidence listed in Schedule F, Part A (*Initial Documentary Conditions Precedent and Credit A Conditions Precedents*) in agreed form or otherwise in form and substance satisfactory to the Bank, including the Credit A Milestone Events.

2.5.2 Credit B – Further Conditions Precedent

No Disbursement Offer will be provided by the Bank under this Contract in relation to Credit B unless the Bank has received all of the additional documents and other evidence listed in Schedule F, Part B (*Credit B – Conditions Precedent*) in agreed form or otherwise in form and substance satisfactory to the Bank, including the Credit B Milestone Events.

2.5.3 All Tranches - Documentary Conditions Precedent

No Disbursement Offer, including the first Disbursement Offer, will be provided by the Bank under this Contract unless the Bank has confirmed that it has received, in form and substance satisfactory to it:

(a) a certificate from the Borrower in the form of Schedule D (*Form of Drawdown Certificate*), signed by an Authorised Signatory of the Borrower and dated no earlier than the date falling 14 (fourteen) days before the respective Disbursement Date; and

(b) a certificate (signed by one or more Authorised Signatories of the Borrower as appropriate) from the Borrower which confirms that the Borrower has sufficient resources to pay its debts as they fall due for at least 6 (six) months from the Disbursement Date not taking into account the disbursement of the proposed Tranche with a current extract from the commercial register (*Handelsregisterauszug*) of the Borrower and an up-to-date search on www.insolvenzbekanntmachungen.de in relation to the Borrower attached.

2.5.4 All Tranches – Other Conditions

The Bank will only be obliged to make any Accepted Tranche available to the Borrower if on the Disbursement Date for the proposed Tranche:

(a) the Repeating Representations made by the Borrower (in respect of itself and, where applicable, the other Obligors) are correct in all respects;

(b) no event or circumstance has occurred and is continuing which constitutes:

(i) or would with the expiry of a grace period and/or the giving of notice under this Contract constitute a Prepayment Event other than pursuant to Article 5.3.1 (*Cost Reduction*); or

(ii) a Default or an Event of Default,

or would, in each case, result from the disbursement of the proposed Tranche; and

(c) the Borrower complies with all preceding and already achieved Milestone Events.

2.6 Cancellation

(a) The Borrower may send a written notice to the Bank requesting the cancellation of the undisbursed portion of the Credit. The written notice:

(i) must specify whether the Borrower would like to cancel the undisbursed portion of the Credit in whole or in part and, if in part, the amount of the Credit the Borrower would like to cancel; and

(ii) must not relate to an Accepted Tranche which has a Disbursement Date falling within [***] Business Days of the date of the written notice.

Upon receipt of such written notice, the Bank shall cancel the requested undisbursed portion of the Credit with immediate effect.

(b) At any time upon the occurrence of the following events, the Bank may notify the Borrower in writing that the undisbursed portion of the Credit shall be cancelled in whole or in part:

(i) a Prepayment Event, which for the avoidance of doubt and only in case of event pursuant to Article 5.3.1 (*Cost Reduction*), by an amount equal to the amount by which it is entitled to cancel the Credit;

(ii) an Event of Default; or

(iii) an event or circumstance which would with the passage of time or giving of notice under this Contract constitute a Prepayment Event other than pursuant to Article 5.3.1 (*Cost Reduction*) or an Event of Default.

On the date of such written notification the relevant undisbursed portion of the Credit shall be cancelled with immediate effect.

2.7 Fee for cancellation of an Accepted Tranche

(a) If pursuant to Sub-Paragraph (a) of Article 2.6 (*Cancellation*) the Borrower cancels an Accepted Tranche, the Borrower shall pay to the Bank the Cancellation Fee in accordance with the terms of the Finance Fee Letter.

(b) If pursuant to Sub-Paragraph (b) of Article 2.6 (*Cancellation*) the Bank cancels all or part of an Accepted Tranche, the Borrower shall pay to the Bank the Cancellation Fee in accordance with the terms of the Finance Fee Letter.

(c) If an Accepted Tranche is not disbursed on the Disbursement Date because the conditions precedent set out in Article 2.5.4 (*All Tranches – Other Conditions*) are not satisfied on such date, such Tranche shall be cancelled and the Borrower shall pay to the Bank the relevant Cancellation Fee in accordance with the terms of the Finance Fee Letter.

2.8 Cancellation after expiry of the Credit

On the day following the Final Availability Date, and unless otherwise specifically agreed to in writing by the Bank, any part of the Credit in respect of which no Disbursement Acceptance has been received in accordance with Article 2.2.3 (*Disbursement Acceptance*) shall be automatically cancelled, without any notice being served by the Bank to the Borrower.

2.9 Standby fee

(a) The Borrower shall pay to the Bank the Standby Fee in accordance with the terms of the Finance Fee Letter.

(b) For the avoidance of doubt, the Standby Fee payable under this Article 2.9 (*Standby fee*) is independent of any other fees stipulated in this Contract.

2.10 Sums due under Article 2

Sums due under this Article 2 shall be payable in EUR. Sums due under this Article 2 shall be payable within [***] days of the Borrower's receipt of the Bank's demand or within any longer period specified in the Bank's demand.

ARTICLE 3

The Loan

3.1 Amount of Loan

The Loan shall comprise the aggregate amount of Tranches disbursed by the Bank under the Credit.

3.2 Currency of repayment, interest and other charges

(a) Interest, Participation Payments, repayments and other charges payable in respect of each Tranche shall be made by the Borrower in EUR.

(b) Any other payment shall be made in the currency specified by the Bank having regard to the currency of the expenditure to be reimbursed by means of that payment.

ARTICLE 4

Interest

4.1 Cash Interest Fixed Rate

The Borrower shall pay interest on the outstanding balance of each Tranche under Credit A and Credit B at the respective Cash Interest Fixed Rate quarterly in arrear on the relevant Payment Dates specified in the Disbursement Offer, and calculated on the basis of Article 6.1 (*Day count convention*). If the period from the Disbursement Date to the first Payment Date is [***] days or less then the payment of interest accrued during such period shall be postponed to the following Payment Date.

4.2 Deferred Interest Fixed Rate

In addition to the interest payable pursuant to Article 4.1 (*Cash Interest Fixed Rate*), interest shall accrue on the outstanding balance of each Tranche under Credit A at the Deferred Interest Fixed Rate, and calculated on the basis of Article 6.1 (*Day count convention*), and such interest shall be due and payable on the Maturity Date of such Tranche or, where such Tranche is cancelled or prepaid, on the date of cancellation or Prepayment Date. For the avoidance of doubt, any such interest shall not be capitalised and shall not bear interest.

4.3 Profit Participation

(a) Subject to Paragraph (b) below and in addition to the interest payable pursuant to Articles 4.1 (*Cash Interest Fixed Rate*) and Article 4.2 (*Deferred Interest Fixed Rate*) above and in consideration of the Bank making the Credit available to the Borrower in accordance with this Contract, the Borrower hereby grants and reserves for the benefit of the Bank, a participation in the Drug Product Revenues for the period starting with the financial year 2023 until and including the financial year 2028 (6 years) (the "**Profit Participation Period**") equal to:

(i) [***]% of the annual Drug Product Revenues below EUR 100,000,000;

(ii) [***]% of the annual Drug Product Revenues between EUR 100,000,000 and EUR 250,000,000; and

(iii) [***]% of the annual Drug Product Revenues between EUR 250,000,000 and EUR 500,000,000,

(the "**Profit Participation Payments**") and hereby undertakes to pay the respective Profit Participation Payments to the Bank subject to the terms of this Contract. For the avoidance of doubt and by way of distinction from a silent partnership (*stille Beteiligung*), the Bank does not participate in any loss of the Borrower or any other Group Company.

(b) The obligation of the Borrower to make Profit Participation Payments pursuant to Paragraph (a) above shall exist only for so long as the Profit Participation Cap is not reached.

(c) Each Profit Participation Payment shall become due and payable on the Payment Date immediately following the delivery date of the Approved Financial Statement for the respective financial year.

(d) In case a Tranche is cancelled or prepaid pursuant to Articles 5.2 (*Voluntary prepayment*) or 5.3 (*Compulsory prepayment*) within the Profit Participation Period, the Bank shall have the right (but not the obligation) to demand from the Borrower the payment of the present value of all future Profit Participation Payments (up to the Profit Participation Cap), as determined by an Independent Expert (the "**Expert Determination**"). The costs related to the Expert's Determination shall be borne by the Borrower and the Expert's Determination shall, in the absence of manifest error, be conclusive and binding on all parties to this Contract as to the matters to which it relates. The Borrower shall, within [***] Business Days of delivery of the Expert's Determination and upon the Bank's demand, pay to the Bank the amount determined by the Expert Determination.

(e) The Borrower shall withhold any statutory withholding tax (*Kapitalertragssteuer*) from the Profit Participation Payments and shall pay it to the competent tax office.

4.4 Interest on overdue sums

(a) Without prejudice to Article 9 (*Events of default*) and by way of exception to Article 4.1 (*Cash Interest Fixed Rate*) and Article 4.2 (*Deferred Interest Fixed Rate*), if the Borrower fails to pay any amount (other than any interest amount) payable by it under the Contract on its due date, interest shall accrue on any such overdue amount (other than any interest amount) from the due date to the date of actual payment at an annual rate equal to:

(i) for overdue sums related to a Tranche, the higher of (A) the applicable Cash Interest Fixed Rate and Deferred Interest Fixed Rate plus [***]% ([***] basis points) or (B) EURIBOR plus [***]% ([***] basis points);

(ii) for overdue sums other than under sub-paragraph (a) of Article 4.4 (*Interest on overdue sums*) above, EURIBOR plus [***]% ([***] basis points),

and shall be payable in accordance with the demand of the Bank.

(b) If the Borrower fails to pay any interest amount payable by it under this Contract on its due date, it shall make a liquidated damages payment (*pauschalierter Schadensersatz*) from the due date up to the date of actual payment at an annual rate equal to the higher of (i) the applicable Fixed Rate plus [***]% ([***] basis points) or (ii) EURIBOR plus [***]% ([***] basis points), provided that the Borrower shall have the right to prove that no damages have arisen, or that damages have not arisen in the asserted amount. The amount determined in accordance with this Article 4.4(b) shall be payable in accordance with the demand of the Bank

For the purpose of determining EURIBOR in relation to this Article 4.4 (*Interest on overdue sums*), the relevant periods within the meaning of Schedule B (*Definition of EURIBOR*) shall be successive periods of one month commencing on the due date.

If the overdue sum is in a currency other than the currency of the Loan, the relevant interbank rate that is generally retained by the Bank for transactions in that currency plus [***]% ([***] basis points) shall apply, calculated in accordance with the market practice for such rate.

ARTICLE 5

Repayment

5.1 Normal repayment

The Borrower shall repay each Tranche, together with all other amounts outstanding under this Contract in relation to that Tranche, in a single instalment on the Maturity Date of that Tranche.

5.2 Voluntary prepayment

5.2.1 Prepayment option

(a) Subject to Articles 5.2.2 (*Prepayment Fee*), 5.2.3 (*Prepayment mechanics*) and 5.4 (*General*), the Borrower may prepay all or part of any Tranche, together with accrued interest (including any interest under Article 4.2 (*Deferred Interest Fixed Rate*), any Profit Participation Payment (up to the Profit Participation Cap) specified under Article 4.3 (*Profit Participation*), any Prepayment Fee and indemnities if any, upon giving a Prepayment Request with at least 30 (thirty) calendar days prior notice specifying:

(i) the Prepayment Amount;

(ii) the Prepayment Date; and

(iii) each Contract Number.

(b) The Prepayment Request shall be irrevocable.

5.2.2 Prepayment Fee

If the Borrower prepays a Tranche, the Borrower shall pay the relevant Prepayment Fee on the Prepayment Date.

5.2.3 Prepayment mechanics

Upon presentation by the Borrower to the Bank of a Prepayment Request, the Bank shall issue a Prepayment Notice to the Borrower, not later than [***] days prior to the Prepayment Date. If the Borrower evidences to the Bank that – taking into account the time for procuring of the Expert Determination - takes longer than [***] days, the Borrower

and the Bank will agree on a longer deadline. The Prepayment Notice shall specify the Prepayment Amount, the accrued interest due thereon, the Prepayment Fee. If the Prepayment Notice specifies Prepayment Fee, it shall also specify the deadline by which the Borrower may accept the Prepayment Notice, and the Borrower must accept the Prepayment Notice no later than such deadline as a condition to prepayment.

The Borrower shall make a prepayment in accordance with the Prepayment Notice and shall accompany the prepayment by the payment of accrued interest (including any interest under Article 4.2 (*Deferred Interest Fixed Rate)* and any Profit Participation Payment specified under Sub-Paragraph (d) of Article 4.3 and Prepayment Fee or indemnity, if any, due on the Prepayment Amount, as specified in the Prepayment Notice, and shall identify each Contract Number in the prepayment transfer.

5.3 Compulsory prepayment

5.3.1 Cost Reduction

If the total cost of the Investment at completion by the final date specified in the Technical Description falls below the figure stated in Recital (A) so that the amount of the Credit exceeds 50% (fifty per cent.) of such total cost, the Bank may forthwith, by notice to the Borrower, cancel the undisbursed portion of the Credit and/or demand prepayment of the Loan Outstanding up to the amount by which the Credit exceeds 50% (fifty per cent.) of the total cost of the Investment.

5.3.2 Change Events

The Borrower shall promptly inform the Bank if:

(a) a Change-of-Control Event has occurred or is likely to occur in respect of itself or a Guarantor; or

(b) a Change-of-Law-Event has occurred or is likely to occur.

In such case, or if the Bank has reasonable cause to believe that a Change-of-Control Event or a Change-of-Law Event has occurred or is likely to occur, the Borrower shall, on request of the Bank, consult with the Bank as to the impact of such event. If [***] days have passed since the date of such request and the Bank is of the reasonable opinion that the effects of such event cannot be mitigated to its satisfaction, or in any event if a Change-of- Control Event or Change-of-Law Event has actually occurred, the Bank may by notice to the Borrower, cancel the undisbursed portion of the Credit and/or demand prepayment of the Loan Outstanding, together with accrued interest (if any) and all other amounts accrued or outstanding under this Contract.

5.3.3 Illegality

If it becomes unlawful in any applicable jurisdiction for the Bank to perform any of its obligations as contemplated in this Contract or to fund or maintain the Loan, the Bank shall promptly notify the Borrower and may immediately cancel the undisbursed portion of the Credit and/or demand prepayment of the Loan Outstanding, together with accrued interest (if any) and all other amounts accrued or outstanding under this Contract.

5.3.4 Disposals

If the Borrower disposes of assets forming part of the Investment or shares in subsidiaries holding assets forming part of the Investment, neither with the approval of the Bank nor in accordance with Sub-Paragraph (c) of Paragraph 7 (*Disposal of assets*) of Schedule H (*General Undertakings*), the Borrower shall apply all proceeds of such disposal to prepay the Loan Outstanding (in part or in whole), together with accrued interest (if any), promptly following receipt of such proceeds.

5.3.5 Expiry of Guarantee Agreement

If (a) a Guarantee Agreement has a shorter duration than this Contract (as modified, extended and/or prolonged from time to time) and (ii) on the date falling [***] days prior to the initial expiry date or, as the case may be, to any subsequent expiry date agreed under the Guarantee Agreement, the Borrower has failed to procure extension of the duration of the obligations of the Guarantor under the Guarantee Agreement or, as the case may be, to replace the Guarantor by another guarantor on terms acceptable to the Bank or provide additional security for the Loan in manner, form and substance satisfactory to the Bank, the Bank may, without prejudice to its other rights, require the Borrower to prepay the Loan Outstanding (in part or in whole), together with accrued interest (if any) and all other amounts accrued or outstanding under this Contract.

5.3.6 Pari Passu to Non-EIB Financing

(a) If a Voluntary Non EIB Prepayment has occurred the Bank may, by notice to the Borrower, cancel the undisbursed portion of the Credit and demand prepayment of the Loan; or

(b) If (i) a Voluntary Non EIB Prepayment is likely to occur, (ii) the Bank has requested a consultation in respect of such Voluntary Non EIB Prepayment, (iii) the Borrower has complied with such request (to the satisfaction of the Bank) and (iv) at least [***] days have passed since the date of such request, the Bank may, by notice to the Borrower, cancel the undisbursed portion of the Credit and demand prepayment of the Loan.

(c) If (i) a Voluntary Non EIB Prepayment is likely to occur, (ii) the Bank has requested a consultation in respect of such Voluntary Non EIB Prepayment, (iii) the Borrower has not complied with such request within a reasonable period set by the Bank and (iv) at least [***] days have passed since the date of such request, the Bank may, by notice to the Borrower, cancel the undisbursed portion of the Credit and demand prepayment of the Loan.

The proportion of the Loan that the Bank may require to be prepaid shall in each case of Paragraphs (a) to (c) above be the same as the proportion that the prepaid amount of the Non-EIB Financing bears to the aggregate outstanding amount of all Non-EIB Financing.

5.3.7 Prepayment Fee

In the case of a Prepayment Event in relation to a Tranche, the Borrower shall pay the relevant Prepayment Fee.

5.3.8 Prepayment mechanics

Any sum demanded by the Bank pursuant to Articles 5.3.1 (*Cost Reduction*) to 5.3.6 (*Pari Passu to Non-EIB Financing*) shall be paid on the date indicated by the Bank in its notice of demand, such date being a date falling not less than [***] days from the date of the demand (or, if earlier, the last day of any applicable grace period permitted by law in respect of the event in Article 5.3.3 (*Illegality*)).

5.4 General

(a) A repaid or prepaid amount may not be reborrowed.

(b) If the Borrower prepays a Tranche on a date other than a relevant Payment Date, or if the Bank exceptionally accepts, solely upon the Bank's discretion, a Prepayment Request with prior notice of less than [***] calendar days, the Borrower shall pay to the Bank an administrative fee in such an amount as the Bank shall notify to the Borrower.

ARTICLE 6

Payments

6.1 Day count convention

Any amount due under this Contract and calculated in respect of a fraction of a year shall be determined based on a year of 360 (three hundred and sixty) days and a month of 30 (thirty) days.

6.2 Time and place of payment

(a) If neither this Contract nor the Bank's demand specifies a due date, all sums other than sums of interest, indemnity and principal are payable within [***] days of the Borrower's receipt of the Bank's demand.

(b) Each sum payable by the Borrower under this Contract shall be paid to the following account:

Bank:	[***]
City:	[***]
Account number:	[***]
SWIFT Code/BIC:	[***]
Remark:	[***]

or such other account notified by the Bank to the Borrower.

(c) The Borrower shall provide each Contract Number as a reference for each payment made under this Contract.

(d) Any disbursements by and payments to the Bank under this Contract shall be made using account(s) acceptable to the Bank. Any duly authorised financial institution in the jurisdiction where the Borrower is incorporated or where the Investment is undertaken is deemed an acceptable account bank and any account in the name of the Borrower with such account bank is deemed acceptable to the Bank.

6.3 No set-off by the Borrower

All payments to be made by the Borrower under this Contract shall be calculated and be made without (and free and clear of any deduction for) set-off or counterclaim, unless the counterclaim is undisputed (*unbestritten*) or has been confirmed in a final non-appealable judgement (*rechtskräftig festgestellt*).

6.4 Disruption to Payment Systems

If either the Bank determines (in its discretion) that a Disruption Event has occurred or the Bank is notified by the Borrower that a Disruption Event has occurred:

(a) the Bank may, and shall if requested to do so by the Borrower, consult with the Borrower with a view to agreeing with the Borrower such changes to the operation or administration of the Contract as the Bank may deem necessary in the circumstances;

(b) the Bank shall not be obliged to consult with the Borrower in relation to any changes mentioned in Sub-Paragraph (a) of Article 6.4 (*Disruption to Payment* Systems) above if, in its opinion, it is not practicable to do so in the circumstances and, in any event, shall have no obligation to agree to such changes; and

(c) the Bank shall not be liable for any damages, costs or losses whatsoever arising as a result of a Disruption Event or for taking or not taking any action pursuant to or in connection with this Article 6.4 (*Disruption to Payment Systems*).

6.5 Application of sums received

6.5.1 General

Sums received from the Borrower shall only discharge its payment obligations if and when received in accordance with the terms of this Contract.

6.5.2 Partial payments

If the Bank receives a payment that is insufficient to discharge all the amounts then due and payable by the Borrower under this Contract, the Bank shall apply that payment in or towards payment of:

(a) first, any unpaid fees, costs, indemnities and expenses due under this Contract;

(b) secondly, any accrued interest due but unpaid under this Contract;

(c) thirdly, any principal due but unpaid under this Contract;

(d) fourthly, any Profit Participation Payments due but unpaid under this Contract; and

(e) lastly, any other sum due but unpaid under this Contract.

6.5.3 Allocation of sums related to Tranches

In case of receipt of sums which cannot be identified as applicable to a specific Tranche, and on which there is no agreement between the Bank and the Borrower on their application, the Bank may apply these between Tranches at its discretion.

ARTICLE 7

Borrower undertakings and representations

(a) The Borrower makes the representations and warranties set out in Schedule G (*Representations and Warranties*) to the Bank on the date of this Contract in respect of itself and, where applicable, the other Obligors.

(b) The Repeating Representations are deemed to be made by the Borrower (in respect of itself and, where applicable, the other Obligors) on the date of each Disbursement Acceptance, each Disbursement Date and each Payment Date by reference to the facts and circumstances then existing.

(c) The undertakings in Schedule H (*General Undertakings*) and Schedule I (*Information and Visits*) remain in force from the date of this Contract for so long as any amount is outstanding under this Contract or the Credit is available.

ARTICLE 8

Charges and expenses

8.1 Taxes, duties and fees

(a) The Borrower shall pay all Taxes, duties, fees (including any notarial andpre-agreed legal fees) and other impositions of whatsoever nature, including stamp duty and registration fees, arising out of the execution or implementation of each Finance Document or any related document and the creation, perfection, registration of any security for the Loan.

(b) The Borrower shall pay all Taxes, duties fees (including any notarial and legal fees) and other impositions whatsoever nature, including stamp duty and registration fees, arising out of the amendment, preservation of any rights under or enforcement of any Finance Document and any security for the Loan to the extent applicable.

(c) The Borrower shall pay all principal, interest, Profit Participation Payments, indemnities and other amounts due under this Contract gross without any withholding or deduction of any national or local impositions whatsoever, provided that if the Borrower is required by law or an agreement with a governmental authority or otherwise to make any such withholding or deduction, it will gross up the payment to the Bank so that after withholding or deduction, the net amount received by the Bank is equivalent to the sum due.

8.2 Other charges

The Borrower shall bear all charges and expenses, including any notarial and legal fees, professional, banking or exchange charges incurred in connection with the preparation, execution, implementation, enforcement and termination of the Finance Documents (including, but not limited to, any Guarantee Agreement entered into pursuant to Paragraph

16 (*Guarantees*) of Schedule H (*General Undertakings*)) or any related document, any amendment, supplement or waiver in respect of the Finance Documents or any related document, and in the amendment, creation, management, enforcement and realisation of any security for the Loan.

The Bank shall provide documentary support for any such charges or expenses upon the Borrower's request.

8.3 Increased costs, indemnity and set-off

(a) The Borrower shall pay to the Bank any costs or expenses incurred or suffered by the Bank as a consequence of the introduction of or any change in (or in the interpretation, administration or application of) any law or regulation or compliance with any law or regulation which occurs after the date of this Contract, in accordance with or as a result of which (i) the Bank is obliged to incur additional costs in order to fund or perform its obligations under this Contract, or (ii) any amount owed to the Bank under this Contract or the financial income resulting from the granting of the Credit or the Loan by the Bank to the Borrower is reduced or eliminated. This Paragraph (a) does not apply to the extent any such costs or expenses are attributable to the wilful breach by the Bank of any law or regulation.

(b) Without prejudice to any other rights of the Bank under this Contract or under any applicable law, the Borrower shall indemnify and hold the Bank harmless from and against any loss incurred as a result of any full or partial discharge that takes place in a manner other than as expressly set out in this Contract.

(c) The Bank may set off any matured obligation due from the Borrower under any Finance Document (to the extent beneficially owned by the Bank) against any satisfiable (*erfüllbar*) obligation (within the meaning of Section 387 BGB) owed by the Bank to the Borrower regardless of the place of payment, booking branch or currency of either obligation. If the obligations are in different currencies, the Bank may convert either obligation at a market rate of exchange in its usual course of business for the purpose of the set-off. If either obligation is unliquidated or unascertained, the Bank may set off in an amount estimated by it in good faith to be the amount of that obligation.

ARTICLE 9

Events of default

9.1 Right to demand repayment

The Bank may demand (in writing) without prior notice or any judicial or extra judicial step immediate repayment by the Borrower of all or part of the Loan Outstanding (as requested by the Bank), together with accrued interest, any Profit Participation Payment, any Prepayment Fee and all other accrued or outstanding amounts under this Contract, if:

(a) any amount payable pursuant to any Finance Document is not paid on the due date at the place and in the currency in which it is expressed to be payable, unless (i) its failure to pay is caused by an administrative or technical error or a Disruption Event and (ii) payment is made within [***] Business Days of its due date;

(b) any information or document given to the Bank by or on behalf of any Obligor or any representation, warranty or statement made or deemed to be made by the Borrower in any Finance Document, pursuant to any Finance Document or for the purposes of entering into any Finance Document is or proves to have been incorrect, incomplete or misleading in any material respect;

(c) following any default of any Obligor in relation to any loan, or any obligation arising out of any financial transaction, other than the Loan,

(i) such Obligor is required or is capable of being required or will, following expiry of any applicable contractual grace period, be required or be capable of being required to prepay, discharge, close out or terminate ahead of maturity such other loan or obligation; or

(ii) any financial commitment for such other loan or obligation is cancelled or suspended; and

(iii) such other loans or obligations or commitments falling under sub-paragraphs (i) and/or (ii) above are in an aggregate principal amount in excess of EUR [***] euro) or its equivalent in any other currency or currencies;

(d) any Obligor is unable or admits inability to pay its debts as they fall due, or suspends any of its debts, or makes or seeks to make a composition with its creditors including a moratorium, or commences negotiations with one or more of its creditors with a view to rescheduling any of its financial indebtedness;

(e) any corporate action, legal proceedings or other procedure or step is taken in relation to the suspension of payments, a moratorium of any indebtedness, dissolution, administration or reorganisation (by way of voluntary arrangement, scheme of arrangement or otherwise) or an order is made or an effective resolution is passed for the winding up of any Obligor, or if any Obligor takes steps towards a substantial reduction in its capital, is declared insolvent or ceases or resolves to cease to carry on the whole or any substantial part of its business or activities or any situation similar to any of the above occurs under any applicable law;

(f) any Obligor incorporated in Germany is unable to pay its debts as they fall due (*zahlungsunfähig*) within the meaning of Section 17 InsO or is overindebted (*überschuldet*) within the meaning of Section 19 InsO;

(g) an encumbrancer takes possession of, or a receiver, liquidator, administrator, administrative receiver or similar officer is appointed, whether by a court of competent jurisdiction or by any competent administrative authority or by any person, of or over, any part of the business or assets of any Obligor or any property forming part of the Investment;

(h) any Obligor defaults in the performance of any obligation in respect of any other loan granted by the Bank or financial instrument entered into with the Bank;

(i) any Obligor defaults in the performance of any obligation in respect of any other loan made to it from the resources of the Bank or the European Union;

(j) any distress, execution, sequestration or other process is levied or enforced upon the property of any Obligor or any property forming part of the Investment and is not discharged or stayed within [***] days;

(k) a Material Adverse Change occurs, as compared with the position at the date of this Contract;

(l) it is or becomes unlawful for any Obligor to perform any of its obligations under the Finance Documents, or the Finance Documents are not effective in accordance with its terms or is alleged by any Obligor to be ineffective in accordance with its terms; or

(m) any Obligor fails to comply with any other provision under the Finance Documents (including, without limitation, each of the undertakings in Schedule H (*General Undertakings*) and Schedule I (*Information and Visits*)), unless the non-compliance or circumstance giving rise to the non-compliance is capable of remedy and is remedied within [***] Business Days from the earlier of the Borrower becoming aware of the non-compliance and a notice served by the Bank on the Borrower.

9.2 Other rights at law

Article 9.1 (*Right to demand repayment*) shall not restrict any other right of the Bank at law (e.g. pursuant to Sections 314 or 490 BGB) to require prepayment of the Loan Outstanding together with any sum, interest, fee or accrued amount, irrespectively of the fact that the Contract might convert into a so called settlement contractual relationship (*Abwicklungsschuldverhältnis*).

9.3 Prepayment Fee

In case of demand under Article 9.1 (*Right to demand repayment*), the Borrower shall pay the Bank the amount demanded together with the relevant Prepayment Fee.

9.4 Non-Waiver

No failure or delay or single or partial exercise by the Bank in exercising any of its rights or remedies under this Contract shall be construed as a waiver of such right or remedy. The rights and remedies provided in this Contract are cumulative and not exclusive of any rights or remedies provided by law.

ARTICLE 10

Law and jurisdiction, miscellaneous

10.1 Governing Law

This Contract and any non-contractual obligations arising out of or in connection with it shall be governed by the laws of Germany.

10.2 Jurisdiction

(a) The courts of Frankfurt am Main, Germany, have exclusive jurisdiction to settle any dispute (a "**Dispute**") arising out of or in connection with this Contract (including a dispute regarding the existence, validity or termination of this Contract or the consequences of its nullity) or any non-contractual obligation arising out of or in connection with this Contract.

(b) The parties agree that the courts of Frankfurt am Main, Germany, are the most appropriate and convenient courts to settle Disputes between them and, accordingly, that they will not argue to the contrary.

(c) This Article 10.2 (*Jurisdiction*) is for the benefit of the Bank only. As a result and notwithstandingSub-Paragraph (a) above, it does not prevent the Bank from taking proceedings relating to a Dispute in any other courts with jurisdiction. To the extent allowed by law, the Bank may take concurrent proceedings in any number of jurisdictions.

10.3 Place of performance

Unless otherwise specifically agreed by the Bank in writing, the place of performance under this Contract, shall be the seat of the Bank.

10.4 Evidence of sums due

In any legal action arising out of this Contract the certificate of the Bank as to any amount or rate due to the Bank under this Contract shall, in the absence of manifest error, be prima facie evidence of such amount or rate.

10.5 Third party rights

A person who is not a party to this Contract has no right to enforce or to enjoy the benefit of any term of this Contract (no*echter Vertrag zugunsten Dritter* within the meaning of Section 328 para. 1 BGB).

10.6 Entire Agreement

This Contract (together with the other Finance Documents) constitutes the entire agreement between the Bank and the Borrower in relation to the provision of the Credit hereunder, and supersedes any previous agreement, whether express or implied, on the same matter.

10.7 Invalidity

If at any time any term of this Contract is or becomes illegal (*nichtig*), invalid or unenforceable in any respect, or this Contract is or becomes ineffective (*unwirksam*) in any respect, under the laws of any jurisdiction, such illegality (*Nichtigkeit*), invalidity, unenforceability or ineffectiveness (*Unwirksamkeit*) shall indisputably (*unwiderlegbar*) not affect:

(a) the legality, validity or enforceability in that jurisdiction of any other term of this Contract or the effectiveness in any other respect of this Contract in that jurisdiction; or

(b) the legality, validity or enforceability in other jurisdictions of that or any other term of this Contract or the effectiveness of this Contract under the laws of such other jurisdictions,

without any party to this Contract having to argue (*darlegen*) and prove (*beweisen*) such parties' intent to uphold this Contract even without the void, invalid or ineffective provisions.

The illegal, invalid, unenforceable or ineffective provision shall be deemed replaced by such legal, valid, enforceable and effective provision that in legal and economic terms comes closest to what the Parties intended or would have intended in accordance with the purpose of this Contract if they had considered the point at the time of conclusion of this Contract. The same applies in the event that this Contract or any other Finance Document does not contain a provision which it needs to contain in order to achieve the economic purpose as expressed herein (*Regelungslücke*).

10.8 Amendments

Any amendment to this Contract (including this Article 10.8) or any other Finance Document shall be made in writing (or in notarial form, if required) and shall be signed by the parties hereto.

10.9 Counterparts

This Contract may be executed in any number of counterparts, all of which taken together shall constitute one and the same instrument. Each counterpart is an original, but all counterparts shall together constitute one and the same instrument.

10.10 Assignment and transfer by the Bank

(a) Subject to sub-paragraph (b) of this Article 10.10 (*Assignment and transfer by the Bank*), the consent of the Borrower is required for an assignment or transfer (by way of assumption of contract (*Vertragsübernahme*), sub-participation or otherwise) by the Bank of all or part of its rights, benefits or obligations under the Finance Documents, unless the assignment or transfer:

(i) is to a Bank Affiliate; or

(ii) is made at a time when an Event of Default has occurred and is continuing; or

(iii) is made in respect of a sub-participation or securitisation (or similar transaction of broadly equivalent economic effect) where the Bank remains the lender of record of the Loan.

(b) The consent of the Borrower to an assignment or transfer must not be unreasonably withheld or delayed. The Borrower will be deemed to have given its consent [***] Business Days after the Bank has requested it unless consent is expressly refused by the Borrower within that time.

(c) The Bank shall have the right to disclose all information relating to or concerning the Borrower, the Group, the Finance Documents and the Loan in connection with or in contemplation of any such assignment or transfer.

For the purpose of this Article 10.10 (*Assignment and transfer by the Bank*):

"Affiliate" means any entity directly or indirectly Controlling, Controlled by or under common Control with the Bank.

"Bank Affiliate" means an Affiliate of the Bank and any other entity or platform initiated, managed or advised by the Bank.

ARTICLE 11

Final Articles

11.1 Notices

11.1.1 Form of notice

(a) Any notice or other communication given under this Contract must be in writing and, unless otherwise stated, may be made by letter and electronic mail.

(b) Notices and other communications for which fixed periods are laid down in this Contract or which themselves fix periods binding on the addressee, may be made by hand delivery, registered letter or by electronic mail. Such notices and communications shall be deemed to have been received by the other party:

(i) on the date of delivery in relation to a hand-delivered or registered letter;

(ii) in the case of any electronic mail, when the electronic mail is received in readable form.

(c) Any notice provided by the Borrower or a Guarantor to the Bank by electronic mail shall:

(i) mention each Contract Number in the subject line; and

(ii) be in the form of a non-editable electronic image (pdf, tif or other common non-editable file format agreed between the parties) of the notice signed by one or more Authorised Signatories of the Borrower as appropriate, attached to the electronic mail.

(d) Notices issued by the Borrower pursuant to any provision of this Contract shall, where required by the Bank, be delivered to the Bank together with satisfactory evidence of the authority of the person or persons authorised to sign such notice on behalf of the Borrower and the authenticated specimen signature of such person or persons, unless such person is listed in the then current List of Authorised Signatories.

(e) Without affecting the validity of electronic mail or communication made in accordance with this Article 11.1 (*Notices*), the following notices, communications and documents shall also be sent by registered letter to the relevant party at the latest on the immediately following Business Day:

(i) Disbursement Acceptance;

(ii) any notices and communication in respect of the cancellation of a disbursement of any Tranche, Prepayment Request, Prepayment Notice, Event of Default, any demand for prepayment, and

(iii) any other notice, communication or document required by the Bank.

(f) The parties agree that any above communication (including via electronic mail) is an accepted form of communication, shall constitute admissible evidence in court and shall have the same evidential value as an agreement under hand.

(g) Any communication or document made or delivered to the Borrower in accordance with this Article 11.1 (*Notices*) will be deemed to have been made or delivered to each of the Obligors or any other member of the Group party to a Finance Document. Each Obligor incorporated in Germany, for this purpose, appoints the Borrower as its receipt agent (*Empfangsboten*).

11.1.2 Addresses

The address and electronic mail address (and the department or officer, if any, for whose attention the communication is to be made) of each party for any communication to be made or document to be delivered under or in connection with this Contract is:

For the Bank	Attention: OPS/ENPST/3-GC&IF
	100 boulevard Konrad Adenauer
	L-2950 Luxembourg
	Email address: [***]
For the Borrower	Attention: Department/Division
	Chief Financial Officer (CFO)
	An der Goldgrube 12
	D-55131 Mainz
	Germany
	Email address: [***]

11.1.3 Demand after notice to remedy

The Bank and the Borrower shall promptly notify the other party in writing of any change in their respective communication details.

11.2 English language

(a) Any notice or communication given under or in connection with this Contract must be in English.

(b) To the extent required by local law, Security Documents shall be in the language required under the relevant local law; in particular any documentation in relation to the Land Charge to be filed with the land register (*Grundbuchamt*) shall be in German.

(c) All other documents provided under or in connection with this Contract must be:

(i) in English; or

(ii) if not in English, and if so required by the Bank, accompanied by a certified English translation and, in this case, the English translation will prevail.

11.3 Conclusion of this Contract (*Vertragsschluss*)

(a) The parties to this Contract may choose to conclude this Contract by an exchange of signed signature page(s), transmitted by any means of telecommunication (*telekommunikative Übermittlung*) such as by way of electronic photocopy.

(b) If the parties to this Contract choose to conclude this Contract pursuant to this Article 11.3 (*Conclusion of this Contract (Vertragsschluss)*), they will transmit the signed signature page(s) of this Contract to Noerr LLP, Börsenstr. 1, 60313 Frankfurt am Main, Germany, [***] (each a "**Recipient**"). The Contract will be considered concluded once a Recipient has actually received the signed signature page(s) (*Zugang der Unterschriftsseite(n)*) from all Parties (whether electronic photocopy or other means of telecommunication and at the time of the receipt of the last outstanding signature page(s) by such one Recipient).

(c) For the purposes of this Article 11.3 (*Conclusion of this Contract (Vertragsschluss)*) only, the parties to this Contract appoint each Recipient as their attorney (*Empfangsvertreter*) and expressly allow (*gestatten*) each Recipient to collect the signed signature page(s) from all and for all parties to this Contract. For the avoidance of doubt, each Recipient will have no further duties connected with its position as Recipient. In particular, each Recipient may assume the conformity to the authentic original(s) of the signature page(s) transmitted to it by means of telecommunication, the genuineness of all signatures on the original signature page(s) and the signing authority of the signatories. (d) For the purposes of proof and confirmation, each party to this Contract has to provide the Recipients with original signature page(s) promptly after signing this Contract in accordance with this Article 11.3 (*Conclusion of this Contract (Vertragsschluss)*). The Bank may demand that the Borrower subsequently sign one or more copies of this Contract.

IN WITNESS WHEREOF the parties hereto have caused this Contract to be executed in three (3) originals (two (2) originals for the Bank and one (1) original for the Borrower) in the English language.

Signed for and on behalf of		Signed for and on behalf of
EUROPEAN INVESTMENT BANK		BIONTECH SE
[***]	[***]	[***]

Investment Specification and Reporting

A.1 Technical Description

Purpose, Location

[***]

Description

[***]

Calendar

[***]

A.2 Information Duties

The information below has to be sent to the Bank under the responsibility of:

	Financial & Technical Contact
Company	BioNTech SE
Contact person	[***]
Title	[***]
Address	An der Goldgrube 12, D-55131 Mainz, Germany
Phone	[***]
Email	[***]

The above-mentioned contact person is the responsible contact for the time being. The Borrower shall inform the EIB immediately in case of any change.

Information on the project's implementation

The Borrower shall deliver to the Bank the following information on project progress during implementation at the latest by the deadline(s) indicated below.

Document / information	**Deadline**	**Frequency of reporting**
Project Progress Report [***]	[***]	*Bi-annually*

Information on the end of works and first year of operation

The Borrower shall deliver to the Bank the following information on project completion and initial operation at the latest by the deadline indicated below.

Document / information	Date of delivery to the Bank
[***]	[***]
Language of reports	*English*

Definition of EURIBOR

"**EURIBOR**" means:

(a) in respect of a relevant period of less than one month, the Screen Rate (as defined below) for a term of one month;

(b) in respect of a relevant period of one or more months for which a Screen Rate is available, the applicable Screen Rate for a term for the corresponding number of months; and

(c) in respect of a relevant period of more than one month for which a Screen Rate is not available, the rate resulting from a linear interpolation by reference to two Screen Rates, one of which is applicable for a period next shorter and the other for a period next longer than the length of the relevant period,

(the period for which the rate is taken or from which the rates are interpolated being the '**Representative Period**").

For the purposes of Paragraphs (b) and (c) above, "available" means the rates, for given maturities, that are calculated and published by Global Rate Set Systems Ltd (GRSS), or such other service provider selected by the European Money Markets Institute (EMMI), under the sponsorship of EMMI and EURIBOR ACI, or any successor to that function of EMMI and EURIBOR ACI as determined by the Bank.

"**Screen Rate**" means the rate of interest for deposits in EUR for the relevant period as published at 11h00, Brussels time, or at a later time acceptable to the Bank on the day (the "**Reset Date**") which falls 2 (two) Relevant Business Days prior to the first day of the relevant period, on Reuters page EURIBOR 01 or its successor page or, failing which, by any other means of publication chosen for this purpose by the Bank.

If such Screen Rate is not so published, the Bank shall request the principal euro-zone offices of four major banks in the euro-zone, selected by the Bank, to quote the rate at which EUR deposits in a comparable amount are offered by each of them as at approximately 11h00, Brussels time, on the Reset Date to prime banks in the euro-zone interbank market for a period equal to the Representative Period. If at least 2 (two) quotations are provided, the rate for that Reset Date will be the arithmetic mean of the quotations.

If fewer than 2 (two) quotations are provided as requested, the rate for that Reset Date will be the arithmetic mean of the rates quoted by major banks in the euro-zone, selected by the Bank, at approximately 11h00, Brussels time, on the day which falls 2 (two) Relevant Business Days after the Reset Date, for loans in EUR in a comparable amount to leading European Banks for a period equal to the Representative Period.

If no rate is available as provided above, EURIBOR shall be the rate (expressed as a percentage rate per annum) which is determined by the Bank to be the all-inclusive cost to the Bank for the funding of the relevant Tranche based upon the then applicable internally generated Bank reference rate or an alternative rate determination method reasonably determined by the Bank.

For the purposes of the foregoing definitions:

(a) All percentages resulting from any calculations referred to in this Schedule B (*Definition of EURIBOR*) will be rounded, if necessary, to the nearest one thousandth of a percentage point, with halves being rounded up.

(b) The Bank shall inform the Borrower without delay of the quotations received by the Bank.

(c) If any of the foregoing provisions becomes inconsistent with provisions adopted under the aegis of EMMI and EURIBOR ACI (or any successor to that function of EMMI and EURIBOR ACI as determined by the Bank), the Bank may by notice to the Borrower amend the provision to bring it into line with such other provisions.

Schedule C

Form of Disbursement Offer/Acceptance

To: BioNTech SE

From: European Investment Bank

Date:

Subject: Disbursement Offer/Acceptance for the Finance Contract between European Investment Bank and BioNTech SE dated 12 December 2019 (the "**Finance Contract**")

Contract Number [***] and [***] Serapis Number [***]

Dear Sirs,

We refer to the Finance Contract. Terms defined in the Finance Contract have the same meaning when used in this letter.

Following your request for a Disbursement Offer from the Bank, in accordance with Article 2.2.2 (*Disbursement Offer*) of the Finance Contract, we hereby offer to make available to you the following Tranche:

(a) Credit: [A / B]

(b) Amount to be disbursed:

(c) Disbursement Date:

(d) Cash Interest Fixed Rate (if applicable):

(e) Deferred Interest Fixed Rate (if applicable):

(f) Payment Dates / interest periods: [●] / quarterly

(g) Terms and frequency for repayment of principal:

(h) Maturity Date:

To make the Tranche available subject to the terms and conditions of the Finance Contract, the Bank must receive a Disbursement Acceptance in the form of a copy of this Disbursement Offer duly signed on your behalf, to the following electronic mail [●] no later than the Disbursement Acceptance Deadline of [*time*], Luxembourg time, on [*date*].

The Disbursement Acceptance below must be signed by an Authorised Signatory and must be fully completed as indicated, to include the details of the Disbursement Account.

If not duly accepted by the above stated time, the offer contained in this document shall be deemed to have been refused and shall automatically lapse.

If you do accept the Tranche as described in this Disbursement Offer, all the related terms and conditions of the Finance Contract shall apply, in particular, the provisions of Article 2.5 (*Conditions of Disbursement*).

Yours faithfully,

EUROPEAN INVESTMENT BANK

[*On letterhead of the Borrower*]

We hereby accept the above Disbursement Offer for and on behalf of the Borrower:

Date:

Account to be credited:

Account N°:

Account Holder/Beneficiary:

(please, provide IBAN format if the country is included in IBAN Registry published by SWIFT, otherwise an appropriate format in line with the local banking practice should be provided)

Bank name, identification code (BIC) and address:

Payment details to be provided:

Please transmit information relevant to:

Name(s) of the Borrower's Authorised Signatory(ies):

Signature(s) of the Borrower's Authorised Signatory(ies):

Name(s)/Title(s):

IMPORTANT NOTICE TO THE BORROWER:

BY COUNTERSIGNING ABOVE YOU CONFIRM THAT THE LIST OF AUTHORISED SIGNATORIES AND ACCOUNTS PROVIDED TO THE BANK WAS DULY UPDATED PRIOR TO THE PRESENTATION OF THE ABOVE DISBURSEMENT OFFER BY THE BANK.

IN THE EVENT THAT ANY SIGNATORIES OR ACCOUNTS APPEARING IN THIS DISBURSEMENT ACCEPTANCE ARE NOT INCLUDED IN THE LATEST LIST OF AUTHORISED SIGNATORIES AND ACCOUNTS RECEIVED BY THE BANK, THE ABOVE DISBURSEMENT OFFER SHALL BE DEEMED AS NOT HAVING BEEN MADE.

Form of Drawdown Certificate

To: European Investment Bank From:

Date: BioNTech SE

Subject: Finance Contract between European Investment Bank and BioNTech SE dated 12 December 2019 (the "**Finance Contract**")

Contract Number [***] and [***] Serapis Number [***]

Dear Sirs,

Terms defined in the Finance Contract have the same meaning when used in this letter.

For the purposes of Article 2.5 (*Conditions of Disbursement*) of the Finance Contract we hereby certify to you as follows:

(a) no Prepayment Event has occurred and is continuing;

(b) no security of the type prohibited under Paragraph 23 (*Negative pledge*) of Schedule H (*General Undertakings*) has been created or is in existence;

(c) there has been no material change to any aspect of the Investment or in respect of which we are obliged to report under the Finance Contract, save as previously communicated by us;

(d) no Default, Event of Default or a Prepayment Event other than pursuant to Article 5.3.1 (*Cost Reduction*) of the Finance Contract has occurred or is continuing, or would, in each case, result from the disbursement of the proposed Tranche;

(e) no litigation, arbitration administrative proceedings or investigation is current or to our knowledge and belief (having made due and careful enquiry) is threatened or pending before any court, arbitral body or agency which has resulted or if adversely determined is reasonably likely to result in a Material Adverse Change, nor is there subsisting against us or any of our subsidiaries any unsatisfied judgement or award;

(f) the Repeating Representations are correct in all respects;

(g) no Material Adverse Change has occurred, as compared with the situation at the date of the Finance Contract; and

(h) the borrowing of the Credit, or any part thereof, by the Borrower is within the corporate powers of the Borrower.

Yours faithfully,

For and on behalf of BioNTech SE

Date:
Name(s)/Title(s):

Form of Compliance Certificate

To: European Investment Bank

From: BioNTech SE

Date:

Subject: Finance Contract between European Investment Bank and BioNTech SE dated 12 December 2019 (the "**Finance Contract**")

Contract Number [***] and [***] Serapis Number [***]

Dear Sirs,

We refer to the Finance Contract. This is a Compliance Certificate. Terms defined in the Finance Contract have the same meaning when used in this Compliance Certificate.

We hereby confirm:

(a) [insert information regarding asset disposal];

(b) [no security of the type prohibited under Paragraph 23 (*Negative pledge*) of Schedule H (*General Undertakings*) has been created or is in existence; and]

(c) [no Default, Event of Default or a Prepayment Event other than pursuant to Article 5.3.1 (Cost Reduction) of the Finance Contract has occurred or is continuing. [*If this statement cannot be made, this certificate should identify any potential event of default that is continuing and the steps, if any, being taken to remedy it*].

Yours faithfully,

For and on behalf of BioNTech SE

Date:
Name(s)/Title(s):

Part A - Initial Documentary Conditions Precedent and Credit A Conditions Precedents

(a) The following, duly executed Finance Documents:

(i) originals of this Contract;

(ii) originals of the Guarantee Agreements;

(iii) originals of each Security Document, including an enforceable copy (*vollstreckbare Ausfertigung*) of the Land Charge Creation Deed; and

(iv) original of the Fee Letters.

(b) The constitutional documents of each Obligor, being in relation to an Obligor incorporated in Germany electronic copies of (i) an up-to-date (dated no earlier than the date falling [***] days before the Disbursement Date) electronic extract from the commercial register (*Handelsregisterauszug*), (ii) its articles of association (*Gesellschaftsvertrag*) and copies of any by-laws and rules of procedures (*Geschäftsordnungen*) and (iii) its list of shareholders (*Gesellschafterliste*) or list of supervisory board members (if applicable).

(c) A copy of the resolution of the competent body (board of directors (*Vorstand*), supervisory board (*Aufsichtsrat*), administrative board (*Verwaltungsrat*) or general meeting of shareholders (*Gesellschafterversammlung*)) of each Obligor:

(i) approving the terms of, and the transactions contemplated by, the Finance Documents to which it is a party as and duly authorising the execution of the Finance Documents to which it is a party;

(ii) duly authorising the relevant signatories to execute the Finance Documents to which it is a party on its behalf; and

(iii) authorising a signatory or signatories, on its behalf, to sign and/or despatch all documents and notices to be signed and/or despatched by it under or in connection with the Finance Documents to which it is a party.

(d) An up-to-date (dated no earlier than the date falling [***] days before the Disbursement Date) structure chart showing the Group certified as being complete and correct by an Authorised Signatory of the Borrower.

(e) A certificate of an Authorised Signatory of each Obligor certifying that each copy document relating to it specified in Paragraph (b) and (c) of this Part A of Schedule F (*Initial Documentary Conditions Precedent and Credit A Conditions Precedents*) is correct, complete and in full force and effect as at a date no earlier than the date falling 14 (fourteen) days before the first Disbursement Date.

(f) The List of Authorised Signatories and Accounts.

(g) A legal enforceability opinion of Noerr LLP, addressed to the Bank on the legality, validity and enforceability of the Finance Documents and including statements as to no consents, registrations or filings are required and no stamp duty is to be paid in respect of the Finance Documents, choice of law and enforceability of judgments.

(h) A legal enforceability opinion of Arendt & Medernach, addressed to the Bank on the legality, validity and enforceability of the Finance Fee Letter under Luxembourg law;

(i) A legal opinion of Osborne Clarke Rechtsanwälte Steuerberater Partnerschaft mbB, legal adviser to the Borrower, addressed to the Bank, and dated no earlier than the date falling [***] days before the Disbursement Date:

(i) which includes an insolvency search on www.insolvenzbekanntmachungen.de on the relevant Obligor conducted on the date of such legal opinion; and

(ii) on the valid existence of each Obligor, the authority and capacity of each Obligor to enter into the Finance Documents and perform its obligations thereunder, non-conflict with constitutional documents and on laws applicable to companies generally in Germany, all corporate and other action required to be taken has indeed been taken, the due execution of the Finance Documents and that the Obligor is not entitled to claim immunity.

(j) The latest audited financial statements of the Obligors.

(k) Evidence of payment of all the fees (including lawyer fees) and expenses as required under the Finance Documents.

(l) Evidence satisfactory to the Bank of the fulfilment of the following milestones (the "**Credit A Milestone Events**"):

(i) achievement of a series B equity raise of at least USD [***] (already achieved at the date of this Contract and fulfilled);

(ii) delivery of a copy of (A) the written completion notification (*Fertigstellungsmitteilung*) or the acceptance report (*Abnahmeprotokoll*) of the new [***] (for the avoidance of doubt, without the [***]); and

(iii) granting of the Land Charge, by way of a certified land register excerpt (*Grundbuchauszug*) for the Property, evidencing the registration of the Land Charge in favour of the Bank.

(m) A copy of any other document, authorisation, opinion or assurance which the Bank has notified the Borrower is necessary or desirable in connection with the entry into and performance of, and the transactions contemplated by, the Finance Documents or the validity and enforceability of the same.

Part B – Credit B Conditions Precedent

(a) Credit A has been fully drawn.

(b) Evidence satisfactory to the Bank of the fulfilment of the following milestones (the "**Credit B Milestone Events**"):

(i) commencement of three additional clinical trials after the end of H1 2019 (two in phase 1 and one beyond phase 1);

(ii) cumulative equity raised in an amount of USD [***] (in addition to the series B equity raise evidenced under the Credit A Milestone Events); and

(iii) conclusion (*Vertragsschluss*) of one or more new partnership agreements/equity deals since end of H1 2019 with a pharmaceutical company, a biotech company or similar companies of international reputation, or institutions that primarily invest in the area of pharmaceuticals, biotechnology or public health, with combined upfront or initial cash contributions of at least USD [***]. In the case of equity investments, these are to be in addition to those evidenced under the Credit A Milestone Events and the Credit B Milestone Events (already achieved at the date of this Contract).

Part C – Guarantor Conditions Precedent

(a) The duly executed Guarantee Agreement or, as applicable, accession letter to the Guarantee Agreement.

(b) The constitutional documents of such Guarantor(s).

(c) If applicable, an original of a certificate of incorporation and an encumbrance certificate of the Guarantor(s) not incorporated or established in Germany ("**Non- German Guarantor**") dated no more than [***] Business Days from the date of execution of the Guarantee Agreement or accession letter to the Guarantee Agreement (as applicable) (or any equivalent document in the jurisdiction of incorporation of such Non-German Guarantor(s)).

(d) A copy of the resolution of the competent body (board of directors, supervisory board (*Aufsichtsrat*), administrative body (*Verwaltungsrat*), advisory board (*Beirat*) or general meeting of shareholders (*Gesellschafterversammlung*)) of each Obligor:

(i) approving the terms of, and the transactions contemplated by, the Finance Documents to which it is a party as and duly authorising the execution of the Finance Documents to which it is a party;

(ii) duly authorising the relevant signatories to execute the Finance Documents to which it is a party on its behalf; and

(iii) authorising a signatory or signatories, on its behalf, to sign and/or despatch all documents and notices to be signed and/or despatched by it under or in connection with the Finance Documents to which it is a party.

(e) A certificate of an authorised signatory of the respective Guarantor(s) certifying that each copy document relating to it specified in Paragraphs (b) to (d) of this Part C of Schedule F is correct, complete and in full force and effect as at a date no earlier than the date of their/its entry into or accession to the Guarantee Agreement, including a specimen of the signature of each person authorised by the resolution in Paragraph (d) above and, if applicable, confirming that guaranteeing or securing, as appropriate, the Loan would not cause any guarantee, security or similar limit or restriction binding on it to be exceeded.

(f) A legal opinion of a reputable law firm, addressed to the Bank, on the valid existence of the Guarantor(s), the authority and capacity of the Guarantor(s) to enter into or accede to the Guarantee Agreement (and execute its/their obligations therein) and on the due execution of the Guarantee Agreement (or the accession letter).

(g) Copies of such documentation and other evidence as the Bank may request to carry out and be satisfied with the results of all necessary "know your customer" requirements or other checks in relation to the identity of any person that it is required (in order to comply with applicable money laundering laws and regulations) to carry out in relation to the concerned Guarantor(s).

(h) A copy of any other document, authorisation, opinion or assurance which the Bank has notified the Borrower or the respective Guarantor is necessary or desirable in connection with the entry into and performance of, and the transactions contemplated by, the Guarantee Agreement or the validity and enforceability of the same.

Representations and Warranties

1. Authorisations and Binding Obligations

(a) Each Obligor is duly incorporated and validly existing as a corporation or company with limited liability under the laws of its jurisdiction of incorporation.

(b) The place of incorporation or establishment of each Obligor is not (a) a jurisdiction classified by any Lead Organisation as being weakly regulated and/or weakly supervised and/or non-transparent and/or uncooperative or any equivalent classification used by any Lead Organisation, in connection with activities such as money laundering, financing of terrorism, tax fraud and tax evasion or harmful tax practices, and/or (b) a jurisdiction that is blacklisted by any Lead Organisation in connection with such activities.[1]

(c) Each Obligor has the power to carry on its business as it is now being conducted and to own its property and other assets, and to execute, deliver and perform its obligations under the Finance Documents.

(d) Each Obligor has obtained all necessary Authorisations in connection with the execution, delivery and performance of the Finance Documents and in order to lawfully comply with its obligations thereunder, and in respect of the Investment, and all such Authorisations are in full force and effect and admissible in evidence.

(e) The execution and delivery of, the performance of each Obligor's obligations under and compliance with the provisions of the Finance Documents do not and will not contravene or conflict with:

(i) any applicable law, statute, rule or regulation, or any judgement, decree or permit to which it is subject;

(ii) any agreement or other instrument binding upon it which might reasonably be expected to have a material adverse effect on its ability to perform its obligations under the Finance Documents; or

(iii) any provision of its constitutional documents.

(f) The obligations expressed to be assumed by each Obligor in each Finance Document to which it is a party are legal, valid, binding and enforceable obligations.

2. No default or other adverse event

(a) There has been no Material Adverse Change since [***]. *(Non-repeating)*

(b) No event or circumstance which constitutes an Event of Default has occurred and is continuing unremedied or unwaived.

---

1 Relevant jurisdictions may be identified on the basis of lists of Lead Organisations, as such lists are updated, amended or supplemented from time to time, including: jurisdictions with strategic deficiencies in the area of AML-CFT as identified by FATF (http://www.fatf-gafi.org/countries/#high-risk); jurisdictions listed "partially compliant", "provisionally partially compliant" or "non-compliant" in the OECD Global Forum progress reports/ Global Forum rating (http://www.oecd.org/tax/transparency/GFratings.pdf; http://www.oecd.org/tax/transparency/exchange-of-information-on-request/ratings/); jurisdictions identified in EU delegated regulation 2016/1675 of 14.7.2016 supplementing Directive (EU) 2015/849 as high-risk third countries with strategic deficiencies

(http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32016R1675); and jurisdictions included in the EU list of non-cooperative jurisdictions for tax purposes (https://ec.europa.eu/taxation_customs/tax-common-eu-list_en).

3. No proceedings

(a) No litigation, arbitration, administrative proceedings or investigation is current or to the best of its knowledge and belief (having made due and careful enquiry) is threatened or pending before any court, arbitral body or agency which has resulted or if adversely determined is reasonably likely to result in a Material Adverse Change, nor is there subsisting against it or any of its Subsidiaries any unsatisfied judgement or award. (*Non-repeating*)

(b) To the best of its knowledge and belief (having made due and careful enquiry) no material Environmental Claim has been commenced or is threatened against any Obligor.

(c) As at the date of this Contract, no Obligor has taken any action to commence proceedings for, nor have any other steps been taken or legal proceedings commenced or, so far as the Borrower is aware, threatened against any Obligor for its insolvency, winding up or dissolution, or for any Obligor to enter into any arrangement or compositions for the benefit of creditors, or for the appointment of an administrator, receiver, administrative receiver, examiner, trustee or similar officer.

4. Security

It is the sole legal and beneficial owner and has good title to the assets which it charges or purports to charge pursuant to the Security Documents. At the date of this Contract, no Security exists over the assets of any Group Company other than Permitted Security.

5. Ranking

(a) Its payment obligations under this Contract rank not less than *pari passu* in right of payment with all other present and future secured and unsubordinated obligations under any of its debt instruments except for obligations mandatorily preferred by law applying to companies generally.

(b) No financial covenants have been concluded with any other creditor of any Obligor.

(c) No Voluntary Non-EIB Prepayment has occurred.

6. Anti-Corruption

(a) Each Obligor is in compliance with all applicable European Union and national legislation, including any applicable anti-corruption legislation.

(b) To the best of its knowledge, no funds invested in the Investment by any Obligor or any other Group Company are of illicit origin, including products of money laundering or linked to the financing of terrorism.

(c) No Obligor is engaged in any Illegal Activities and to the best of the Borrower's knowledge no Illegal Activities have occurred in connection with the Investment. (*Non-repeating*)

7. Accounting and Tax

(a) The latest available consolidated and unconsolidated audited accounts of the Borrower and the other Obligors have been prepared on a basis consistent with previous years and have been approved by its auditors as representing a true and fair view of the results of its operations for that year and accurately disclose or reserve against all the liabilities (actual or contingent) of the Borrower and the other Obligors, as relevant.

(b) The accounting reference date of the Borrower and each Obligor is 31 December.

(c) No Obligor is required to make any deduction for or on account of any Tax from any payment it may make under the Finance Documents, except for withholding tax (*Kapitalertragssteuer*) which have to be deducted pursuant to Article 4.3(e) (*Profit Participation*). (*Non-repeating*)

(d) All Tax returns required to have been filed by each Obligor or on its behalf under any applicable law have been filed when due and contain the information required by applicable law to be contained in them.

(e) Each Obligor has paid when due all Taxes payable by it under applicable law except to the extent that it is contesting payment in good faith and by appropriate means.

(f) With respect to Taxes which have not fallen due or which it is contesting, each Obligor is maintaining reserves adequate for their payment and in accordance, where applicable, with GAAP.

(g) Under the laws of the jurisdiction of incorporation of each Obligor, it is not necessary that the Finance Documents be filed, recorded or enrolled with any court or other authority or that any stamp, registration or similar tax be paid on or in relation to the Finance Documents, or the transactions contemplated by the Finance Documents other than the official certification (*öffentliche Beglaubigung*) of the Land Charge Creation Deed (*Grundschuldbestellungsurkunde*) and payment of related notary fees and the registration of the Land Charge in the land register (*Grundbuch*) and payment of the related registration fees. (*Non-repeating*)

8. Information provided

(a) Any factual information provided by any Group Company for the purposes of entering into this Contract and any related documentation was true and accurate in all material respects as at the date it was provided or as at the date (if any) at which it is stated and continues to be true and accurate in all material respect as at the date of this Contract. (*Non-repeating*)

(b) The Group structure chart is true, complete and accurate in all material respects and represents the complete corporate structure of the Group as at the date of this Contract, and other than as set out therein the Borrower owns no other equity and/or shares in any other business entity. (*Non-repeating*)

9. No indebtedness

No Obligor has Indebtedness outstanding other than Permitted Indebtedness. (*Non-repeating*).

10. No Immunity

No Obligor, nor any of its assets, is entitled to immunity from suit, execution, attachment or other legal process.

11. Pensions

The pension schemes for the time being operated by the Obligors (if any) are funded in accordance with their rules and to the extent required by law or otherwise comply with the requirements of any law applicable in the jurisdiction in which the relevant pension scheme is maintained.

General Undertakings

1. Use of Loan

The Borrower shall use all amounts borrowed by it under the Loan to carry out the Investment.

2. Completion of Investment

The Borrower shall or shall procure that the Investment is carried out in accordance with the Technical Description as may be modified from time to time with the approval of the Bank, and complete it by the final date specified therein.

3. Procurement procedure

The Borrower shall secure goods and services for the Investment (a) in so far as they apply to it or to the Investment, in accordance with EU Law in general and in particular with the relevant EU Directives, and (b) in so far as EU Directives do not apply, by procurement procedures which conform to the relevant requirements set out in the Bank's "Guide to Procurement for projects financed by the EIB (2018)".

4. Compliance with laws

Each Obligor shall comply in all respects with all laws and regulations to which it or the Investment is subject.

5. Environment

The Borrower shall:

(a) implement and operate the Investment in compliance with Environmental Law;

(b) obtain, maintain and comply with requisite Environmental Approvals for the Investment,

and upon becoming aware of any breach of this Paragraph 5 (*Environment*):

(i) the Borrower shall promptly notify the Bank;

(ii) the Borrower and the Bank will consult for up to [***] Business Days from the date of notification with a view to agreeing the manner in which the breach should be rectified; and

(iii) the Borrower shall remedy the breach within [***] Business Days of the end of the consultation period.

6. Integrity

The Borrower shall take, within a reasonable timeframe, appropriate and legally permissible measures in respect of any member of its management bodies who has been convicted by a final and irrevocable court ruling of an Illegal Activity perpetrated in the course of the exercise of his/her professional duties, in order to ensure that such member is excluded from any Borrower's activity in relation to the Loan or the Investment.

7. Disposal of assets

(a) Except as provided under Paragraph (b) below, the Borrower shall not, and shall procure that no Group Company shall, either in a single transaction or in a series of transactions whether related or not and whether voluntarily or involuntarily dispose of all or any part of any Group Company's business, undertaking or assets (including any shares, real estate or security of any entity or a business or undertaking, or any interest in any of them).

(b) Sub-Paragraph (a) above does not apply to any such disposal ("**Permitted Disposal**"):

(i) made with the prior written consent of the Bank;

(ii) made on arm's length terms in the ordinary course of business of a Group Company;

(iii) made on arm's length terms and at fair market value for cash, which is reinvested in assets of comparable or superior type, value and quality;

(iv) made on arm's length terms in exchange for other assets (other than shares, businesses and real estate) comparable or superior as to type, value and quality;

(v) by (A) one Obligor to another Obligor, or (B) a group Company which is not an Obligor to another Group Company which is not an Obligor;

(vi) constituted by a licence of Intellectual Property Rights on arm's length terms in the ordinary course of business of a Group Company;

(vii) made in relation to non-material assets which have depreciated to less than [***] of their initial value or which are obsolete;

(viii) excluding any disposal otherwise permitted under (ii) to (vii) above, disposals where the higher of the market value or consideration receivable for such disposals does not exceed EUR [***] over the lifetime of this Contract; or

(ix) arising as a result of Permitted Security.

(c) A disposal shall in each case only qualify as Permitted Disposal within the meaning of paragraph (b) above, if the relevant disposal is not of assets forming part of the Investment or shares in subsidiaries holding assets forming part of the Investment, which may not be disposed of unless either (i) such disposal is made in accordance with Paragraph (b)(vi) above, (ii) the Borrower consults the Bank in relation to such disposal, and the Bank approves such disposal (such approval not to be unreasonably withheld), or (iii) the proceeds of such disposal are applied to prepay the Bank in accordance with Article 5.3.4 (*Disposals*).

For the purposes of this Paragraph 7 (*Disposal of assets*), "dispose" and "disposal" includes any act effecting sale, transfer, lease or other disposal (*Verfügung*).

8. Maintenance of assets

The Borrower shall maintain, repair, overhaul and renew all assets required in relation to the Investment as required to keep such assets in good working order (ordinary wear and tear excepted).

9. Insurances

The Borrower shall, and shall procure that each Group Company shall, maintain insurances on and in relation to its business and assets with reputable underwriters or insurance companies against those risks and to the extent as is usual for companies carrying on the same or substantially similar business.

10. Change in business

The Borrower shall procure that no substantial change is made to the general nature business of the Borrower or the Group as a whole from that carried on at the date of this Contract.

11. Merger

The Borrower shall not, and shall procure that no Group Company shall, enter into any amalgamation, demerger, merger or corporate reconstruction (including the conclusion of any domination and/or profit and loss transfer agreements (*Beherrschungs- und/oder Gewinnabführungsverträge*) or any other enterprise agreements (*Unternehmensverträge*) with the meaning of section 291 AktG) unless:

(a) with the prior written consent of the Bank; or

(b) such amalgamation, demerger, merger or corporate reconstruction does not result in a Material Adverse Change and is on a solvent basis, and provided that:

(i) only Group Companies are involved and if a Guarantor is involved, the surviving entity will also be or become a Guarantor;

(ii) the resulting entity will not be incorporated or located in a country which is in a jurisdiction that is blacklisted by any Lead Organisation in connection with activities such as money laundering, financing of terrorism, tax fraud and tax evasion or harmful tax practices as such blacklist may be amended from time to time; and

(iii) if the Borrower is involved, (A) the rights and obligations of the Borrower under this Contract will remain with the Borrower, (B) the surviving entity will be the Borrower and the statutory seat of the Borrower would not as a result of such merger be transferred to a different jurisdiction, (C) the merger will not have an effect on the validity, legality or enforceability of the Borrower's obligations under this Contract; and (D) all of the business and assets of the Borrower are retained by it; or

(c) the enterprise value of the company (including any Indebtedness remaining in such company) involved in an amalgamation, demerger, merger or corporate reconstruction not already permitted under Paragraph (b) above (i) does not exceed an amount of EUR [***] in a single transaction and EUR [***] during the Term of the Credit and (ii) provided Paragraphs (b)(ii) and (iii) above are fulfilled.

12. Books and records

Each Obligor shall ensure that it has kept and will continue to keep proper books and records of account, in which full and correct entries shall be made of all financial transactions and its assets and business, including expenditures in connection with the Investment, in accordance with GAAP as in effect from time to time.

13. Ownership

(a) The Borrower shall maintain more than 50% (fifty per cent.) of the share capital, directly or indirectly, of each of its Material Subsidiaries, unless a prior written consent of the Bank is received by the Borrower.

(b) The Borrower shall in aggregate maintain not less than 100% (one hundred per cent.) of the share capital, directly or indirectly, of each Guarantor and each Material Subsidiary, unless:

(i) the percentage of the share capital in the relevant Guarantor or Material Subsidiary at the date of this Contract is lower than 100% (one hundred per cent.) ("**Initial Ownership Stake**"), in which case the Borrower shall maintain such Initial Ownership Stake; or

(ii) prior written consent of the Bank is received by the Borrower.

(c) The Borrower shall immediately notify the Bank in the event of a new entity becoming a Subsidiary of the Borrower through any means, including but not limited to acquisition, creation and spin-off.

(d) The undertakings in Sub-Paragraphs (a), (b) and (c) above shall be calculated in accordance with GAAP as applied by the Borrower on the date of this Contract and as GAAP is amended from time to time and tested annually.

14. Acquisitions

The Borrower shall not, and shall procure that no Group Company shall, invest in (including by way of payment into the capital reserve (*Kapitalrücklage*)) or acquire any entity or a business going concern or an undertaking (whether whole or substantially the whole of the assets or business), or any division or operating unit thereof, or any shares or securities of any entity or a business or undertaking (or in each case, any interest in any of them) (or agree to any of the foregoing), save for an acquisition or investment:

(a) with the prior written consent of the Bank;

(b) by one Obligor of an asset sold, leased, transferred or otherwise disposed of by another Obligor;

(c) by a Group Company of all the shares or other ownership interests in any limited liability company or corporation, limited liability partnership or any equivalent company, provided that:

(i) such entity has not yet commenced commercial operations;

(ii) such entity is incorporated in a country that is a member of either or both of the European Union or the Organisation of Economic Co-Operation and Development; and

(iii) no Event of Default is continuing on the date the relevant acquisition agreement is entered into or would occur as a result of the acquisition; or

(d) of shares or other ownership interests in any limited liability company or corporation, limited liability partnership or any equivalent company, the consideration for which does not exceed an aggregate amount of (x) EUR [***] during any financial year, and (y) EUR [***] during the term of the Credit, provided that:

(i) no Event of Default is continuing on the date the relevant acquisition agreement is entered into or would occur as a result of the acquisition;

(ii) the acquired entity is engaged in a business similar or complementary to the business carried on by the Group as at the date of this Contract;

(iii) the acquired entity is not incorporated or located in a jurisdiction that is blacklisted by any Lead Organisation in connection with activities such as money laundering, financing of terrorism, tax fraud and tax evasion or harmful tax practices as such blacklist may be amended from time to time;

(iv) in respect of any acquisition where the consideration exceeds EUR [***], legal and financial due diligence reports (including customary reliance letters in favour of the Bank) and a business plan (in the form of the most recent budget adjusted for the expected effects of the acquisition) in respect of the [***] next following financial years and any other due diligence reports received in connection with the acquisition (if any) are provided to the Bank; and

(v) the Borrower provides a Compliance Certificate for the [***] month financial periods immediately following the acquisition, updated on a pro forma basis as if the acquisition has occurred.

(e) In relation to Paragraph (d) above the Parties agree, that if:

(i) the EBITDA of the Borrower is positive for the Relevant Period ending on the most recent Semi-Annual Date prior to that acquisition or investment; and

(ii) the revenues of the Borrower exceed EUR [***], (together the "**Replacement Conditions**"), the threshold included:

(i) in Paragraph (d)(x) above will be replaced by a threshold of "[***]% of the Total Assets during any financial year"; and

(ii) in Paragraph (d)(y) above will be replaced by a threshold of "[***]% of the Total Assets during the term of the Credit ",

(together the "**Replaced Thresholds**"), whereby (x) the amounts of already done acquisitions or investments permitted under Paragraphs (a) to (d) above shall count towards the Replaced Thresholds and (y) to the extent and for so long as the Borrower complies with the Replacement Conditions. In case the Borrower does not further comply with any of the Replacement Conditions, the thresholds included in Paragraph (d)(x) and (d)(y) above shall apply again and the Borrower shall use its reasonable best efforts to comply with such thresholds within a reasonable timeframe.

The Borrower shall provide evidence satisfactory to the Bank of the fulfilment of the Replacement Conditions and compliance with the Replacement Conditions upon demand of the Bank.

15. Indebtedness

The Borrower shall not, and shall procure that no other Group Company shall, incur any Indebtedness, save for any Existing Indebtedness and Indebtedness ("**Permitted Indebtedness**"):

(a) incurred with the prior written consent of the Bank;

(b) incurred under this Contract;

(c) under Permitted Hedging;

(d) in respect of a Permitted Guarantee;

(e) owing by an Obligor to another Obligor;

(f) unsecured Indebtedness to trade creditors and, in respect of the German trade creditors, Indebtedness secured by customary retention of title arrangements (*Eigentumsvorbehalte*) incurred in the ordinary course ofday-to-day business; or

(g) not permitted by the preceding Sub-Paragraphs and the outstanding amount of indebtedness (including drawn down EIB debt and other existing outstanding interest-bearing liabilities) which does not exceed 2x the last 12 months EBITDA.

16. Guarantees

(a) The Borrower shall not, and shall procure that no other Group Company shall, issue or allow to remain outstanding any guarantees or sureties (*Bürgschaften*) in respect of any liability or obligation of any person save for:

(i) any guarantee or surety (*Bürgschaft*) under any Security Document or with the prior written consent of the Bank; or

(ii) guarantees or sureties (*Bürgschaften*) issued by any Group Company under or in connection with:

(1) under any negotiable instruments in the ordinary course of trade;

(2) in connection with any performance bond in the ordinary course of trade;

(3) in connection with any Permitted Indebtedness;

(4) issued by one Obligor to another Obligor;

(5) any bank guarantee issued the benefit of a contractor in connection with construction work to secure such contractor's claims (*Bauhandwerkersicherung*);

(6) any guarantee created or subsisting in order to comply with Section 8a of the German Altersteilzeitgesetz (*AltTZG*) or pursuant to Section 7e of the German Social Law Act No. 4 (*Sozialgesetzbuch IV*); or

(7) any guarantees or sureties (*Bürgschaften*) not permitted by the preceding Sub-Paragraphs and the outstanding amount of which does not exceed EUR [***] (or its equivalent) in aggregate for the Group at any time. If and for so long as the Borrower fulfils the Replacement Conditions prior to issuing the guarantee or surety (*Bürgschaft*), the threshold amount of EUR [***] increases to EUR [***]. In case the Borrower does not further comply with any of the Replacement Conditions, the threshold of EUR [***] shall apply again and the Borrower shall use its reasonable best efforts to comply with such threshold within a reasonable timeframe.

(b) The Borrower shall procure that, as soon as any Group Company becomes a Material Subsidiary (as identified in any accounts delivered to the Bank from time to time pursuant to Paragraph 2 (*Information concerning the Borrower*) of Schedule I (*Information and Visits*), that Group Company shall promptly notify the Bank and on the Bank's request enter into a Guarantee Agreement and provide the Bank with the documentary conditions precedent (each in form and substance satisfactory to the Bank) listed in Part C of Schedule F (*Guarantor Conditions Precedent*) within [***] Business Days following the date on which such Group Company qualifies as a Material Subsidiary.

17. Hedging

The Borrower shall not, and shall procure that no other Group Company shall, enter into any derivative transaction other than Permitted Hedging, where "**Permitted Hedging**" means:

(a) any derivative transaction entered into by a Group Company with the prior written consent of the Bank;

(b) any derivative transaction by a Group Company to hedge actual or projected exposure arising in the ordinary course of trading and not for speculative purposes; and

(c) any derivative instrument of a Group Company which is accounted for on a hedge accounting basis but is not entered into for speculative purposes.

18. Restrictions on distributions

The Borrower shall not, and shall procure that no other Group Company shall, declare or distribute dividends, or return or purchase shares, save for:

(a) with the prior written consent of the Bank;

(b) payments to a Group Company as a result of a solvent liquidation or reorganisation of a Group Company which is not an Obligor; and

(c) any dividend payments made by any Subsidiary.

19. Restrictions on loans

The Borrower shall not, and shall ensure that no other member of the Group will, be a creditor in respect of any Indebtedness, save for:

(a) with the prior written consent of the Bank;

(b) any trade credit extended by any member of the Group to its customers on normal commercial terms and in the ordinary course of its trading activities;

(c) any loan made by one member of the Group (other than an Obligor) to another member of the Group;

(d) a loan made by one Obligor to another Obligor;

(e) a loan made by one Obligor to a member of the Group (other than an Obligor) not exceeding an amount of EUR [***] during the Term of the Credit; or

(f) any other Indebtedness or loan advanced to or made available by any member of the Group with the prior written consent of the Bank.

20. Restrictions on intercompany loans

The Borrower shall not, and shall procure that no other Group Company shall, make any payment in respect of any intercompany loan, save for:

(a) with the prior written consent of the Bank;

(b) where the lender of the intercompany loan is the Borrower or an Obligor; or

(c) the payments to a Group Company as a result of a solvent liquidation or reorganisation of a Group Company which is not an Obligor.

21. Intellectual Property Rights

The Borrower shall, and shall procure that each other Group Company shall, (i) obtain, safeguard and maintain its rights with respect to the Intellectual Property Rights required for the implementation of the Investment in accordance with this Contract, including complying with all material contractual provisions and that the implementation of the Investment in accordance with this Contract will not result in the infringement of the rights of any person with regard to the Intellectual Property Rights and (ii) ensure that any Intellectual Property Rights required for the implementation of the Investment will be owned by or licensed to the Borrower, and where such Intellectual Property Rights which are owned by a Group Company are capable of registration, are registered to such party.

22. Maintenance of Status

The Borrower shall, and shall procure that each other Group Company shall, remain duly incorporated and validly existing as a corporate entity with limited liability under the jurisdiction in which it is incorporated and that it will have no centre of main interests, permanent establishment or place of business outside the jurisdiction in which it is incorporated, and that it will continue to have the power to carry on its business as it is now being conducted and continue to own its property and other assets.

23. Negative pledge

(a) The Borrower shall not (and shall procure that no other Group Company shall) create or permit to subsist any Security over any of its assets.

(b) For the purposes of this Paragraph 23 (*Negative pledge*), the term Security shall also include any arrangement or transaction on assets or receivables or money (such as the sale, transfer or other disposal of assets on terms whereby they are or may be leased to or re-acquired by any Group Company, the sale, transfer or other disposal of any receivables on recourse terms or any arrangement under which money or the benefit of a bank account or other account may be applied or set off or any preferential arrangement having a similar effect) in circumstances where the arrangement or transaction is entered into primarily as a method of raising credit or of financing the acquisition of an asset.

(c) Sub-Paragraph (a) above does not apply to any Existing Security and any Security, listed below ("**Permitted Security**"):

(i) any Security created under the Security Documents in favour of the Bank;

(ii) any netting or set-off arrangement entered into by any Group Company in the ordinary course of its banking arrangements for the purpose of netting debit and credit balances and any Security arising under general business conditions (*Allgemeine Geschäftsbedingungen*) of banks or financial institutions;

(iii) any payment or close out netting or set-off arrangement pursuant to any Permitted Hedging, but excluding any Security under a credit support arrangement in relation to a hedging transaction;

(iv) any Security arising by operation of law and in the ordinary course of trading;

(v) any Security over or affecting any asset acquired by Group Company after the date of this Contract if:

(1) the Security was not created in contemplation of the acquisition of that asset by a Group Company;

(2) the principal amount secured has not been increased in contemplation of or since the acquisition of that asset by a Group Company; and

(3) the Security is removed or discharged within [***] months of the date of acquisition of such asset;

(vi) any Security over or affecting any asset of any company which becomes a Group Company after the date of this Contract, where the Security is created prior to the date on which that company becomes a Group Company, if:

(1) the Security was not created in contemplation of the acquisition of that company;

(2) the principal amount secured has not increased in contemplation of or since the acquisition of that company; and

(3) the Security is removed or discharged within [***] months of that company becoming a Group Company;

(vii) any Security entered into pursuant to this Contract;

(viii) any Security arising under any retention of title (including extended retention of title (*verlängerter Eigentumsvorbehalt*)), hire purchase or conditional sale arrangement or arrangements having similar effect in respect of goods supplied to a Group Company in the ordinary course of trading and on the supplier's standard or usual terms and not arising as a result of any default or omission by any Group Company;

(ix) in respect of the Property to the extent restrictions on further charges are prohibited by Section 1136 BGB;

(x) in respect of the Property interests, rights, easements or other matter whatsoever evidenced in section II of the land register (*Grundbuch*) as reflected in the copy of the land register excerpt (*Grundbuchauszug*) provided to the Bank;

(xi) any Security created or subsisting in order to comply with Section 8a of the German Altersteilzeitgesetz (*AltTZG*) or pursuant to Section 7e of the German Social Law Act No. 4 (*Sozialgesetzbuch IV*);

(xii) any contractor's lien arising by operation of law (*Werkunternehmerpfandrecht*) in connection with repairs and maintenance work and any landlord's pledge (*Vermieterpfandrecht*) arising by operation of law under a lease in favour of the relevant third party landlord; or

(xiii) any Security securing indebtedness the principal amount of which (when aggregated with the principal amount of any other indebtedness which has the benefit of Security given by a Group Company other than any permitted under sub-paragraphs (i) to (xii) above) does not exceed EUR [***] during the term of this Credit. In relation to this Paragraph (xiii) the Parties agree, that if and for so long as the Borrower fulfils the Replacement Conditions prior to providing the security, the threshold in this Paragraph (xiii) will be replaced by a threshold constituting the lesser of (A) [***]% of the Total Assets during any financial year, and (B) EUR [***].

24. Other Undertakings

The Borrower shall take note of the Bank's group statement on tax fraud, tax evasion, tax avoidance, aggressive tax planning, money laundering and financing of terrorism (as published on the Bank's website and as may be amended from time to time).

25. Clauses by inclusion

If the Borrower or any Group Company concludes with any other secured and unsubordinated creditor a financing agreement that includes a loss-of-rating clause or a covenant or other provision regarding its financial ratios, if applicable, that is not provided for in this Contract or is more favourable to the relevant creditor than any equivalent provision of this Contract is to the Bank, the Borrower shall promptly inform the Bank and shall provide a copy of the more favourable provision to the Bank. The Bank may request that the Borrower promptly executes an agreement to amend this Contract so as to provide for an equivalent provision in favour of the Bank.

Information and Visits

1. Information concerning the Investment

Subject to Paragraph 5 below:

(a) The Borrower shall deliver to the Bank:

(i) the information in content and in form, and at the times, specified in Part A.2 (*Information Duties*) of Schedule A (*Investment Specification and Reporting*) or otherwise as agreed from time to time by the parties to this Contract;

(ii) any such information or further document concerning the Investment as the Bank may require to comply with its obligations under the EFSI Regulation; and

(iii) any such information or further document concerning the financing, procurement, implementation, operation and environmental matters of or for the Investment as the Bank may reasonably require within a reasonable time;

provided always that if such information or document is not delivered to the Bank on time, and the Borrower does not rectify the omission within a reasonable time set by the Bank in writing, the Bank may remedy the deficiency, to the extent feasible, by employing its own staff or a consultant or any other third party, at the Borrower's expense and the Borrower shall provide such persons with all assistance necessary for the purpose.

(b) The Borrower shall submit for the approval of the Bank without delay any material changes to the Investment, also taking into account the disclosures made to the Bank in connection with the Investment prior to the signing of this Contract, in respect of, inter alia, the total cost, plans, timetable or to the expenditure programme or financing plan for the Investment.

(c) The Borrower shall promptly inform the Bank of:

(i) any action initiated or any objection raised by any third party or any genuine complaint received by the Borrower or any Environmental Claim that is to its knowledge commenced, pending or threatened against it with regard to environmental or other matters affecting the Investment; and

(ii) any fact or event known to the Borrower, which may substantially prejudice or affect the Borrower's ability to execute the Investment;

(iii) a genuine allegation, complaint or information with regard to Illegal Activities related to the Loan and/or the Investment;

(iv) any non-compliance by it with any applicable Environmental Law; and

(v) any suspension, revocation or modification of any Environmental Approval,

and set out the action to be taken with respect to such matters;

(d) If the total cost of the Investment exceeds the estimated figure set out in Recital (A), the Borrower shall notify the Bank without delay and shall inform the Bank of its plans to fund the increased costs.

(e) The Borrower shall, and shall procure that each other Group Company shall, promptly inform the Bank if at any time it becomes aware of the illicit origin (including products of money laundering or linked to the financing of terrorism) of any funds invested in the Investment by the Borrower or another Group Company.

(f) The Borrower shall provide to the Bank, if so requested:

(i) a certificate of its insurers showing that all assets required in order to carry out the Investment are insured with reputable underwriters or insurance companies against those risks and to the extent as is usual for companies carrying on the same or substantially similar business; and

(ii) annually, a list of policies in force covering any aspect of the Investment, together with confirmation of payment of the current premiums.

2. Information concerning the Borrower

Subject to Paragraph 5 below:

(a) The Borrower shall deliver to the Bank:

(i) as soon as they become available but in any event within [***] months after the end of each of its financial years its audited consolidated and unconsolidated annual report, balance sheet, cash flow statement, profit and loss account and auditors report for that financial year (the "**Approved Financial Statements**") together with a Compliance Certificate signed by 2 (two) directors (*Vorstände*) and the unconsolidated financial statements (audited, if available) of each Obligor for such financial year;

(ii) as soon as they become available but in any event within [***] months after the end of each of the relevant accounting periods its interim consolidated and unconsolidated semi-annual report, balance sheet, profit and loss account and cash flow statement for the first half-year of each of its financial years together with a Compliance Certificate signed by [***] directors (*Vorstände*);

(iii) from time to time, such further information, evidence or document concerning its general financial situation or such certificates of compliance with the undertakings of Article 7 (*Borrower undertakings and representations*) as the Bank may reasonably deem necessary or may reasonably require to be provided within a reasonable time;

(iv) any such information or further document concerning customer or any other type of due diligence matters of, or for, the Borrower or the Group, including without limitation to comply with "Know your customer" (KYC) or similar identification procedures as the Bank may deem necessary or may reasonably require to be provided within a reasonable time; and

(v) from time to time, such further information, evidence or document concerning the factual information or documents provided to the Bank for the purposes of entering into this Contract, as the Bank may deem necessary or may require to be provided within a reasonable time.

(b) The Borrower shall deliver to the Bank as soon as possible but in any event within [***] days after the start of each half-year a budget for that half-year ("**Budget**"). The Borrower shall ensure that each Budget:

(i) includes [***];

(ii) is prepared in all material respects in accordance with GAAP and the accounting practices and financial reference periods applied to the consolidated financial statements of the Group; and

(iii) has been approved by Authorised Signatories of the Borrower.

(c) the Borrower shall inform the Bank immediately of:

(i) any Default or Event of Default having occurred or being threatened or anticipated;

(ii) to the extent permitted by law, any material litigation, arbitration, administrative proceedings or investigation carried out by a court, administration or similar public authority, which, to the best of its knowledge and belief is current, threatened or pending:

(1) against any Obligor or its controlling entities or members of the Borrower's management bodies in connection with Illegal Activities related to the Loan or the Investment; or

(2) which would if adversely determined result in a Material Adverse Change;

(iii) to the extent permitted by any law applicable to the Borrower, any measure taken by the Borrower pursuant to Paragraph 6 (*Integrity*) of Schedule H (*General Undertakings*);

(iv) any change in the beneficial ownership of the Borrower and any material update of or change to the Budget; and

(v) any Voluntary Non EIB Prepayment that has occurred or is likely to occur.

3. Visits by the Bank

(a) Each Obligor shall allow the Bank and, when either required by the relevant mandatory provisions of EU law or pursuant to the EFSI Regulation, the competent EU institutions, including the European Court of Auditors, the Commission, the European Anti-Fraud Office, as well as persons designated by the foregoing;

(i) to visit during normal business hours with prior notice, except in cases of emergency, the sites, installations and works comprising the Investment;

(ii) to interview representatives of each Obligor, and not obstruct contacts with any other person involved in or affected by the Investment; and

(iii) to conduct such on the spot audits and checks as they may wish and review the Obligors' books and records in relation to the execution of the Investment and to be able to take copies of related documents to the extent not prohibited by the law.

(b) Each Obligor shall provide the Bank, or ensure that the Bank is provided, with all necessary assistance for the purposes described in this Paragraph 3 (*Visits by the Bank*).

(c) In the case of a genuine allegation, complaint or information with regard to Illegal Activities related to the Loan and/or the Investment, the Borrower shall consult with the Bank in good faith regarding appropriate actions. In particular, if it is proven that a third party committed Illegal Activities in connection with the Loan and/or the Investment with the result that the Loan or the EFSI financing were misapplied, the Bank may, without prejudice to the other provisions of this Contract, inform the Borrower if, in its view, the Borrower should take appropriate recovery measures against such third party. In any such case, the Borrower shall in good faith consider the Bank's views and keep the Bank informed.

4. Disclosure and publication

(a) The Bank acknowledges and agrees that the Borrower may be obliged to disclose the terms of this Contract and make any other public written disclosure regarding the existence of, or performance under, this Contract, to the extent required, in the reasonable opinion of BioNTech's legal counsel, to comply with (i) law, statute or regulation applicable to the Borrower, including the rules and regulations promulgated by the United States Securities and Exchange Commission or (ii) any equivalent governmental authority, securities exchange or securities regulator in any country shares of the Borrower are listed. Before disclosing this Contract or any of the terms hereof pursuant to this Paragraph 4(a), the Borrower will inform the Bank with at least [***] Business Days prior notice of the intended disclosure and will consult with the Bank in making any such disclosure acceptable to the Bank. Further, if the Borrower discloses this Contract or any of the terms hereof in accordance with this Paragraph 4(a), the Borrower will, at its own expense, seek such confidential treatment of confidential portions of this Contract and limit its disclosure of such terms to that the extent required to comply with law, statute or regulation applicable to the Borrower.

(b) The Borrower acknowledges and agrees that:

(i) the Bank may be obliged to communicate information relating to any Obligor and the Investment to any competent institution or body of the European Union in accordance with the relevant mandatory provisions of European Union law or pursuant to the EFSI Regulation; and

(ii) the Bank may publish in its website or produce press releases containing information related to the financing provided pursuant to this Contract with support of the EFSI, including the name, address and country of establishment of the Borrower the purpose of the financing, and the type and amount of financial support received under this Contract.

To the extent legally and practically possible, the Bank shall communicate and/or publish such information only upon prior coordination with the Borrower. To the extent the Bank has coordinated such communication/publication with the Borrower, the Borrower will ensure that to the same extent and at the same time such information is made available to the United States Securities and Exchange Commission.

(c) The Borrower agrees to cooperate with the Bank to ensure that any press releases or publications made by the Borrower regarding the financing and the Investment include an appropriate acknowledgement of the financial support provided by the Bank with the backing of the European Union through EFSI.

(d) The Obligors are entitled and, if requested by the Bank, each Obligor undertakes to refer to this financing and other Bank financings in its public communications, if appropriate, during the availability period, and in connection with any drawdowns, and communications on major corporate events.

5. Confidential information

Where the Borrower provides information to the Bank in connection with this Contract, it shall clearly indicate whether such information is already public or being maintained by the Borrower as confidential information. If regulated or prohibited by applicable legislation including the rules and regulations promulgated by the United States Securities and Exchange Commission and securities law relating to insider dealing and market abuse, the Borrower will not share (and is not obliged to do so) any inside information with the Bank before it is published to the market. For the avoidance of doubt, the Parties agree that the Borrower shall only be required to provide information to the Bank to the extent legally permissible and in particular in compliance with applicable laws on inside information. The Bank is not responsible or liable for any determination as to whether any information provided or to be provided to it is non-public information the use of which may be regulated or prohibited by applicable law or regulation relating to insider dealing or otherwise.

Schedule J

Existing Indebtedness

1. Indebtedness in connection with a secured EUR 10,000,000 loan agreement dated 21 November 2017 and entered into by BioNTech Innovative Manufacturing Services GmbH as borrower and Deutsche Bank AG as lender.

2. Indebtedness in connection with a secured EUR 9,450,000 loan agreement dated 18 July 2018 and entered into by JPT Peptide Technologies GmbH as borrower and Deutsche Bank AG as lender.

Schedule K

Existing Security

1) EUR 10,000,000.00 loan agreement dated 21 November 2017 with BioNTech Innovative Manufacturing Services GmbH as borrower and Deutsche Bank AG as lender.

   - First-priority land charges (*Grundschulden*) of EUR 10,000,000 on commercial property (*Betriebsimmobilie*) in 55743 Idar-Oberstein, Germany, Idar-Oberstein [***], granted by BioNTech Innovative Manufacturing Services GmbH;
   - [***];
   - [***].

2) EUR 9,450,000 loan agreement dated 18 July 2018 with JPT Peptide Technologies GmbH as borrower and Deutsche Bank AG as lender.

   - First-priority land charges (*Grundschulden*) of EUR 9,450,000 on commercial property *(Betriebsimmobilie)* Berlin-Adlershof; Germany, [***], granted by JPT Peptide Technologies GmbH;
   - [***];
   - [***].

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

FINANCE FEE LETTER

From: European Investment Bank
100 boulevard Konrad Adenauer
L-2950 Luxembourg
Grand Duchy of Luxembourg

(the "**Bank**")

To: BioNTech SE
An der Goldgrube 12
55131 Mainz
Germany

(the "**Borrower**")

Date: 12 December 2019

Subject: Finance Contract between European Investment Bank and BioNTech SE dated on or about 12 December 2019

Contract numbers (FI No) 90272 and 91603; Serapis No.: 2018-0810

Dear Sirs

We refer to the EUR 50,000,000 finance contract dated 12 December 2019 between the Bank as lender and the Borrower (the "**Finance Contract**").

This Finance Fee Letter is a Fee Letter as referred to in the Finance Contract.

1. **DEFINITIONS**

1.1 Terms defined in the Finance Contract shall have the same meaning when used in this Fee Letter, unless a contrary indication appears. This Fee Letter is a Finance Document.

1.2 In this Fee Letter:

"**Cancellation Fee**" means, in relation to the cancellation of an Accepted Tranche by the Borrower underSub-Paragraph (a) of Article 2.6 (*Cancellation*) of the Finance Contract, or in relation to an amount cancelled by the Bank underSub-Paragraphs (b) or (c) of Article 2.6 (*Cancellation*) of the Finance Contract, a fee of 2% (200 basis points) of the cancelled amount.

2. **STANDBY FEE**

2.1 If no Disbursement Offer is made by the Bank within [***] years from the date of the Finance Contract or in case the Credit is cancelled in full under Article 2.6 (*Cancellation*) of the Finance Contract prior to the expiry of this term, the Borrower shall pay to the Bank aone-off contractual fee equal to 1% (100 basis points) of the Credit (the "**Standby Fee**").

2.2 The Standby Fee shall be payable by the Borrower to the Bank within [***] days of the Borrower's receipt of the Bank's demand or within any longer period specified in the Bank's demand.

3. **CANCELLATION FEE**

If the Borrower pursuant to Article 2.7(a) (*Fee for cancellation of an Accepted Tranche*) or the Bank pursuant to Article 2.7(b) (*Fee for cancellation of an Accepted Tranche*) or Article 2.7(c) (*Fee for cancellation of an Accepted Tranche*) of the Finance Contract cancels an Accepted Tranche, the Borrower shall pay to the Bank the relevant Cancellation Fee.

4. **MISCELLANEOUS**

4.1 The provisions of Article 2.10 (*Sums due under Article 2*) and Article 8.1 (*Taxes, duties and fees*) of the Finance Contract shall apply to all payments made or to be made under this Fee Letter.

4.2 If the date on which a fee under this Fee Letter is due to be paid is not a Relevant Business Day, payment shall be made on the next Relevant Business Day.

5. **COUNTERPARTS**

This Fee Letter may be executed in any number of counterparts, and this has the same effect as if the signatures on the counterparts were on a single copy of this Fee Letter.

6. **GOVERNING LAW**

This Fee Letter and any non-contractual obligations arising out of or in connection with it are governed by Luxembourg law. The parties submit to the exclusive jurisdiction of the Luxembourg courts.

If you agree to the above, please sign, date and return to the Bank the enclosed copy of this Fee Letter.

Yours faithfully

[***]	[***]
Name: [***]	Name: [***]
Title: [***]	Title: [***]

For and on behalf of
European Investment Bank

We acknowledge and agree to the above:

[***]	[***]
Name: [***]	Name: [***]
Title: [***]	Title: [***]

For and on behalf of
BioNTech SE

Exhibit 21.1

Subsidiary	Jurisdiction of Incorporation
BioNTech RNA Pharmaceuticals GmbH	Germany
BioNTech Protein Therapeutics GmbH	Germany
BioNTech Diagnostics GmbH	Germany
BioNTech Small Molecules GmbH	Germany
BioNTech Business Services GmbH	Germany
BioNTech Innovative Manufacturing Services GmbH	Germany
JPT Peptide Technologies GmbH	Germany
BioNTech Cell & Gene Therapies GmbH	Germany
BioNTech Real Estate Holding GmbH	Germany
BioNTech Real Estate Verwaltungs GmbH	Germany
BioNTech Real Estate GmbH & Co. KG	Germany
BioNTech Austria Beteiligungen GmbH	Austria
reBOOST Management GmbH	Germany
JPT Inc.	Delaware
BioNTech USA Holding, LLC	Delaware
BioNTech Research and Development Inc.	Delaware
Endor Lights, Inc.	Delaware