**Filed pursuant to Rule 424(b)(3)**
**Registration No. 333-237515**

MERGER PROPOSED—YOUR VOTE IS VERY IMPORTANT

April 2, 2020

Dear Stockholder:

As previously announced, on January 15, 2020, Neon Therapeutics, Inc., or Neon, entered into an Agreement and Plan of Merger, or, as amended, modified or otherwise supplemented from time to time, the Merger Agreement, with BioNTech SE, a *Societas Europaea* organized and existing under the laws of Germany, or BioNTech and Endor Lights, Inc., a Delaware corporation and a direct, wholly-owned subsidiary of BioNTech, or Merger Sub. Under the Merger Agreement, Merger Sub will merge with and into Neon, with Neon continuing as the surviving corporation and a wholly-owned subsidiary of BioNTech, or the Merger. Before Neon completes the Merger, Neon stockholders must approve and adopt the Merger Agreement. Neon stockholders will vote to approve and adopt the Merger Agreement and approve related matters as more fully described in this proxy statement/prospectus at Neon's virtual special meeting of stockholders, which will be held on May 4, 2020, at 10:00 a.m. Eastern Time, or the Neon Special Meeting. In light of COVID-19 (coronavirus) and to support the well-being of our stockholders and partners, the Neon Special Meeting will be completely virtual. You may attend the meeting, submit questions and vote your shares electronically during the meeting via live webcast by visiting www.virtualshareholdermeeting.com/NTGN2020. You will need the control number that is printed on your proxy card to enter the Neon Special Meeting. We recommend that you log in at least 15 minutes before the meeting to ensure you are logged in when the Neon Special Meeting starts. Please note that you will not be able to attend the Neon Special Meeting in person.

If the Merger is completed, each share of Neon common stock, par value $0.001 per share, or the Neon common stock, that was issued and outstanding immediately prior to the effective time of the Merger, excluding shares owned by the parties to the Merger Agreement, will be converted into the right to receive 0.063 American Depositary Shares of BioNTech, or the BioNTech ADSs, and such number of BioNTech ADSs, referred to as the Exchange Ratio, without interest, but subject to any withholding under applicable law, plus the right, if any, to receive cash in lieu of fractional shares of BioNTech ADSs, or collectively, the Merger Consideration. Although the Exchange Ratio for the Merger Consideration is fixed, the market value of the Merger Consideration will fluctuate with the market price of the BioNTech ADSs. Based on the closing price of the BioNTech ADSs on January 15, 2020, the last trading day before the public announcement of the signing of the Merger Agreement, the implied aggregate value of the Merger Consideration is approximately $67 million, or $2.18 per share of Neon common stock. Based on the closing price of the BioNTech ADSs on March 26, 2020, the last practicable date before the date of this proxy statement/prospectus, the implied aggregate value of the Merger Consideration will be up to approximately $107.2 million, or $3.47 per share of Neon common stock, depending on the number of options to purchase Neon common stock exercised prior to the closing of the Merger. **We urge you to obtain current market quotations of the BioNTech ADSs and Neon common stock.**

BioNTech estimates that it may issue up to approximately 1,949,458 BioNTech ADSs to Neon stockholders in the Merger pursuant to the Merger Agreement. The BioNTech ADSs and the shares of Neon common stock are each listed on the Nasdaq Global Select Market, or Nasdaq, under the trading symbols "BNTX" and "NTGN," respectively. Upon completion of the Merger, Neon will no longer be a publicly held corporation, so shares of Neon common stock will be delisted from Nasdaq and Neon will stop filing periodic reports with the United States Securities and Exchange Commission, or the SEC.

At the Neon Special Meeting, Neon stockholders will be asked to consider and vote on: (i) a proposal to approve and adopt the Merger Agreement, or the Merger Proposal; and (ii) a proposal to approve the adjournment of the Neon Special Meeting, if necessary or appropriate, to solicit additional proxies in favor of approval of the Merger Proposal, or the Adjournment Proposal.

The record date for determining the Neon stockholders entitled to receive notice of, and to vote at, the Neon Special Meeting is March 23, 2020. Only Neon stockholders of record at that time are entitled to notice of, and to vote at, the Neon Special Meeting, or any adjournment or postponement of the Neon Special Meeting. The

Merger cannot be completed unless, among other matters, Neon stockholders approve the Merger Proposal by the affirmative vote of holders of a majority of the outstanding shares of Neon common stock entitled to vote on such matter.

The Neon board of directors, or the Neon Board, unanimously (1) determined that the Merger Agreement and the transactions contemplated thereby, including the Merger, upon the terms and subject to the conditions set forth therein, were in the best interests of Neon stockholders; (2) approved and declared advisable the Merger Agreement and the transactions contemplated thereby in accordance with the requirements of the Delaware General Corporation Law; and (3) recommended that Neon stockholders approve and adopt the Merger Agreement at the Neon Special Meeting. **The Neon Board unanimously recommends that Neon stockholders vote "FOR" the Merger Proposal and "FOR" the Adjournment Proposal.**

**Your vote is important. Whether or not you expect to attend the Neon Special Meeting online, we urge you to vote your shares of Neon common stock as promptly as possible by (1) accessing the Internet website specified on your proxy card; (2) calling the toll-free number specified on your proxy card; or (3) signing and returning the enclosed proxy card in the postage-paid envelope provided, so that your shares of Neon common stock may be represented and voted at the Neon Special Meeting.** If your shares of Neon common stock are held in the name of a bank, broker or other fiduciary, please follow the instructions on the voting instruction card furnished by the record holder.

**The obligations of Neon and BioNTech to complete the Merger are subject to the satisfaction or waiver of several conditions set forth in the Merger Agreement. More information about Neon, BioNTech and the Merger is contained in this proxy statement/prospectus. Please read this entire proxy statement/prospectus carefully, including "Risk Factors" located elsewhere in this proxy statement/prospectus.**

Sincerely,

Hugh O'Dowd
President and Chief Executive Officer

**Neither the SEC nor any state securities commission has approved or disapproved the Merger described in this proxy statement/prospectus, or the issuance of the BioNTech ADSs in connection with the Merger, or passed upon the accuracy or adequacy of this proxy statement/prospectus. Any representation to the contrary is a criminal offense.**

**This proxy statement/prospectus is dated April 2, 2020 and is first being mailed to the stockholders of Neon on or about April 3, 2020.**


**Neon Therapeutics, Inc.**
**40 Erie St., Suite 110**
**Cambridge, MA 02139**

**NOTICE OF SPECIAL MEETING OF STOCKHOLDERS**
**To Be Held on May 4, 2020**

Notice is hereby given that Neon Therapeutics, Inc., or Neon, will hold a special meeting of stockholders on May 4, 2020, at 10:00 a.m. Eastern Time, or the Neon Special Meeting. You may attend the Neon Special Meeting, submit questions and vote your shares electronically during the meeting via live webcast by visiting www.virtualshareholdermeeting.com/NTGN2020. You will need the control number that is printed on your proxy card to enter the Neon Special Meeting. We recommend that you log in at least 15 minutes before the meeting to ensure you are logged in when the meeting starts. Please note that you will not be able to attend the Neon Special Meeting in person. The Neon Special Meeting will be held for the purpose of allowing stockholders of Neon to consider and vote upon the following matters:

- a proposal to approve and adopt the Agreement and Plan of Merger, dated as of January 15, 2020, or as amended, modified or otherwise supplemented from time to time, the Merger Agreement, by and among Neon, BioNTech SE, or BioNTech, and Endor Lights, Inc., or Merger Sub, pursuant to which Merger Sub will merge with and into Neon, with Neon continuing as the surviving corporation and as a wholly-owned subsidiary of BioNTech, or the Merger, as more fully described in the attached proxy statement/prospectus, or the Merger Proposal; and
- a proposal to approve the adjournment of the Special Meeting, if necessary or appropriate, to solicit additional proxies in favor of approval of the Merger Proposal, or the Adjournment Proposal.

The Merger cannot be completed unless, among other matters, Neon stockholders approve the Merger Proposal by the affirmative vote of holders of a majority of the shares of outstanding Neon common stock, par value $0.001 per share, or Neon common stock, entitled to vote on such matter. The Merger Proposal is described in more detail in the accompanying proxy statement/prospectus, which you should read carefully in its entirety before you vote. A copy of the Merger Agreement is attached as **Annex A** to the accompanying proxy statement/prospectus.

The record date for determining the Neon stockholders entitled to receive notice of, and to vote at, the Neon Special Meeting is March 23, 2020. Only Neon stockholders of record at that time are entitled to notice of, and to vote at, the Neon Special Meeting, or any adjournment or postponement of the Neon Special Meeting.

**Your vote is important. Whether or not you expect to attend the Neon Special Meeting online, we urge you to vote your shares of Neon common stock as promptly as possible by (1) accessing the Internet website specified on your proxy card; (2) calling the toll-free number specified on your proxy card; or (3) signing and returning the enclosed proxy card in the postage-paid envelope provided, so that your shares of Neon common stock may be represented and voted at the Neon Special Meeting.** If your shares of Neon common stock are held in the name of a bank, broker or other fiduciary, please follow the instructions on the voting instruction card furnished by the record holder.

The Neon Board unanimously (1) determined that the Merger Agreement and the Transactions contemplated hereby, including the Merger, upon the terms and subject to the conditions set forth therein, were in the best interests of Neon stockholders; (2) approved and declared advisable the Merger Agreement and the transactions contemplated thereby in accordance with the requirements of the Delaware General Corporation Law; and (3)

recommended that Neon stockholders approve and adopt the Merger Agreement at the Neon Special Meeting. **The Neon Board unanimously recommends that Neon stockholders vote "FOR" the Merger Proposal and "FOR" the Adjournment Proposal**.

**BY ORDER OF THE BOARD OF DIRECTORS**

Hugh O'Dowd
*President and Chief Executive Officer*

April 2, 2020

Cambridge, Massachusetts

## ABOUT THIS PROXY STATEMENT/PROSPECTUS

This proxy statement/prospectus, which forms part of a registration statement on Form F-4 filed with the U.S. Securities and Exchange Commission, or the SEC, by BioNTech SE, or BioNTech, constitutes a prospectus of BioNTech under Section 5 of the Securities Act of 1933, as amended, or the Act or the Securities Act, with respect to the ordinary shares, each of no par value, in the share capital of BioNTech, or the BioNTech Shares or a BioNTech Share, which will be represented by American Depositary Shares of BioNTech, or the BioNTech ADSs or the ADSs, to be issued to stockholders of Neon Therapeutics, Inc., or Neon, pursuant to the merger of Endor Lights, Inc., a wholly-owned subsidiary of BioNTech, with and into Neon, with Neon continuing as the surviving corporation in the merger and a wholly-owned subsidiary of BioNTech, or the Merger. This proxy statement/prospectus also constitutes a proxy statement of Neon under Section 14(a) of the Securities Exchange Act of 1934, as amended, or the Exchange Act, and constitutes a notice of meeting with respect to a special meeting of Neon stockholders, or the Neon Special Meeting.

No person has been authorized to provide you with information that is different from that which is contained in this proxy statement/prospectus. BioNTech and Neon take no responsibility for, and can provide no assurances as to the reliability of, any other information that others may give you and, if given, such information must not be relied upon as having been authorized. This proxy statement/prospectus is dated April 2, 2020. You should not assume that the information contained in this proxy statement/prospectus is accurate as of any date other than that date. Neither the mailing of this proxy statement/prospectus to Neon stockholders nor the issuance by BioNTech of the BioNTech ADSs in connection with the Merger will create any implication to the contrary.

**This proxy statement/prospectus does not constitute an offer to sell, or a solicitation of an offer to buy, any securities, or the solicitation of a proxy, in any jurisdiction to or from any person to whom it is unlawful to make any such offer or solicitation. Information contained in this proxy statement/prospectus regarding BioNTech has been provided by BioNTech and information contained in this proxy statement/prospectus regarding Neon has been provided by Neon.**

Neither BioNTech shareholders nor Neon stockholders should construe the contents of this proxy statement/prospectus as legal, tax or financial advice. BioNTech shareholders and Neon stockholders should consult with their own legal, tax, financial or other professional advisors. All summaries of, and references to, the agreements governing the terms of the transactions described in this proxy statement/prospectus are qualified by the full copies of and complete text of such agreements in the forms attached hereto as annexes.

**Neither the SEC nor any state securities commission has approved or disapproved the Merger described in this proxy statement/prospectus, the issuance of the BioNTech ADSs in connection with the Merger, or passed upon the accuracy or adequacy of this proxy statement/prospectus. Any representation to the contrary is a criminal offense. For the avoidance of doubt, this proxy statement/prospectus does not constitute an offer to sell, or a solicitation of an offer to buy, any securities, or the solicitation of a proxy, in any jurisdiction to or from any person to whom or from whom it is unlawful to make any such offer or solicitation in that jurisdiction.**

Neon Therapeutics, Inc.
Attention: Corporate Secretary
40 Erie Street, Suite 110
Cambridge, Massachusetts 02139
Telephone number: (617) 337-4701

In addition, if you have questions about the Merger, the Neon Special Meeting, or the proposals to be considered at the Neon Special Meeting, need additional copies of this document and the annexes to this document or need to obtain proxy cards or other information related to the proxy solicitation, you may contact Neon's proxy solicitor, Innisfree M&A Incorporated, or Innisfree, at the following address and telephone number:

Innisfree M&A Incorporated
501 Madison Avenue, 20th Floor
New York, NY 10022
Stockholders Call: (888) 750-5834
Banks and Brokers Call: (212) 750-5833

**In order for Neon stockholders to receive timely delivery of the documents in advance of the Neon Special Meeting, Neon stockholders must request the documents no later than April 27, 2020.**

## INDUSTRY AND MARKET DATA

This proxy statement/prospectus contains industry, market and competitive position data that are based on industry publications and studies conducted by third parties as well as BioNTech's 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 BioNTech believes that each of these publications and third-party studies is reliable, BioNTech has 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 proxy statement/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 BioNTech's forecasts or estimates or those of independent third parties. While BioNTech believes its internal research is reliable and the definitions of its market and industry are appropriate, neither such research nor these definitions have been verified by any independent source.

## PRESENTATION OF FINANCIAL INFORMATION

This proxy statement/prospectus includes BioNTech's audited consolidated financial statements as of December 31, 2019 and 2018 and for the years ended December 31, 2019, 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.

BioNTech's financial information is presented in Euros. For the convenience of the reader, BioNTech has translated some of its financial information into U.S. dollars. Unless otherwise indicated, these translations were made at the rate of €1.00 to $1.1026, the noon buying rate of the Federal Reserve Bank of New York on January 24, 2020. Such U.S. dollar amounts are not necessarily indicative of the amounts of U.S. dollars that could actually have been purchased upon exchange of Euros at the dates indicated. All references in this proxy statement/prospectus to "$" mean U.S. dollars and all references to "€" mean Euros.

BioNTech has made rounding adjustments to some of the figures contained in this proxy statement/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 TRADENAMES

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

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## QUESTIONS AND ANSWERS ABOUT THE MERGER AND THE NEON SPECIAL MEETING

*The following questions and answers address briefly some questions you may have regarding the Merger and the Neon Special Meeting. These questions and answers may not address all questions that may be important to you. Please refer to the more detailed information contained elsewhere in this proxy statement/prospectus, as well as the additional documents referred to in this proxy statement/prospectus.*

### General Questions and Answers about the Merger

***What is the proposed transaction on which I am being asked to vote?***

You are being asked to vote to approve and adopt the Agreement and Plan of Merger, dated as of January 15, 2020, or as may be further amended from time to time, the Merger Agreement, entered into by and among BioNTech SE, a *Societas Europaea* organized and existing under the laws of Germany, or BioNTech, Endor Lights, Inc., a Delaware corporation and a direct, wholly-owned subsidiary of BioNTech, or Merger Sub, and Neon Therapeutics, Inc., a Delaware corporation, or Neon. A copy of the Merger Agreement is included as **Annex A** to this proxy statement/prospectus. Pursuant to the Merger Agreement, Merger Sub will merge with and into Neon, with Neon surviving the merger as a wholly-owned subsidiary of BioNTech, or the Merger. Following the Merger, Neon will no longer be a publicly traded corporation. BioNTech and its subsidiaries following the Merger, including Neon, are referred to in this proxy statement/prospectus as the Combined Company.

***Why am I receiving this document and why am I being asked to vote on the Merger Agreement?***

BioNTech has agreed to acquire Neon under the terms of the Merger Agreement that are described in this proxy statement/prospectus. If the Merger Proposal is approved by Neon stockholders and the other conditions to closing under the Merger Agreement are satisfied or waived, Merger Sub will merge with and into Neon, with Neon surviving the Merger as a wholly owned subsidiary of BioNTech. As a result of the Merger, Neon will no longer be a publicly held corporation. Following the Merger, shares of Neon common stock will be delisted from the Nasdaq Global Select Market, or Nasdaq, and deregistered under the Exchange Act, and Neon will no longer file periodic reports with the SEC.

This proxy statement/prospectus includes important information about the Merger, the Merger Agreement, a copy of which is attached as **Annex A** to this proxy statement/prospectus, the form of voting agreement, a copy of which is attached as **Annex B** to this proxy statement/prospectus, and the Neon Special Meeting. Neon stockholders should read this information carefully and in its entirety. The enclosed voting materials allow stockholders to vote their shares without attending the special meeting in person.

***Is my vote important?***

Your vote is important. Whether or not you expect to attend the Neon Special Meeting online, we urge you to vote your shares of Neon common stock as promptly as possible by: (1) accessing the Internet website specified on your proxy card; (2) calling the toll-free number specified on your proxy card; or (3) signing and returning the enclosed proxy card in the postage-paid envelope provided, so that your shares of Neon common stock may be represented and voted at the Neon Special Meeting. If your shares of Neon common stock are held in the name of a bank, broker or other fiduciary, please follow the instructions on the voting instruction card furnished by the record holder.

***What will Neon stockholders receive in the Merger?***

If the Merger is completed, each share of Neon common stock that was issued and outstanding immediately prior to the effective time of the Merger, or the Effective Time, excluding shares owned by the parties to the

Merger Agreement, will be converted into the right to receive 0.063 American Depositary Shares of BioNTech, or the BioNTech ADSs, and such number of BioNTech ADSs, referred to as the Exchange Ratio, without interest, but subject to any withholding under applicable law, plus the right, if any, to receive cash in lieu of fractional shares of BioNTech ADSs, or, collectively, the Merger Consideration. Although the Exchange Ratio for the Merger Consideration is fixed, the market value of the Merger Consideration will fluctuate with the market price of the BioNTech ADSs. Based on the closing price of the BioNTech ADSs on January 15, 2020, the last trading day before the public announcement of the signing of the Merger Agreement, the implied aggregate value of the Merger Consideration is approximately $67 million, or $2.18 per share of Neon common stock. Based on the closing price of the BioNTech ADSs on March 26, 2020, the last practicable date before the date of this proxy statement/prospectus, the implied aggregate value of the Merger Consideration will be up to approximately $107.2 million, or $3.47 per share of Neon common stock, depending on the number of options to purchase Neon common stock exercised prior to the closing of the Merger.

***After the Merger, how much of the Combined Company will Neon stockholders own?***

As of immediately following the Effective Time, former Neon stockholders are expected to own approximately 0.85% of the outstanding equity interests of the Combined Company on an undiluted basis.

***Can the value of the Merger Consideration change between now and the time the Merger is consummated?***

Yes. Although the Exchange Ratio is fixed, the value of the Merger Consideration will fluctuate between the date of this proxy statement/prospectus and the completion of the Merger based on the market value of BioNTech ADSs. Any change in the market price of BioNTech ADSs after the date of this proxy statement/prospectus will change the value of the Merger Consideration that Neon stockholders will receive.

***What will happen to my Neon options, Neon restricted stock units, and/or Neon restricted stock in the Merger?***

*Neon Options*

At the Effective Time, each stock option to acquire shares of Neon common stock pursuant to the Neon 2015 Stock Option and Grant Plan or the Neon 2018 Stock Option and Incentive Plan, as applicable, or collectively, the Neon Equity Plans, which is outstanding immediately prior to the Effective Time, whether or not then vested or exercisable, or each, a Neon Option, will be automatically cancelled and converted 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 equal to (i) the excess, if any, of the Cash Merger Consideration over the applicable per-share exercise price of such cancelled Neon Option, multiplied by (ii) the number of shares of Neon common stock subject to such Neon Option immediately prior to such cancellation. Each Neon Option that has a per-share exercise price that is equal to or greater than the Cash Merger Consideration shall be cancelled at the Effective Time for no consideration. No Neon Options will remain outstanding following the consummation of the Merger. “Cash Merger Consideration” means the product of the volume weighted average price of one BioNTech ADS for the ten trading days immediately prior to the second business day prior to the date of the closing of the Merger, starting with the opening of trading on the first trading day to the closing of the second to last trading day prior to the date of closing of the Merger, as reported by Bloomberg, multiplied by the Exchange Ratio.

*Neon Units*

At the Effective Time, each restricted stock unit granted under the Neon Equity Plans and held by a current Neon employee that is outstanding immediately prior to the Effective Time, or each, a Neon Unit, shall vest in full and be cancelled and converted into the right to receive from the Company Trust (as defined below) as soon as reasonably practicable after the Effective Time (but no later than five business days thereafter) the Merger Consideration for each share of Neon common stock underlying each such Neon Unit. No Neon Units will remain outstanding following the consummation of the Merger.

Prior to the Effective Time, Neon shall establish a trust (which will not be affiliated with either BioNTech or Neon) to hold shares of Neon common stock (before the Merger and BioNTech ADSs thereafter), or the

Company Trust. Prior to the Effective Time, Neon shall issue and deliver to the Company Trust such number of shares of Neon common stock as is necessary to satisfy the obligations under all Neon Units outstanding as of immediately prior to the Effective Time.

*Neon Restricted Stock*

At the Effective Time, each share of Neon common stock that is subject to a risk of forfeiture or repurchase by Neon, whether subject to time- or performance-based vesting and whether granted by Neon pursuant to the Neon Equity Plans or otherwise issued or granted, or each, a share of Neon Restricted Stock, which is outstanding immediately prior to the Effective Time, shall vest in full and be cancelled and converted into the right to receive the Merger Consideration in the same manner as other outstanding shares of Neon common stock.

***What is a BioNTech ADS?***

A BioNTech ADS is an American Depositary Share, which is a security that allows persons in the United States to more easily hold and trade interests in companies incorporated or organized outside of the United States. BioNTech is a *Societas Europaea* organized and existing under the laws of Germany that issues ordinary shares that are equivalent in many respects to the common stock of a U.S. company. See "Comparison of Shareholder Rights" located elsewhere in this proxy statement/prospectus for a discussion of the differences between shares of Neon common stock and BioNTech Shares. Each BioNTech ADS represents one BioNTech Share. BioNTech has applied to list the BioNTech ADSs on Nasdaq, under the symbol "BNTX." The Bank of New York Mellon is the depositary of the BioNTech Shares underlying the BioNTech ADSs and will be responsible for issuing BioNTech ADSs to Neon stockholders in the Merger.

***Will Neon stockholders be able to trade the BioNTech ADSs that they receive in the transaction?***

Yes. BioNTech has applied to list the BioNTech ADSs on Nasdaq under the symbol "BNTX." BioNTech ADSs received in exchange for shares of Neon common stock in the transaction will be freely transferable under United States federal securities laws. BioNTech ADSs will be listed for trading, and be quoted, in U.S. dollars.

***Can I receive BioNTech Shares in the Merger instead of BioNTech ADSs?***

No. However, you may turn in your BioNTech ADSs at the depositary's corporate office or by providing appropriate instructions to your broker. Upon payment of the fees provided in the deposit agreement and any applicable taxes, the depositary will deliver to you the BioNTech Shares underlying your BioNTech ADSs held on deposit by the custodian.

***What are the material U.S. federal income tax considerations of the Merger for U.S. holders of shares of Neon common stock?***

It is intended that, for U.S. federal income tax purposes, the Merger will qualify as a "reorganization" within the meaning of Section 368(a) of the Internal Revenue Code of 1986, as amended. If the Merger qualifies for such intended tax treatment, a U.S. holder (as defined under "Certain Material U.S. Federal Income Tax Considerations") generally will not recognize any gain or loss for U.S. federal income tax purposes upon the exchange of such holder's shares of Neon common stock for BioNTech ADSs in the Merger, except that such holder of Neon common stock may recognize gain or loss with respect to cash received in lieu of a fractional BioNTech ADSs.

You should read "Certain Material U.S. Federal Income Tax Considerations" located elsewhere in this proxy statement/prospectus for a more complete summary of the U.S. federal income tax considerations of the Merger to U.S. holders of shares of Neon common stock. Tax matters can be complicated, and the tax consequences of the merger to you will depend on your particular situation. ***You should consult your tax advisor to determine the tax consequences of the Merger to you.***

***What are the material German tax considerations of owning BioNTech ADSs for me?***

You are referred to "Material German Tax Considerations" located elsewhere in this proxy statement/prospectus for a summary of the anticipated material German tax considerations of ownership of BioNTech ADSs. **You are urged to consult with your own tax advisor for a full understanding of the German tax considerations to you of owning BioNTech ADSs.**

***When is the Merger expected to be completed?***

BioNTech and Neon expect to complete the Merger promptly after Neon receives, at the Neon Special Meeting, an affirmative vote in favor of the approval and adoption of the Merger Agreement by holders of a majority of the shares of Neon common stock entitled to vote at the Neon Special Meeting, or the Neon Stockholder Approval. BioNTech and Neon currently anticipate that the Merger will occur during the second quarter of 2020. However, neither BioNTech nor Neon can predict the exact timing of the completion of the Merger because the Merger is subject to certain other conditions to closing as set forth in the Merger Agreement. See "The Merger Agreement—Conditions to Closing" located elsewhere in this proxy statement/prospectus.

***What is required to complete the Merger?***

Each of BioNTech's and Neon's obligation to consummate the Merger is subject to a number of conditions specified in the Merger Agreement, including, among other customary conditions (i) the approval and adoption of the Merger Agreement by Neon stockholders, (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 the BioNTech 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 parties expect the Merger will be completed during the second quarter of 2020. See "The Merger Agreement—Conditions to Closing" located elsewhere in this proxy statement/prospectus.

***What happens if the Merger is not completed?***

If the Merger Agreement is not approved and adopted by Neon stockholders or if the Merger is not completed for any other reason, Neon stockholders will not receive the Merger Consideration in exchange for their shares of Neon common stock. Instead, Neon will remain an independent public company and Neon common stock will continue to be listed and traded on Nasdaq. Under specified circumstances, Neon may be required to pay BioNTech a termination fee, as described in "The Merger Agreement—Termination Fees" located elsewhere in this proxy statement/prospectus.

***What do I need to do?***

You should carefully read and consider the information contained in this proxy statement/prospectus, including its annexes. Even if you plan to attend the Neon Special Meeting online, after carefully reading and considering the information contained in this proxy statement/prospectus, please vote promptly to ensure that your shares are represented at the Neon Special Meeting, as applicable.

**Questions and Answers about the Neon Special Meeting**

***When and where is the Neon Special Meeting?***

The Neon Special Meeting will be held on May 4, 2020, at 10:00 a.m. Eastern Time. In light of COVID-19 (coronavirus) and to support the well-being of our stockholders and partners, the Neon Special Meeting will be completely virtual. Stockholders can attend the Neon Special Meeting by visiting www.virtualshareholdermeeting.com/NTGN2020.

***How can I attend the Neon Special Meeting?***

You may attend the Neon Special Meeting, submit questions and vote your shares electronically during the meeting via live webcast by visiting www.virtualshareholdermeeting.com/NTGN2020. You will need the control number that is printed on your proxy card to enter the Neon Special Meeting. We recommend that you log in at least 15 minutes before the Neon Special Meeting to ensure you are logged in when the meeting starts. Please note that you will not be able to attend the Neon Special Meeting in person.

***Why is the Neon Special Meeting a virtual meeting?***

We have decided to hold our Special Meeting virtually due to COVID-19; we are sensitive to the public health and travel concerns of our stockholders and employees and the protocols that federal, state and local governments may impose. We believe that hosting a virtual meeting will enable greater stockholder attendance and participation from any location around the world.

***What matters will Neon stockholders vote on at the special meeting?***

Neon is asking its stockholders to consider and vote on: (i) a proposal to approve and adopt the Merger Agreement, or the Merger Proposal; and (ii) a proposal to approve the adjournment of the Neon Special Meeting, if necessary or appropriate, to solicit additional proxies in favor of approval of the Merger Proposal, or the Adjournment Proposal.

***What if during the check-in time or during the Neon Special Meeting I have technical difficulties or trouble accessing the virtual meeting website?***

If you encounter any difficulties accessing the virtual meeting during the check-in or meeting time, please call the technical support number that will be posted on the Virtual Shareholder Meeting log in page.

***How many votes are needed for the proposals considered by Neon stockholders at the Neon Special Meeting?***

The Merger cannot be completed unless, among other matters, Neon stockholders approve the Merger Proposal by the affirmative vote of holders of a majority of the shares of outstanding Neon common stock entitled to vote on such matter. Approval of the Adjournment Proposal requires the affirmative vote of a majority of the shares of Neon common stock present online at the meeting in person or by proxy entitled to vote.

***Are there any voting agreements with existing stockholders?***

On January 15, 2020, concurrently with the execution and delivery of the Merger Agreement, certain directors, executive officers and Third Rock Ventures entered into voting agreements with BioNTech, pursuant to which such stockholders have agreed, among other things, to vote their respective shares of Neon common stock in favor of the Merger Agreement and the transactions contemplated thereby. As of the public announcement of the Merger, those certain directors and executive officers who signed the Neon voting agreements owned an aggregate of approximately 36% in voting power of the outstanding shares of Neon common stock. As of the record date for the Neon Special Meeting, the directors and executive officers of Neon

who signed the Neon voting agreements owned an aggregate of approximately 39% of the voting power of the outstanding Neon common stock as described in "The Neon Special Meeting—Neon Voting Agreement" located elsewhere in this proxy statement/prospectus. The form of Neon voting agreements are attached to this proxy statement/prospectus as **Annex B**.

***What is the quorum requirement for the Neon Special Meeting?***

The presence, online or represented by proxy, of a majority of all issued and outstanding shares of Neon common stock entitled to vote at the Neon Special Meeting will constitute a quorum at the meeting. Holders of shares of Neon common stock present online at the Neon Special Meeting but not voting, and shares of Neon common stock for which Neon has received proxies indicating that their holders have abstained, will be counted as present at the Neon Special Meeting for purposes of determining whether a quorum is established.

***As a Neon stockholder, how can I vote?***

Whether or not you expect to attend the Neon Special Meeting online, we urge you to vote your shares of Neon common stock as promptly as possible by (1) accessing the Internet website specified on your proxy card; (2) calling the toll-free number specified on your proxy card; or (3) signing and returning the enclosed proxy card in the postage-paid envelope provided, so that your shares of Neon common stock may be represented and voted at the Neon Special Meeting. If your shares of Neon common stock are held in the name of a bank, broker or other fiduciary, please follow the instructions on the voting instruction card furnished by the record holder.

Stockholders who choose to participate in the Neon Special Meeting can vote their shares electronically during the meeting via live webcast by visiting www.virtualshareholdermeeting.com/NTGN2020. You will need the control number that is printed on your proxy card to enter the Neon Special Meeting. We recommend that you log in at least 15 minutes before the meeting to ensure you are logged in when the meeting starts.

Instructions on how to attend and participate via the Internet, including how to demonstrate proof of stock ownership, are posted at www.virtualshareholdermeeting.com/NTGN2020. Even if you plan to participate in the Neon Special Meeting online, we recommend that you also vote by proxy as described above so that your vote will be counted if you later decide not to participate in the Neon Special Meeting.

***As a Neon stockholder, what happens if I do not vote?***

Failure to vote or give voting instructions to your broker or nominee for the Neon Special Meeting could make it more difficult to meet the voting requirement that the total affirmative votes cast to approve the Merger Proposal and the Adjournment Proposal. Therefore, Neon urges Neon stockholders to vote.

***As a Neon stockholder, may I change my vote after I have submitted a proxy card or voting instruction card?***

Yes. You may revoke your election at or prior to the election deadline by submitting a written notice of revocation to Neon or by submitting new election materials. Revocations must specify the name in which your shares are registered on the share transfer books of Neon and any other information that Neon may request. If you wish to submit a new election, you must do so in accordance with the election procedures described in this proxy statement/prospectus and the form of election. If you instructed a bank, brokerage firm or other nominee holder to submit an election for your shares, you must follow your bank's, brokerage firm's or other nominee's directions for changing those instructions. The notice of revocation must be received by Neon at or prior to the election deadline in order for the revocation or new election to be valid.

***Should Neon stock certificates be sent in now?***

**No, please do NOT return your share certificate(s) with your proxy.** You will be mailed appropriate and customary transmittal materials within five business days of the mailing of this proxy statement/prospectus, but

under separate cover, describing how you may exchange your shares of Neon common stock for the per share Merger Consideration. If your shares of Neon common stock are held in "street name" through a bank, brokerage firm or other nominee, you will receive instructions from your bank, brokerage firm or other nominee as to how to effect the surrender of your "street name" shares of Neon common stock in exchange for the per share Merger Consideration.

***What do Neon stockholders need to do now?***

Even if you plan to attend the Neon Special Meeting online, after carefully reading and considering the information contained in this proxy statement/prospectus, please vote promptly to ensure that your shares are represented at the Neon Special Meeting. If you are a stockholder of record, you may vote using any of the following methods:

- by telephone or on the Internet, by calling the toll-free telephone number or visiting the Internet website specified on the enclosed proxy card. Please have your proxy card handy to verify your identity using the control number provided on your proxy card. When voting over the telephone or online you can confirm that your instructions have been properly recorded;
- by completing, signing, dating and returning the enclosed proxy card or voting instruction card in the accompanying prepaid reply envelope; or
- by attending the Neon Special Meeting online and casting your vote there. You may also be represented by another person at the special meeting if you execute a proper proxy designating that person.

If you decide to attend the Neon Special Meeting and vote online, your vote by ballot will revoke any proxy previously submitted. If you are a beneficial owner, please refer to the instructions provided by your bank, brokerage firm or other nominee to see which of the above choices are available to you. Please note that if you are a beneficial owner and wish to vote online at the special meeting, you must obtain a legal proxy from your bank, broker or other holder of record and present it to the inspectors of election with your ballot.

***Who can answer questions?***

If you need assistance in voting or completing your proxy card or have questions regarding the Neon Special Meeting, please contact Innisfree, the proxy solicitor for Neon, by telephone at (888) 750-5834. Banks and brokers can call (212) 750-5833 (collect).

## SUMMARY

*This summary highlights information contained elsewhere in this proxy statement/prospectus. This summary may not contain all the information that may be important to you, and you are urged to read this entire proxy statement/prospectus carefully, including the attached annexes, and the other documents to which this proxy statement/prospectus refers in order for you to fully understand the Merger.*

### Information about the Companies

***BioNTech SE***

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, BioNTech combines 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. BioNTech leverages powerful new therapeutic mechanisms and exploits 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. BioNTech believes it is 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.

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

BioNTech has established relationships with eight 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, and Shanghai Fosun Pharmaceutical (Group) Co., Ltd., or Fosun Pharma.

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

***Merger Sub***

Merger Sub is a wholly-owned direct subsidiary of BioNTech and was formed on January 8, 2020 exclusively for the purpose of effecting the Merger. Merger Sub has not carried on any activities to date, except for activities incidental to its formation and activities undertaken in connection with the Merger. Merger Sub's separate corporate existence will cease upon the consummation of the Merger and Neon will continue as the surviving corporation. The address and telephone number for Merger Sub's principal executive offices are 228 E. 45th Street, Suite 9e, New York, NY 10017 and +1 (347) 694-5321, respectively.

***Neon Therapeutics, Inc.***

Neon 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. Neon is leveraging its neoantigen platform and over a decade of insights from its founders to

develop neoantigen-targeted therapies that use two distinct approaches. The first are fully personal therapies that target neoantigens specific to each individual and the second are therapies that target neoantigens that are shared across subsets of patients or tumor types. These approaches focus on targeting a prioritized set of what Neon believes are the most therapeutically-relevant neoantigens. Neon is applying these two approaches to develop neoantigen-targeted product candidates using multiple treatment modalities.

NEO-PTC-01, Neon's personal neoantigen adoptive T cell therapy, consists of multiple T cell populations targeting what Neon predicts to be the most therapeutically-relevant neoantigens from each patient's tumor. NEO-PTC-01 is currently in preclinical development, and Neon announced the filing of a clinical trial application in Europe in December 2019 to evaluate NEO-PTC-01 in solid tumors in patients who are refractory to checkpoint inhibitors. Neon plans to initiate a Phase 1 dose escalation clinical trial in metastatic melanoma in collaboration with the Netherlands Cancer Institute in the middle of 2020. The second planned indication for NEO-PTC-01 is metastatic ovarian cancer, with the potential to both expand to other solid tumor types and pursue clinical development in the United States.

In parallel to its personal therapies, Neon is advancing additional therapies that use a precision medicine approach. These include multiple neoantigen-targeted therapies that direct the immune system towards prevalent mutations that are shared across patients in specific tumor types. Neon intends to develop product candidates targeting shared neoantigens using both non-engineered and non-engineered T cell modalities. Neon's first product candidate using this approach, NEO-STC-01, is a shared neoantigen adoptive T cell therapy for the treatment of RAS-mediated cancers. Neon continues to make significant progress with respect to its precision T cell approach and have also assembled libraries of high-quality T cell receptors, or TCRs, against various shared neoantigens across common human leukocyte antigens, or HLAs which are suitable for an engineered TCR-T cell therapy approach.

Neon also has two neoantigen vaccines in its portfolio: NEO-PV-01 and NEO-SV-01. The most clinically advanced of these is NEO-PV-01, a fully personal neoantigen cancer vaccine, custom-designed and manufactured for each individual patient's tumor mutations. It is in Phase 1b clinical development in metastatic disease settings, with three ongoing trials. Neon reported top line results from the first trial, NT-001, recently at the Society of Immunotherapy for Cancer 2019 meeting. Neon subsequently announced in November 2019, that it will cease undertaking new announced the cessation of additional spending commitments related to its cancer vaccine programs, NEO-PV-01 and NEO-SV-01. Neon will continue to conduct follow-up from its ongoing 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 initial clinical data from this trial in the third quarter of 2020. Neon has also ceased future enrollment in its NT-003 trial in metastatic melanoma.

Neon generates its product candidate pipeline using our proprietary neoantigen platform, which continuously improves as our product candidates generate data. This platform comprises two key elements: our Real-time Epitope Computation for ONcology, or RECON, bioinformatics engine and our combined T cell biology and immune-monitoring expertise, in particular NEO-STIM, our proprietary antigen-specific T cell induction protocol.

The principal executive offices of Neon are located at 40 Erie Street, Suite 110 Cambridge, Massachusetts 02139. Its telephone number is (617) 337-4701. Its website address is https://neontherapeutics.com/. This proxy statement/prospectus incorporates important business and financial information about Neon from other documents that are not included in or delivered with this proxy statement/prospectus.

**Summary of the Merger (page 196)**

Subject to the terms and conditions of the Merger Agreement, Merger Sub, a wholly owned direct subsidiary of BioNTech, will be merged with and into Neon, and Neon will continue as the surviving corporation in the Merger and a wholly owned direct subsidiary of BioNTech. At the Effective Time, the certificate of incorporation and the bylaws of Merger Sub, each as in effect immediately prior to completion of the Merger, will be the certificate of incorporation and bylaws, respectively, of the surviving corporation in the Merger, in each case, as amended to change the name of the surviving corporation and to comply with the indemnification obligations provided in the Merger Agreement.

**Merger Consideration (page 225)**

At the Effective Time, each share of Neon common stock, excluding shares owned by the parties to the Merger Agreement, that is issued and outstanding immediately prior to the Effective Time will be automatically cancelled and converted into the right to receive the Merger Consideration, with each BioNTech ADS representing one BioNTech Share, without interest but subject to any withholding required under applicable law.

As of immediately following the Effective Time, former Neon stockholders are expected to own approximately 0.85% of the outstanding equity interests of the Combined Company on an undiluted basis. No fractional BioNTech ADSs will be issued in the Merger. Each holder of shares of Neon common stock converted pursuant to the Merger who would otherwise have been entitled to receive a fraction of a BioNTech 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 BioNTech ADS multiplied by the volume weighted average price of one BioNTech ADS for the ten trading days immediately prior to the second business day prior to the date of the closing of the Merger, starting with the opening of trading on the first trading day to the closing of the second to last trading day prior to the date of closing of the Merger, as reported by Bloomberg.

**Treatment of Neon Options, Neon Units and Neon Restricted Stock (page 226)**

*Neon Options*

At the Effective Time, each Neon Option will be automatically cancelled and converted 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 equal to (i) the excess, if any, of the Cash Merger Consideration over the applicable per-share exercise price of such cancelled Neon Option, multiplied by (ii) the number of shares of Neon common stock subject to such Neon Option immediately prior to such cancellation. Each Neon Option that has a per-share exercise price that is equal to or greater than the Cash Merger Consideration shall be cancelled at the Effective Time for no consideration. No Neon Options will remain outstanding following the consummation of the Merger.

*Neon Units*

Prior to the Effective Time, Neon shall issue and deliver to the Company Trust such number of shares of Neon common stock as is necessary to satisfy the obligations under all Neon Units outstanding as of immediately prior to the Effective Time.

At the Effective Time, each Neon Unit shall vest in full and be cancelled and converted 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 for each share of Neon common stock underlying each such Neon Unit. No Neon Units will remain outstanding following the consummation of the Merger.

*Neon Restricted Stock*

At the Effective Time, each share of Neon Restricted Stock, which is outstanding immediately prior to the Effective Time, shall vest in full and be cancelled and converted into the right to receive the Merger Consideration in the same manner as other outstanding shares of Neon common stock.

**Risk Factors (page 37)**

You should carefully read this proxy statement/prospectus and especially consider the factors discussed in "Risk Factors" in connection with your consideration of the Merger before deciding whether to vote for approval of the Merger Proposal.

**The Neon Special Meeting (page 190)**

The Neon Special Meeting will be held on May 4, 2020, at 10:00 a.m. Eastern Time. In light of COVID-19 (coronavirus) and to support the well-being of our stockholders and partners, the Neon Special Meeting will be completely virtual. Stockholders can attend the Neon Special Meeting by visiting www.virtualshareholdermeeting.com/NTGN2020. At the Neon Special Meeting, Neon stockholders will be asked to consider and vote upon the following proposals:

- the Merger Proposal; and
- the Adjournment Proposal.

You may vote at the Neon Special Meeting if you owned shares of Neon common stock at the close of business on March 23, 2020, the Neon record date. You may cast one vote for each share of Neon common stock that you owned as of the Neon record date, including (i) shares held directly in your name as the stockholder of record and (ii) shares held for you as the beneficial owner in street name through a broker, bank, or other nominee. On the Neon record date, there were outstanding a total of 28,931,978 shares of Neon common stock entitled to vote at the Neon Special Meeting.

Completion of the Merger is conditioned on the approval of the Merger Proposal. Approval of the Merger Proposal requires the affirmative vote of a majority of the outstanding shares of Neon common stock entitled to vote on such matter. Approval of the Adjournment Proposal requires the affirmative vote of a majority of the shares of Neon common stock present at the meeting online or by proxy.

**Share Ownership and Voting by Neon Directors and Executive Officers (page 459)**

As of the record date, approximately 40% of the outstanding shares of Neon common stock was held by Neon directors and executive officers and their respective affiliates.

**Recommendation of the Neon Board and its Reasons for the Merger (page 208)**

At a meeting of the Neon Board held on January 15, 2020, the Neon Board unanimously: (1) determined that the Merger Agreement and the transactions contemplated thereby, including the Merger, upon the terms and conditions set forth therein, were in the best interests of Neon stockholders; (2) approved and declared advisable the Merger Agreement and the transactions contemplated thereby in accordance with the requirements of the Delaware General Corporation Law; and (3) recommended that Neon stockholders approve and adopt the Merger Agreement at the Neon Special Meeting.

The Neon Board unanimously recommends that the Neon stockholders vote **"FOR"** the Merger Proposal, and **"FOR"** the Adjournment Proposal. For the factors considered by the Neon Board in reaching its decision to approve the Merger Agreement and the recommendations of the Neon Board, see "The Merger— Recommendation of the Neon Board and its Reasons for the Merger" located elsewhere in this proxy statement/prospectus.

**Opinion of Neon's Financial Advisor (page 213 and Annex C)**

In connection with the Merger, at the meeting of the Neon Board on January 15, 2020, Duff & Phelps LLC, or Duff & Phelps, rendered an oral opinion to the Neon Board, which was subsequently confirmed by delivery of a written opinion immediately after the meeting on January 15, 2020, to the effect that, as of that date, the Exchange Ratio provided for in the proposed transaction was fair, from a financial point of view, to the holders of shares of Neon common stock (without giving effect to any impact of the proposed transaction on any particular stockholders other than in its capacity as a stockholder).

**The full text of the Duff & Phelps written opinion, dated January 15, 2020 which describes the assumptions made and limitations upon the review undertaken by Duff & Phelps in preparing its opinion, is attached hereto as Annex C and is incorporated by reference herein. You should read the opinion carefully in its entirety.**

**Accounting Treatment (page 219)**

The Merger will be accounted for in accordance with International Financial Reporting Standards, or IFRS, as issued by the International Accounting Standards Board, or IASB, and in particular, with IFRS 3, *Business Combinations*, or IFRS 3, under which the Merger qualifies since the acquisition of Neon by BioNTech fulfills the definition of a business. On the date of the acquisition, the identifiable assets and liabilities of Neon will be recorded by BioNTech at their respective acquisition-date fair values. Any excess of the purchase price over the net acquisition-date fair value of the identifiable assets acquired and liabilities assumed will be recognized as goodwill.

**Regulatory Approvals Required for the Merger (page 224)**

In connection with the issuance of BioNTech ADSs in the Merger, pursuant to the Merger Agreement, as a condition to the closing of the Merger, BioNTech must file a registration statement with the SEC under the Act, of which this proxy statement/prospectus forms a part, that is declared effective by the SEC.

**Appraisal Rights (page 224)**

Under Delaware law, the Neon stockholders are not entitled to appraisal rights in connection with the Merger or any other transaction contemplated by the Merger Agreement.

**Interests of Neon's Directors and Executive Officers in the Merger (page 220)**

In considering the recommendation of the Neon board of directors, or the Neon Board, to approve and declare advisable the Merger Agreement, Neon stockholders should be aware that some of the Neon directors and executive officers have interests in the Merger and have arrangements that are different from, or in addition to, those of Neon stockholders generally, including, but not limited to, the following:

- Neon has entered into executive employment agreements with certain employees, including its executive officers, entitling them to certain payments and benefits in connection with a termination of employment following a change of control of Neon;
- Neon has entered into retention letter agreements with certain employees, including its executive officers, entitling them to a retention bonus upon the closing of the Merger;
- pursuant to the terms of the Merger Agreement, all outstanding equity awards will accelerate upon the closing of the Merger; and
- directors and officers of Neon have continuing rights to indemnification and directors' and officers' liability insurance.

These interests and arrangements may create potential conflicts of interest. The Neon Board was aware of these potential conflicts of interest and considered them, among other matters, in reaching its decision to approve and declare advisable the Merger Agreement and recommend that the Neon stockholders approve and adopt the Merger Agreement.

**Board of Directors and Senior Management of the Combined Company (page 219)**

The Supervisory Board (*Aufsichtsrat*) and Management Board (*Vorstand*) of the Combined Company will be comprised of the Supervisory Board (*Aufsichtsrat*) and Management Board (*Vorstand*) of BioNTech prior to the Effective Time.

Dr. Ulrich Wandschneider and Mr. Michael Motschmann qualify as "independent directors" as such term is defined in Rule 10A-3 under the Exchange Act and Nasdaq Rule 5605(a)(2).

**BioNTech's Reasons for the Merger (page 223)**

At each of their respective meetings on January 15, 2020, the BioNTech Supervisory Board and the BioNTech Management Board determined that the Merger Agreement and the transactions contemplated thereby, including the Merger, upon the terms and subject to the conditions set forth therein, are fair to, and in the best interests of, BioNTech and BioNTech's stockholders, and approved and declared advisable the Merger Agreement and the transactions contemplated thereby, including the Merger, upon the terms and subject to the conditions set forth therein.

In reaching their respective decisions to approve the Merger Agreement and transactions provided for therein, the BioNTech Supervisory Board and BioNTech Management Board evaluated the Merger and the Merger Agreement in consultation with BioNTech's senior management and outside financial, legal and other advisors, reviewed various financial data and due diligence information, and considered a variety of factors, determining that the Merger would expand BioNTech's cell therapy pipeline through the addition of neoantigen specific cell therapies which are complementary to BioNTech's pipeline and focus on solid tumors. These include an adoptive T cell therapy targeting individual neoantigens, and a T cell therapy targeting shared RAS oncogenes. Moreover, the Merger would accelerate BioNTech's strategy to expand its capabilities and build BioNTech's presence in the United States by creating a U.S. hub for research and clinical development. Finally, BioNTech believes the acquisition creates long-term value for BioNTech and Neon shareholders by combining capabilities, intellectual property and synergistic pipeline programs.

**Listing of the BioNTech ADSs (page 224)**

The BioNTech ADSs are listed on Nasdaq under the symbol "BNTX."

**Delisting and Deregistration of Neon Common Stock (page 224)**

When the Merger is completed, the shares of Neon common stock currently listed on Nasdaq will cease to be quoted on Nasdaq and will be deregistered under the Exchange Act.

**Litigation Related to the Merger (page 224)**

It is a condition to the Merger that no temporary restraining order, preliminary or permanent injunction or any other order precluding, restraining, enjoining, prohibiting, suspending or making illegal the consummation of the Merger nor any law that precludes, restrains, enjoins or prohibits the consummation of the Merger shall have been issued by any governmental entity or a court of competent jurisdiction. 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.

**The Merger Agreement (page 225 and Annex A)**

A complete copy of the Merger Agreement is attached as **Annex A** to this proxy statement/prospectus. You should read the entire Merger Agreement carefully because it is the principal document governing the Merger. For a further discussion of the Merger Agreement, see "The Merger Agreement" located elsewhere in this proxy statement/prospectus.

**No Solicitation of Offers (page 234 and Annex A)**

As more fully described in this proxy statement/prospectus and in the Merger Agreement, and subject to the exceptions described below and in the Merger Agreement, Neon has agreed, among other things, that it will not, directly or indirectly:

- 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;
- 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 Neon 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;
- 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);
- approve, endorse or recommend any proposal that constitutes or could reasonably be expected to lead to any acquisition proposal;
- enter into any letter of intent, agreement, contract, commitment or agreement in principle (other than a customary confidentiality agreement on terms not less favorable in the aggregate to Neon than the terms of the existing confidentiality agreements between BioNTech and Neon) with respect to an acquisition proposal or enter into any agreement, contract or commitment requiring Neon to abandon, terminate or fail to consummate, or that could otherwise materially impede the ability of BioNTech and Merger Sub to consummate, the Merger or the other transactions contemplated by the Merger Agreement; or
- propose, resolve or agree to do any of the foregoing.

Neon has further agreed (1) to immediately cease and terminate any existing solicitations, encouragements, facilitations, discussions or negotiations with any third party with respect to any acquisition proposal, and (2) promptly 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 Neon or any of its subsidiaries to any third party or representative to be returned or destroyed in accordance with the applicable confidentiality agreement.

However, at any time prior to the approval and adoption of the Merger Agreement by Neon stockholders, Neon receives an unsolicited written *bona fide* acquisition proposal from a third party, which did not result from a breach of provisions of the Merger Agreement related to unsolicited proposals and adverse board

recommendation changes, and the Neon 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 failure to take the following actions would be inconsistent with fiduciary duties under applicable law, then Neon may:

- furnish information and data with respect to Neon 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 Neon and its subsidiaries; and
- 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;

provided, however, that Neon will not furnish any non-public information except pursuant to a customary confidentiality agreement on terms not less favorable in the aggregate to Neon than the terms of the existing confidentiality agreement between BioNTech and Neon and Neon will concurrently provide to BioNTech any information concerning Neon or its subsidiaries provided to such third party which was not previously provided to BioNTech.

Notwithstanding the foregoing, Neon and its representatives may, 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 in order to permit the Neon 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 direct any persons to the Merger Agreement.

The Merger Agreement provides that the term “acquisition proposal” means, with respect to Neon, 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 Neon, 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 Neon, (ii) any merger, amalgamation, consolidation, share exchange, asset acquisitions, business combination, joint venture, license, collaboration, research and development or other similar transaction involving Neon or any of its subsidiaries, the business of which constitutes 15% or more of the net revenues, net income or assets of Neon and its subsidiaries, taken as a whole, (iii) any liquidation, dissolution, recapitalization, extraordinary dividend or other significant corporate reorganization of Neon or any of its subsidiaries, the business of which constitutes 15% or more of the net revenues, net income or assets of Neon and its subsidiaries, taken as a whole, or (iv) any combination of the foregoing.

The Merger Agreement provides that the term “superior proposal” means any *bona fide* written acquisition proposal made after the date hereof that the Neon 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 BioNTech in response to such proposal pursuant to the provisions of the Merger Agreement related to adverse board recommendation changes, which (a) would, if consummated, result in a transaction that is more favorable from a financial point of view to Neon 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%”.

**Change of Recommendation (page 236)**

*Neon's Board Recommendation*

Subject to the exceptions described below and in the Merger Agreement, Neon has agreed to recommend that the Neon stockholders approve and adopt the Merger Agreement at the Neon Special Meeting, or the Neon Board Recommendation.

Notwithstanding the above, the Neon 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 an adverse board recommendation change, provided that:

- Neon shall have provided at least four business days' prior written notice to BioNTech advising BioNTech that the Neon Board intends to make an adverse board recommendation change, or 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;
- during such notice period, Neon shall, and shall cause its representatives to, to the extent requested by BioNTech, negotiate with BioNTech in good faith to make such adjustments to the terms and conditions of the Merger Agreement as would enable the Neon Board to maintain the Neon Board Recommendation; and
- taking into account all adjustments to the terms of the Merger Agreement that may be irrevocably offered in writing by BioNTech as described above, the Neon Board (no earlier than the end of such four business day notice period) 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 an adverse board recommendation change would be inconsistent with its fiduciary duties under applicable law.

Notwithstanding the above, the Neon Board may fail to (i) make, withdraw, amend, modify, or materially qualify, in a manner adverse to BioNTech or Merger Sub, or otherwise make any statement or proposal inconsistent with, the Neon Board Recommendation; (ii) include the Neon Board Recommendation in the proxy statement that is mailed to Neon's stockholders; or (iii) reaffirm (publicly, if so requested by BioNTech) the Neon Board Recommendation within ten business days after the date any acquisition proposal (or material modification thereto) is first publicly disclosed by Neon or the person making such acquisition proposal, each following the occurrence of an intervening event, if the Neon 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 that:

- Neon shall have provided at least four business days' prior written notice to BioNTech advising BioNTech that the Neon Board intends to make an adverse board recommendation change and specifying the material facts underlying the determination by the Neon Board that an intervening event has occurred and the reason for such adverse board recommendation change, in reasonable detail (a "Notice of Intervening Event");
- during such notice period, Neon shall, and shall cause its representatives to, to the extent requested by BioNTech, negotiate with BioNTech in good faith to make such adjustments to the terms and conditions of the Merger Agreement as would enable the Neon Board to maintain the Neon Board Recommendation; and
- taking into account all adjustments to the terms of the Merger Agreement that may be irrevocably offered in writing by BioNTech as described above, the Neon Board (no earlier than the end of such four business day notice period) determines in good faith after consultation with its financial advisor

and outside legal counsel that the failure to effect an adverse board recommendation change would be inconsistent with its fiduciary duties under applicable law.

**Indemnification and Insurance (page 238)**

Pursuant to the terms of the Merger Agreement, Neon's directors and executive officers will be entitled to certain ongoing indemnification and coverage under directors' and officers' liability insurance policies of, and the organizational documents of, Neon and BioNTech. See "The Merger Agreement—Indemnification and Insurance" located elsewhere in this proxy statement/prospectus.

**Conditions to Closing (page 239)**

Each party's obligation to effect the Merger is subject to satisfaction at or prior to the Effective Time of each of the following conditions (which may be waived in whole or in part by such party):

- the Neon Stockholder Approval shall have been obtained;
- no law shall have been enacted 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;
- no order (whether temporary, preliminary or permanent) of a governmental entity or court of competent jurisdiction is in effect precluding, restraining, enjoining, prohibiting, suspending or making illegal the consummation of the Merger;
- 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;
- the BioNTech ADSs issued in the Merger shall have been approved for listing on Nasdaq, subject to official notice of issuance; and
- as required by German law, a draft of the determination of adequacy of the contribution-in-kind by the German court-appointed accounting firm shall confirm such adequacy.

The obligations of BioNTech and Merger Sub to effect the Merger are further subject to the satisfaction or waiver of BioNTech at or prior to the Effective Time of the following conditions:

- the representations and warranties of Neon in the Merger Agreement (without giving effect to any references therein to material adverse effect or other materiality qualifiers), other than the representations and warranties related to capitalization, due organization, absence of changes, authority and the binding nature of the Merger Agreement, takeover statutes, the fairness opinion and the financial advisor, will be true and correct in all respects as of January 15, 2020 and as of the date of closing of the Merger 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 Neon to be so true and correct, individually or in the aggregate, has not had and would not reasonably be expected to have a material adverse effect with respect to Neon;
- the representations and warranties relating to capitalization will be true and correct in all respects (except to a *de minimis* extent) as of January 15, 2020 and as of the date of the closing of the Merger as though made on and as of such date and time;

- the representations and warranties relating to due organization, absence of changes, authority and the binding nature of the Merger Agreement, takeover statutes, the fairness opinion and the financial advisor will be true and correct in all material respects as of January 15, 2020 and as of the date of the closing of the Merger 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);
- Neon shall have performed or complied in all material respects with all of the obligations, agreements and covenants required to be performed or complied with by Neon under the Merger Agreement at or prior to the closing of the Merger;
- BioNTech shall have received a closing certificate signed by an authorized executive officer of Neon, dated as of the date of the closing of the Merger to the effect that certain conditions in the Merger Agreement have been satisfied;
- since January 15, 2020, a material adverse effect with respect to Neon shall not have occurred;
- no more than 30 days prior to the closing of the Merger, Neon shall have delivered to BioNTech a certificate (in form and substance reasonably satisfactory to BioNTech) pursuant to Treasury Regulations Section 1.1445-2(c)(3), stating that Neon is not and has not been a United States real property holding corporation (as defined in Section 897(c)(2) of the Internal Revenue Code) during the applicable period specified in Section 897(c)(1)(A)(ii) of the Internal Revenue Code; and
- BioNTech shall have received its counsel's tax opinion, dated as of the date of the closing of the Merger.

Neon's obligation to effect the Merger is further subject to the satisfaction or waiver of Neon at or prior to the Effective Time of the following conditions:

- the representations and warranties of BioNTech and Merger Sub in the Merger Agreement (without giving effect to any references therein to material adverse effect or other materiality qualifiers), other than the representations and warranties related to capitalization, due organization, SEC filings and financial statements, absence of changes, authority and the binding nature of the Merger Agreement, and the financial advisor, will be true and correct in all respects as of January 15, 2020 and as of the date of the closing of the Merger 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 BioNTech 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 material adverse effect with respect to BioNTech;
- the representations and warranties relating to capitalization will be true and correct in all respects (except to a *de minimis* extent) as of January 15, 2020 and as of the date of the closing of the Merger as though made on and as of such date and time;
- the representations and warranties relating to due organization, SEC filings and financial statements, absence of changes, authority and the binding nature of the Merger Agreement, and the financial advisor will be true and correct in all material respects as of January 15, 2020 and as of the date of the closing of the Merger 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);

- BioNTech and Merger Sub shall have performed or complied in all material respects with all of the obligations, agreements and covenants required to be performed or complied with by BioNTech and Merger Sub under the Merger Agreement at or prior to the closing of the Merger;
- Neon shall have received a closing certificate signed by an authorized executive officer of BioNTech, dated as of the date of the closing of the Merger to the effect that certain conditions in the Merger Agreement have been satisfied; and
- Neon shall have received its counsel's tax opinion, dated as of the date of the closing of the Merger.

**Termination Events (page 241)**

The Merger Agreement may be terminated at any time prior to the Effective Time by mutual written consent of BioNTech and Neon, and either party may terminate the Merger Agreement in the following circumstances:

- if the Merger shall not have been consummated by October 15, 2020, or the End Date, except that the right to terminate the Merger Agreement on this basis shall not be available to any party whose breach of any representation, warranty, covenant, or agreement set forth in the Merger Agreement has been the cause of, or resulted in, the failure of the Merger to be consummated on or before the End Date;
- 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 Merger or the other transactions contemplated by the Merger Agreement and such law or order shall have become final and nonappealable; provided, however, the right to terminate the Merger Agreement on this basis shall not be available to any party whose breach of any representation, warranty, covenant, or agreement set forth in the Merger Agreement has been the cause of, or resulted in, the issuance, promulgation, enforcement, or entry of any such law or order; or
- if the Merger Agreement has been submitted to the Neon stockholders for adoption at a duly convened Neon stockholders' meeting and the Neon Stockholder Approval shall not have been obtained at such meeting (unless such Neon stockholders' meeting has been adjourned or postponed, in which case at the final adjournment or postponement thereof).

BioNTech may terminate the Merger Agreement at any time prior to the Effective Time as follows:

- if an adverse board recommendation change shall have occurred or Neon shall have materially breached its obligations under the Merger Agreement related to unsolicited proposal and adverse board recommendation changes; or
- if there shall have been a breach by Neon of any representation, warranty, covenant, or agreement on the part of Neon set forth in the Merger Agreement such that the conditions to the closing of the Merger set forth in the Merger Agreement 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 BioNTech stating BioNTech's intention to terminate the Merger Agreement on this basis and (ii) three business days before the End Date.

Neon may terminate the Merger Agreement at any time prior to the Effective Time as follows:

- if there shall have been a breach by BioNTech or Merger Sub of any representation, warranty, covenant or agreement on the part of BioNTech or Merger Sub set forth in the Merger Agreement such that the conditions to the closing of the Merger set forth in the Merger Agreement 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 with the earlier of (i) 30 calendar days after the receipt of written notice

thereof from Neon stating Neon's intention to terminate the Merger Agreement and (ii) three business days before the End Date.

**Termination Fees (page 242)**

Neon will be required to pay to BioNTech a termination fee of $3,200,000 by wire transfer of immediately available funds if the Merger Agreement is terminated as follows:

- by BioNTech in the event that an adverse board recommendation change shall have occurred or Neon shall have materially breached its obligations under the Merger Agreement related to unsolicited proposal and adverse board recommendation changes;
- by BioNTech in the event that there shall have been a breach by Neon of any representation, warranty, covenant, or agreement on the part of Neon set forth in the Merger Agreement such that the conditions to the closing of the Merger set forth in the Merger Agreement 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 BioNTech stating BioNTech's intention to terminate the Merger Agreement on this basis and (ii) three business days before the End Date, an acquisition proposal is made or communicated to Neon or is publicly disclosed and not withdrawn before such termination, and during the period from January 15, 2020 through twelve months after such termination, Neon consummates an acquisition proposal or enters into a definitive agreement in respect of an acquisition proposal, which acquisition proposal is subsequently consummated; or
- by BioNTech or Neon in the event that the Merger Agreement has been submitted to the Neon stockholders for adoption at a duly convened Neon stockholders' meeting and the Neon Stockholder Approval shall not have been obtained at such meeting, an acquisition proposal is made or communicated to Neon or is publicly disclosed and not withdrawn before the Neon Special Meeting, and during the period from January 15, 2020 through twelve months after such termination, Neon consummates an acquisition proposal or enters into a definitive agreement in respect of an acquisition proposal, which acquisition proposal is subsequently consummated.

**Certain Material U.S. Federal Income Tax Considerations (page 462)**

It is intended that, for U.S. federal income tax purposes, the Merger will qualify as a "reorganization" within the meaning of Section 368(a) of the Internal Revenue Code of 1986. If the Merger qualifies for such intended tax treatment, a U.S. holder (as defined in "Certain Material U.S. Federal Income Tax Considerations" located elsewhere in this proxy statement/prospectus) generally will not recognize any gain or loss for U.S. federal income tax purposes upon the exchange of such holder's shares of Neon common stock for BioNTech ADSs in the Merger, except that such holder of shares of Neon common stock may recognize gain or loss with respect to cash received in lieu of a fractional BioNTech ADSs.

For a more complete discussion of the material U.S. federal income tax considerations of the Merger applicable to U.S. holders of shares of Neon common stock, please carefully review the information set forth in "Certain Material U.S. Federal Income Tax Considerations" located elsewhere in this proxy statement/prospectus. The discussion of U.S. federal income tax considerations of the Merger contained in this proxy statement/prospectus is intended to provide only a general summary and is not a complete analysis or description of all potential U.S. federal income tax consequences of the Merger. The discussion does not address tax consequences that may vary with, or are contingent on, individual circumstances. In addition, it does not address the effects of any non-U.S., state or local tax laws. ***Holders of shares of Neon common stock should consult their tax advisor to determine the tax consequences of the Merger to them.***

**Material German Tax Considerations (page 466)**

For a summary of the anticipated material German tax considerations of ownership of BioNTech ADSs, please see "Material German Tax Considerations" located elsewhere in this proxy statement/prospectus.

**Comparison of Shareholder Rights (page 496)**

As a result of the Merger, Neon stockholders will become holders of BioNTech ADSs, and will have different rights as holders of BioNTech ADSs than they had as holders of Neon common stock. The differences between the rights of these respective holders result from the differences among (1) German, European and Delaware law, (2) the respective governing documents of BioNTech and Neon, and (3) the terms of the deposit agreement among The Bank of New York Mellon, BioNTech and the holders and beneficial owners of BioNTech ADSs. For additional information, see "Comparison of Shareholder Rights" and "Description of the BioNTech ADSs" located elsewhere in this proxy statement/prospectus. For a copy of Neon's current certificate of incorporation or bylaws, see "Where You Can Find More Information" located elsewhere in this proxy statement/prospectus. BioNTech's articles of association as of the date hereof are included as an exhibit to the registration statement of which this proxy statement/prospectus is a part.

## SELECTED CONSOLIDATED FINANCIAL DATA OF BIONTECH

The following tables present selected consolidated financial data of BioNTech as of December 31, 2019 and 2018 and for the years ended December 31, 2019, 2018 and 2017. We derived the selected consolidated statements of operations for the years ended December 31, 2019, 2018 and 2017 and the selected consolidated statement of financial position data as of December 31, 2019 and 2018 from our audited consolidated financial statements included elsewhere in this proxy statement/prospectus. 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 included elsewhere in this proxy statement/prospectus. Our historical results for any prior period are not necessarily indicative of results to be expected in any future period.

| | For the Years Ended December 31, | | |
|---|---|---|---|
| **(in thousands except per share data)** | **2019** | **2018** | **2017** |
| **Consolidated statement of operations:** | | | |
| Revenues from contracts with customers | € 108,589 | € 127,575 | € 61,598 |
| Cost of sales | (17,361) | (13,690) | (9,318) |
| **Gross profit** | 91,228 | 113,885 | 52,280 |
| Research and development expenses | (226,466) | (143,040) | (85,496) |
| **Operating loss** | (181,518) | (53,854) | (61,277) |
| **Loss before tax** | (179,440) | (47,662) | (85,905) |
| Income taxes | 268 | (600) | (45) |
| **Loss for the period** | €(179,172) | € (48,262) | €(85,950) |
| Loss attributable to non-controlling interests | (116) | (243) | (297) |
| **Loss attributable to equity holders of the parent** | €(179,056) | € (48,019) | €(85,653) |
| **Basic and diluted loss per share** | € (0.85) | € (0.25) | € (0.51) |

| | As of December 31, | |
|---|---|---|
| **(in thousands)** | 2019 | 2018 |
| **Consolidated statement of financial position:** | | |
| Cash and cash equivalents | €519,149 | €411,495 |
| Total assets | 797,647 | 652,986 |
| Total current liabilities | 138,142 | 126,121 |
| Total non-current liabilities | 166,013 | 259,865 |
| Ordinary shares outstanding | 226,779 | 193,296 |
| Total equity | 493,492 | 267,000 |

## SELECTED CONSOLIDATED FINANCIAL DATA OF NEON

The following tables present selected consolidated financial data of Neon as of and for the years ended December 31, 2019 and 2018. Neon derived the selected consolidated statements of operations and comprehensive loss for the years ended December 31, 2019 and 2018 and the selected consolidated statement of financial position data as of December 31, 2019 from Neon's audited consolidated financial statements included elsewhere in this proxy statement/prospectus. We present our consolidated financial statements in US dollars and in accordance with GAAP. The selected consolidated financial data below should be read together with Neon's consolidated financial statements and related notes included elsewhere in this proxy statement/prospectus. Neon's historical results for any prior period are not necessarily indicative of results to be expected in any future period.

| (In thousands, except share and per share amounts) | Year Ended December 31, 2019 | 2018 |
|---|---|---|
| **Consolidated statements of operations and comprehensive loss:** | | |
| Operating expenses: | | |
| Research and development | $ 59,718 | $ 60,425 |
| General and administrative | 21,420 | 18,276 |
| Total operating expenses | 81,138 | 78,701 |
| Loss from operations | (81,138) | (78,701) |
| Other income (expense), net | | |
| Interest income | 1,401 | 1,792 |
| Other expense | (39) | (25) |
| Total other income (expense), net | 1,362 | 1,767 |
| Net loss | (79,776) | (76,934) |
| Accretion of redeemable convertible preferred stock to redemption value | — | (6,371) |
| Net loss attributable to common stockholders | $ (79,776) | $ (83,305) |
| Net loss per share attributable to common stockholders, basic and diluted | $ (2.86) | $ (5.54) |
| Weighted average common shares outstanding, basic and diluted | 27,878,701 | 15,036,397 |
| Comprehensive loss: | | |
| Net loss | $ (79,776) | $ (76,934) |
| Other comprehensive loss: | | |
| Unrealized gains (losses) on marketable securities | 75 | (62) |
| Total other comprehensive income (loss) | 75 | (62) |
| Comprehensive loss | $ (79,701) | $ (76,996) |

| (in thousands) | As of December 31, 2019 | 2018 |
|---|---|---|
| **Consolidated statement of financial position:** | | |
| Cash, cash equivalents and marketable securities | $29,395 | $103,311 |
| Total current assets | 31,243 | 105,427 |
| Total assets | 46,372 | 114,088 |
| Total liabilities | 16,955 | 12,839 |
| Total stockholders' equity | 29,417 | 101,249 |

## UNAUDITED PRO FORMA CONDENSED COMBINED FINANCIAL INFORMATION

On January 15, 2020 BioNTech entered into an agreement to acquire Neon in exchange for a consideration of 0.063 ADSs, representing BioNTech's ordinary shares, per share of Neon. The relevant 30-day volume weighted average price on March 24, 2020, the trading day a week prior to the date of this proxy statement/prospectus, equaled $57.50 per ADS. BioNTech plans to finance the acquisition by issuing new ordinary shares.

Although the exchange ratio of BioNTech ADS to each share of Neon common stock is fixed at 0.063, the value of the Merger Consideration will fluctuate between the date of this proxy statement/prospectus and the completion of the Merger based on the market value of BioNTech ADSs. Any change in the market price of BioNTech ADSs after the date of this proxy statement/prospectus will change the value of the Merger Consideration that Neon stockholders will receive.

The following unaudited pro forma condensed combined financial information are based on BioNTech'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 BioNTech's pending acquisition of Neon. Additionally, as Neon prepared its financial statements in accordance with U.S. general 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 statement of operations for the year ended December 31, 2019 gives effect to this transaction as if it had occurred on January 1, 2019. The unaudited pro forma condensed combined statement of financial position as of December 31, 2019 gives effect to this transaction as if it had occurred on December 31, 2019.

As of the date of this filing, BioNTech has not performed the detailed valuation studies necessary to derive the required estimates of the fair value of the Neon's assets to be acquired and liabilities to be assumed and the related allocations of the purchase price, and BioNTech 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 BioNTech.

As indicated in Note 5 to the unaudited pro forma condensed consolidated financial information, BioNTech 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 BioNTech 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 information 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 information should be read together with:

- BioNTech's audited consolidated financial statements and related notes included in this proxy statement/prospectus as of December 31, 2019 and 2018 and for the years ended December 31, 2019, 2018 and 2017; and
- Neon's audited consolidated financial statements and related notes included in this proxy statement/prospectus as of and for the years ended December 31, 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 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 Statement of Financial Position**
as of December 31, 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 | 89,434 | — | — | — | 72,919 | 5 a), 5 d) | 162,353 |
| Property, plant and equipment | 148,062 | 14,651(2) | 13,042 | (484) | (541) | 2 a), 5 d) | 160,079 |
| Other non-current assets | — | 478 | 425 | — | — | | 425 |
| Total non-current assets | 237,496 | 15,129 | 13,467 | (484) | 72,378 | | 322,857 |
| Inventories | 11,722 | — | — | — | — | | 11,722 |
| Trade receivables | 11,913 | — | — | — | — | | 11,913 |
| Deferred expenses and other current assets | 17,367 | 1,848 | 1,645 | — | — | | 19,012 |
| Cash and cash equivalents | 519,149 | 29,395 | 26,166 | — | — | | 545,315 |
| Total assets | 797,647 | 46,372 | 41,278 | (484) | 72,378 | | 910,819 |
| Total shareholders equity | 493,492 | 29,416 | 26,185 | (484) | 66,940 | 5 a), 5 c) | 586,133 |
| Contract liabilities | 97,109 | — | — | — | — | | 97,109 |
| Deferred tax liabilities | — | — | — | — | 5,438 | 5 b) | 5,438 |
| Other non-current liabilities | 68,904 | 6,548(3) | 5,829 | — | — | | 74,733 |
| Total non-current liabilities | 166,013 | 6,548 | 5,829 | — | 5,438 | | 177,280 |
| Trade payables | 20,498 | 1,702 | 1,515 | — | — | | 22,013 |
| Contract liabilities | 93,583 | — | — | — | — | | 93,583 |
| Other current liabilities | 24,061 | 8,705(4) | 7,749 | — | — | | 31,810 |
| Total liabilities | 304,155 | 16,955 | 15,093 | — | 5,438 | | 324,686 |
| Total liabilities and equity | 797,647 | 46,372 | 41,278 | (484) | 72,378 | | 910,819 |

(1) Please see “3 Foreign currency adjustments.”
(2) Consists of property, plant and equipment of $7,109 and operating lease right of use asset of $7,542.
(3) Consists of operating lease liabilities of $6,542 and other liabilities of $6.
(4) Consists of accrued expenses of $7,464 and operating lease liabilities of $1,241.

**Unaudited Pro Forma Condensed Statement of Operations**
For the period ended December 31, 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 Combined EUR(1) |
|---|---|---|---|---|---|---|---|
| Revenue | 108,589 | — | — | — | — | | 108,589 |
| Cost of sales | (17,361) | — | — | — | — | | (17,361) |
| Research and development expenses | (226,466) | (59,718) | (53,768) | (181) | (1,231) | 2 a), 2 b) | (281,646) |
| Sales and marketing expenses | (2,718) | — | — | — | — | | (2,718) |
| General and administrative expense | (45,547) | (21,420) | (19,286) | (705) | — | 2 a), 2 b) | (65,538) |
| Other operating income | 2,724 | — | — | — | — | | 2,724 |
| Other operating expenses | (739) | — | — | — | — | | (739) |
| Operating loss | (181,518) | (81,138) | (73,054) | (886) | (1,231) | | (256,689) |
| Finance income, net | 2,078 | 1,401 | 1,261 | (723) | — | 2 a) | 2,616 |
| Other expenses | — | (39) | (35) | — | — | | (35) |
| Loss before tax | (179,440) | (79,776) | (71,828) | (1,609) | (1,231) | | (254,108) |
| Income taxes | 268 | — | — | — | — | | 268 |
| Loss for the period | (179,172) | (79,776) | (71,828) | (1,609) | (1,231) | | (253,840) |
| Net loss attributable to non-controlling interests | (116) | — | — | — | — | | (116) |
| Net loss attributable to common stockholders | (179,056) | (79,776) | (71,828) | (1,609) | (1,231) | | (253,724) |
| Basic and diluted loss per share | (0.85) | | | | | | (1.19) |
| Weighted-average shares | 211,499 | | | | | | 213,309 |

(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 BioNTech 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, BioNTech 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 BioNTech.

a) Neon adopted ASC 842 as of January 1, 2019 for lease accounting. For the year ended December 31, 2019, BioNTech applied IFRS 16 for lease accounting. The following adjustments reflect as if Neon had adopted IFRS 16 as of January 1, 2019:

- Decrease in research and development expenses of k€394 and decrease of general and administrative expenses of k€88 and increase of finance expense of k€723 the year ended December 31, 2019, respectively, due to increased depreciation and reclassification of operating lease interest expense into finance expense.
- Decrease in property, plant and equipment and total shareholder's equity of k€484 as of December 31, 2019.

b) Increase in research and development expenses of k€575 and increase in general and administrative expenses of k€793 for the year ended December 31, 2019 reflect the change from straight-line method to the accelerated method of recognizing stock compensation expense per IFRS 2 and the reversal of mark-to-market expense for stock options granted to non-employees.

**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 Euro using the following historical exchange rates:

| | $ /€ |
|---|---|
| Average exchange rate for the year ended December 31, 2019 | 1.11 |
| Period end exchange rate as of December 31, 2019 | 1.12 |

**4 Financing transaction**

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

**Preliminary purchase price allocation**

BioNTech 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 December 31, 2019, 28,729,725, and included the relevant 30-day volume weighted average price on March 24, 2020 translated into Euro using the period end exchange rate as of December 31, 2019. The reference to this date intends to reflect the latest changes in share price upon a week prior to the date of this proxy statement/prospectus.

| | |
|---|---|
| Total consideration | €92,641 |
| Intangible assets | € 541 |
| Property, plant and equipment | €12,017 |
| In-process research and development | €20,922 |
| Prepaid expenses and other assets | € 2,070 |
| Cash and cash equivalents | €26,166 |
| Long-term liabilities | € (5,829) |
| Accounts payable | € (1,515) |
| Other liabilities | € (7,749) |
| Deferred tax liabilities, net | € (5,438) |
| **Goodwill** | **€51,456** |

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 BioNTech 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 BioNTech'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 BioNTech to their estimated fair values. As part of the preliminary valuation analysis, BioNTech identified intangible assets in form of in-process research and development projects. The fair value of identifiable intangible assets is determined primarily using the income method 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, BioNTech used certain assumptions based on publicly available data for the industry. Amortization for the in-process research and development in the amounts of k€1,231 for the year ended December 31, 2019 has been reflected in the pro forma statements of operations. These preliminary estimates of fair value will likely differ from final amounts BioNTech 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 k€5,438 stems primarily from the fair value adjustments for non-deductible intangible assets based on an estimated tax rate of 25.99%. 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 ordinary shares to finance the acquisition, as follows (in thousands):

| | |
|---|---|
| Net equity proceeds from issuance of 0.063 American Depositary Shares of BioNTech per share of Neon | € 92.641 |
| Less: historical Neon shareholders' equity converted into Euro and IFRS adjusted as of December 31, 2019 | €(25.701) |
| **Pro forma adjustment to shareholder's equity** | **€ 66,940** |

d) The adjustment reclassifies software assets of k€541 from property, plant and equipment to intangibles to conform the presentation of the balance of BioNTech's presentation.

## UNAUDITED COMPARATIVE HISTORICAL AND PRO FORMA PER SHARE DATA

The table set forth below contains selected unaudited historical, pro forma and pro forma equivalent per share information for the BioNTech ADSs and shares of Neon common stock.

**Historical Per Share Data for BioNTech Shares and Neon Common Stock**

The historical per share data for BioNTech Shares and Neon common stock below is derived from the audited consolidated financial statements of each of BioNTech and Neon as of and for the year ended December 31, 2019, respectively. For BioNTech, this information is under IFRS. For Neon, this information is under U.S. GAAP.

**Combined Unaudited Pro Forma Per Share Data for BioNTech Shares**

The combined unaudited pro forma per share data for BioNTech Shares is extracted from the pro forma financial statements appearing elsewhere in this proxy statement/prospectus. The pro forma financial statements are based on, and should be read in conjunction with, the historical consolidated financial statements and accompanying notes of each of BioNTech and Neon for the applicable periods, which are included elsewhere in this proxy statement/prospectus. See “Unaudited Pro Forma Condensed Combined Financial Information” located elsewhere in this proxy statement/prospectus for additional information.

The combined unaudited pro forma per share data for BioNTech Shares does not purport to represent what the Combined Company’s actual results of operations or financial condition would have been had the acquisition occurred on the dates assumed, nor is it necessarily indicative of the Combined Company’s future results of operations or financial condition. In particular, the unaudited pro forma combined financial information does not reflect the effect of anticipated cost and revenue synergies associated with the combination of BioNTech and Neon.

**Combined Unaudited Pro Forma Per Neon Equivalent Share Data**

The combined unaudited pro forma per Neon equivalent share data set forth below shows the effect of the Merger from the perspective of an owner of Neon common stock. The information was calculated by multiplying the unaudited pro forma combined per share data for BioNTech Shares by the exchange rate at the end of the applicable period.

Because the number of BioNTech Shares to be exchanged for each share of Neon common stock will be adjusted based on the shares of Neon common stock outstanding at the Effective Time, the notional value of the Merger Consideration and the exact number of BioNTech Shares that will be issued to Neon stockholders as of the date of the Neon Special Meeting and as of the closing date of the Merger cannot be determined with precision in advance of the Effective Time.

**Generally**

You should read the below information in conjunction with the selected consolidated financial information of BioNTech and Neon included elsewhere in this proxy statement/prospectus, the historical consolidated financial statements of BioNTech and related notes included elsewhere in this proxy statement/prospectus and the historical consolidated financial statements of Neon and related notes of Neon that have been filed with the SEC and included elsewhere in this proxy statement/prospectus. See “Selected Consolidated Financial Information of BioNTech” and “Selected Financial Information of Neon” included elsewhere in this proxy statement/prospectus.

| | As of and for the Year Ended December 31, 2019 |
|---|---|
| **BioNTech Historical Data (€):** | |
| Basic income from continuing operations per share | (0.85) |
| Diluted income from continuing operations per share | (0.85) |
| Book value per share | 2.33 |
| Cash dividends declared per share | — |
| **Neon Historical Data ($):** | |
| Basic income from continuing operations per share | (2.86) |
| Diluted income from continuing operations per share | (2.86) |
| Book value per share | 1.06 |
| Cash dividends declared per share | — |
| **Combined Unaudited Pro Forma per BioNTech Share Data (€):** | |
| Basic income from continuing operations per share | (1.19) |
| Diluted income from continuing operations per share | (1.19) |
| Book value per share | 2.75 |
| Cash dividends declared per share | — |
| **Combined Unaudited Pro Forma per Neon Equivalent Share Data (€):** | |
| Basic income from continuing operations per share | (0.07) |
| Diluted income from continuing operations per share | (0.07) |
| Book value per share | 0.17 |
| Cash dividends declared per share | — |

## COMPARATIVE PER SHARE MARKET PRICE AND DIVIDEND INFORMATION

### Comparative Per Share Market Price Information

BioNTech ADSs and shares of Neon common stock are both traded on Nasdaq under the symbols “BNTX” and “NTGN”, respectively. The following table presents the high and low price per share of BioNTech ADSs and shares of Neon common stock on January 15, 2020, the last full trading day before public announcement that BioNTech and Neon had entered into the Merger Agreement, and March 26, 2020, the last practicable trading day before the date of this proxy statement/prospectus.

| | BioNTech ADSs | | | Neon Common Stock | | |
|---|---|---|---|---|---|---|
| Date | High | Low | Close | High | Low | Close |
| January 15, 2020 | 39.85 | 33.60 | 34.55 | 1.29 | 1.19 | 1.23 |
| March 26, 2020 | 55.75 | 50.00 | 55.00 | 2.30 | 2.12 | 2.30 |

For illustrative purposes, the following table provides the equivalent high and low price per share of Neon common stock on each of the specified dates. These equivalent high and low price per share amounts reflect the fluctuating value of BioNTech ADSs that Neon stockholders would receive in exchange for each share of Neon common stock if the Merger were completed on either of these dates and are calculated by multiplying the high and low price per share of BioNTech ADSs by the exchange ratio of 0.063.

| | BioNTech ADSs | | | Neon Equivalent Per Share | | |
|---|---|---|---|---|---|---|
| Date | High | Low | Close | High | Low | Close |
| January 15, 2020 | 39.85 | 33.60 | 34.55 | 2.51 | 2.12 | 2.18 |
| March 26, 2020 | 55.75 | 50.00 | 55.00 | 3.51 | 3.15 | 3.47 |

The market value of the BioNTech ADSs to be issued in exchange of shares of Neon common stock upon the completion of the Merger will not be known at the time of the Neon Special Meeting. The above tables show only historical comparisons. Because the market prices of BioNTech ADSs and shares of Neon common stock will likely fluctuate prior to the Merger, these comparisons may not provide meaningful information to Neon stockholders in determining whether to approve the Merger Proposal. Neon stockholders are encouraged to obtain current market quotations for shares of BioNTech ADSs and Neon common stock and to review carefully the other information contained in this proxy statement/prospectus in considering whether to approve the Merger Proposal.

### Comparative Stock Prices and Dividends

The following tables set forth, for the periods indicated, the high and low sale prices per share of BioNTech common stock as reported by Nasdaq and the high and low sale prices per share Neon common stock as reported by Nasdaq. The table also provides information as to dividends paid per share of BioNTech common stock and Neon common stock. As of March 26, 2020 the last practicable trading day prior to the mailing of this proxy statement/prospectus, there were 226,779,744 shares of BioNTech common stock issued and outstanding and approximately 66 shareholders of record and 28,931,978 shares of Neon common stock issued and outstanding and approximately 32 shareholders of record.

***BioNTech***

| Quarterly Data | Common Stock Price High | Common Stock Price Low |
|---|---|---|
| Fourth Quarter 2019 Fiscal Year (beginning October 10, 2019) | $ 38.75 | $ 12.53 |

***Neon***

| Quarterly Data | Common Stock Price High | Common Stock Price Low |
|---|---|---|
| Fourth Quarter 2019 Fiscal Year | $ 2.34 | $ 0.88 |

Neon has never declared or paid dividends on its common stock and does not anticipate declaring or paying any cash dividends for the foreseeable future. Neon anticipates that we will retain future earnings for the development, operation and expansion of its business.

BioNTech has never declared or paid dividends on its ADSs and does not anticipate paying any cash dividends in the foreseeable future, if ever. It is the present policy of the BioNTech Supervisory Board and BioNTech Management Board to retain its earnings, if any, for the development of its business.

## CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS

This proxy statement/prospectus contains statements that constitute forward-looking statements (including within the meaning of the U.S. Private Securities Litigation Reform Act of 1995). Many of the forward-looking statements contained in this proxy statement/prospectus can be identified by the use of forward-looking words such as “anticipate,” “believe,” “could,” “expect,” “foresee,” “should,” “plan,” “intend,” “estimate,” “would,” “may,” “outlook,” and “potential,” among others. The absence of these words, however, does not mean that the statements are not forward-looking.

Forward-looking statements appear in a number of places in this proxy statement/prospectus and include, but are not limited to, statements regarding intent, belief or current expectations. Forward-looking statements are based on the current beliefs and assumptions of the management of BioNTech and Neon and on information currently available to such management. While the management of BioNTech and Neon believe that these forward-looking statements are reasonable as and when made, there can be no assurance that future developments will be as anticipated. 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 of various factors, including, but not limited to, those identified under “Risk Factors” located elsewhere in this proxy statement/prospectus. These risks and uncertainties include factors relating to:

- the ability to satisfy the conditions to the Merger, including the ability to obtain the shareholder approval solicited hereby, 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;
- the occurrence of any change, effect, event, development, matter, state of facts, series of events or circumstances that could give rise to the termination of the Merger Agreement, including a termination of the Merger Agreement under circumstances that could require Neon to pay a termination fee to BioNTech;
- the effect of the announcement of the Merger on Neon’s and BioNTech’s business relationships, employees, customers, suppliers, vendors, other partners, standing with regulators, operating results and businesses generally;
- risks relating to expectations regarding the capitalization, resources and ownership of the Combined Company;
- the initiation, timing, progress, results, and cost of research and development programs and 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 research and development programs;
- the timing of and ability to obtain and maintain regulatory approval for product candidates;
- the ability to identify research opportunities and discover and develop investigational medicines;
- the ability and willingness of third-party collaborators to continue research and development activities relating to development candidates and investigational medicines;
- expectations regarding the size of the patient populations for product candidates, if approved for commercial use;
- the impact of the COVID-19 pandemic on development programs, supply chains, collaborators and financial performance;

- estimates of expenses, ongoing losses, future revenue and capital requirements and needs for or ability to obtain additional financing;
- the ability to identify, recruit and retain key personnel;
- the ability to protect and enforce intellectual property protection for proprietary and collaborative product candidates, and the scope of such protection;
- the development of and projections relating to competitors or industries;
- the ability to commercialize product candidates, if approved;
- the pricing and reimbursement of investigational medicines, if approved;
- the rate and degree of market acceptance of investigational medicines;
- the amount of and ability to use net operating losses and research and development credits to offset future taxable income;
- the ability to manage development and expansion;
- regulatory developments in the United States and foreign countries;
- the ability to manufacture product candidates with advantages in turnaround times or manufacturing cost; and
- the ability to implement, maintain and improve effective internal controls; and expectations regarding the time during which the Combined Company will be an emerging growth company under the JOBS Act and a foreign private issuer.

Each of the factors listed above may be affected by the COVID-19 pandemic currently affecting the global community and the global economy.

The foregoing list of factors is not exhaustive. You should carefully consider the foregoing factors and the other risks and uncertainties that affect the parties' businesses, including those described in this proxy statement/prospectus, as well as in BioNTech's Annual Report on Form 20-F and Reports on Form 6-K, and in Neon's Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, and other documents filed from time to time with the SEC.

Forward-looking statements speak only as of the date they are made, and neither BioNTech nor Neon 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.

## RISK FACTORS

*In addition to the other information included in this proxy statement/prospectus, including the matters addressed in "Cautionary Statement Regarding Forward-Looking Statements" located elsewhere in this proxy statement/prospectus, you should carefully consider the following risk factors in connection with your consideration of the Merger before deciding whether to vote for approval of the Merger Proposal. In addition, you should read and consider the risks associated with each of the businesses of BioNTech and Neon because these risks will relate to the Combined Company. The risks and uncertainties described below are not the only risks and uncertainties the parties may face. Additional risks and uncertainties not presently known to the parties, or that the parties currently consider immaterial, could also negatively affect the business, financial condition, results of operations, prospects, profits and stock prices of BioNTech, Neon or the Combined Company. If any of the risks described below actually occur, the business, financial condition, results of operations, prospects, profits and stock prices of BioNTech, Neon or the Combined Company could be materially adversely affected. You should also consider the other information in this proxy statement/prospectus.*

### Risk Factors Related to the Merger

***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 Merger Agreement contains a number of conditions that must be fulfilled (or waived by the parties) to complete the Merger. These conditions include, among other customary conditions, (i) the approval and adoption of the Merger Agreement by the Neon stockholders, (ii) the absence of an enacted or promulgated law by any governmental entity of competent jurisdiction that remains in effect 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 in effect precluding, restraining, enjoining, prohibiting, suspending or making 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 issued by the SEC and remaining in effect and the absence of any proceeding initiated for that purpose by the SEC and not subsequently withdrawn, (v) the approval for listing on Nasdaq, subject to official notice of issuance, of the BioNTech 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 (or waiver) 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 BioNTech 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 the receipt of the Neon Stockholder Approval, as applicable.

***Failure to complete the Merger could negatively affect BioNTech's or Neon's stock 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 BioNTech a termination fee. In addition, BioNTech 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, BioNTech 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 BioNTech's 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, excluding shares owned by the parties to the Merger Agreement, that is issued and outstanding immediately prior to the Effective Time will be automatically canceled and converted into the right to receive 0.063 of a BioNTech ADS without interest. This Exchange Ratio will not be adjusted for changes in the market price of either BioNTech 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 BioNTech ADSs prior to the completion of the Merger will affect the value of BioNTech ADSs delivered upon completion of the Merger. An increase in the price of BioNTech ADSs will increase the value of the consideration BioNTech delivers. Similarly, a decrease in the price of Neon common stock will increase the premium that BioNTech pays per share of Neon common stock.

Stock price changes may result from a variety of factors, including, among others, general market and economic conditions, changes in BioNTech's 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 BioNTech and/or Neon, or the members of the Neon Board, 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 any other order precluding, restraining, enjoining, prohibiting, suspending or making illegal the consummation of the Merger nor any law that precludes, restrains, enjoins or prohibits the consummation of the Merger shall have been issued by any governmental entity or a court of competent jurisdiction. 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.

***Some of the directors and executive officers of Neon have interests in the Merger that may be different from, or in addition to, the interests of Neon stockholders generally.***

In considering whether to approve the proposals at the Neon Special Meeting, Neon stockholders should recognize that directors and executive officers of Neon have interests in the Merger that may differ from, or that are in addition to, their interests as Neon stockholders. The Neon Board was aware of these interests at the time it approved the Merger Agreement. These interests may cause Neon's directors and executive officers to view the Merger differently than you may view it as a stockholder. See "The Merger—Interests of Neon Directors and Executive Officers in the Merger" located elsewhere in this proxy statement/prospectus.

***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 BioNTech, Neon or the Combined Company;
- delay or defer other decisions concerning BioNTech, Neon or the Combined Company, or refuse to extend credit to BioNTech, Neon or the Combined Company; or
- otherwise seek to change the terms on which they do business with BioNTech, Neon or the Combined Company.

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

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

***The Merger Agreement contains provisions that limit Neon's ability to pursue alternatives to the Merger, could discourage a potential competing acquiror of Neon from making an alternative transaction proposal and, in specified circumstances, could require Neon to pay a termination fee to BioNTech.***

The Merger Agreement provides that Neon shall not, and requires Neon to refrain from permitting its representatives to, among other things, solicit, participate in negotiations with respect to or approve or recommend any third party proposal for an alternative transaction, subject to exceptions set forth in the Merger Agreement relating to the receipt of certain unsolicited proposals. If the Merger Agreement is terminated by either party, in certain circumstances, Neon may be required to pay a termination fee of $3,200,000.

These provisions could discourage a potential third-party acquiror or merger partner that might have an interest in acquiring all or a significant portion of Neon or pursuing an alternative transaction from considering or proposing such a transaction, even if it were prepared to pay consideration with a higher per share cash or market value than the consideration in the Merger, or might result in a potential third-party acquiror or merger partner proposing to pay a lower price to Neon stockholders than it might otherwise have proposed to pay because of the added expense of the termination fee that may become payable in certain circumstances.

If the Merger Agreement is terminated and Neon determines to seek another business combination, Neon may not be able to negotiate a transaction with another party on terms comparable to, or better than, the terms of the Merger.

***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, BioNTech and Neon are each prohibited from entering into certain transactions and taking certain actions that might otherwise be beneficial to BioNTech or Neon and their respective shareholders.***

Until the Merger is completed, the Merger Agreement restricts BioNTech and Neon from taking specified actions without the consent of the other party, and, in regards to Neon, requires Neon to operate in the ordinary course of business consistent with past practice. These restrictions may prevent BioNTech and Neon from making appropriate changes to their respective businesses or pursuing attractive business opportunities that may arise prior to the completion of the Merger. See "The Merger Agreement—Restrictions on Neon's Business Pending the Closing of the Merger" and "—Restrictions on BioNTech's Business Pending the Closing of the Merger" located elsewhere in this proxy statement/prospectus for a description of the restrictive covenants applicable to each of BioNTech and Neon.

***After the Merger, Neon stockholders will have a significantly lower ownership and voting interest in the Combined Company than they currently have in Neon, and will exercise less influence over management.***

As of immediately following the Effective Time, Neon stockholders will own a significantly smaller percentage of the Combined Company than their ownership of Neon prior to the Merger. After the completion of the Merger, former Neon stockholders are expected to own approximately 0.85% of the outstanding equity interests in the Combined Company on an undiluted basis. These estimates are based on the anticipated Exchange Ratio and are subject to adjustment as provided in the Merger Agreement. Consequently, Neon stockholders will have less influence over the management and policies of the Combined Company than they currently have over Neon.

***The opinion of Neon's financial advisor does not reflect changes in circumstances that may occur between the original signing of the Merger Agreement and the completion of the Merger.***

Consistent with market practices, the Neon Board has not obtained an updated opinion from its financial advisor as of the date of this proxy statement/prospectus and does not expect to receive an updated, revised or reaffirmed opinion prior to the completion of the Merger. Changes in the operations and prospects of Neon, general market and economic conditions and other factors that may be beyond the control of Neon, and on which Neon's financial advisor's opinion was based, may significantly alter the value of Neon or the price of shares of Neon common stock by the time the Merger is completed. The opinion does not speak as of the time the Merger will be completed or as of any date other than the date of such opinion. Because Neon's financial advisor will not be updating its opinion, the opinion will not address the fairness of the Merger Consideration from a financial point of view at the time the Merger is completed. The Neon Board's recommendation that Neon stockholders vote "**FOR**" the Merger Proposal, however, is made as of the date of this proxy statement/prospectus. For a description of the opinion that the Neon Board received from its financial advisor, please refer to "The Merger—Opinion of Neon's Financial Advisor" located elsewhere in this proxy statement/prospectus.

***If the merger does not qualify as a "reorganization" for U.S. federal income tax purposes, U.S. holders of shares of Neon common stock will be required to recognize gain or loss for U.S. federal income tax purposes at the time of the exchange of their Neon common stock for the Merger Consideration in the Merger.***

The U.S. federal income tax considerations of the Merger applicable to U.S. holders (as defined under the heading "Certain Material U.S. Federal Income Tax Considerations") will depend on whether the Merger qualifies as a "reorganization" within the meaning of Section 368(a) of the Internal Revenue Code of 1986, as amended, or the Code. The Merger is conditioned upon the delivery of legal opinions from Goodwin Procter LLP and Covington & Burling LLP to Neon and BioNTech, respectively, substantially to the effect that the Merger (i) will constitute a reorganization within the meaning of Section 368(a) of the Code, and (ii) will not result in the recognition of gain under Section 367(a)(1) of the Code by any holder of shares of Neon common stock (other than any holder of shares of Neon common stock that is a five-percent transferee shareholder of BioNTech within

the meaning of Treasury Regulations Section 1.367(a)-3(c)(5)(ii) immediately following the Merger or that held BioNTech Shares or BioNTech ADSs immediately prior to the Merger).

There can be no assurance, that the Internal Revenue Service, or the IRS, will not take a contrary position to views expressed herein or that a court will not agree with a contrary position of the IRS. If, contrary to the opinion from counsel, the Merger fails to qualify as a reorganization or if any requirement for the Merger to qualify as a "reorganization" within the meaning of Section 368(a) of the Code is not satisfied, a U.S. holder would recognize gain or loss for U.S. federal income tax purposes on each share of Neon common stock surrendered in the Merger in an amount equal to the difference between (1) the fair market value of the Merger Consideration received in exchange for such surrendered share upon completion of the Merger and (2) the holder's basis in the share of Neon common stock surrendered. Any gain or loss recognized would be long-term capital gain or loss if the U.S. holder's holding period in a particular block of Neon common stock exceeds one year at the Effective Time of the merger. Long-term capital gain of non-corporate U.S. holders (including individuals) is taxed at reduced U.S. federal income tax rates. The deductibility of capital losses is subject to limitations. For a more complete discussion of the material U.S. federal income tax consequences of the Merger, please carefully review the information set forth in "Certain Material U.S. Federal Income Tax Considerations" located elsewhere in this proxy statement/prospectus.

**Risk Factors Related to the Combined Company**

***The Combined 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 Combined 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 Combined Company, and may affect the value of BioNTech Shares and the BioNTech ADSs representing the BioNTech Shares after the completion of the Merger.

***The Combined Company will incur significant transaction-related costs in connection with the Merger.***

BioNTech 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 Combined 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. BioNTech 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.

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

The Combined 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 Combined 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 Combined 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 Combined Company's results of operations.

***Future results of the Combined Company may differ materially from the unaudited pro forma financial information included in this proxy statement/prospectus.***

The Combined Company's future results may be materially different from those shown in the unaudited pro forma financial information presented in this proxy statement/prospectus that show only a combination of our and Neon's historical results. BioNTech expects 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 BioNTech for future income-earning investments.

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

While the financial projections utilized by BioNTech, 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 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 BioNTech and Neon and will be beyond the control of the Combined 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 Combined Company's business, financial condition, results of operations and prospects.

**Risk Factors Related to the BioNTech ADSs**

***The price of the ADSs may be volatile and fluctuate substantially, which could result in substantial losses.***

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 price at which you obtained the ADSs. The market price for the ADSs may be influenced by many factors, including:

- results of clinical trials of BioNTech's product candidates or those of BioNTech's 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 BioNTech's product candidates or clinical development programs;
- the results of BioNTech's efforts to discover, develop, acquire or in-license additional product candidates;
- actual or anticipated changes in estimates as to financial results, development timelines or recommendations by securities analysts;

- variations in BioNTech's financial results or those of companies that are perceived to be similar to BioNTech;
- 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 BioNTech's pipeline, the development of which could each generate news or significant adverse events that could impact financial results or recommendations by securities analysts.

If BioNTech's 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 BioNTech's results may, in turn, cause the price of the ADSs to fluctuate substantially. BioNTech believes that period-to-period comparisons of its results are not necessarily meaningful and should not be relied upon as an indication of its 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 BioNTech, could cause BioNTech to incur substantial costs to defend such claims and divert management's attention and resources, which could seriously harm BioNTech's business, financial condition, results of operations and prospects.

***BioNTech has incurred increased costs as a result of operating as a public company, and its management has been required to devote substantial time to new compliance initiatives. BioNTech is subject to financial reporting and other requirements for which its accounting and other management systems and resources may not be adequately prepared. BioNTech may fail to comply with the rules that apply to public companies, includingSection 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 BioNTech is no longer an "emerging growth company" as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act, BioNTech expects to incur significant legal, accounting and other expenses that it did not incur as a private company. BioNTech expects that it will cease to be an emerging growth company beginning January 1, 2021. 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 Nasdaq have imposed various requirements on public companies, including requirements to file annual and event-driven reports with respect to BioNTech's business and financial condition, and to establish and maintain effective disclosure and financial controls and corporate governance practices. BioNTech's management and other personnel need to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations have increased BioNTech's legal and financial compliance costs and have made some activities more time-consuming and costly. BioNTech 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, BioNTech could make errors in its financial statements that could require it to restate its financial statements.

Pursuant to Section 404 of the Sarbanes-Oxley Act, or Section 404, concurrent with BioNTech's second Annual Report on Form 20-F BioNTech is required to furnish a report by its management on its internal control over financial reporting, including the attestation report on internal control over financial reporting issued by its independent registered public accounting firm. However, while BioNTech remains an emerging growth company, BioNTech will not be required to include an attestation report on internal control over financial reporting issued by its independent registered public accounting firm in its annual filings with the SEC. To achieve compliance with Section 404 within the prescribed period, BioNTech has initiated the process to

document and evaluate its internal control over financial reporting, which is both costly and challenging. In this regard, BioNTech 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. BioNTech 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 BioNTech's efforts, there is a risk that neither it nor its independent registered public accounting firm (once BioNTech is no longer an emerging growth company) will be able to conclude within the prescribed timeframe that its 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 BioNTech's 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 initial public offerings. BioNTech intends to take advantage of this new legislation but cannot guarantee that it 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 BioNTech operates its business in ways BioNTech cannot currently anticipate. BioNTech's management and other personnel need to devote a substantial amount of time to these compliance initiatives.

***BioNTech has identified a material weakness in its internal control over financial reporting and may identify additional material weaknesses in the future that may cause it to fail to meet its reporting obligations or result in material misstatements in its financial statements. If BioNTech fails to remediate its material weakness, BioNTech may not be able to report its financial results accurately or to prevent fraud.***

BioNTech's 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 BioNTech's initial public offering, BioNTech 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. BioNTech has historically operated with limited accounting personnel and other resources with which to address its internal control over financial reporting.

BioNTech and its 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 providing technical accounting services and (iii) a lack of consistent application of accounting processes and procedures by BioNTech's accounting personnel. These deficiencies constitute a material weakness in BioNTech'sr 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. BioNTech has relied on the assistance of outside advisors with expertise in these matters to

prepare its financial statements and comply with SEC reporting obligations, and BioNTech expects to continue to do so while it remediates this material weakness.

BioNTech is continuing to develop and implement a remediation plan to address the material weakness; however, BioNTech's overall control environment still requires enhancement and may expose it to errors, losses or fraud. BioNTech's remediation plan includes the hiring of additional suitably qualified staff. Additionally, BioNTech intends to document and implement consistent accounting policies and procedures and provide additional training to its accounting and finance staff. While BioNTech is working to remediate the material weakness as quickly and efficiently as possible, BioNTech cannot at this time provide an estimate of the costs it expects to incur or the expected timeline in connection with implementing its remediation plan. These remediation measures may be time-consuming and costly, and might place significant demands on its financial and operational resources. If BioNTech is unable to successfully remediate this material weakness or successfully supervise and rely on outside advisors with expertise in these matters to assist in the preparation of its financial statements, BioNTech's financial statements could contain material misstatements that, when discovered in the future, could cause it to fail to meet its future reporting obligations and cause the price of BioNTech ADSs to decline.

***BioNTech is an "emerging growth company" and the reduced disclosure requirements applicable to emerging growth companies may make BioNTech Shares and the ADSs less attractive to investors.***

BioNTech is an "emerging growth company" under the JOBS Act, and it will remain an emerging growth company until the earlier of:

- the last day of the first fiscal year in which its annual gross revenues exceed $1.07 billion;
- the date on which it has issued more than $1 billion in nonconvertible debt securities during the previous three years;
- the date on which it is 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 its most recently completed second fiscal quarter, the market value of its 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 its initial public offering.

BioNTech expects that it will cease to be an emerging growth company beginning January 1, 2021. For so long as it remains an emerging growth company, BioNTech is 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.

BioNTech may choose to take advantage of some, but not all, of the available exemptions. BioNTech has taken advantage of reduced reporting burdens in this proxy statement/prospectus. In particular, BioNTech has not included all of the executive compensation information that would be required if it were not an emerging growth company. BioNTech cannot predict whether investors will find the ADSs less attractive if it relies 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, BioNTech 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," BioNTech is exempt from a number of rules under the U.S. securities laws, as well as Nasdaq rules, and BioNTech is 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 BioNTech Shares and the ADSs less attractive to investors.***

BioNTech is a "foreign private issuer," as defined in the rules and regulations of the SEC, and, consequently, BioNTech is not subject to all of the disclosure requirements applicable to companies organized within the United States. For example, BioNTech is exempt from certain rules under 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, BioNTech's 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 BioNTechsecurities. Moreover, BioNTech is 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 BioNTech than there is for U.S. public companies.

As a foreign private issuer, BioNTech will file an Annual Report on Form 20-F within four months of the close of each fiscal year ending December 31 and reports on Form 6-K relating to certain material events promptly after BioNTech publicly announces these events. Additionally, BioNTech relies on a provision in Nasdaq's Listed Company Manual that allows BioNTech 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 BioNTechto 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, BioNTech is 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 BioNTech Shares.

As a foreign private issuer, BioNTech is permitted to follow home country practice in lieu of the above requirements. BioNTech therefore continues to follow German corporate governance practices in lieu of the corporate governance requirements of Nasdaq in certain respects. In particular, BioNTech follows German corporate governance practices in connection with the distribution of annual and interim reports to shareholders, the application of BioNTech's code of conduct to its 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 BioNTech's Nasdaq listing, BioNTech's 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 BioNTech is a foreign private issuer, however, BioNTech's audit committee is not subject to additional requirements of Nasdaq applicable to listed U.S. companies, including an affirmative determination that all members of the audit committee are "independent," using more stringent criteria than those applicable to BioNTech as a foreign private issuer.

Due to the above exemptions for foreign private issuers, BioNTech's 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 BioNTech's total outstanding BioNTech Shares 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 BioNTech to register them for sale could cause the market price of the ADSs to drop significantly, even if BioNTech's business is performing well.***

Sales of a substantial number of BioNTech 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. As of December 31, 2019, BioNTech had 226,779,744 ordinary shares outstanding.

In connection with BioNTech's initial public offering, BioNTech, all of its directors and officers, and substantially all of its shareholders entered into lock-up agreements with the underwriters and/or are subject to market standoff agreements or other agreements with BioNTech under which BioNTech and they agreed, subject to specific exceptions, not to sell any of BioNTech's shares for at least 180 days following the date of BioNTech's initial public offering. The remaining BioNTech Shares will be available for sale 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 the lock-up period at the discretion of the lead underwriters for the respective offerings. 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.

BioNTech intends to file one or more registration statements on Form S-8 under the Act to register all BioNTech Shares issued or issuable under BioNTech's 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.

Sales of ADSs or BioNTech Shares as restrictions end or pursuant to registration rights may make it more difficult for BioNTech to finance its operations through the sale of equity securities in the future at a time and at a price that BioNTech deems appropriate. These sales also could cause the trading price of the ADSs to fall and make it more difficult for BioNTech to sell the ADSs.

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

Holders of ADSs are not treated as BioNTech shareholders unless they cancel the ADSs and withdraw the BioNTech Shares underlying the ADSs from the depositary, which is the holder of the BioNTech Shares underlying the ADSs. Holders of ADSs, therefore, do not have any rights as shareholders of BioNTech, 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 BioNTech Shares. Holders of ADSs may instruct the depositary how to vote the BioNTech Shares underlying their ADSs. If BioNTech asks 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, BioNTech is not required to instruct the depositary to take action with respect to shareholder meetings. If BioNTech does 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 BioNTech Shares directly.

***If BioNTech sells BioNTech 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.***

BioNTech may from time to time issue additional BioNTech Shares or sell ADSs at a discount from the current trading price of BioNTech Shares or the ADSs. As a result, holders of ADSs would experience further immediate dilution upon the purchase of any BioNTech Shares or ADSs sold at such discount. In addition, as opportunities present themselves, BioNTech may enter into financing or similar arrangements in the future, including the issuance of debt securities, BioNTech Shares or ADSs. If BioNTech issues BioNTech Shares or securities convertible or exchangeable into BioNTech 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 BioNTech existing shareholders, restrict BioNTech's operations, or require BioNTech to relinquish rights to its technologies or product candidates.***

BioNTech may seek additional capital through a combination of public and private equity offerings, debt financings, collaborations and licensing arrangements. To the extent that BioNTech raises additional capital through the sale of equity securities, including securities convertible or exchangeable into BioNTech 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 BioNTech's ability to incur additional debt, limitations on BioNTech's ability to acquire or license intellectual property rights and other operating restrictions that could adversely impact BioNTech's ability to conduct its business. If BioNTech raises additional funds through collaborations and licensing arrangements with third parties or through asset sales, BioNTech may have to relinquish valuable rights to its technologies or product candidates, or grant licenses on terms unfavorable to BioNTech.

***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 BioNTech registers 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. BioNTech is 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, BioNTech may not be able to establish an exemption from registration under the Securities Act. Accordingly, ADS holders may be unable to participate in BioNTech's 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 BioNTech is 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 BioNTech's income and assets and the value of BioNTech's assets, including goodwill, which is based on the current market price of the ADSs, BioNTech does not expect to be treated as a PFIC for its current taxable year or in any future taxable year. However, because PFIC status is based on BioNTech's income, assets and activities for the entire taxable year, which BioNTech expects may vary substantially over time, it is not possible to determine whether BioNTech will be characterized as a PFIC for any taxable year until after the close of the taxable year. Moreover, BioNTech must determine its PFIC status annually based on tests that are factual in nature, and BioNTech's status in future years will depend on its income, assets and activities in each of those years. There can be no assurance that BioNTech will not be considered a PFIC for any taxable year. If BioNTech were to be or become a PFIC for any taxable year during which a U.S. holder (defined below in "Certain Material U.S. Federal Income Tax Considerations") holds ADSs, certain adverse U.S. federal income tax consequences could apply to such U.S. holder. See "Taxation—Material U.S. Federal Income Tax Considerations—Passive Foreign Investment Company Considerations" in BioNTech's registration statement on Form F-1 filed with the SEC on September 9, 2019.

***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 BioNTech and members of its Supervisory Board and Management Board and the experts named in this proxy statement/prospectus.***

BioNTech is incorporated under the laws of Germany as a European stock corporation (*Societas Europaea*) pursuant to the SE Regulation. The majority of BioNTech's assets are located outside the United States and all of

the members of BioNTech's 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 BioNTech 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 BioNTech or any members of its 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.***

BioNTech is a European stock corporation (*Societas Europaea*) with its registered office in Germany. BioNTech's corporate affairs are governed by the laws governing stock corporations and European stock corporations incorporated in Germany, the SE Regulation and BioNTech's 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 BioNTech's detriment or the detriment of other shareholders.

As a general rule under German law, in the case of a two-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 when it is able to fulfill its third party obligations, certain tortious conduct of board members 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 BioNTech's Management Board and Supervisory Board may differ from the duties of directors of U.S. corporations. For example, in the performance of their duties, BioNTech's Management Board and Supervisory Board may take into account a broad range of considerations, including BioNTech's interests, the interests of BioNTech's 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, BioNTech has provided summaries of relevant German corporation law and of its articles of association under "Management" and "Description of Share Capital and Articles of Association (*Satzung*)."

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

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

***BioNTech's principal shareholders and management own a significant percentage of BioNTech Shares and will be able to exert significant control over matters subject to shareholder approval.***

BioNTech's executive officers, directors, five percent or greater shareholders, and their affiliates beneficially own approximately 83.40% of BioNTech Shares as of February 10, 2020. Therefore, these shareholders will have the ability to influence BioNTech 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 BioNTech's 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 BioNTech Shares that you may believe are in your best interest as one of BioNTech's shareholders.

***Because BioNTech does not currently pay cash dividends on BioNTech Shares and does 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 BioNTech 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. BioNTech's ability to pay dividends is also limited under the terms of the investment agreement BioNTech has 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 BioNTech 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 BioNTech 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.

***BioNTech 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 BioNTech because biopharmaceutical companies have experienced significant price volatility in recent years. If BioNTech faces such litigation, it could result in substantial costs and a diversion of management's attention and resources, which could harm BioNTech's 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 BioNTech 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 BioNTech or the depositary arising out of or relating to BioNTech Shares, the ADSs or the deposit agreement, including any claim under U.S. federal securities laws.

If BioNTech 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 BioNTech's 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, BioNTech believes 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. BioNTech believes 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 BioNTech 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 BioNTech or the depositary. If a lawsuit is brought against BioNTech 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 BioNTech or the depositary of compliance with any substantive provision of the U.S. federal securities laws and the rules and regulations promulgated thereunder.

**Risk Factors Related to BioNTech's Business**

*Risks Related to BioNTech's Financial Condition and Capital Requirements*

***BioNTech is a clinical-stage biopharmaceutical company with no pharmaceutical products approved for commercial sale. BioNTech has incurred significant losses since its inception and BioNTech anticipates that it will continue to incur significant losses for the foreseeable future, which makes it difficult to assess its future viability.***

BioNTech has incurred net losses in each year since its inception in 2008, including net losses of €179.2 million and €48.3 million for the years ended December 31, 2019 and December 31, 2018, respectively. As of December 31, 2019, BioNTech had accumulated losses of €424.8 million.

BioNTech has devoted most of its financial resources to research and development, including its clinical and preclinical development activities and the development of its platforms. To date, BioNTech has financed its 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 BioNTech's future net losses will depend, in part, on the rate of its future expenditures and its ability to obtain funding through equity or debt financings, sales of assets, collaborations or grants. BioNTech has not commenced or completed pivotal clinical trials for its programs and it will be several years, if ever, before BioNTech or its collaborators have a product candidate ready for commercialization. Even if BioNTech obtains regulatory approval to market a product candidate, its future revenues will depend upon the size of any markets in which its product candidates have received approval, and BioNTech's ability to achieve sufficient market acceptance, reimbursement from third-party payors, and adequate market share in those markets. BioNTech may never achieve profitability.

BioNTech expects to continue to incur significant expenses and increasing operating losses for the foreseeable future. BioNTech anticipates that its expenses will increase substantially if and as BioNTech and its collaborators:

- continue or expand BioNTech's research or development of BioNTech's programs in preclinical development;
- continue or expand the scope of BioNTech's clinical trials for its product candidates;
- initiate additional preclinical, clinical, or other trials for BioNTech's product candidates, including under its collaboration agreements;
- continue to invest in BioNTech's 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 BioNTech'squality control, quality assurance, legal, compliance and other groups to support its operations as BioNTech progresses its product candidates toward commercialization;
- attract and retain skilled personnel;

- create additional infrastructure to support BioNTech's operations as a public company and BioNTech's 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 BioNTech's product candidates;
- establish a sales, marketing, and distribution infrastructure to commercialize any products for which BioNTech 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 BioNTech's intellectual property portfolio; and
- experience any delays or encounter issues with any of the above.

***BioNTech's operating results may fluctuate significantly, which makes BioNTech's future operating results difficult to predict. If BioNTech's operating results fall below expectations, the price of the ADSs could decline.***

BioNTech's 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 BioNTech's control. Factors relating to BioNTech's business that may contribute to these fluctuations include the following, as well as other factors described elsewhere in this proxy statement/prospectus:

- delays or failures in advancement of existing or future product candidates into the clinic or in clinical trials;
- BioNTech's ability to develop, manufacture and commercialize its programs;
- BioNTech's ability to manage its growth;
- the outcomes of research programs, clinical trials, or other product development or approval processes conducted by BioNTech and its collaborators;
- the ability of BioNTech's collaborators to develop and successfully commercialize products developed from its suite of therapeutic classes;
- BioNTech's relationships, and any associated exclusivity terms, with collaborators;
- BioNTech'scontractual or other obligations to provide resources to fund its product candidates, and to provide resources to its collaborators or to the collaborations themselves;
- BioNTech's operation in a net loss position for the foreseeable future;
- risks associated with the international aspects of BioNTech's business outside Germany, including the conduct of clinical trials in multiple locations and potential commercialization in such locations;
- BioNTech's ability to consistently manufacture its product candidates;
- BioNTech's ability to accurately report its financial results in a timely manner;
- BioNTech's dependence on, and the need to attract and retain, key management and other personnel;
- BioNTech's ability to obtain, protect, maintain, defend and enforce its intellectual property rights;
- BioNTech's ability to prevent the theft or infringement, misappropriation or other violation of its intellectual property, trade secrets, know-how or technologies;

- potential advantages that BioNTech's competitors and potential competitors may have in securing funding, obtaining the rights to critical intellectual property or developing competing technologies or products;
- BioNTech's ability to obtain additional capital that may be necessary to expand its business;
- BioNTech's collaborators' ability to obtain additional capital that may be necessary to develop and commercialize products under its collaboration agreements;
- business interruptions such as power outages, strikes, acts of terrorism or natural disasters; and
- BioNTech's ability to use its net operating loss carryforwards to offset future taxable income.

Due to the various factors mentioned above, and others, the results of any of BioNTech's periods should not be relied upon as indications of BioNTech's future operating performance.

The net losses BioNTech incurs may fluctuate significantly from one reporting period to the next, such that a period-to-period comparison of BioNTech's results of operations may not be a good indication of BioNTech's future performance.

In any particular period, BioNTech's 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 BioNTech intends to periodically report on the status of its product candidate pipeline, including articulating anticipated next steps in the form of development plans or potential data readouts, BioNTech may not always be able to provide forward-looking guidance on the timing of those next steps. In addition, BioNTech does not control the timing of disclosures of any milestones related to any of its programs that are managed by its collaborators. Any disclosure by a collaborator of data that are perceived as negative, whether or not such data are related to other data that BioNTech 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 BioNTech's programs, including adverse safety events reported for any of BioNTech's programs.

***BioNTech has only generated limited revenue and may never be profitable.***

BioNTech's ability to generate revenue and achieve profitability depends on its ability, alone or with collaborators, to successfully complete the development of, and obtain the regulatory approvals necessary to commercialize, its product candidates. Although BioNTech generates limited revenue from sales of products by its external services business unit, BioNTech does not anticipate generating revenues from pharmaceutical product sales in the near term. BioNTech's ability to generate future revenues from pharmaceutical product sales depends heavily on its success in:

- completing research and preclinical and clinical development of its product candidates;
- seeking and obtaining U.S. and non-U.S. marketing approvals for product candidates for which BioNTech completes clinical trials;
- furthering the development of BioNTech's 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 its product candidates, if approved;
- obtaining market acceptance of its product candidates as a treatment option;
- launching and commercializing product candidates for which BioNTech obtains 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 BioNTech may enter;
- maintaining, defending, protecting, enforcing and expanding BioNTech's 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 BioNTech develops is approved for commercial sale, BioNTech anticipates incurring significant costs associated with commercializing any approved product candidate. BioNTech's expenses could increase beyond its expectations if it is 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 its manufacturing or quality systems in addition to those that BioNTech currently anticipates. Even if BioNTech is able to generate revenues from the sale of any approved products, it may not become profitable and may need to obtain additional funding to continue operations.

***The amount of and BioNTech's 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, BioNTech has unused tax loss carryforwards for corporate taxes, though it has 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, BioNTech may in the future have U.S. federal and state NOL carryforwards due to its subsidiary in the United States.

BioNTech may not be able to utilize a material portion of its 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 BioNTech's recognition could be subject to challenge by taxing authorities. In the event any such challenge is sustained, BioNTech's NOLs could be materially reduced or BioNTech could be determined to be a material cash taxpayer for one or more years. Furthermore, BioNTech's ability to use its NOLs or credits is conditioned upon it attaining profitability and generating taxable income. As described above, BioNTech has incurred significant net losses since its inception and anticipate that it will continue to incur significant losses for the foreseeable future. BioNTech does not know whether or when it will generate the taxable income necessary to utilize its NOL or credit carryforwards.

***Under German tax laws, BioNTech is obligated to withhold a percentage of royalty payments it makes to third party licensors of intellectual property rights and remit those withholdings to German tax authorities, and late withholding tax payments may subject BioNTech to penalties and fees.***

Under German tax laws, BioNTech is obligated to withhold a percentage of royalty payments it makes 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, BioNTech has discovered that in the 11-year period before April 2019 BioNTech and certain of its 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 BioNTech's and their financial books and records in relation thereto. BioNTech has notified the tax authorities of the late payments and made the respective payments in 2019. No administrative offense or criminal proceedings were opened or are expected in the future.

It is possible to seek the refund of these withholding taxes from the German Federal Central Tax office after filing exemption and refund applications. BioNTech started to process the filing of such refund and exemption

applications and part of the taxes paid have already been refunded and we expect further refunds to be paid out in the future. 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.

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

As of December 31, 2019, BioNTech had €519.1 million in cash and cash equivalents. BioNTech's operating plan may change as a result of many factors currently unknown to it, and BioNTech 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, BioNTech will require additional capital to obtain regulatory approval for, and to commercialize, its product candidates. Even if BioNTech believes it has sufficient funds for its current or future operating plans, BioNTech may seek additional capital if market conditions are favorable or if it has specific strategic considerations. BioNTech's 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 its product candidates, BioNTech is unable to estimate the actual funds it will require for development, marketing and commercialization activities.

BioNTech's 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 its product candidates;
- the results of research and its other platform activities;
- the clinical development plans BioNTech establishes for its product candidates;
- the terms of any agreements with its current or future collaborators;
- the number and characteristics of product candidates that BioNTech develops or may in-license;
- the outcome, timing and cost of meeting regulatory requirements established by the FDA, the EMA and other comparable regulatory authorities;
- the cost of filing, prosecuting, obtaining, maintaining, protecting, defending and enforcing its 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 BioNTech regarding its product candidates or actions by BioNTech 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 its product candidates;
- the cost and timing of completion and further expansion of clinical and commercial scale manufacturing activities sufficient to support all of its current and future programs; and
- the cost of establishing sales, marketing, and distribution capabilities for any product candidates for which BioNTech may receive marketing approval and reimbursement in regions where it chooses to commercialize its products on its own.

To date, BioNTech has financed its operations primarily through the sale of equity securities and revenue from collaborations and BioNTech cannot be certain that additional funding will be available on favorable terms, or at all. Until BioNTech can generate sufficient product sales or royalty revenue to finance its operations, which

BioNTech may never do, BioNTech expects to finance its 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 BioNTech's management from their day-to-day activities, which may adversely affect its ability to develop and commercialize its product candidates. In addition, BioNTech cannot guarantee that future financing will be available in sufficient amounts, at the right time, on favorable terms, or at all, including as a result of the impact that the COVID-19 pandemic may have on the capital markets.

Negative clinical trial data or setbacks, or perceived setbacks, in BioNTech's programs or with respect to its technology could impair BioNTech's 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 BioNTech's shareholders, and the issuance of additional securities, whether equity or debt, by BioNTech, or the possibility of such issuance, may cause the market price of its shares to decline. If BioNTech raises additional funds through public or private equity offerings, the terms of these securities may include liquidation or other preferences that may adversely affect its shareholders' rights.

Further, to the extent that BioNTech raises additional capital through the sale of ADSs, BioNTech Shares or securities convertible or exchangeable into BioNTech Shares, your ownership interest will be diluted. BioNTech has entered into three secured credit facilities with an aggregate drawing capacity of €70 million. In addition, BioNTech may enter into additional credit facilities from time to time, which may be secured, to fund certain of its operations. If BioNTech raises additional capital through debt financing, BioNTech would be subject to fixed payment obligations and may be subject to security interests in its assets and covenants limiting or restricting its ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If BioNTech raises additional capital through marketing and distribution arrangements, sales of assets or other collaborations, or licensing arrangements with third parties, BioNTech may have to relinquish certain valuable rights to its product candidates, technologies, future revenue streams or research programs. BioNTech also could be required to seek collaborators for one or more of its current or future product candidates at an earlier stage than otherwise would be desirable or relinquish its rights to product candidates or intellectual property that it otherwise would seek to develop or commercialize on its own. If BioNTech is unable to raise additional capital in sufficient amounts, at the right time, on favorable terms, or at all, BioNTech may have to significantly delay, scale back or discontinue the development or commercialization of one or more of its products or product candidates, or one or more of its other research and development initiatives. Any of the above events could significantly harm its business, prospects, financial condition and results of operations, cause the price of the ADSs to decline, and negatively impact its ability to fund operations.

***BioNTech will need to develop and expand its company, and BioNTech may encounter difficulties in managing this development and expansion, which could disrupt its operations.***

As of December 31, 2019, BioNTech had more than 1,300 full-time employees and, in connection with the growth and advancement of its pipeline and becoming a public company, BioNTech expects to increase the number of employees and the scope of its operations. To manage its anticipated development and expansion, BioNTech must continue to implement and improve its managerial, operational, legal, compliance and financial systems, expand its facilities, and continue to recruit and train additional qualified personnel. Also, BioNTech's 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, BioNTech is 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 its limited resources, BioNTech may not be able to effectively manage this simultaneous execution and the expansion of its operations or recruit and train additional qualified personnel. This may result in

weaknesses in its 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 its operations may lead to significant costs and may divert financial resources from other projects, such as the development of BioNTech's product candidates. If BioNTech's management is unable to effectively manage its expected development and expansion, BioNTech's expenses may increase more than expected, its ability to generate or increase its revenue could be reduced and BioNTech may not be able to implement its business strategy. BioNTech's future financial performance and its ability to compete effectively and commercialize its product candidates, if approved, will depend in part on its ability to effectively manage the its future development and expansion.

***BioNTech faces risks related to health epidemics, such as the current coronavirus outbreak, that could adversely affect its operations.***

BioNTech's business could be adversely impacted by the effects of COVID-19 (more commonly referred to as coronavirus) or other epidemics. The recent COVID-19 outbreak may negatively impact BioNTech's revenue or operations in the future. The COVID-19 pandemic could also affect BioNTech's ability to enroll patients in clinical studies and complete clinical trials on the timelines it currently anticipates.

BioNTech's suppliers, licensors or collaborators could also be disrupted by conditions related to COVID-19, or other epidemics, possibly resulting in disruption to BioNTech's supply chain, clinical trials, partnerships or operations. If BioNTech's suppliers, licensors, CROs or collaborators are unable or fail to fulfill their obligations to BioNTech for any reason, its business could be adversely affected. BioNTech's customers could also be disrupted by conditions related to COVID-19 or other epidemics, possibly through deferring purchasing decisions or delaying research programs. BioNTech's operations, including research and manufacturing, could also be disrupted due to the potential of the impact of staff absences as a result of self-isolation procedures or extended illness.

At this point in time, there is uncertainty relating to the potential effect of COVID-19 on BioNTech's business. Infections may become more widespread and a significant health epidemic could adversely affect the economies and financial markets of many countries, resulting in an economic downturn that could affect demand for BioNTech's products and services or its ability to raise capital, which could have a material adverse effect on its business, operating results and financial condition.

***BioNTech's insurance policies are expensive and protect only against some business risks, which leaves BioNTech exposed to significant uninsured liabilities.***

BioNTech does not carry insurance for all categories of risk that BioNTech may encounter and insurance coverage is becoming increasingly expensive. BioNTech does not know if it will be able to maintain existing insurance with adequate levels of coverage, and any liability insurance coverage BioNTech acquires in the future may not be sufficient to reimburse for any expenses or losses BioNTech may suffer. If BioNTech obtains marketing approval for any product candidates that it or its collaborators may develop, BioNTech intends to acquire insurance coverage to include the sale of commercial products, but BioNTech may be unable to obtain such insurance on commercially reasonable terms or in adequate amounts. BioNTech currently maintains insurance coverage for losses relating to an interruption of its 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 BioNTech's insurance policies may not be adequate. If BioNTech's losses exceed its insurance coverage, BioNTech's financial condition would be adversely affected. In the event of contamination or injury, BioNTech could be held liable for damages or be penalized with fines in an amount exceeding its resources. Clinical trials or regulatory approvals for any of BioNTech's product candidates could be suspended, which could adversely affect BioNTech's results of operations and business, including by preventing or limiting the development and commercialization of any product candidates that BioNTech or its collaborators may develop. Additionally, operating as a public company has made it more expensive for it to obtain director and officer liability insurance. As a result, it may be more difficult for BioNTech to attract and retain qualified individuals to serve on its Supervisory Board, its board committees or its Management Board.

*Risks Related to BioNTech's Business*

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

Even if BioNTech completes the necessary preclinical studies and clinical trials, the marketing approval process is expensive, time-consuming and uncertain, and BioNTech may not be able to obtain approvals for the commercialization of any product candidates it may develop. Any immunotherapy BioNTech 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 BioNTech's product candidates, BioNTech and its collaborators must demonstrate through extensive preclinical studies and clinical trials that BioNTech's 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 BioNTech from commercializing the product candidate in a given jurisdiction. BioNTech has not received approval to market any biopharmaceutical product candidates from regulatory authorities in any jurisdiction, and it is possible that none of BioNTech's product candidates, or any product candidates BioNTech may seek to develop in the future, will ever obtain regulatory approval. BioNTech has 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 BioNTech in this process. To BioNTech's knowledge, there is no current precedent for an mRNA-based immunotherapy such as the type BioNTech is developing being approved for sale by the FDA, European Commission or any other regulatory agency elsewhere in the world. Although BioNTech expects to submit BLAs for its 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 BioNTech's 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 BioNTech develops 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 BioNTech from 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 BioNTech ultimately obtains 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, BioNTech 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 BioNTech's 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 BioNTech experiences delays in obtaining, or if BioNTech fails to obtain, approval of any product candidates it may develop, the commercial prospects for those product candidates will be harmed, and BioNTech's ability to generate revenues will be materially impaired. Additionally, even if BioNTech is successful in obtaining marketing approval for product candidates, because its preclinical studies and clinical trials have not been designed with specific commercialization considerations, the commercial prospects for those product candidates could be harmed, and BioNTech's 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 BioNTech's 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 BioNTech or its collaborators is highly uncertain and depends on numerous factors, many of which are beyond BioNTech's or their control. To date, there has never been a Phase 3 trial for an mRNA-based product or a commercialized mRNA-based product. BioNTech's 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 BioNTech's product candidates commercially unattractive;
- BioNTech's improvements in the manufacturing processes may not be sufficient to satisfy the clinical or commercial demand of BioNTech's product candidates or regulatory requirements for clinical trials;
- changes that BioNTech makes to optimize its manufacturing, testing or formulating of GMP materials could impact the safety, tolerability and efficacy of its 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 BioNTech's 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 BioNTech's inability to obtain sufficient funding; and
- the proprietary rights, products and technologies of BioNTech's competitors may prevent BioNTech's 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 BioNTech's 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.

***BioNTech's 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 BioNTech's 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 BioNTech's product candidates could cause BioNTech 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 BioNTech's trials could reveal a high and unacceptable severity and prevalence of side effects.

If unacceptable side effects arise in the development of BioNTech's product candidates, BioNTech, the FDA, competent authorities of European Union member states, ethics committees, the institutional review boards, or IRBs, at the institutions in which BioNTech's studies are conducted, or the Data Safety Monitoring Board, or DSMB, could suspend or terminate BioNTech's clinical trials. The FDA or comparable regulatory authorities could also order BioNTech to cease clinical trials or deny approval of BioNTech's 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 BioNTech's 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. BioNTech expects to have to train medical personnel using BioNTech's product candidates to understand the side effect profiles for BioNTech's clinical trials and upon any commercialization of any of BioNTech's product candidates. Inadequate training in recognizing or managing the potential side effects of BioNTech's product candidates could result in patient injury or death. Any of these occurrences may harm BioNTech's business, financial condition and prospects significantly.

***Monitoring the safety of patients receiving BioNTech's product candidates is challenging, which could adversely affect BioNTech's ability to obtain regulatory approval and commercialize its product candidates.***

In BioNTech's ongoing and planned clinical trials, BioNTech has 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 BioNTech or the FDA, EMA or other comparable regulatory authority delaying, suspending or terminating one or more of BioNTech's clinical trials, and which could jeopardize regulatory approval. BioNTech also expecst the centers using its 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 BioNTech's 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 BioNTech's product candidates.

In addition, even if BioNTech successfully advances one of its product candidates into and through clinical trials, such trials will likely only include a limited number of subjects and limited duration of exposure to its product candidates. As a result, BioNTech cannot be assured that adverse effects of its 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 BioNTech's product candidates over a multi-year period.

If any of BioNTech's product candidates receives marketing approval and BioNTech 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;
- BioNTech 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;
- BioNTech 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;
- BioNTech could be sued and held liable for harm caused to patients;
- the product may become less competitive; and
- BioNTech's reputation may suffer.

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

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

Much of BioNTech's pipeline is in preclinical development and these programs could be delayed or not advance into the clinic. Before BioNTech can initiate clinical trials for product candidates, BioNTech must complete extensive preclinical studies, including IND-enabling Good Laboratory Practice toxicology testing, that support its planned Investigational New Drug applications, or INDs, in the United States or similar applications in other jurisdictions. BioNTech 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 BioNTech scales up its manufacturing and may occur in the future. In addition, BioNTech has in the past and may in the future have difficulty identifying appropriate buffers and storage conditions to enable sufficient shelf life of batches of its preclinical or clinical product candidates. If BioNTech is required to produce new batches of its 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, BioNTech cannot be certain of the timely completion or outcome of its preclinical testing and studies and cannot predict if the FDA or other regulatory authorities will accept the results of its preclinical testing or its proposed clinical programs or if the outcome of its preclinical testing, studies and CMC activities will ultimately support the further development of BioNTech's programs. As a result, BioNTech cannot be sure that it will be able to submit INDs or similar applications for its preclinical programs on the timelines it expects, if at all, and BioNTech 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 BioNTech's control. Clinical trials of BioNTech's product candidates may be delayed, and certain programs may never advance in the clinic or may be more costly to conduct than BioNTech anticipates, any of which can affect BioNTech's ability to fund its company and would have a material adverse impact on its business.***

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

- the FDA, other regulators, IRBs or ethics committees may not authorize BioNTech or its 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;
- BioNTech 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;
- BioNTech has optimized in the past and may in the future optimize its 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 its 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 BioNTech's preclinical studies and its 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;

- BioNTech may be unable to establish clinical endpoints that applicable regulatory authorities would consider clinically meaningful;
- in an effort to optimize product features, BioNTech has made in the past and may continue to make changes to its product candidates after it commences clinical trials of a medicine which may require it 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 BioNTech may decide, or regulators may require BioNTech, to conduct additional nonclinical studies or clinical trials, or BioNTech 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;
- BioNTech's 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 BioNTech or its investigators, IRBs or ethics committees to suspend or terminate the trial of that product candidate or any other of its 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 BioNTech anticipates, identification of trial participants for such trials may be limited, enrollment in these clinical trials may be slower than BioNTech anticipates 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 BioNTech anticipates;
- BioNTech's third-party contractors may fail to comply with regulatory requirements or meet their contractual obligations to BioNTech in a timely manner, or at all, or may deviate from the clinical trial protocol or withdraw from the trial, which may require that BioNTech add new clinical trial sites;
- regulators may elect to impose a clinical hold, or BioNTech, BioNTech's 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 BioNTech anticipates;
- the supply or quality of BioNTech's product candidates or other materials necessary to conduct clinical trials may be insufficient or inadequate;
- safety or efficacy concerns regarding BioNTech's 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 BioNTech's; and
- the FDA or other regulatory authorities may require BioNTech to submit additional data, such as long-term toxicology studies, or impose other requirements before permitting BioNTech to initiate a clinical trial.

BioNTech could also encounter delays if a clinical trial is suspended or terminated by BioNTech, 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. BioNTech 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 BioNTech's clinical trial design or other elements of BioNTech's 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 BioNTech's 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 BioNTech's product candidates. BioNTech could also experience delays if physicians encounter unresolved ethical issues associated with enrolling patients in clinical trials of BioNTech's product candidates in lieu of prescribing existing treatments that have established safety and efficacy profiles. BioNTech must also complete extensive work on CMC activities that require extensive manufacturing processes and analytical development, which are uncertain and lengthy.

BioNTech expects the novel nature of its 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 BioNTech's 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 BioNTech's 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 BioNTech's 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 BioNTech's mRNA-based product candidates BioNTech 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 BioNTech's clinical trial design and BioNTech's interpretation of data for its clinical trials or may change the requirements for approval even after they have reviewed and commented on the design for BioNTech's clinical trials.

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

***If BioNTech or its collaborators encounter difficulties enrolling participants in BioNTech's clinical trials, BioNTech's clinical development activities could be delayed or otherwise adversely affected.***

BioNTech depends on enrollment of participants in BioNTech's clinical trials for its product candidates. In the past, BioNTech's collaborators have found, and BioNTech or its collaborators may in the future find, it difficult to enroll trial participants in BioNTech's clinical studies, which could delay or prevent clinical studies of BioNTech's product candidates. Identifying and qualifying trial participants to participate in clinical studies of BioNTech's product candidates is critical to BioNTech's success. The timing of BioNTech's clinical studies depends on the speed at which BioNTech can recruit trial participants to participate in testing its 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 BioNTech's ability to advance the development of its product candidates. If trial participants are unwilling to participate in BioNTech's studies because of negative publicity from adverse events in BioNTech's 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 BioNTech's product development, delays in testing the effectiveness of BioNTech's product, or termination of the clinical studies altogether.

BioNTech 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 BioNTech's 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 BioNTech's 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 BioNTech is investigating;
- BioNTech's 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, BioNTech's clinical trials will compete with other clinical trials for product candidates that are in the same therapeutic areas as BioNTech's product candidates, and this competition will reduce the number and types of trial participants available to BioNTech because some trial participants who might have opted to enroll in BioNTech's trials may instead opt to enroll in a trial being conducted by a third party. Since the number of qualified clinical investigators is limited, BioNTech expects to conduct some of its clinical trials at the same clinical trial sites that some of BioNTech's competitors use, which will reduce the number of trial participants who are available for BioNTech's clinical trials at such clinical trial sites. Moreover, because in some cases BioNTech's 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 BioNTech's clinical trials.

In particular, certain conditions for which BioNTech plans to evaluate its current product candidates are rare diseases with limited patient pools from which to draw for clinical trials. The eligibility criteria of BioNTech's clinical trials will further limit the pool of available trial participants. Additionally, the process of finding and diagnosing patients may prove costly. Each of the risks set forth above may be exacerbated by the COVID-19 pandemic currently affecting the global community and the global economy.

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

Clinical trials of BioNTech's 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 BioNTech plans to commercialize its product candidates, if approved, globally. Accordingly, BioNTech is subject to additional risks related to operating in multiple countries, including:

- differing regulatory requirements in such countries;
- unexpected changes in tariffs, trade barriers, price and exchange controls and other regulatory requirements;
- increased difficulties in managing the logistics and transportation of storing and shipping product candidates produced in Germany and shipping the product candidate to the patient abroad;
- import and export requirements and restrictions;
- economic weakness, including inflation, or political instability in particular economies and markets;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- taxes, including withholding of payroll taxes;
- currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incident to doing business in another country;
- difficulties staffing and managing operations outside of Germany;
- workforce uncertainty in countries where labor unrest is more common;
- differing payor reimbursement regimes, governmental payors or patient self-pay systems, and price controls;
- potential liability under the U.S. Foreign Corrupt Practices Act of 1977 or comparable regulations in other jurisdictions;
- challenges enforcing BioNTech's 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 and public health epidemics.

The extent to which the COVID-19 pandemic impacts BioNTech's operations will depend on future developments, which are highly uncertain and cannot be predicted with confidence, including the duration of the outbreak, new information which may emerge concerning the severity of the coronavirus and the actions to contain the coronavirus or treat its impact, among others. In particular, the spread of the coronavirus globally could adversely impact BioNTech's clinical trial operations, including the availability of specialist raw materials required to manufacture BioNTech's clinical candidates and BioNTech's ability to deliver clinical candidates to clinical trial sites. In the future, similar events could affect BioNTech's ability to manufacture and commercialize its product candidates.

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

***Interim top-line and preliminary data from studies or trials that BioNTech announces or publishes from time to time may change as more data becomes available and are subject to audit and verification procedures that could result in material changes in the final data.***

From time to time, BioNTech may publish interim top-line or preliminary data from preclinical studies or clinical trials. Interim data are subject to the risk that one or more of the outcomes may materially change as more data become available. BioNTech also makes assumptions, estimations, calculations and conclusions as part of its analyses of data, and BioNTech may not have received or had the opportunity to fully evaluate all data. As a result, the top-line results that BioNTech reports 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 BioNTech 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 BioNTech 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 becomes available. Adverse differences between preliminary or interim data and final data could significantly harm BioNTech's business prospects.

Further, others, including regulatory agencies, may not accept or agree with BioNTech's 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 BioNTech in general. In addition, the information BioNTech chooses 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 BioNTech determines is the material or otherwise appropriate information to include in BioNTech's disclosure. Any information BioNTech determines 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 BioNTech's business. If the top-line data that BioNTech reports differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, BioNTech's ability to obtain approval for, and commercialize, product candidates may be harmed, which could significantly harm BioNTech's business prospects.

***Results of earlier studies and trials of BioNTech's 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, BioNTech cannot be certain that it will not face similar setbacks. Even if BioNTech's clinical trials are completed, the results may not be sufficient to obtain regulatory approval for BioNTech's product candidates. In addition, the results of BioNTech's preclinical studies may not be predictive of the results of outcomes in human clinical trials. For example, BioNTech's 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 BioNTech is able to initiate and complete clinical trials, the results may not be sufficient to obtain regulatory approval for BioNTech's product candidates.

***BioNTech's planned clinical trials or those of BioNTech's collaborators may reveal significant adverse events not seen in BioNTech's 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 BioNTech's 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 BioNTech's current or future clinical trials will ultimately be successful or support further clinical development of any of BioNTech's product candidates.

Some of BioNTech's product candidates are being developed or are intended to be co-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 BioNTech's current or future clinical trials, BioNTech may have difficulty recruiting trial participants to any of BioNTech's clinical trials, trial participants may withdraw from trials, or BioNTech may be required to abandon the trials or BioNTech's development efforts of one or more product candidates altogether. BioNTech, 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 BioNTech's business, financial condition and prospects.

***BioNTech may not be able to develop or obtain approval for companion diagnostics required for commercialization of some of its product candidates.***

Administration of some of BioNTech's product candidates may require the use of immuno-assays and bioinformatic tools in which patients are screened for optimal target antigens of BioNTech's 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 Européenne* Mark, or CE Mark, and the conformity assessment process to obtain the CE Mark can be lengthy.

For BioNTech's 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. BioNTech does not have experience or capabilities in developing or commercializing companion diagnostics and plans 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 BioNTech's individualized therapeutic candidates. If BioNTech, or any third parties that BioNTech engages to assist it, are unable to successfully develop companion diagnostic assays for use with BioNTech's individualized therapeutic candidates, or are unable to obtain regulatory approval or experience delays in either development or obtaining regulatory approval, BioNTech may be unable to identify patients with the specific profile targeted by BioNTech's product candidates for enrollment in BioNTech's 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 BioNTech's ability to conduct additional clinical trials or obtain regulatory approval.

***Because BioNTech is developing some of its 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 BioNTech's clinical trials to provide clinically meaningful results.***

There may not be pharmacologic therapies approved to treat the underlying causes of many diseases that BioNTech may address in the future. For instance, BioNTech and its collaborators are applying BioNTech's 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 BioNTech decides to conduct clinical trials and the FDA does find BioNTech's success criteria to be sufficiently validated and clinically meaningful, BioNTech may not achieve the pre-specified endpoint to a degree of statistical significance in any pivotal or other clinical trials BioNTech or its collaborators may conduct for BioNTech's programs. Further, even if BioNTech does achieve the pre-specified criteria, BioNTech's 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 BioNTech achieves statistically significant results on that endpoint, if BioNTech does not do so on its 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 BioNTech's regulatory plan and BioNTech may fail to obtain regulatory approval of its product candidates.***

If the results of BioNTech's clinical trials are sufficiently compelling, BioNTech or its collaborators intend to discuss with the FDA submission of a BLA for BioNTech's product candidates. However, BioNTech does not have any agreement or guidance from the FDA that BioNTech's regulatory development plans will be sufficient for submission of a BLA for any of BioNTech's product candidates. The FDA, EMA or other regulatory agencies may grant accelerated approval for BioNTech's 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 BioNTech is studying. This may result in the FDA, EMA or other regulatory agencies requesting additional studies to show that BioNTech's product candidate is superior to the new products.

BioNTech's clinical trial results may also not support approval. In addition, BioNTech's 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 BioNTech's clinical trials;
- BioNTech may be unable to demonstrate to the satisfaction of the FDA, the EMA or comparable regulatory authorities that BioNTech's 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;
- BioNTech may be unable to demonstrate that its product candidates' clinical and other benefits outweigh their safety risks;
- the FDA, the EMA or comparable regulatory authorities may disagree with BioNTech's interpretation of data from preclinical studies or clinical trials;
- the data collected from clinical trials of BioNTech's 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 BioNTech's manufacturing facilities and may not approve BioNTech's facilities; and
- the approval policies or regulations of the FDA, the EMA or comparable regulatory authorities may significantly change in a manner rendering BioNTech's clinical data insufficient for approval.

***BioNTech 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 BioNTech expects, and even if BioNTech is able to, one or more of these regulatory authorities may not permit BioNTech to proceed.***

The timing of filing on BioNTech's product candidates is dependent on further preclinical, clinical and manufacturing success. BioNTech 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, BioNTech cannot guarantee that such regulatory authorities will not change their requirements in the future.

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

BioNTech's strategy includes filing for orphan drug designation where available for BioNTech's 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 BioNTech seeks 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 BioNTech obtains 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 BioNTech may seek orphan drug designation for its product candidates, BioNTech may never receive such designations.

***BioNTech may seek breakthrough therapy or fast-track designation for one or more of its product candidates, but BioNTech may not receive such designations. Even if BioNTech does, 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.***

BioNTech may seek a breakthrough therapy designation in the United States for one or more of its 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 BioNTech believes that one of its 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 BioNTech's 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.

BioNTech may also seek Fast Track Designation in the United States for some of its 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 BioNTech

believes a particular product candidate is eligible for this designation, BioNTech cannot assure you that the FDA would decide to grant it. Even if BioNTech does receive Fast Track Designation, BioNTech 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 BioNTech's clinical development program. Fast Track Designation alone does not guarantee qualification for the FDA's priority review procedures.

***BioNTech expects some of the product candidates it develops 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.

BioNTech believes that any of its product candidates approved as a biological product under a BLA should qualify for a 12-year period of exclusivity. However, there is a risk that this exclusivity could be shortened due to congressional action or otherwise, or that the FDA will not consider BioNTech's 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 BioNTech's 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 BioNTech's product candidates are classified as gene therapies by the FDA and the EMA, and the FDA has indicated that BioNTech's product candidates will be reviewed within its Center for Biologics Evaluation and Research, or CBER. Even though BioNTech's mRNA product candidates are designed to have a different mechanism of action from gene therapies, the association of BioNTech's product candidates with gene therapies could result in increased regulatory burdens, impair the reputation of BioNTech's product candidates, or negatively impact BioNTech's platform or BioNTech's 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, BioNTech expects that its product candidates will have a different potential side effect profile from gene therapies because they lack risks associated with altering cell DNA irreversibly. Further, BioNTech may avail themselves of ways of mitigating side effects in developing BioNTech's product candidates to address safety concerns that are not available to all gene therapies, such as lowering the dose of BioNTech's 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 BioNTech. Specifically, in Japan, the Pharmaceuticals and Medical Devices Agency has not taken a position on the regulatory classification. Notwithstanding the differences between BioNTech's mRNA product candidates and gene therapies, the classification of some of BioNTech's mRNA product candidates as gene therapies in the United States, the European Union and potentially other counties could adversely impact BioNTech's ability to develop its product candidates, and could negatively impact BioNTech's platform and BioNTech's 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 BioNTech's 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 BioNTech's programs. Although BioNTech's 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 BioNTech's mRNA investigational therapies, and as a result may delay one or more of BioNTech's 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 BioNTech's business by lengthening the regulatory review process, requiring BioNTech to perform additional or larger studies, or increasing BioNTech's development costs, any of which could lead to changes in regulatory positions and interpretations, delay or prevent advancement or approval and commercialization of BioNTech's product candidates or lead to significant post-approval studies, limitations or restrictions. As BioNTech advances its product candidates, BioNTech will be required to consult with these regulatory agencies and advisory committees and comply with applicable requirements and guidelines. If BioNTech fails to do so, BioNTech may be required to delay or discontinue development of some or all of its product candidates.

***The regulatory landscape that will govern BioNTech's 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 BioNTech's product candidates or unexpected costs in obtaining regulatory approval.***

The regulatory requirements to which BioNTech's 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 BioNTech's product candidates.

Complex regulatory environments exist in other jurisdictions in which BioNTech might consider seeking regulatory approvals for BioNTech's 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 BioNTech to perform additional studies, increase BioNTech's development costs, lead to changes in regulatory positions and interpretations, delay or prevent approval and commercialization of BioNTech's product candidates or lead to significant post-approval limitations or restrictions. As the regulatory landscape for BioNTech's CAR-T cell immunotherapy product candidates is new, BioNTech may face even more cumbersome and complex regulations than those emerging for gene therapy products and cell therapy products. Furthermore, even if BioNTech's 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 BioNTech's ability to generate sufficient product sales revenue to maintain BioNTech's business.

***BioNTech may be unable to obtain regulatory approval for its product candidates under applicable international regulatory requirements. The denial or delay of such approval would delay commercialization of BioNTech's product candidates and adversely impact BioNTech's potential to generate revenue, BioNTech's business and BioNTech's 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 BioNTech's product candidates in any other jurisdiction, BioNTech 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 BioNTech 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 BioNTech's products in those countries. The European Union and other jurisdictions' regulatory approval processes involve all of the risks associated with FDA approval. BioNTech does not have any product candidates approved for sale in any jurisdiction, including international markets, and BioNTech does not have experience in obtaining regulatory approval in international markets. If BioNTech fails to comply with regulatory requirements in international markets or to obtain and maintain required approvals, or if regulatory approvals in international markets are delayed, BioNTech's target market will be reduced and BioNTech's ability to realize the full market potential of its products will be unrealized.

***A third-party investigational drug used in combination with BioNTech's product candidates may be unable to obtain regulatory approval, which may delay commercialization of BioNTech's product candidates.***

BioNTech is developing several of its product candidates to be used in combination with BioNTech's and third-party drugs. Even if any product candidate BioNTech develops were to receive marketing approval or be commercialized for use in combination with other existing therapies, BioNTech 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 BioNTech's product or that safety, efficacy, manufacturing or supply issues

could arise with any of those existing therapies. If the therapies BioNTech uses in combination with its product candidates are replaced as the standard of care for the indications BioNTech chooses for any of its product candidates, the FDA, the EMA or similar regulatory authorities in other jurisdictions may require BioNTech to conduct additional clinical trials. The occurrence of any of these risks could result in BioNTech's own products, if approved, being removed from the market or being less successful commercially. BioNTech also plans 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. BioNTech will not be able to market any product candidate it develops 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 BioNTech's 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 BioNTech chooses to evaluate in combination with any product candidate BioNTech develops, BioNTech may be unable to obtain approval of or market any product candidate BioNTech develops.

***Even if BioNTech receives regulatory approval of its product candidates, BioNTech will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense. BioNTech may be subject to penalties if BioNTech fails to comply with regulatory requirements or experiences unanticipated problems with BioNTech's product candidates.***

Even if BioNTech obtains regulatory approval in a jurisdiction, the applicable regulatory authority may still impose significant restrictions on the indicated uses or marketing of BioNTech's 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 BioNTech fails to comply with applicable regulatory requirements following approval of any of BioNTech's product candidates, a regulatory agency may:

- issue a warning letter asserting that BioNTech is 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 BioNTech;
- seize product; or
- refuse to allow BioNTech to enter into supply contracts, including government contracts.

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

If any of BioNTech's 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 BioNTech 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 BioNTech's 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 BioNTech's product candidates could be suspended or terminated.

If in the future BioNTech is unable to demonstrate that such adverse events were caused by factors other than BioNTech's product candidate, the FDA, the EMA or other regulatory authorities could order BioNTech to cease further development of, or deny approval of, any of BioNTech's product candidates for any or all targeted indications. Even if BioNTech is 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 BioNTech elects, or is required, to delay, suspend or terminate any clinical trial of any of BioNTech's product candidates, the commercial prospects of such product candidates may be harmed and BioNTech's ability to generate product sale revenues from any of these product candidates may be delayed or eliminated. Any of these occurrences may harm BioNTech's ability to identify and develop product candidates, and may harm BioNTech's business, financial condition, result of operations and prospects significantly.

Additionally, if BioNTech successfully obtains regulatory approval for a product candidate, the FDA or other regulatory authority could require BioNTech 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 BioNTech or others later identify undesirable side effects caused by any product that BioNTech develops, 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;
- BioNTech may be required to change the way a product is administered or conduct additional clinical trials;
- BioNTech could be sued and held liable for harm caused to patients and their children; and
- BioNTech's reputation may suffer.

Any of these events could prevent BioNTech from achieving or maintaining market acceptance of any products BioNTech may identify and develop and could have a material adverse impact on BioNTech's business, financial condition, results of operations and prospects.

If BioNTech is successful in gaining approval for any of its product candidates BioNTech will continue to face significant regulatory oversight of the manufacturing and distribution of BioNTech's 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 BioNTech 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 BioNTech is not successful in discovering, developing and commercializing additional product candidates beyond BioNTech's current portfolio, BioNTech's ability to expand its business and achieve its strategic objectives would be impaired.***

Although a substantial amount of BioNTech's efforts will focus on the clinical trials and potential approval of BioNTech's existing product candidates, a key element of BioNTech's strategy is to discover, develop and potentially commercialize additional products beyond BioNTech's current portfolio to treat various conditions and in a variety of therapeutic areas. BioNTech intends to do so by investing in its 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 BioNTech identifies product candidates that initially show promise, BioNTech 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 BioNTech's product candidates obsolete;
- product candidates BioNTech develops 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 BioNTech is unsuccessful in identifying and developing additional products, BioNTech's potential for growth may be impaired.

*Risks Related to the Manufacturing of BioNTech's Product Candidates and Future Pipeline*

***BioNTech's mRNA product candidates are based on novel technologies and any product candidates BioNTech develops may be complex and difficult to manufacture. BioNTech may encounter difficulties in manufacturing, product release, shelf life, testing, storage, supply chain management or shipping. If BioNTech or any of the third-party manufacturers BioNTech works with encounter such difficulties, BioNTech's ability to supply materials for clinical trials or any approved product could be delayed or stopped.***

The manufacturing processes for BioNTech's 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, BioNTech 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, BioNTech has in the past and may in the future make changes to its product candidates in their manufacturing and stability formulation and conditions. This has in the past resulted in and may in the future result in BioNTech 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 BioNTech's product candidates could materially delay BioNTech or its collaborators' ability to continue the clinical trial for that product candidate or require BioNTech to begin a new clinical trial with a newly formulated drug product, due to the need to manufacture additional preclinical or clinical supply.

BioNTech's 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, BioNTech has not manufactured immunotherapies at commercial scale. BioNTech may encounter difficulties in scaling up its manufacturing process, thereby potentially impacting clinical and commercial supply. Additionally, for individualized therapies, BioNTech may encounter issues with its ability to timely and efficiently manufacture product given the on-demand requirements of such therapies, thereby potentially impacting clinical and commercial supply.

As BioNTech continues developing new manufacturing processes for BioNTech's drug substance and drug product, the changes BioNTech implements to manufacturing process may in turn impact specification and stability of the drug product. Changes in BioNTech's manufacturing processes may lead to failure of lots and this could lead to a substantial delay in BioNTech's clinical trial. BioNTech's 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.

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

Due to the number of different programs, BioNTech may have cross contamination of products inside of its factories, CROs, suppliers, or in the clinic that affect the integrity of BioNTech's products. Additionally, for some programs the manufacturing scale is extremely small compared to the standard volumes of supply, such that BioNTech runs the risk of contaminating the process each time BioNTech reopens a container to use remaining supplies.

As BioNTech scales the manufacturing output for particular programs, BioNTech plans to continuously improve yield, purity, and the pharmaceutical properties of its 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, BioNTech 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.

BioNTech is 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 BioNTech's product candidates. Further, now and in the future one or more of BioNTech's programs may have a single source of supply for raw materials and excipients.

BioNTech has established a number of analytical assays, and may have to establish several more, to assess the quality of BioNTech's mRNA product candidates. BioNTech may identify gaps in its analytical testing strategy that might prevent release of product or could require product withdrawal or recall. For example, BioNTech 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.

BioNTech products and product intermediates are extremely temperature sensitive, and BioNTech may learn that any or all of its products are less stable than desired. BioNTech 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 BioNTech's 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 BioNTech's product candidates are uniquely manufactured for each patient and BioNTech may encounter difficulties in production, particularly with respect to scaling BioNTech's manufacturing capabilities. If BioNTech or any of the third-party manufacturers with whom BioNTech contracts encounter these types of difficulties, BioNTech's ability to provide its product candidates for clinical trials or its products for patients, if approved, could be delayed or stopped, or BioNTech may be unable to maintain a commercially viable cost structure.***

BioNTech custom designs and manufactures 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 BioNTech's 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 BioNTech's 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
- BioNTech's reliance on single-source suppliers.

BioNTech also continues to evolve its 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 BioNTech's clinical

development plans are expanded, due to the custom nature of the equipment and single-use assemblies, BioNTech may not be able to supply this expanded need reliably without significant investments. In addition, there will be considerable time to scale up BioNTech's facilities or build new facilities before BioNTech can begin to meet any commercial demand if one or more of BioNTech's 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 BioNTech's product candidates are manufactured for each individual patient, BioNTech 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 BioNTech's product candidates are developed through early-stage clinical studies to later-stage clinical trials towards approval and commercialization, BioNTech expects 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 BioNTech's product candidates to perform differently than BioNTech expects, potentially affecting the results of clinical trials.

***BioNTech's inability to manufacture sufficient quantities of its product candidates, or BioNTech's failure to comply with applicable regulatory requirements, would materially and adversely affect BioNTech's business.***

Manufacturing is a vital component of BioNTech's individualized immunotherapy approach, and BioNTech has invested significantly in its manufacturing facilities. All internal manufacturing is performed under GMP guidelines. BioNTech does not rely on any external CMOs for the manufacture of BioNTech's product candidates and at this time, BioNTech has limited redundancy among its facilities. Due to the individualized nature of BioNTech's product candidates, BioNTech does not maintain product reserves. If any of BioNTech's manufacturing facilities experiences difficulties, including related to manufacturing, product release, shelf life, testing, storage and supply chain management or shipping, BioNTech's clinical development programs may be delayed or suspended until BioNTech can resume operations. BioNTech may also be required to incur significant expenditures to resolve such difficulties.

BioNTech facilities are subject to various regulatory requirements and may be subject to the inspection of the FDA or other regulatory authorities. If BioNTech cannot successfully manufacture material that conforms to BioNTech's specifications and the strict regulatory requirements of the FDA, EMA or comparable regulatory authorities in other jurisdictions, BioNTech may not be able to rely on its manufacturing facilities for the manufacture of its product candidates. If the FDA, EMA or another comparable regulatory authority finds BioNTech's facilities inadequate for the manufacture of its product candidates or if such facilities are subject to enforcement action in the future or are otherwise inadequate, BioNTech may need to find alternative manufacturing facilities, which would significantly impact BioNTech's ability to develop, obtain regulatory approval for or market BioNTech's product candidates.

Additionally, BioNTech may experience manufacturing difficulties due to resource constraints or as a result of labor disputes or unstable political environments. If BioNTech were to encounter any of these difficulties, BioNTech's ability to provide its product candidate to patients in clinical trials, or to provide product for the treatment of patients once approved, would be jeopardized.

***BioNTech is subject to regulatory and operational risks associated with the physical and digital infrastructure at both BioNTech's internal manufacturing facilities and at those of BioNTech's external service providers.***

While the design of BioNTech's facilities is based on current standards for biotechnology facilities, it has not been reviewed or pre-approved by any regulatory agency, nor have BioNTech's facilities been inspected by

any regulatory agency such as the FDA. BioNTech has designed its facilities to incorporate a significant level of automation of equipment with integration of several digital systems to improve efficiency of operations. BioNTech has 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 BioNTech's facilities. Any disruption in BioNTech's manufacturing capabilities could cause delays in BioNTech's production capacity for BioNTech's drug substances or drug products, impose additional costs, or may require BioNTech to identify, qualify and establish an alternative manufacturing site, the occurrence of which could have a material adverse effect on BioNTech's business, financial condition, results of operations and prospects.

As BioNTech expands its development and commercial capacity, BioNTech may establish additional manufacturing capabilities and expand to other locations or geographies, which may lead to regulatory delays or prove costly. If BioNTech fails to select the correct location, complete the construction in an efficient manner, recruit the required personnel, and generally manage BioNTech's growth effectively, the development and production of BioNTech's product candidates could be delayed or curtailed. Additional investments may be needed if changes in BioNTech's manufacturing process lead to required changes in BioNTech's infrastructure.

***Certain of BioNTech's product candidates rely on the availability of specialty raw materials, which may not be available to BioNTech on acceptable terms or at all.***

BioNTech's 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 BioNTech's 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 BioNTech's needs, especially in non-routine circumstances like an FDA inspection or medical crisis, such as widespread contamination. BioNTech also does not have contracts with many of these suppliers, and BioNTech may not be able to contract with them on acceptable terms or at all. Accordingly, BioNTech has experienced and BioNTech 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. BioNTech cannot be sure that these suppliers will remain in business or that they will not be purchased by one of BioNTech's competitors or another company that is not interested in continuing to produce these materials for BioNTech's intended purpose. In addition, the lead time needed to establish a relationship with a new supplier can be lengthy, and BioNTech may experience delays in meeting demand in the event BioNTech 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 BioNTech's operating results. Further, BioNTech may be unable to enter into agreements with a new supplier on commercially reasonable terms, which could have a material adverse impact on BioNTech's business.

***BioNTech's product candidates are inherently sensitive to shipping and storage conditions and could be subject to risk of loss or damage.***

BioNTech's 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 BioNTech's product candidates may vary by product and is not fully quantified and is expected to be variable, and it is possible that BioNTech's 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 BioNTech's ability to supply required quantities for clinical trials or otherwise.

***BioNTech is subject to significant regulatory oversight with respect to manufacturing its product candidates. BioNTech manufacturing facilities or the manufacturing facilities of BioNTech's 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 BioNTech's 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 BioNTech's 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 BioNTech's developing understanding of the manufacturing process as BioNTech scales; and
- failed or defective components or consumables.

BioNTech 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 BioNTech or one of its third- party manufacturing sites fails to provide sufficient quality assurance or control, approval to commercialize BioNTech's 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 BioNTech's third-party manufacturers or suppliers to fulfill their supply obligations, impacting or delaying supply or delaying programs.

The manufacturing process for any products that BioNTech may develop is subject to the FDA's, the EMA's and other regulatory authorities' approval processes, and BioNTech may need to contract with manufacturers who BioNTech believes can meet applicable regulatory authority requirements on an ongoing basis. If BioNTech or its third-party manufacturers are unable to reliably produce product candidates to specifications acceptable to the FDA, the EMA or other regulatory authorities, BioNTech or its collaborators may not obtain or maintain the approvals BioNTech or they need to commercialize such products. Even if BioNTech or its collaborators obtain regulatory approval for any of BioNTech's immunotherapies, there is no assurance that either BioNTech or BioNTech's CMOs will be able to manufacture BioNTech's 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 BioNTech's product candidates, impair commercialization efforts or increase BioNTech's cost of goods. The occurrence of any of the foregoing could have an adverse effect on BioNTech's business, financial condition, results of operations and growth prospects.

In addition, BioNTech may not have direct control over the ability of its contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. Furthermore, all of BioNTech's contract manufacturers are engaged with other companies to supply or manufacture materials or products for such companies, which exposes BioNTech's 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 BioNTech's CMOs' facilities. BioNTech's failure, or the failure of its third-party manufacturers, to comply with applicable regulations could result in sanctions being imposed on BioNTech, 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 BioNTech's products and product candidates (including those of BioNTech's collaborators) and BioNTech's overall business operations. BioNTech's potential future dependence upon others for the manufacture of BioNTech's product candidates and raw materials may adversely affect BioNTech's future profit margins and BioNTech's ability to commercialize any products that receive regulatory approval on a timely and competitive basis.

The FDA, EMA and other regulatory authorities may require BioNTech 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 BioNTech does 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. BioNTech's 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 BioNTech's own facilities or those of BioNTech's third-party manufacturers could cause BioNTech and its collaborators to delay clinical trials or product launches, which could be costly to BioNTech and otherwise harm BioNTech's business, financial condition, results of operations and prospects.

BioNTech also may encounter problems hiring and retaining the experienced scientific, quality-control and manufacturing personnel needed to operate BioNTech's manufacturing processes and operations, which could result in delays in production or difficulties in maintaining compliance with applicable regulatory requirements. While BioNTech will train and qualify all personnel around the appropriate handling of its products and materials, BioNTech 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 BioNTech's Pipeline*

***The successful commercialization of BioNTech's 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 BioNTech's product candidates. Failure to obtain or maintain coverage and adequate reimbursement for BioNTech's product candidates, if approved, could limit BioNTech's ability to market those products and decrease BioNTech's 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 BioNTech hopes to develop and sell.

In addition, because several of BioNTech's product candidates represent new approaches to the treatment of cancer, BioNTech cannot accurately estimate how these products would be priced, whether reimbursement could be obtained, or any potential revenue. Sales of BioNTech's product candidates will depend substantially, both domestically and abroad, on the extent to which the costs of BioNTech's 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, BioNTech may not be able to successfully commercialize its product candidates. Even if coverage is provided, the approved reimbursement amount may not be high enough to allow BioNTech to establish or maintain pricing sufficient to realize a sufficient return on BioNTech's investment in any of its 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 BioNTech's. 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. BioNTech cannot be sure that such prices and reimbursement will be acceptable to BioNTech or its collaborators. If the regulatory authorities in these jurisdictions set prices or reimbursement levels that are not commercially attractive for BioNTech or its collaborators, BioNTech's revenues from sales by BioNTech or its collaborators, and the potential profitability of BioNTech's 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, BioNTech might obtain marketing approval for a product in a particular country, but then may experience delays in the reimbursement approval of BioNTech's product or be subject to price regulations that would delay BioNTech's commercial launch of the product, possibly for lengthy time periods, which could negatively impact the revenues BioNTech is 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 BioNTech's 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.

BioNTech expects to experience pricing pressures in connection with the sale of any of BioNTech's 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.

***BioNTech faces significant competition in an environment of rapid technological and scientific change, and BioNTech's failure to effectively compete would prevent BioNTech from achieving significant market penetration. Most of BioNTech's competitors have significantly greater resources than BioNTech does and BioNTech 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 BioNTech is targeting or expects to target. Many of BioNTech's competitors have:

- greater financial, technical and human resources than BioNTech has 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 BioNTech's target markets with leading companies and research institutions.

BioNTech 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 BioNTech may develop drugs. BioNTech also expects 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 BioNTech is 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 BioNTech develops.

BioNTech anticipates 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 BioNTech currently has. In addition to these large pharmaceutical companies, BioNTech 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 BioNTech successfully develops product candidates, and obtains approval for them, BioNTech will face competition based on many different factors, including:

- the safety and effectiveness of BioNTech's products relative to alternative therapies, if any;
- the ease with which BioNTech's 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.

BioNTech's competitors may develop or commercialize products with significant advantages over any products BioNTech develops based on any of the factors listed above or on other factors. In addition,

BioNTech's competitors may develop collaborations with or receive funding from larger pharmaceutical or biotechnology companies, providing them with an advantage over BioNTech. BioNTech's competitors may therefore be more successful in commercializing their products than BioNTech is, which could adversely affect BioNTech's competitive position and business. Competitive products may make any products BioNTech develops obsolete or noncompetitive before BioNTech can recover the expenses of developing and commercializing BioNTech's products, if approved.

***The market opportunities for certain of BioNTech's 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 BioNTech's programs are small, BioNTech 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. BioNTech expects to initially seek approval of certain of its product candidates in this context. Subsequently, for those products that prove to be sufficiently beneficial, if any, BioNTech would expect to seek approval in earlier lines of treatment and potentially as a first-line therapy but there is no guarantee that BioNTech's product candidates, even if approved, would be approved for earlier lines of therapy, and, prior to any such approvals, BioNTech may have to conduct additional clinical trials. BioNTech is also developing product candidates for the treatment of rare diseases.

BioNTech's projections of the number of people who have or will have the diseases BioNTech 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 BioNTech's product candidates may be limited or may not be amenable to treatment with BioNTech's product candidates. Even if BioNTech obtains significant market share for its products, if approved, because the potential target populations are small, BioNTech may never achieve profitability without obtaining regulatory approval for additional indications.

***BioNTech currently has no marketing and sales organization and as a company, BioNTech has no experience in marketing pharmaceutical products. If BioNTech is unable to establish marketing and sales capabilities on its own or through third parties, BioNTech may not be able to market and sell its product candidates effectively in the United States and other jurisdictions, if approved, or generate product sales revenue.***

Given BioNTech's stage of development, BioNTech has no sales, distribution or marketing capabilities, and BioNTech has not designed its preclinical studies and clinical trials with specific commercialization or marketing considerations in mind. To successfully commercialize any products that may result from BioNTech's development programs, BioNTech will need to develop sales and marketing capabilities in the United States, Europe and other regions, either on its own or with others. BioNTech may enter into collaborations with other entities to utilize their mature marketing and distribution capabilities, but BioNTech may be unable to enter into marketing agreements on favorable terms, if at all. If BioNTech's future collaborators do not commit sufficient resources to commercialize BioNTech's future products, if any, and BioNTech is unable to develop the necessary marketing capabilities on its own, BioNTech may be unable to generate sufficient product sales revenue to sustain its business. BioNTech 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, BioNTech may be unable to compete successfully against these more established companies.

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

BioNTech's future profitability, if any, will depend in part on BioNTech's ability and the ability of its collaborators to commercialize any products that BioNTech or its collaborators may develop in markets throughout the world. Commercialization of products in various markets could subject BioNTech 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 BioNTech or its 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;
- the impact of public health epidemics on employees and the global economy, such as the current coronavirus epidemic;
- reimbursement, pricing and insurance regimes; and
- the interpretation of contractual provisions governed by local laws in the event of a contract dispute.

BioNTech does not have prior experience in all of these areas, and the experience BioNTech does have in some of these areas is limited. BioNTech's 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 BioNTech or its collaborators may develop, which would limit their commercial potential and BioNTech's revenues.

***Even if BioNTech obtains regulatory approval for its 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 BioNTech's products will depend in part on the medical community, patients, and third-party or governmental payors accepting immunotherapies in general, and BioNTech's products in particular, as medically useful, cost-effective and safe. Any product that BioNTech brings 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 BioNTech may use. If these products do not achieve an adequate level of acceptance, BioNTech may not generate significant product sales revenue and may not become profitable. The degree of market acceptance of BioNTech's 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 BioNTech's 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 BioNTech's products are administered;
- relative convenience and ease of administration;
- any restrictions on the use of BioNTech's 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 BioNTech's 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. BioNTech's 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. BioNTech's efforts to educate the marketplace may require more resources than are required by the conventional technologies marketed by BioNTech's competitors due to the complexity and uniqueness of BioNTech's 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 BioNTech 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 BioNTech's resources. If government and other healthcare payors do not provide adequate coverage and reimbursement levels for any of BioNTech's products once approved, whether due to healthcare reform legislation or otherwise, market acceptance and commercial success would be reduced.

In addition, if any of BioNTech's products are approved for marketing, BioNTech 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 BioNTech's third-party providers comply) with GMP and current good clinical practices, or GCP, for any clinical trials that BioNTech or a collaborator conduct post-approval. In addition, there is always the risk that BioNTech 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 BioNTech's product candidates identified post-approval could have a material adverse impact on BioNTech's business, financial condition and results of operations.

***Coverage and reimbursement may be limited or unavailable in certain market segments for BioNTech's product candidates, which could make it difficult for BioNTech to sell its product candidates, if approved, profitably.***

Successful sales of BioNTech's 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 BioNTech obtains regulatory approval. In addition, because BioNTech's product candidates represent new approaches to the treatment of cancer, BioNTech cannot accurately estimate the potential revenue from its 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 BioNTech to provide to the payor supporting scientific, clinical and cost-effectiveness data for the use of BioNTech's products. Even if BioNTech obtains coverage for a given product, if the resulting reimbursement rates are insufficient, hospitals may not approve BioNTech's product for use in their facility or third-party payors may require co-payments that patients find unacceptably high. Patients are unlikely to use BioNTech's product candidates unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of BioNTech's 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 BioNTech's 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 BioNTech's 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 BioNTech to maintain price levels sufficient to realize an appropriate return on BioNTech's investment in product development.

BioNTech intends to seek approval to market its product candidates in the United States, the European Union and other selected jurisdictions. If BioNTech obtains approval for its product candidates in any particular jurisdiction, BioNTech 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 BioNTech receives regulatory approval for commercial sale may suffer if government and other third-party payors fail to provide coverage and adequate reimbursement. BioNTech expects 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 BioNTech receives 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 BioNTech to obtain marketing approval of and commercialize any product candidates BioNTech or its 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 BioNTech and BioNTech’s 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 BioNTech's product candidates, restrict or regulate post- approval activities, and affect BioNTech's ability to commercialize any products for which BioNTech obtains marketing approval.

BioNTech expects 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 BioNTech's product candidates or additional pricing pressures. In the event that the pricing structures for healthcare products, such as the product candidates BioNTech is developing, change materially and limit payments for such product candidates, BioNTech's business will be adversely impacted as BioNTech's products may no longer be commercially viable based on their expected net present value; BioNTech may have invested significant resources in products that cannot be commercially developed; or BioNTech 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 BioNTech's collaborations may no longer be deemed commercially viable to pursue based on BioNTech's collaborators' assessments of the impact of any proposed, announced, or legislated pricing reforms.

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

***European Union drug marketing and reimbursement regulations may materially affect BioNTech's ability to market and receive coverage for BioNTech's products in the European Union member states.***

BioNTech intends to seek approval to market its product candidates in both the United States and in other selected jurisdictions. If BioNTech obtains approval for its product candidates in a particular jurisdiction, BioNTech 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 BioNTech's 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 BioNTech's product candidates will depend significantly on the availability of adequate coverage and reimbursement from third-party payors for BioNTech's 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, BioNTech may be required to conduct a clinical trial or other studies that compare the cost-effectiveness of any of BioNTech's 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 BioNTech's 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 BioNTech's products is unavailable or limited in scope or amount, BioNTech's revenues from sales by BioNTech or its collaborators and the potential profitability of any of BioNTech's product candidates in those countries would be negatively affected.

*Risks Related to BioNTech's Reliance on Third Parties*

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

BioNTech has 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 the year ended December 31, 2019 until the resignation of Prof. Ugur Sahin, M.D. as Managing Director for Science and Research at TRON on September 10, 2019, and during the year ended December 31, 2018, the aggregate value of the transactions related to these agreements with TRON amounted to €6.3 million and €6.6 million, respectively, and TRON's research has historically constituted a significant portion of BioNTech's discovery pipeline and target discovery engine. Prof. Ugur Sahin, M.D., BioNTech's 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 BioNTech's Supervisory Board, served on TRON's supervisory board until his resignation in April 2019. BioNTech and TRON also share certain intellectual property. Prof. Ugur Sahin, M.D., our co-founder and Chief Executive Officer, owns a significant amount of shares in TRON. During the year ended December 31, 2019, the aggregate value of transactions related to these agreements with TRON amounted to €10.0 million pursuant to these agreements (€6.6 million during the year ended December 31, 2018).

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 BioNTech's officers may favor their personal interests over those of BioNTech's shareholders.

***BioNTech relies on third parties in the conduct of significant aspects of BioNTech's 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, BioNTech may be unable to obtain regulatory approval for its product candidates.***

BioNTech currently relies and expects 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 BioNTech's clinical trials. BioNTech currently relies and expects 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 BioNTech. If BioNTech needs to enter into alternative arrangements, it would delay BioNTech's discovery or product development activities.

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

Moreover, the FDA requires BioNTech 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. BioNTech also is 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 BioNTech's preclinical studies and clinical trials, BioNTech could be subject to warning letters or enforcement action that may include civil penalties up to and including criminal prosecution.

BioNTech and its 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. BioNTech also is responsible for ensuring that the rights of its 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 BioNTech or its CROs fail to comply with applicable GCP, the clinical data generated in BioNTech's clinical trials may be deemed unreliable and the FDA or comparable regulatory authorities of other jurisdictions may require BioNTech to perform additional clinical trials before approving BioNTech's marketing applications. BioNTech cannot assure you that, upon inspection, the FDA will determine that any of BioNTech's future clinical trials will comply with GCP. In addition, BioNTech's clinical trials must be conducted with product candidates produced in accordance with the requirements of GMP regulations. BioNTech's failure or the failure of its CROs to comply with these regulations may require BioNTech to repeat clinical trials, which would delay the regulatory approval process and could also subject BioNTech to enforcement action.

Although BioNTech has designed and in the future intends to design the clinical trials for certain of its product candidates, BioNTech's collaborators will design the clinical trials that they are managing (in some cases, with BioNTech's input) and in the case of clinical trials controlled by BioNTech, BioNTech expects that CROs will conduct all of the clinical trials. As a result, many important aspects of BioNTech's development programs, including their conduct and timing, are outside of BioNTech's direct control. BioNTech's 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 BioNTech were relying entirely upon its 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 BioNTech's competitors;
- have human errors; or
- be subject to cyberattacks.

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

BioNTech also relies on other third parties to transport, store and distribute the required materials for BioNTech's clinical trials. In the past certain of BioNTech's third-party vendors have mishandled BioNTech's 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 BioNTech may develop or commercialization of BioNTech's medicines, if approved, producing additional losses and depriving BioNTech of potential product sales revenue, causing BioNTech to default on its contractual commitments, result in losses that are not covered by insurance, and damage BioNTech's reputation and overall perception of BioNTech's products in the marketplace. Each of the risks set forth above may be exacerbated by the COVID-19 pandemic currently affecting the global community and the global economy.

***BioNTech's existing collaborations, or any future collaboration arrangements that BioNTech 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 BioNTech's ability to develop and commercialize its product candidates.***

BioNTech has entered into collaborations under which its collaborators have provided, and may in the future provide, funding and other resources for developing and potentially commercializing BioNTech's product candidates. BioNTech expects to enter into additional collaborations to access additional funding, capabilities and expertise in the future. BioNTech's existing collaborations, and any future collaborations BioNTech enters 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 BioNTech's 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 BioNTech's;

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

If BioNTech's collaborations do not result in the successful development and commercialization of programs, or if one of BioNTech's collaborators terminates its agreement with BioNTech, BioNTech may not receive any future research funding or milestone, earn-out, royalty, or other contingent payments under the collaborations. If BioNTech does not receive the funding it expects under these agreements, BioNTech's development of product candidates could be delayed and BioNTech may need additional resources to develop its product candidates. In addition, in general BioNTech's collaborators have the right to terminate their agreements with BioNTech for convenience. If one of BioNTech's collaborators terminates its agreement with BioNTech, BioNTech may find it more difficult to attract new collaborators and the perception of BioNTech 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 proxy statement/prospectus apply to the activities of BioNTech's collaborators.

***If BioNTech is not able to establish collaborations on commercially reasonable terms, BioNTech may have to alter its research, development and commercialization plans.***

BioNTech's research and product development programs and the potential commercialization of any product candidates BioNTech develops alone or with collaborators will require substantial additional cash to

fund expenses, and BioNTech expects that it 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. BioNTech faces 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 BioNTech reaches a definitive agreement for a collaboration will depend, among other things, upon BioNTech's 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 BioNTech's 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 BioNTech. Additionally, BioNTech 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, BioNTech has granted exclusive rights or options to Pfizer for certain targets, and under the terms of BioNTech's respective collaboration agreements with them BioNTech will be restricted from granting rights to other parties to use BioNTech's mRNA technology to pursue potential products that address those targets. Similarly, BioNTech's collaboration agreements have in the past and may in the future contain non-competition provisions that could limit BioNTech's ability to enter into collaborations with future collaborators.

Collaborations are complex and time-consuming to negotiate and document. BioNTech may not be able to negotiate collaborations on a timely basis, on acceptable terms, or at all. If BioNTech does enter into additional collaboration agreements, the negotiated terms may force BioNTech to relinquish rights that diminish BioNTech's potential profitability from development and commercialization of the subject product candidates or others. If BioNTech is unable to enter into additional collaboration agreements, BioNTech may have to curtail the research and development of the product candidate or technology for which BioNTech is 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 BioNTech's own expense. If BioNTech elects to increase its expenditures to fund research, development or commercialization activities on its own, BioNTech may need to obtain additional capital, which may not be available to BioNTech on acceptable terms or at all.

***BioNTech has entered into in-licensing arrangements and may form or seek to enter into additional licensing arrangements in the future, and BioNTech may not realize the benefits of such licensing arrangements.***

BioNTech is a party to licenses that give BioNTech rights to third-party intellectual property, including patents and patent applications, that are necessary or useful for BioNTech's business. In particular, BioNTech has 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. BioNTech 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 BioNTech's current and future licensors to prosecute, obtain, maintain, protect, enforce and defend patent protection for BioNTech's in-licensed intellectual property. BioNTech's current and future licensors may not successfully prosecute the patent applications BioNTech licenses. Even if patents were issued in respect of these

patent applications, BioNTech's 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 BioNTech would. Without protection for the intellectual property BioNTech licenses, other companies might be able to offer substantially identical products for sale, which could adversely affect BioNTech's competitive business position and harm BioNTech's business prospects. In addition, BioNTech sublicenses its rights under various third-party licenses to BioNTech's collaborators. Any impairment of these sublicensed rights could result in reduced revenues under BioNTech's collaboration agreements or result in termination of an agreement by one or more of BioNTech's collaborators.

Disputes may also arise between BioNTech and BioNTech's 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 BioNTech's technology and processes infringe, misappropriate or otherwise violate the intellectual property of the licensor that is not subject to the licensing agreement;
- BioNTech's right to sublicense patent and other intellectual property rights to third parties under collaborative relationships;
- BioNTech's diligence obligations with respect to the use of the licensed intellectual property and technology in relation to BioNTech's development and commercialization of its 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 BioNTech's licensors and BioNTech and BioNTech's collaborators; and
- the priority of invention of patented technology.

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

BioNTech is generally also subject to all of the same risks with respect to protection of intellectual property that BioNTech licenses, as BioNTech is for intellectual property that BioNTech owns, which are described below. If BioNTech, its co-owners or its licensors fail to adequately protect, defend, maintain or enforce this intellectual property, BioNTech's ability to commercialize products could suffer.

***If BioNTech commits certain material breaches and fails to cure them (if such breach is curable), BioNTech is required to repurchase shares held by the Bill & Melinda Gates Foundation.***

If BioNTech commits 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), BioNTech is 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 BioNTech cannot meet the requirements under (i) (e.g., because BioNTech does not have sufficient cash reserves), then BioNTech must use its best efforts to effect BMGF's withdrawal right as soon as practicable, which may mean acquiring the shares in tranches over time. If BioNTech is required to repurchase BMGF's shares, BioNTech's financial position could be materially and adversely affected.

***BioNTech relies on third parties to manufacture certain of its clinical product supplies, and BioNTech may have to rely on third parties to produce and process its product candidates, if approved.***

Although BioNTech expects to continue using its own clinical manufacturing facilities, BioNTech may need to rely on outside vendors to manufacture supplies and process its product candidates. BioNTech has not yet

caused its 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 BioNTech's product candidates.

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

In addition, BioNTech's reliance on a limited number of third-party manufacturers exposes BioNTech to the following risks:

- BioNTech 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 BioNTech's products after receipt of regulatory authority questions, if any;
- BioNTech's third-party manufacturers might be unable to timely formulate and manufacture BioNTech's product or produce the quantity and quality required to meet BioNTech's clinical and commercial needs, if any;
- CMOs may not be able to execute BioNTech's manufacturing procedures appropriately;
- BioNTech's future CMOs may not perform as agreed or may not remain in the contract manufacturing business for the time required to supply BioNTech's clinical trials or to successfully produce, store and distribute BioNTech's 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. BioNTech does not have control over third-party manufacturers' compliance with these regulations and standards;
- BioNTech may not own, or may have to share, the intellectual property rights to any improvements made by BioNTech's third-party manufacturers in the manufacturing process for BioNTech's products;
- BioNTech's third-party manufacturers could breach or terminate their agreement with BioNTech; and
- BioNTech's CMOs would also be subject to the same risks BioNTech faces in developing its own manufacturing capabilities, as described above.

Each of these risks could delay BioNTech's clinical trials, the approval, if any, of BioNTech's product candidates by the FDA or regulatory authorities in other jurisdictions or the commercialization of BioNTech's product candidates, or result in higher costs or deprive BioNTech of potential product sales revenue. In addition, BioNTech will rely on third parties to perform release tests on BioNTech's 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.

***BioNTech is dependent on single-source suppliers for some of the components and materials used in, and the processes required to develop, BioNTech's product candidates.***

BioNTech currently depends on single-source suppliers for some of the components and materials used in, and manufacturing processes required to develop, BioNTech's product candidates. BioNTech cannot ensure that these suppliers or service providers will remain in business, or have sufficient capacity or supply to meet BioNTech's needs, or that they will not be purchased by one of BioNTech's competitors or another company that

is not interested in continuing to work with BioNTech. BioNTech's use of single-source suppliers of raw materials, components, key processes and finished goods exposes BioNTech 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 BioNTech's future demands for its 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 BioNTech's business, financial condition, results of operations and prospects.

If BioNTech has to switch to a replacement supplier, the manufacture and delivery of BioNTech's product candidates could be interrupted for an extended period, which could adversely affect BioNTech's business. Establishing additional or replacement suppliers for any of the components or processes used in BioNTech's product candidates, if required, may not be accomplished quickly. If BioNTech is 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 BioNTech seeks to maintain adequate inventory of the single source components and materials used in its products, any interruption or delay in the supply of components or materials, or BioNTech's inability to obtain components or materials from alternate sources at acceptable prices in a timely manner, could impair BioNTech's ability to meet the demand for its product candidates.

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

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

- delays to the development timelines for BioNTech's 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 BioNTech's 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 BioNTech's 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 BioNTech's suppliers' prioritizing other customer orders over BioNTech;
- damage to BioNTech's reputation caused by defective components produced by BioNTech's suppliers; and
- fluctuation in delivery by BioNTech's suppliers due to changes in demand from BioNTech or their other customers.

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

*Risks Related to BioNTech's Intellectual Property*

***If BioNTech's efforts to obtain, maintain, protect, defend and/or enforce the intellectual property related to its product candidates and technologies are not adequate, BioNTech may not be able to compete effectively in BioNTech's market.***

BioNTech's commercial success depends in part on its ability to obtain, maintain, protect, defend and enforce patent and other intellectual property, including trade secret and know-how, protection for BioNTech's product candidates, proprietary technologies and their uses, as well as BioNTech's ability to operate, develop, manufacture and commercialize its product candidates without infringing, misappropriating or otherwise violating the intellectual property or other proprietary rights of BioNTech's competitors or any other third parties, including any non-practicing entities or patent assertion entities. BioNTech generally seeks to protect its intellectual property position by filing and/or licensing patent applications in the United States and abroad related to BioNTech's product candidates, proprietary technologies (including methods of manufacture) and their uses that are important to BioNTech's business. BioNTech's 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. BioNTech cannot be certain that the claims in any of its 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 BioNTech be certain that the claims in its issued patents will not be found invalid or unenforceable if challenged. Accordingly, there can be no assurance that BioNTech's patent applications or those of BioNTech's licensors will result in additional patents being issued or that issued patents will adequately cover BioNTech's 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, BioNTech may not be able to apply for patents on certain aspects of its 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 BioNTech obtains 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 BioNTech's intellectual property and other proprietary rights is uncertain. Only limited protection may be available and may not adequately protect BioNTech's rights or permit BioNTech to gain or keep any competitive advantage. If BioNTech does not adequately obtain, maintain, protect, defend and enforce BioNTech's intellectual property and proprietary technology, competitors may be able to use BioNTech's product candidates and proprietary technologies and erode or negate any competitive advantage BioNTech may have, which could have a material adverse effect on BioNTech's financial condition and results of operations.

The patent application process is subject to numerous risks and uncertainties, and there can be no assurance that BioNTech or any of its 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 BioNTech's 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 BioNTech owns (solely or jointly) or have in-licensed may be challenged, invalidated, modified, revoked, circumvented, found to be unenforceable or otherwise may not provide any competitive advantage;
- BioNTech's competitors, many of whom have substantially greater resources than BioNTech 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 BioNTech's ability to make, use, sell, import or otherwise exploit BioNTech's product candidates or other technologies;
- other parties may have designed around BioNTech's patent claims or developed technologies that may be related or competitive to BioNTech's 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 BioNTech's 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 BioNTech's patent claims;
- any successful opposition to any patents owned by or in-licensed to BioNTech could deprive BioNTech of rights necessary for the development and exploitation of its product candidates and other technologies or the successful commercialization of any product candidates and other technologies that BioNTech may develop;
- because patent applications in the United States and most other jurisdictions are confidential for a period of time after filing, BioNTech cannot be certain that BioNTech, its co-owners or its licensors were the first to file any patent application related to BioNTech's 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 BioNTech's patent filings, or in those BioNTech licensed, was first invented by someone else, so that BioNTech 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 BioNTech's patent claims and might result in invalidation or revision of one or more of BioNTech's 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 BioNTech's, 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 BioNTech's intellectual property rights.

Furthermore, the patent prosecution process is also expensive and time-consuming, and BioNTech 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 BioNTech will fail to identify patentable aspects of BioNTech's research and development output in time to obtain patent protection. Although BioNTech enters into non-disclosure and confidentiality agreements with parties who have access to confidential or patentable aspects of BioNTech's research and development output, such as BioNTech's 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 BioNTech's ability to seek patent protection. BioNTech also relies to a certain extent on trade secrets, know-how, and technology, which are not protected by patents, to maintain BioNTech's 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, BioNTech's 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 BioNTech 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 BioNTech 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 BioNTech's ability to stop others from using or commercializing similar or identical products, or limit the scope and/or term of patent protection of BioNTech's products and product candidates and/ or eliminate it altogether, thus hindering or removing BioNTech's ability to limit third parties from making, using or selling products or technologies that are similar or identical to BioNTech's, and/or reduce or eliminate royalty payments to BioNTech from its 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, BioNTech's pending and future patent applications may not result in patents being issued which protect BioNTech's technology or product candidates or which effectively prevent others from commercializing competitive technologies and product candidates. As a result, BioNTech's intellectual property may not provide BioNTech with sufficient rights to exclude others from commercializing products similar or identical to BioNTech's.

BioNTech's ability to enforce its owned and in-licensed patent and other intellectual property rights depends on BioNTech's 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 BioNTech may not be able to introduce obtained evidence into a proceeding or otherwise utilize it to successfully demonstrate infringement. BioNTech may not prevail in any lawsuits that it initiates and the damages or other remedies awarded if BioNTech were to prevail may not be commercially meaningful.

In addition, proceedings to enforce or defend BioNTech's owned or in-licensed patents could put BioNTech's patents at risk of being invalidated, held unenforceable or interpreted narrowly. Such proceedings could also provoke third parties to assert claims against BioNTech, including that some or all of the claims in one or more of BioNTech's 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 BioNTech's ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of BioNTech's technology and product candidates. If any of BioNTech's owned or in-licensed patents covering BioNTech's 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 BioNTech's product candidates or other technologies, BioNTech's competitive position could be harmed or BioNTech could be required to incur significant expenses to protect, enforce or defend its rights. If BioNTech initiates lawsuits to protect, defend or enforce BioNTech's patents, or litigates against third-party claims, such proceedings would be expensive and would divert the attention of BioNTech's management and technical personnel, even if the eventual outcome is favorable to BioNTech.

The degree of future protection for BioNTech's intellectual property and other proprietary rights is uncertain, and BioNTech cannot ensure that:

- any of BioNTech's patents, or any of BioNTech's pending patent applications, if issued, or those of BioNTech's licensors, will include claims having a scope sufficient to protect BioNTech's product candidates and other technologies;
- any of BioNTech's pending patent applications or those of BioNTech's 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 BioNTech's own but that are not covered by the claims of the patents that BioNTech owns or licenses;
- BioNTech will be able to successfully commercialize its products on a substantial scale, if approved, before the relevant patents that BioNTech owns or licenses expire;
- BioNTech was the first to make the inventions covered by each of the patents and pending patent applications that BioNTech owns or licenses;
- BioNTech, its co-owners or its 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 BioNTech owns or licenses;
- any of the patents BioNTech owns or licenses will be found to ultimately be valid and enforceable;
- any patents issued to BioNTech or its licensors will provide a basis for an exclusive market for BioNTech's commercially viable product candidates and other technologies or will provide BioNTech with any competitive advantages;
- a third party may not challenge the patents BioNTech owns or licenses and, if challenged, a court would hold that such patents are valid, enforceable and infringed;
- BioNTech may develop or in-license additional proprietary technologies that are patentable;
- the patents of others will not have an adverse effect on BioNTech's business;
- BioNTech's competitors do not conduct research and development activities in countries where BioNTech does not have enforceable patent rights and then use the information learned from such activities to develop competitive products for sale in BioNTech's major commercial markets;
- BioNTech will develop additional proprietary technologies or product candidates that are separately patentable; or
- BioNTech's development and commercialization activities, including its manufacturing processes, or products will not infringe upon the patents of BioNTech's competitors or any other third parties, including anynon-practicing entities or patent assertion entities.

***Other companies or organizations may challenge BioNTech's intellectual property rights or may assert intellectual property rights that prevent BioNTech from developing and commercializing BioNTech's product candidates and other technologies.***

BioNTech practices 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. BioNTech owns and in-licenses 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 BioNTech's delivery technologies, including LNPs. If BioNTech, its co-owners or its licensors are unable to obtain, maintain, protect, defend or enforce patent protection with respect to BioNTech's product candidates and other technology and any product candidates and technology BioNTech develops, BioNTech's business, financial condition, results of operations and prospects could be materially harmed.

As the scientific fields mature, BioNTech's 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, BioNTech cannot predict whether the patent applications BioNTech and its 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.

BioNTech, its co-owners or its 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. BioNTech expects that its 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 BioNTech and the patents and patent applications that BioNTech owns and in-licenses. BioNTech expect that it will be subject to similar proceedings or priority disputes, including oppositions, in Europe or other foreign jurisdictions relating to patents and patent applications in its portfolio.

If BioNTech, its co-owners or its 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 BioNTech or they are subject, BioNTech may lose valuable intellectual property rights through the narrowing or loss of one or more patents owned or in-licensed, or its owned or in-licensed patent claims may be narrowed, invalidated or held unenforceable. In many cases, the possibility of appeal exists for either BioNTech or its 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 BioNTech's business if BioNTech is not successful in defending the patentability and scope of its pending and issued patent claims. In addition, third parties may attempt to invalidate BioNTech's intellectual property rights. Even if BioNTech's rights are not directly challenged, disputes could lead to the weakening of its intellectual property rights. BioNTech's defense against any attempt by third parties to circumvent or invalidate its intellectual property rights could be costly to BioNTech , could require significant time and attention of BioNTech's management and could have a material adverse impact on its business and ability to successfully compete against current and future competitors.

There are many issued and pending patent filings that claim aspects of technologies that BioNTech may need for its 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 BioNTech wishes to develop. In addition, there may be issued and pending patent applications that may be asserted against BioNTech in a court proceeding or otherwise based upon the asserting party's belief that BioNTech may need such patents for the development, manufacturing and commercialization of its product candidates. Thus, it is possible that one or more organizations, ranging from

BioNTech's competitors to non-practicing entities or patent assertion entities, has or will hold patent rights to which BioNTech may need a license, or hold patent rights which could be asserted against BioNTech. Such licenses may not be available on commercially reasonable terms or at all, or may be non-exclusive. If those organizations refuse to grant BioNTech a license to such patent rights on reasonable terms or a court rules that BioNTech needs such patent rights that have been asserted against BioNTech and BioNTech is not able to obtain a license on reasonable terms or at all, BioNTech may be unable to perform research and development or other activities or market products covered by such patents, and BioNTech may need to cease the development, manufacture and commercialization of one or more of the product candidates BioNTech may develop. Any of the foregoing could result in a material adverse effect on BioNTech's business, financial condition, results of operations or prospects.

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

BioNTech currently has rights to certain intellectual property, through its owned and in-licensed patents and other intellectual property rights, relating to identification and development of its product candidates or other technologies. As its 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 its business could depend in part on its ability to acquire, in-license or use such intellectual property and proprietary rights. In addition, its product candidates may require specific formulations to work effectively and efficiently and these intellectual property and other proprietary rights may be held by others. BioNTech 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 BioNTech identifies as necessary, on reasonable terms, or at all, for product candidates and other technologies that BioNTech 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 BioNTech may consider attractive or necessary. These established companies may have a competitive advantage over BioNTech due to their size, cash resources, and greater clinical development and commercialization capabilities.

For example, BioNTech sometimes collaborates with academic institutions in certain aspects of its preclinical research or development under written agreements with these institutions. Typically, these institutions provide BioNTech 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 BioNTech's option and right of first negotiation for intellectual property rights or BioNTech may otherwise be unable to negotiate a license within the specified time frame or under terms that are acceptable to BioNTech. If BioNTech is unable to do so, the institution may offer the intellectual property rights to other parties, potentially blocking BioNTech's ability to pursue its program or otherwise continue to develop certain product candidates or other technologies.

Moreover, some of BioNTech's owned patents and patent applications are, and may in the future be, co-owned with third parties. If BioNTech is 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 BioNTech's competitors, and BioNTech's competitors could market competing products and technologies. In addition, BioNTech may need the cooperation of any such co-owners of BioNTech's patents in order to enforce such patents against third parties, and such cooperation may not be provided to BioNTech. Any of the foregoing could have a material adverse effect on BioNTech's competitive position, business, financial conditions, results of operations and prospects.

In addition, third parties that perceive BioNTech to be a competitor may be unwilling to assign or license rights to BioNTech. BioNTech also may be unable to license or acquire third-party intellectual property rights on terms that would allow BioNTech to make an appropriate return on it investment. If BioNTech is unable to successfully obtain rights to required third-party intellectual property rights or maintain, protect, defend or

enforce the existing intellectual property rights BioNTech has, BioNTech may have to abandon the development and commercialization of the relevant program or product candidate, which could have a material adverse effect on its business, financial condition, results of operations and prospects.

***The lifespans of BioNTech's patents may not be sufficient to effectively protect its 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 BioNTech's product candidates, proprietary technologies and their uses are obtained, once the patent term has expired, BioNTech 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 BioNTech owns or in-licenses expire, BioNTech would not be able to stop others from using or commercializing similar or identical technology and products, and BioNTech's competitors could market competing products and technology. Any of the foregoing could have a material adverse effect on BioNTech's competitive position, business, financial conditions, results of operations and prospects.

***If BioNTech does not obtain patent term extension and data exclusivity for any product candidates it may develop, its business may be materially harmed.***

Depending upon the timing, duration and specifics of any FDA marketing approval of any product candidates BioNTech may develop, one or more of its 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, BioNTech 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 BioNTech requests. If BioNTech is unable to obtain patent term extension or the term of any such extension is less than BioNTech requests, BioNTech's competitors may obtain approval of competing products following BioNTech's patent expiration, and BioNTech's business, financial condition, results of operations and prospects could be materially harmed.

***If BioNTech fails to comply with its obligations in the agreements under which it licenses intellectual property rights from third parties or otherwise experience disruptions to its business relationships with its licensors, it could lose license rights that are important to its business.***

BioNTech is 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 its technology and product candidates, and it expects to enter into similar license agreements in the future. Licensing of intellectual property is important to BioNTech's business and involves complex legal, business and scientific issues and is

complicated by the rapid pace of scientific discovery in BioNTech's industry. BioNTech's 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 it may wish to develop or commercialize its technology and products in the future. As a result, it may not be able to prevent competitors from developing and commercializing competitive products in territories included in any or all of its licenses.

Where BioNTech obtains licenses from, or collaborates with, third parties, in some circumstances it may not have the right to control the preparation, filing, prosecution, maintenance, enforcement and defense of patents and patent applications covering the technology that it licenses from third parties, or such activities, if controlled by BioNTech, may require the input of such third parties. In some cases, patent prosecution of BioNTech's in-licensed intellectual property is controlled solely by the licensor. BioNTech may also require the cooperation of its licensors and collaborators to enforce or defend any in-licensed patent rights, and such cooperation may not be provided. Therefore, BioNTech 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 its business. Any patents or patent applications that BioNTech in-licenses may be challenged, narrowed, circumvented, invalidated or held unenforceable, or BioNTech's licensors may not properly maintain such patents or patent applications and they may expire. If BioNTech's licensors fail to obtain, maintain, defend, protect or enforce the intellectual property BioNTech licenses from them, BioNTech could lose its rights to the intellectual property and its competitors could market competing products using the inventions in such intellectual property. In certain cases, BioNTech controls the prosecution of patents included from in-licensed technology. In the event BioNTech breaches any of its obligations related to such prosecution, it may incur significant liability to its collaborators. Any of the foregoing could have a material adverse effect on BioNTech's competitive position, business, financial conditions, results of operations and prospects.

Moreover, any failure to satisfy obligations or any material breach under any of BioNTech's licenses to third-party intellectual property could give the licensor the right to terminate the license. BioNTech's existing license agreements impose, and BioNTech expects that future license agreements will impose, various diligence, milestone and royalty payment, exclusivity and other obligations on BioNTech. If BioNTech fails to comply with its obligations under these agreements, or BioNTech is subject to a bankruptcy, the licensor may have the right to terminate the license agreement, in which event BioNTech would not be able to develop, market and commercialize product candidates covered by the license agreement. In spite of its best efforts and even if it disagrees, BioNTech's licensors might still conclude that BioNTech has materially breached its license agreements and might therefore terminate the license agreements, thereby removing BioNTech's ability to develop and commercialize the product candidates covered by these license agreements. In the event that any of BioNTech's license agreements were to be terminated by the licensor, BioNTech may need to negotiate new or reinstated agreements, which may not be available to BioNTech 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 BioNTech's. In addition, BioNTech may seek to obtain additional licenses from its licensors and, in connection with obtaining such licenses, BioNTech may agree to amend its 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 BioNTech's competitors) to receive licenses to a portion of the intellectual property that is subject to BioNTech's existing licenses.

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

***Some of BioNTech's 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 BioNTech's exclusive rights and its ability to contract with manufacturers.***

Certain intellectual property rights that have been in-licensed, including patent applications and patents that BioNTech in-licenses 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 BioNTech's 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 BioNTech's 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 BioNTech 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. BioNTech may not be able to obtain a waiver of this preference for U.S. industry, and this preference may limit its ability to contract with non-U.S. product manufacturers for products covered by such intellectual property. To the extent any of BioNTech's owned or in-licensed future intellectual property is generated through the use of U.S. government funding, the provisions of the Bayh-Dole Act may similarly apply. If BioNTech is unable to comply with these manufacturing requirements, BioNTech may experience a material adverse effect on its competitive position, business, financial conditions, results of operations and prospects.

***BioNTech's current proprietary position for certain product candidates depends upon its 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 BioNTech has obtained patent protection covering components of certain product candidates, manufacturing-related methods, formulations and/or methods of use, BioNTech does not currently have any claims in its owned or in-licensed issued U.S. patents that cover, for example, the overall construct used in its iNeST product candidates, and BioNTech cannot be certain that claims in any future patents issuing from BioNTech's pending owned or in-licensed patent applications or its future owned or in-licensed patent applications will cover the composition of matter of its 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 BioNTech's targeted indications or uses for which BioNTech 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, BioNTech may not be able to prevent third parties from practicing its inventions in the United States or abroad.

***Intellectual property rights of third parties could adversely affect BioNTech's ability to commercialize its product candidates, and BioNTech might be required to litigate or obtain licenses from third parties in order to develop or market its product candidates.***

Because its 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, BioNTech cannot be confident that BioNTech is aware of all third-party intellectual property that might be relevant to products that BioNTech eventually hopes 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 BioNTech's ability to commercialize products. Furthermore, while U.S. patent laws provide a "safe harbor" to BioNTech's 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, BioNTech cannot be certain of the timing of their completion and it is possible that BioNTech 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 BioNTech commercializes its product candidates, one or more third parties may have issued patent claims that cover its products or critical features of their production or use. BioNTech may not be able to commercialize its products if patents issued to third parties or other third-party intellectual property rights cover, or may be alleged to cover, BioNTech's products or elements thereof, or their methods of manufacture or use at the time that BioNTech seeks to commercialize them. In such cases, BioNTech may not be in a position to develop or commercialize product candidates unless it successfully pursues litigation to nullify or invalidate the third-party intellectual property right concerned, successfully design around their claims, or enters 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 BioNTech has failed to identify relevant third-party patents that cover, or applications that will mature into patents that cover, one or more aspects of BioNTech's 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 BioNTech 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 BioNTech's products or activities when published could be amended to cover one or more aspects of BioNTech's platform or product candidates over time, and BioNTech might not be aware that such amendment had been made.

***BioNTech may be involved in lawsuits to protect or enforce its intellectual property or the intellectual property of its licensors, or to defend against third-party claims that it infringes, misappropriates or otherwise violates such third party's intellectual property, each of which could be expensive, time consuming and unsuccessful.***

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

Competitors and other third parties may infringe, misappropriate or otherwise violate BioNTech's intellectual property rights or those of its licensors. To prevent infringement, misappropriation or other unauthorized use, BioNTech may be required to file claims, which can be expensive and time-consuming. In certain instances, BioNTech has 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. BioNTech has 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 BioNTech's product candidates may be subject to claims of infringement of the patent rights of third parties.

In addition, in a patent infringement proceeding, BioNTech's owned or in-licensed patents may be challenged and a court may decide that a patent BioNTech owns or in-licenses is not valid, is unenforceable and/or is not infringed. If BioNTech or any of its potential future collaborators were to initiate legal proceedings against a third party to enforce a patent directed at one of BioNTech's product candidates, the defendant could counterclaim that BioNTech's 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 BioNTech holds in the future. The outcome following legal assertions of invalidity and unenforceability is unpredictable, and prior art could render BioNTech's patents or those of its licensors invalid. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, BioNTech 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 BioNTech's competitive position, business, financial conditions, results of operations and prospects.

Third parties, ranging from BioNTech's competitors to non-practicing entities or patent assertion entities, may assert that BioNTech is 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 BioNTech's 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 BioNTech's product candidates may infringe. In addition, third parties may obtain patents in the future and claim that BioNTech's 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 BioNTech's 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 BioNTech's ability to develop and commercialize such product candidate unless it 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 BioNTech's formulations, processes for manufacture or methods of use, including combination therapy, the holders of any such patents may be able to block BioNTech's ability to develop and commercialize the applicable product candidate unless BioNTech 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 BioNTech or declared by the USPTO may be necessary to determine the priority of inventions with respect to BioNTech's patents or patent applications or those of its licensors. An unfavorable outcome could require BioNTech to cease using the related technology or to attempt to license rights to it from the prevailing party. BioNTech's business could be harmed if the prevailing party does not offer BioNTech a license on commercially reasonable terms or at all, or if a

non-exclusive license is offered and BioNTech's competitors gain access to the same intellectual property and technology. BioNTech's defense of litigation, interference, derivation or similar proceedings may fail and, even if successful, may result in substantial costs and distract BioNTech's management and other employees. In addition, the uncertainties associated with litigation could have a material adverse effect on BioNTech's ability to raise the funds necessary to continue its clinical trials, continue its research programs, license necessary technology from third parties or enter into development or manufacturing collaborations that would help BioNTech bring its product candidates to market.

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

In the event of a successful claim of infringement, misappropriation or other violation against BioNTech, BioNTech may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, pay royalties, redesign its 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, BioNTech's competitors may have access to the same intellectual property and technology licensed to BioNTech. If BioNTech fails to obtain a required license and is unable to design around a patent, BioNTech may be unable to effectively market some of its technology and product candidates, which could limit its ability to generate revenues or achieve profitability and possibly prevent BioNTech from generating revenue sufficient to sustain its operations. Moreover, certain of BioNTech's collaborations provide, and BioNTech expects additional collaborations to provide, that royalties payable to it for licenses to its intellectual property may be offset by amounts paid by BioNTech's collaborators to third parties for licenses to such third parties' intellectual property in the relevant fields, which could result in significant reductions in BioNTech's revenues from products developed through collaborations.

In addition, in connection with certain license and collaboration agreements, BioNTech has 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 BioNTech of any litigation or other proceeding relating to intellectual property rights, even if resolved in its 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 BioNTech's 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 BioNTech's patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and BioNTech's 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. BioNTech has systems in place to remind BioNTech to pay these fees and BioNTech employs an outside firm and relies on its outside counsel to pay these fees due to non-U.S. patent agencies; however, BioNTech cannot guarantee that it 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. BioNTech employs reputable law firms and other professionals to help it 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. BioNTech is also dependent on its licensors to take the necessary action to comply with these requirements with respect to its in-licensed intellectual property, and BioNTech cannot guarantee that they will do so. In such an event, BioNTech's competitors might be able to enter the market with similar or identical products or technology, and this would have a material adverse impact on BioNTech's 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 BioNTech's ability to protect its products.***

As is the case with other biotechnology companies, BioNTech's success is heavily dependent on its intellectual property rights, particularly patents that it owns and in-licenses. 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 BioNTech's patent applications and the enforcement or defense of BioNTech's issued patents, all of which could have a material adverse effect on BioNTech's 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 BioNTech's 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 BioNTech's existing patent portfolio and BioNTech's ability to obtain, maintain, protect, defend or enforce its intellectual property in the future.

***If BioNTech is unable to protect the confidentiality of its trade secrets, its business and competitive position would be harmed.***

In addition to seeking patent protection for some of its technology and product candidates, BioNTech also seeks to rely on trade secret protection and confidentiality agreements to maintain its competitive position and protect proprietary know-how that is not patentable, processes for which patents are difficult to enforce and any other elements of its 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.

BioNTech seeks 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

BioNTech's employees, corporate collaborators, outside scientific collaborators, CROs, contract manufacturers, consultants, advisors and other third parties. BioNTech also enters into confidentiality and invention or patent assignment agreements with its employees and consultants and requires all of its employees and key consultants who have access to its trade secrets, proprietary know-how, information or technology to enter into confidentiality agreements. BioNTech cannot guarantee that BioNTech has entered into such agreements with each party that may have or have had access to its trade secrets or proprietary technology and processes. Despite BioNTech's best efforts, any of these parties may breach the agreements and BioNTech cannot be certain that its trade secrets and other confidential proprietary information will not be disclosed or that competitors will not otherwise gain access to its trade secrets or independently develop substantially equivalent information and techniques. BioNTech 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 BioNTech's trade secrets or know-how were to be lawfully obtained or independently developed by a competitor or other third party, BioNTech would have no right to prevent them from using that technology or information to compete with BioNTech. If BioNTech is unable to prevent unauthorized material disclosure of its intellectual property to third parties, BioNTech will not be able to establish or maintain a competitive advantage in its market, which could materially adversely affect its business, operating results, financial condition and prospects.

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

BioNTech has received confidential and proprietary information from third parties in the course of its research and other collaborations with others in the industry, academic institutions and other third parties. In addition, many of its employees, consultants and advisors are currently or were previously employed at universities or other biotechnology or pharmaceutical companies, including its competitors or potential competitors. Although BioNTech tries to ensure that its 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 BioNTech, BioNTech may be subject to claims that it has inadvertently or otherwise used or disclosed confidential or proprietary information, trade secrets or know-how of these third parties, or that its 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 BioNTech fails in defending any such claims, in addition to paying monetary damages, BioNTech may lose valuable intellectual property rights or personnel. Litigation may be necessary to defend against these claims. Even if BioNTech is successful in defending against these claims, litigation could result in substantial cost and be a distraction to its management and employees. Claims that BioNTech, its 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 its business, financial condition, results of operations and prospects.

***BioNTech may be subject to claims challenging the inventorship or ownership of its patents and other intellectual property.***

BioNTech 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 its patents or other intellectual property as an inventor or co-inventor. While it is BioNTech's policy to require its 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 BioNTech, BioNTech may be unsuccessful in executing such an agreement with each party who, in fact, conceives, develops or reduces to practice such intellectual property that BioNTech regards as its own. The assignment of intellectual property rights may not be self-executing, or the assignment agreements may be

breached. For example, BioNTech 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 its product candidates. Litigation may be necessary to defend against these and other claims challenging inventorship. If BioNTech fails in defending any such claims, in addition to paying monetary damages, BioNTech 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 BioNTech's business, operating results and financial condition. Even if BioNTech is 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 BioNTech's 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. BioNTech faces the risk that disputes can occur between BioNTech and its employees or former employees pertaining to alleged non-adherence to the provisions of this act that may be costly to defend and take up BioNTech's management's time and efforts whether BioNTech prevails or fails in any such dispute. There is a risk that the compensation BioNTech provided to employees who assign patents to BioNTech may be deemed to be insufficient and BioNTech 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 BioNTech, BioNTech may need to pay compensation for the use of those patents. If BioNTech is required to pay additional compensation or face other disputes under the German Act on Employees' Inventions, its business, results of operations and financial condition could be adversely affected.

***BioNTech will not seek to protect its intellectual property rights in all jurisdictions throughout the world, and may not be able to adequately enforce its intellectual property rights even in the jurisdictions where it seeks protection.***

Filing, prosecuting and defending patents on product candidates and product candidates in all countries throughout the world would be prohibitively expensive, and BioNTech's 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, BioNTech may not be able to prevent third parties from practicing its inventions in all countries outside the United States, or from selling or importing products made using its inventions in and to the United States or other jurisdictions. Competitors may use BioNTech's technologies in jurisdictions where BioNTech has not obtained patent protection to develop their own product candidates and further, may export otherwise infringing products to territories where BioNTech has patent protection, but enforcement is not as strong as that in the United States. These products may compete with BioNTech's product candidates, and BioNTech's 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 BioNTech to stop the infringement, misappropriation or other violation of BioNTech's patents and other intellectual property or development, marketing and commercialization of competing products in violation of its intellectual property and other proprietary rights generally. Proceedings to enforce BioNTech's intellectual property rights in such jurisdictions could result in substantial costs and divert BioNTech's efforts and attention from other aspects of its business, could put its patents at risk of being invalidated or interpreted narrowly and its patent applications at risk of not issuing and could provoke third parties to assert claims against BioNTech. BioNTech may not prevail in any lawsuits that it initiates and the damages or other remedies awarded, if any, may not be commercially

meaningful. Accordingly, BioNTech's efforts to enforce its intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that it develops or in-licenses.

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 BioNTech or any of its licensors is forced to grant a license to third parties with respect to any patents relevant to BioNTech's business, BioNTech's competitive position may be impaired, and its business, financial condition, results of operations and prospects may be adversely affected.

***If BioNTech's trademarks and trade names are not adequately protected, then BioNTech may not be able to build name recognition in its markets of interest and its business may be adversely affected.***

BioNTech's registered or unregistered trademarks or trade names may be challenged, infringed, circumvented or declared generic or determined to be infringing on other marks. BioNTech may not be able to protect its rights to these trademarks and trade names, which it needs to build name recognition among potential collaborators or customers in its markets of interest. At times, competitors may adopt trade names or trademarks similar to BioNTech's, thereby impeding its 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 BioNTech's registered or unregistered trademarks or trade names. Over the long term, if BioNTech is unable to establish name recognition based on its trademarks and trade names, then it may not be able to compete effectively and its business may be adversely affected. BioNTech may license its trademarks and trade names to third parties, such as distributors. Though these license agreements may provide guidelines for how BioNTech's trademarks and trade names may be used, a breach of these agreements or misuse of BioNTech's trademarks and trade names by its licensees may jeopardize its rights in or diminish the goodwill associated with its trademarks and trade names. BioNTech's efforts to enforce or protect its 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 its business, financial condition, results of operations and prospects.

***Intellectual property rights do not necessarily address all potential threats to BioNTech's competitive advantage.***

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

- others may be able to make personalized cancer immunotherapies that are similar to any product candidates it may develop and commercialize or utilize similar technologies that are not covered by the claims of the patents that BioNTech now or may in the future own or have exclusively in-licensed;
- BioNTech, its co-owners or its licensors or future collaborators might not have been the first to make the inventions covered by the issued patents or pending patent applications that it owns or have exclusively in-licensed;
- BioNTech, its co-owners or its licensors or future collaborators might not have been the first to file patent applications covering certain of its or their inventions;
- others may independently develop similar or alternative technologies or duplicate any of BioNTech's technologies without infringing its owned or in-licensed intellectual property rights;
- it is possible that its pending patent applications or those that it may own or in-license in the future will not lead to issued patents;

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

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

**Risks Related to Government Regulation**

***BioNTech may be subject, directly or indirectly, to federal and state healthcare fraud and abuse laws, false claims laws, and other healthcare laws. If BioNTech is unable to comply, or has not fully complied, with such laws, it could face substantial penalties.***

BioNTech 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 BioNTech conducts its business. If BioNTech obtains FDA approval for any of its product candidates and begins commercializing those products in the United States, its operations will be directly, or indirectly through its 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, BioNTech's proposed sales, marketing and educational programs. In addition, BioNTech may be subject to patient privacy laws enacted by both the federal government and the states in which it conducts its business. The laws that will affect its 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 BioNTech, and many of them differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts in certain circumstances.
- the U.S. Foreign Corrupt Practices Act of 1977, as amended, which prohibits, among other things, U.S. companies and their employees and agents, as well as non-U.S. companies that are registered with the SEC from authorizing, promising, offering or providing, directly or indirectly, corrupt or improper payments or anything else of value to foreign government officials, employees of public international organizations and foreign government owned or affiliated entities, candidates for foreign political office, and foreign political parties or officials thereof; and
- similar 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 BioNTech's business activities could be subject to challenge under one or more of such laws. If BioNTech's operations are found to be in violation of any of the laws described above or any other government regulations that apply to it, it 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 its operations, any of which could adversely affect its ability to operate its business and its 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.

***BioNTech is subject to certain anti-corruption, anti-money laundering, export control, sanctions, and other trade laws and regulations. BioNTech 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. BioNTech has direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities and other organizations. BioNTech plans to engage third parties for clinical trials and/or to obtain necessary permits, licenses, intellectual property (including patents) and other regulatory approvals, and it can be held liable for the corrupt or other illegal activities of its personnel, agents or collaborators, even if it does not explicitly authorize or have prior knowledge of such activities.

***BioNTech is subject to stringent privacy laws, information security policies and contractual obligations governing the use, processing, and cross-border transfer of personal information and BioNTech's data privacy and security practices.***

BioNTech receives, generates and stores significant and increasing volumes of sensitive information, such as employee, personal and patient data. BioNTech is 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 BioNTech operates, 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 BioNTech to incur substantial costs or require BioNTech to change its business practices and compliance procedures in a manner adverse to its business. Moreover, complying with these various laws could require BioNTech to take on more onerous obligations in its contracts, restrict its ability to collect, use and disclose data, or in some cases, impact its 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 BioNTech's operating results and business. Claims that BioNTech has violated individuals' privacy rights, failed to comply with data protection laws, or breached its contractual obligations, even if BioNTech is not found liable, could be expensive and time consuming to defend, could result in adverse publicity and could have a material adverse effect on BioNTech's 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 BioNTech is located in the European Union, it is subject to the GDPR. Additionally, as the GDPR applies extraterritorially, BioNTech is also subject to the GDPR even where its 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 BioNTech processes and it 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 BioNTech's development activities, and adversely affect its 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 BioNTech's compliance costs and the risks associated with non-compliance. BioNTech cannot guarantee that it is, or will be, in compliance with all applicable international regulations as they are enforced now or as they evolve. For example, its privacy policies may be insufficient to protect any personal information it collects, or may not comply with applicable laws, in which case it may be subject to regulatory enforcement actions, lawsuits or reputational damage, all of which may adversely affect its 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 BioNTech's business, financial condition, results of operations and prospects. If BioNTech fails to comply with the GDPR and the applicable national data protection laws of the European Union member states, or if regulators assert BioNTech has 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, BioNTech's business and financial results could be significantly disrupted and adversely affected.

Although BioNTech takes measures to protect sensitive data from unauthorized access, use or disclosure, BioNTech's 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 BioNTech's 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 BioNTech's reputation and its 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 BioNTech has implemented security measures to prevent unauthorized access to patient data, such data is currently accessible through multiple channels, and there is no guarantee BioNTech can protect its data from breach. Unauthorized access, loss or dissemination could also damage its reputation or disrupt its operations, including its ability to conduct its 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 its tests and other patient and physician education and outreach efforts through its website, and manage the administrative aspects of its business.

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

BioNTech 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. Its operations will involve the use of hazardous and flammable materials, including chemicals and biological materials. Its operations also may produce hazardous waste products.

BioNTech generally anticipates contracting with third parties for the disposal of these materials and wastes. BioNTech 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 it of hazardous materials, BioNTech could be held liable for any resulting damages, and any liability could exceed its resources. BioNTech also could incur significant costs associated with civil or criminal fines and penalties for failure to comply with such laws and regulations.

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

In addition, BioNTech 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 its research, development or production efforts. BioNTech's failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

***BioNTech's 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 BioNTech to penalties.***

BioNTech's business operations and current and future arrangements with investigators, healthcare professionals, consultants, third-party payors, patient organizations and customers, may expose it 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 BioNTech conducts its operations, including how it researches, markets, sells and distributes its product candidates, if approved.

Ensuring that BioNTech's 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 its 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 BioNTech expects 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 BioNTech's ability to operate its business. Further, defending against any such actions can be costly and time-consuming and may require significant personnel resources. Therefore, even if BioNTech is successful in defending against any such actions that may be brought against it, its business may be impaired.

*General Risks Related to BioNTech's Business*

***BioNTech's future success depends on its ability to retain key employees, consultants and advisors and to attract, retain and motivate qualified senior management and scientific personnel.***

BioNTech's ability to compete in the highly competitive biotechnology and pharmaceutical industries depends upon its ability to attract and retain highly qualified managerial, scientific and medical personnel. BioNTech is highly dependent upon members of its management and scientific teams. It 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 BioNTech's research, development, financing and commercialization objectives. BioNTech currently does not have "key person" insurance on any of its employees.

In addition, BioNTech relies on consultants, contractors and advisors, including scientific and clinical advisors, to assist it in formulating its research and development, regulatory approval and commercialization

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

Recruiting and retaining other qualified employees, consultants and advisors for BioNTech's business, including scientific and technical personnel, also will be critical to its 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. BioNTech 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 BioNTech's research, development and commercialization objectives and have a material adverse impact on its business, financial condition, results of operations and prospects.

***BioNTech's 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 BioNTech's results of operations.***

BioNTech is exposed to the risk of fraud or other misconduct by its 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 BioNTech. 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 BioNTech's reputation. BioNTech has adopted a code of conduct applicable to all of its employees, but it is not always possible to identify and deter employee misconduct, and the precautions BioNTech takes to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting BioNTech 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 BioNTech, and BioNTech is not successful in defending itself or asserting its rights, those actions could have a significant impact on its 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 BioNTech's future business.***

BioNTech's employees may, from time to time, bring lawsuits against BioNTech 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 BioNTech were to face any employment-related claims, its business could be negatively affected.

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

BioNTech's internal computer systems and those of its 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 BioNTech's operations, it could result in a material disruption of BioNTech's development programs and its business operations, whether due to a loss of its 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 BioNTech's regulatory approval efforts and significantly increase BioNTech's costs to recover or reproduce the data. In addition, because of BioNTech's approach to running multiple clinical trials in parallel, any breach of its computer systems may result in a loss of data or compromised data integrity across many of BioNTech's programs in many stages of development. Any such breach, loss or compromise of clinical trial participant personal data may also subject BioNTech 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, BioNTech could incur liability, its competitive position could be harmed and the further development and commercialization of BioNTech's product candidates could be delayed.

While BioNTech has not experienced any material system failures, accidents or security breaches to date, BioNTech and a vendor have separately in the past been subject to a security breach resulting in BioNTech unknowingly making payments to third parties that were able to gain unauthorized access to its and the vendor's email systems. BioNTech has since put systems and procedures in place to minimize the likelihood of such incidents reoccurring; however, it cannot guarantee that third parties will not be able to gain unauthorized access to or otherwise breach its systems in the future. Any such unauthorized access or breach could adversely affect its business, results of operations and financial condition.

***BioNTech's business continuity and disaster recovery plans may not adequately protect it from a serious disaster.***

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

***Product liability lawsuits against BioNTech could cause it to incur substantial liabilities and could limit commercialization of its current or future product candidates.***

BioNTech faces an inherent risk of product liability exposure related to the testing of any of its current or future product candidates in clinical trials, and it may face an even greater risk if it commercializes any product candidate that it may develop. If BioNTech cannot successfully defend itself against claims that its product candidates caused injuries, it could incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for any product candidate that BioNTech 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 BioNTech may develop; and
- injury to BioNTech's reputation and significant negative media attention.

BioNTech carries clinical trial insurance, including product liability insurance, which it believes to be sufficient in light of its current clinical programs; however, it may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect it against losses due to liability. If and when BioNTech obtains marketing approval for product candidates, it intends to expand its insurance coverage to include the sale of commercial products; however, it 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 BioNTech could cause the price of the ADS to decline and, if judgments exceed BioNTech's insurance coverage, could adversely affect its results of operations and business.

***If BioNTech's products become subject to a product recall it could harm BioNTech's 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 BioNTech could occur as a result of manufacturing errors, design or labeling defects or other deficiencies and issues. Recalls of any of BioNTech's product candidates would divert managerial and financial resources and have an adverse effect on BioNTech's financial condition and results of operations. A recall announcement could harm BioNTech's reputation with customers and negatively affect its sales, if any.

***If BioNTech engages in future acquisitions, joint ventures or collaborations, this may increase its capital requirements, dilute its shareholders, cause it to incur debt or assume contingent liabilities, and subject it to other risks. BioNTech may not realize the benefits of these acquisitions, joint ventures or collaborations.***

BioNTech 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 BioNTech's management's attention from its 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 BioNTech's 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

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

In addition, if BioNTech undertakes acquisitions, it may utilize its 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, BioNTech may not be able to locate suitable acquisition or collaboration opportunities and this inability could impair its ability to grow or obtain access to technology or products that may be important to the development of its business.

**Risk Factors Related to Neon's Business**

*Risks Related to the Merger*

***Failure to complete, or delays in completing, the Merger announced on January 16, 2020 could materially and adversely affect Neon's results of operations, business, financial results and/or stock price.***

On January 15, 2020, we entered into an agreement with BioNTech pursuant to which, if all of the conditions to closing are satisfied or waived, we will become a wholly-owned subsidiary of BioNTech. Consummation of the Merger is subject to certain closing conditions, a number of which are not within our control. Any failure to satisfy these required conditions to closing may prevent, delay or otherwise materially adversely affect the completion of the transaction. We cannot predict with certainty whether or when any of the required closing conditions will be satisfied or if another uncertainty may arise and cannot assure you that we will be able to successfully consummate the proposed merger as currently contemplated under the Merger Agreement or at all.

Our efforts to complete the Merger could cause substantial disruptions in, and create uncertainty surrounding, our business, which may materially adversely affect our results of operation and our business. Uncertainty as to whether the Merger will be completed may affect our ability to recruit prospective employees or to retain and motivate existing employees. Employee retention may be particularly challenging while the transaction is pending because employees may experience uncertainty about their roles following the transaction. Uncertainty as to our future could adversely affect our business and our relationship with collaborators, suppliers, vendors, regulators and other business partners. For example, vendors, collaborators and other counterparties may defer decisions about working with us or seek to change existing business relationships with us. Changes to, or termination of, existing business relationships could adversely affect our results of operations and financial condition, as well as the market price of our common stock. The adverse effects of the pendency of the transaction could be exacerbated by any delays in completion of the transaction or termination of the Merger Agreement.

Risks related to the failure of the proposed merger to be consummated include, but are not limited to, the following:

- we would not realize any or all of the potential benefits of the Merger, including any synergies that could result from combining our financial and proprietary resources with those of BioNTech, which could have a negative effect on our stock price;
- under some circumstances, we may be required to pay a termination fee to BioNTech of $3,200,000;
- we will remain liable for significant transaction costs, including legal, accounting, financial advisory and other costs relating to the Merger regardless of whether the Merger is consummated;
- the trading price of our common stock may decline to the extent that the current market price for our stock reflects a market assumption that the Merger will be completed;

- the attention of our management and employees may have been diverted to the Merger rather than to our own operations and the pursuit of other opportunities that could have been beneficial to us;
- we could be subject to litigation related to any failure to complete the Merger;
- the potential loss of key personnel during the pendency of the Merger as employees and other service providers may experience uncertainty about their future roles with us following completion of the Merger; and
- under the Merger Agreement, we are subject to certain restrictions on the conduct of our business prior to completing the Merger, which restrictions could adversely affect our ability to conduct our business as we otherwise would have done if we were not subject to these restrictions.

The occurrence of any of these events individually or in combination could materially and adversely affect our results of operations, business, and our stock price.

***Neon cannot be sure if or when the Merger will be completed.***

The consummation of the Merger is subject to the satisfaction or waiver of various conditions, including the authorization of the Merger by our shareholders. We cannot guarantee that the closing conditions set forth in the Merger Agreement will be satisfied. If we are unable to satisfy the closing conditions in BioNTech's favor or if other mutual closing conditions are not satisfied, BioNTech will not be obligated to complete the Merger. Under certain circumstances, we would be required to pay BioNTech a termination fee of $3,200,000.

If the Merger is not completed, our board of directors, in discharging its fiduciary obligations to our shareholders, will evaluate other strategic alternatives or financing options that may be available, which alternatives may not be as favorable to our shareholders as the Merger. Any future sale or merger, financing or other transaction may be subject to further shareholder approval. We may also be unable to find, evaluate or complete other strategic alternatives, which may materially adverse affect our business.

Our efforts to complete the Merger could cause substantial disruptions in, and create uncertainty surrounding, our business, which may materially adversely affect our results of operation and our business. Uncertainty as to whether the Merger will be completed may affect our ability to recruit prospective employees or to retain and motivate existing employees. Employee retention may be particularly challenging while the transaction is pending because employees may experience uncertainty about their roles following the transaction. A substantial amount of our management's and employees' attention is being directed toward the completion of the transaction and thus is being diverted from our day-to-day operations. Uncertainty as to our future could adversely affect our business and our relationship with collaborators, suppliers, vendors, regulators and other business partners. For example, vendors, collaborators and other counterparties may defer decisions concerning working with us, or seek to change existing business relationships with us. Changes to, or termination of, existing business relationships could adversely affect our results of operations and financial condition, as well as the market price of our common stock. The adverse effects of the pendency of the transaction could be exacerbated by any delays in completion of the transaction or termination of the Merger Agreement.

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

***Because the Merger Agreement provides for a fixed exchange ratio for the number of shares of BioNTech ADSs that will be issued for each outstanding share of Neon common stock, the consideration received at the time of the Merger may be lower than the public trading value of shares of Neon common stock when Neon entered into the Merger Agreement.***

The Merger Agreement provides for a fixed exchange ratio for the number of shares of BioNTech ADSs that will be issued for each outstanding share of our common stock in the Merger. If the public trading value of shares of BioNTech common stock declines over the period of time required to satisfy the Merger's closing conditions, the consideration received at the time of the Merger may be lower than the public trading value of shares of our common stock when we entered into the Merger Agreement.

***The Merger Agreement contains provisions that limits Neon's ability to pursue alternatives to the Merger, could discourage a potential competing acquiror of Neon from making an alternative transaction proposal and, in specified circumstances, could require Neon to pay a termination fee to BioNTech.***

The Merger Agreement provides that we shall not, and requires us to refrain from permitting our representatives to, among other things, solicit, participate in negotiations with respect to or approve or recommend any third party proposal for an alternative transaction, subject to exceptions set forth in the Merger Agreement relating to the receipt of certain unsolicited proposals. Further, while our board of directors is permitted to make a recommendation change to our stockholders with respect to the Merger under certain circumstances, unless BioNTech terminates the Merger Agreement, we nonetheless will be required to submit the proposals to a stockholder vote at a special meeting. This requirement, which is often called a "force the vote" provision, means that we do not have the right before the stockholder vote to terminate the Merger Agreement to accept a superior proposal. If the Merger Agreement is terminated, in certain circumstances, we may be required to pay BioNTech a termination fee of $3,200,000.

These provisions could discourage a potential third-party acquiror or merger partner that might have an interest in acquiring all or a significant portion of us or pursuing an alternative transaction from considering or proposing such a transaction, even if it were prepared to pay consideration with a higher per share cash or market value than the consideration in the Merger, or might result in a potential third-party acquiror or merger partner proposing to pay a lower price to our stockholders than it might otherwise have proposed to pay because of the added expense of the termination fee that may become payable in certain circumstances.

If the Merger Agreement is terminated and we determine to seek another business combination, we may not be able to negotiate a transaction with another party on terms comparable to, or better than, the terms of the Merger.

***Lawsuits may be filed against Neon and the members of the Neon board arising out of the Merger, which may delay or prevent the Merger.***

Putative stockholder complaints, including stockholder class action complaints, and other complaints may be filed against us, our board of directors, BioNTech, BioNTech's board of directors and others in connection with the transactions contemplated by the Merger Agreement. The outcome of litigation is uncertain, and we may not be successful in defending against any such future claims. Lawsuits that may be filed against us, our board of directors, BioNTech, or BioNTech's board of directors could delay or prevent the Merger, divert the attention of our management and employees from our day-to-day business and otherwise adversely affect us financially.

*Risks Related to Neon Business, Technology and Industry*

***Neon has incurred net losses in every year since Neon's inception and anticipates that Neon will continue to incur net losses in the future.***

We are a clinical-stage biopharmaceutical immuno-oncology company with a limited operating history. Investment in biopharmaceutical product development is highly speculative because it entails substantial upfront

capital expenditures and significant risk that any potential product candidate will fail to demonstrate adequate effect or an acceptable safety profile, gain regulatory approval and become commercially viable. We have no products approved for commercial sale and have not generated any revenue from product sales to date, and we continue to incur significant research and development and other expenses related to our ongoing operations. As a result, we are not profitable and have incurred losses in each period since our inception in October 2013. For the years ended December 31, 2019 and 2018, we reported net losses of $79.8 million and $76.9 million, respectively. As of December 31, 2019, we had an accumulated deficit of $253.5 million. We expect to continue to incur significant losses for the foreseeable future, and we expect these losses to increase as we continue our research and development of, and seek regulatory approvals for, our product candidates. We expect to continue to incur substantial expenses in connection with our ongoing activities if, and as, we:

- initiate or continue clinical trials of our product candidates;
- advance our development programs into and through preclinical and clinical development;
- seek regulatory approvals for any product candidates that successfully complete clinical trials;
- hire additional clinical, quality assurance and scientific personnel;
- expand our operational, financial and management systems and increase personnel, including personnel to support our clinical development, manufacturing and commercialization efforts and our operations as a public company;
- maintain, expand and protect our intellectual property portfolio;
- establish a sales, marketing, medical affairs and distribution infrastructure to commercialize any products for which we may obtain marketing approval and intend to commercialize on our own or jointly with third parties; and
- acquire or in-license other product candidates and technologies.

To become and remain profitable, we or any potential future collaborator must develop and eventually commercialize products with significant market potential. This will require us to be successful in a range of challenging activities, including completing preclinical studies and clinical trials, obtaining marketing approval for product candidates, manufacturing, marketing and selling products for which we may obtain marketing approval and satisfying any post-marketing requirements. We may never succeed in any or all of these activities and, even if we do, we may never generate revenue that is significant or large enough to achieve profitability. If we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would decrease the value of our company and could impair our ability to raise capital, maintain our research and development efforts, expand our business or continue our operations. A decline in the value of our company also could cause you to lose all or part of your investment.

Even if we succeed in commercializing one or more of our product candidates, we will continue to incur substantial research and development and other expenditures to develop and market additional product candidates. We may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business. The size of our future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate revenue. Our prior losses and expected future losses have had and will continue to have an adverse effect on our stockholders' equity and working capital.

***To date, Neon has not generated any product revenue, has a history of losses and will need to raise additional capital to fund its operations. If Neon fails to obtain necessary financing, Neon will not be able to complete the development and commercialization of its product candidates.***

Our operations have consumed substantial amounts of cash since our inception. We expect to continue to spend substantial amounts to conduct further research and development and preclinical or nonclinical testing and studies and clinical trials of our current and future programs, to seek regulatory approvals for our product

candidates and to launch and commercialize any products for which we receive regulatory approval, including potentially building our own commercial organization. As of December 31, 2019, we had approximately $29.4 million in cash and cash equivalents. Based on our current operating plan, we believe that our existing cash and cash equivalents as of December 31, 2019 will be sufficient to fund our operating expenses and capital expenditure requirements into the third quarter of 2020. However, our future capital requirements and the period for which our existing resources will support our operations may vary significantly from what we expect. We will in any event require additional capital in order to complete clinical development of any of our current programs. Our monthly spending levels will vary based on new and ongoing development and corporate activities. Because the length of time and activities associated with development of our product candidates is highly uncertain, we are unable to estimate the actual funds we will require for development and any approved marketing and commercialization activities. Our funding requirements, both near and long-term, as well as the timing and amount of our operating expenditures, will depend largely on:

- the initiation, progress, scope, timing, costs and results of preclinical or nonclinical testing and studies and clinical trials for our product candidates;
- the clinical development plans we establish for these product candidates;
- the number and characteristics of product candidates that we develop or may in-license;
- the terms of any collaboration agreements we may choose to execute;
- the outcome, timing and cost of meeting regulatory requirements established by the FDA, the EMA, the Dutch Health Authority, and other comparable foreign regulatory authorities;
- the cost of filing, prosecuting, defending and enforcing our patent claims and other intellectual property rights;
- the cost of defending intellectual property disputes, including any patent infringement actions that may be brought by third parties in the future against us or our product candidates;
- the effect of competing technological and market developments;
- the cost and timing of formulation development and manufacturing, including the completion of commercial-scale outsourced manufacturing activities; and
- the cost of establishing sales, marketing and distribution capabilities for any product candidates for which we may receive regulatory approval in regions where we choose to commercialize our products on our own.

We do not have any committed external source of funds or other support for our development efforts and we cannot be certain that additional funding will be available on acceptable terms, or at all. Until we can generate sufficient product or royalty revenue to finance our cash requirements, 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, strategic alliances, licensing arrangements and other marketing or distribution arrangements. If we raise additional funds through public or private equity offerings, the terms of these securities may include liquidation or other preferences that adversely affect our stockholders' rights. Further, to the extent that we raise additional capital through the sale of common stock or securities convertible or exchangeable into common stock, your ownership interest will be diluted. If we raise additional capital through debt financing, we would be subject to fixed payment obligations and may be subject to 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 or other collaborations, strategic alliances 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 or grant licenses on terms that may not be favorable to us. 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 technologies that we otherwise would seek to develop or commercialize ourselves. If we are unable to raise

additional capital in sufficient amounts or on terms acceptable to us, 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 and cause the price of our common stock to decline.

***Neon's independent registered public accounting firm has included an explanatory paragraph relating to Neon's ability to continue as a going concern in its report on Neon's audited financial statements included in this proxy statement/prospectus.***

As a result of our recurring losses from operations, recurring negative cash flows from operations and substantial cumulative losses, there is uncertainty regarding our ability to maintain liquidity sufficient to operate our business effectively, which raises substantial doubt about our ability to continue as a going concern. The report from our independent registered public accounting firm for the year ended December 31, 2019 includes an explanatory paragraph stating that our recurring losses and negative cash flows from operations since inception and required additional funding to finance our operations raise substantial doubt about our ability to continue as a going concern. If we seek additional financing to fund our business activities and there remains substantial doubt about our ability to continue as a going concern, investors or other financing sources may be unwilling to provide additional funding to us on commercially reasonable terms or at all. If we are unable to obtain sufficient funding, we could be forced to delay, reduce or eliminate all of our research and development programs or other business activities, and our financial condition and results of operations will be materially and adversely affected and we may be unable to continue as a going concern. In the future, reports from our independent registered public accounting firm may also contain statements expressing substantial doubt about our ability to continue as a going concern.

***Neon's most advanced product candidates are uniquely manufactured for each patient and Neon may encounter difficulties in production, particularly with respect to scaling Neon's manufacturing capabilities. If Neon or any of Neon's third-party manufacturers with whom Neon contracts encounter these types of difficulties, Neon's ability to provide supply of Neon's product candidates for clinical trials or Neon's products for patients, if approved, could be delayed or stopped, or Neon may be unable to maintain a commercially viable cost structure.***

The manufacturing process used to produce our product candidates is complex and novel and has not been validated for clinical or commercial production. For example, for NEO-PTC-01, we will harvest T cells from a patient and then, through a proprietary *ex vivo* process, prime, activate and expand those T cells to create an autologous T cell therapy that will ultimately be infused back into the patient's body. Similarly, for NEO-PV-01, we custom design and manufacture up to 20 individually selected peptides with a proprietary formulation to construct a unique vaccine for each patient. As a result of these complexities, the cost to manufacture our product candidates is generally higher than traditional small molecule chemical compounds and the manufacturing process is less reliable and is more difficult to reproduce.

Our manufacturing process will be susceptible to product loss or failure due to logistical issues associated with the collection of a patient's tumor and blood or other samples, shipping that material to analytical laboratories, and shipping the final product back to the location using cold chain distribution where it will be administered to the patient, manufacturing issues associated with the differences in patient starting materials, interruptions in the manufacturing process, contamination, equipment or reagent failure, improper installation or operation of equipment, vendor or operator error, inconsistency in cell growth, and variability in product characteristics. Even minor deviations from normal manufacturing processes could result in reduced production yields, lot failures, product defects, product delays, product recalls, product liability claims and other supply disruptions. If for any reason we lose a patient's starting material or one of our custom manufactured products at any point in the process, the manufacturing process for that patient will need to be restarted and the resulting delay may adversely affect that patient's outcome. If microbial, viral or other contaminations are discovered in

our product candidates or in the manufacturing facilities in which our product candidates are made, the manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination, which could result in our inability to produce or ship product. Because our product candidates are manufactured for each particular patient, we will be required to maintain a chain of identity with respect to materials as they move from the patient to the manufacturing facility, through the manufacturing process and back to the patient. Maintaining this type of chain of identity is difficult and complex and the failure to do so could result in adverse patient outcomes, loss of product, or regulatory action, including withdrawal of any approved products from the market. Further, as product candidates are developed through preclinical to later-stage clinical trials towards approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods, are altered in an effort to optimize processes and results. If we make these types of changes, we may not achieve our 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.

Although we continually attempt to optimize our manufacturing process, doing so is a difficult and uncertain task and there are risks associated with scaling to the level required for advanced clinical trials or commercialization, including, among others, cost overruns, potential problems with process scale-out, process reproducibility, stability issues, lot consistency and timely availability of reagents or raw materials. If we are unable to adequately validate or scale-up the manufacturing process with any of our current manufacturers, we will need to transfer to another manufacturer and complete the manufacturing validation process, which can be a lengthy process. We ultimately may not be successful in transferring our production system or the manufacturers on whom we rely may not have the necessary capabilities to complete the implementation and development process. If we are able to adequately validate and scale-up the manufacturing process for our product candidates with a contract manufacturer, we will still need to negotiate an agreement for commercial supply with that contract manufacturer and it is not certain we will be able to come to agreement on terms acceptable to us. As a result, we may ultimately be unable to reduce the cost of goods for our product candidates to levels that will allow for an attractive return on investment if and when those product candidates are approved and commercialized.

The manufacturing process for any products that we may develop is subject to the FDA and foreign regulatory authority approval processes and we will need to contract with manufacturers who we believe can meet applicable FDA and foreign regulatory authority requirements on an ongoing basis. If we or our CMOs are unable to reliably produce products to specifications acceptable to the FDA or other regulatory authorities, we may not obtain or maintain the approvals we need to commercialize our products. Even if we obtain regulatory approval for any of our product candidates, there is no assurance that either we or our CMOs will be able to manufacture the approved product to specifications and under required good manufacturing practices acceptable to the FDA 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, increase our cost of goods and have an adverse effect on our business, financial condition, results of operations and growth prospects.

Our future success depends on our ability to manufacture our products on a timely basis with acceptable manufacturing costs, while at the same time maintaining good quality control and complying with applicable regulatory requirements and an inability to do so could have a material adverse effect on our business, financial condition, prospects and results of operations. In addition, we could incur higher manufacturing costs if manufacturing processes or standards change and we could need to replace, modify, design or build and install equipment, all of which would require additional capital expenditures. Specifically, because our product candidates may have a higher cost of goods than conventional therapies and may require long-term follow up evaluations, the risk that coverage and reimbursement rates may be inadequate for us to achieve profitability may be greater.

We may in the future evaluate the use of one or more CMOs, as well as the possibility of establishing our own capabilities and infrastructure, including a manufacturing facility. If we were to choose to build our own manufacturing facility, we would need significant funding and would need to select an adequate location. We expect that development of our own manufacturing facility would provide us with enhanced control of material supply for both clinical trials and the commercial market, enable the more rapid implementation of process changes and allow for better long-term margins. However, we have no experience in developing a manufacturing facility and may never be successful in developing our own manufacturing facility or capability. If we determine to establish our own manufacturing capabilities and infrastructure, we will also need to hire additional personnel to manage our operations and facilities and develop the necessary infrastructure to continue the research and development and eventual commercialization, if approved, of our product candidates. 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 curtailed or delayed. We may establish multiple manufacturing facilities as we expand our commercial footprint to multiple geographies, which may lead to regulatory delays or could prove costly. Even if we are successful, our manufacturing capabilities could be affected by cost-overruns, unexpected delays, equipment failures, labor shortages, natural disasters, power failures and numerous other factors that could prevent us from realizing the intended benefits of our manufacturing strategy and have a material adverse effect on our business, financial condition, results of operations and prospects.

In addition, the FDA, the EMA and other foreign regulatory authorities may require us to submit 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, the EMA or other foreign regulatory authorities may require that we not distribute a lot until the relevant agency authorizes its release. Slight 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. Lot failures or product recalls could cause us to delay product launches or clinical trials, which could be costly to us and otherwise harm our business, financial condition, results of operations and prospects. Problems in our manufacturing process could restrict our ability to meet market demand for our products.

We also may encounter problems hiring and retaining the experienced scientific, quality control and manufacturing personnel needed to operate our manufacturing processes, which could result in delays in production or difficulties in maintaining compliance with applicable regulatory requirements.

Any problems in our manufacturing process or facilities could make us a less attractive collaborator for potential partners, including larger pharmaceutical companies and academic research institutions, which could limit our access to additional attractive development programs.

***Neon's business is highly dependent on the success of its product candidates. All of Neon's product candidates will require significant additional nonclinical and clinical development before Neon can seek regulatory approval for and launch a product commercially.***

Our business and future success depend on our ability to obtain regulatory approval of and then successfully launch and commercialize our product candidates. All of our product candidates will require additional clinical and nonclinical development, regulatory review and approval in multiple jurisdictions, substantial investment, access to sufficient commercial manufacturing capacity, and significant marketing efforts before we can generate any revenue from product sales.

In December 2019, we filed a clinical trial authorization with the Dutch Health Authority for our planned trial of NEO-PTC-01 in the Netherlands in patients with metastatic melanoma who are refractory to checkpoint inhibitors. NEO-PTC-01 involves the priming, activation and expansion of neoantigen-specific T cells *ex vivo*, an approach that may be less effective than anticipated, and our planned clinical trial is subject to risks related to trial execution, including uncertainty of timing or achievement of approval from the Dutch Health Authority to conduct the trial, difficulties with patient enrollment, trial design and establishing trial protocols.

We announced in November 2019 that we would cease undertaking new additional spending commitments related to our NEO-PV-01 and NEO-SV-01 programs. NEO-PV-01 is currently being investigated in three Phase 1b clinical trials. We plan to continue to conduct follow-up from our NT-002 clinical trial of NEO-PV-01 in first-line patients with untreated advanced or metastatic non-small cell lung cancer and will cease future enrollment in our NT-003 trial in metastatic melanoma. We received approval on an IND submitted to the FDA for NEO-SV-01, a neoantigen vaccine for the treatment of a genetically defined subset of hormone-receptor-positive breast cancer, but do not currently have plans to initiate a trial of NEO-SV-01. As a result, we currently have fewer active programs and expect that a substantial portion of our efforts and expenditures over the next several years will be devoted to NEO-PTC-01 and NEO-STC-01. Accordingly, our business currently depends heavily on the successful development, regulatory approval, and commercialization of NEO-PTC-01 and NEO-STC-01. We cannot be certain that either of our programs or any future programs will receive regulatory approval or be successfully commercialized even if we receive regulatory approval. If we were required to discontinue development of our current programs or if they do not receive regulatory approval or fail to achieve significant market acceptance, we would be delayed in our ability to achieve profitability, if ever.

***The successful development of biopharmaceuticals, such as neoantigen-targeted therapies, is highly uncertain.***

Successful development of biopharmaceuticals, such as neoantigen-targeted therapies, is highly uncertain and is dependent on numerous factors, many of which are beyond our control. Neoantigen-targeted therapies that appear promising in the early phases of development may fail to reach the market for several reasons including:

- nonclinical or preclinical testing or study results may show the neoantigen-targeted therapies to be less effective than desired or to have harmful or problematic side effects;
- clinical trial results may show the neoantigen-targeted therapies to be less effective than expected (e.g., a clinical trial could fail to meet its primary endpoint(s)) or could have unacceptable side effects or toxicities;
- we may fail to receive the necessary regulatory approvals or experience a delay in receiving those approvals, including delays that may be caused by slow enrollment in clinical trials, patients dropping out of trials, the required length of time to achieve trial endpoints, additional time requirements for data analysis or biologics license application, or BLA, preparation, discussions with the FDA or other foreign regulatory authorities , requests from regulatory authorities for additional nonclinical or clinical data, or unexpected safety or manufacturing issues;
- manufacturing costs, turnaround time, formulation issues, pricing or reimbursement issues, or other factors that make the neoantigen-targeted therapy uneconomical; and
- the proprietary rights of others and their competing products and technologies that may prevent the neoantigen-targeted therapy from being commercialized.

The length of time necessary to complete clinical trials and to submit an application for marketing approval for a final decision by a regulatory authority may vary significantly from one therapy to the next and may be difficult to predict.

Even if we are successful in getting market approval for our product candidates, 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 managed care organizations, which may be affected by existing and future healthcare reform measures designed to reduce the cost of healthcare. In order to qualify for reimbursement, third-party payors could require us to conduct additional studies, including post-marketing studies related to the cost effectiveness of a product, which could be costly and divert our resources. If government and other healthcare payors were not to provide adequate coverage and reimbursement levels for any of our products once approved, market acceptance and commercial success would be reduced.

In addition, if any of our products is approved for marketing, we will be subject to significant regulatory obligations regarding the submission of safety and other post-marketing information and reports and registration, and will need to continue to comply (or ensure that our third-party providers comply) with cGMPs and GCPs for any clinical trials that we conduct post-approval. In addition, there is always the risk that we or a 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 failure to comply or other issues with our product candidates post-approval could have a material adverse effect on our business, financial condition, prospects and results of operations.

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

With the exception of NEO-PV-01, all of our other product candidates are still in the preclinical discovery stage and their risk of failure is high. Before we can commence clinical trials for a product candidate, we must complete extensive preclinical testing and studies that support our planned INDs in the United States, or similar applications in other jurisdictions. We cannot be certain of the timely completion or outcomes of our preclinical testing and studies and cannot predict if the FDA or other regulatory authorities will accept our proposed clinical programs or if the outcomes of our preclinical testing and studies 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.

For example, in December 2019 we filed a clinical trial authorization with the Dutch Health Authority for our planned trial of NEO-PTC-01 in the Netherlands in patients with metastatic melanoma who are refractory to checkpoint inhibitors. NEO-PTC-01 involves the priming, activation and expansion of neoantigen-specific T cells *ex vivo*, an approach that may be less effective than anticipated, and our planned clinical trial is subject to risks related to trial execution, including uncertainty of timing or achievement of approval from the Dutch Health Authority to conduct the trial, difficulties with patient enrollment, trial design and establishing trial protocols.

***Clinical development is a lengthy and expensive process with an uncertain outcome. Neon may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of any product candidates.***

To obtain the requisite regulatory approvals to commercialize any product candidates, we must demonstrate through extensive preclinical studies and clinical trials that our products are safe, pure and potent or effective in humans. Clinical testing is expensive and can take many years to complete and the outcome of any clinical trial is inherently uncertain. We may be unable to establish clinical endpoints that applicable regulatory authorities would consider clinically meaningful and a clinical trial can fail at any stage of testing. The outcome of nonclinical studies and early clinical trials, or interim analyses of these 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. For example, our ongoing Phase 1b clinical trials of NEO-PV-01 are open-label and not all enrolled patients have completed these trials. Further, we expect any later-stage clinical trials of NEO-PV-01 will require placebo comparison or comparison with an active comparator. Differences in trial design between early stage clinical trials and later-stage clinical trials make it difficult to extrapolate the results of earlier clinical trials to later clinical trials. Moreover, nonclinical and clinical data are often susceptible to varying interpretations and analyses and many companies that have believed their product candidates performed satisfactorily in nonclinical studies and clinical trials have nonetheless failed to obtain marketing approval of their products.

Successful completion of clinical trials is a prerequisite to submitting a BLA to the FDA, a Marketing Authorization Application, or MAA, to the EMA, and similar marketing applications to comparable foreign

regulatory authorities for each product candidate and, consequently, the ultimate approval and commercial marketing of any product candidates. We do not know whether any of our clinical trials will begin or be completed on schedule, if at all.

For example, in December 2019 we filed a clinical trial authorization with the Dutch Health Authority for our planned trial of NEO-PTC-01 in the Netherlands in patients with metastatic melanoma who are refractory to checkpoint inhibitors. NEO-PTC-01 involves the priming, activation and expansion of neoantigen-specific T cells *ex vivo*, an approach that may be less effective than anticipated, and our planned clinical trial is subject to risks related to trial execution, including uncertainty of timing or achievement of approval from the Dutch Health Authority to conduct the trial, difficulties with patient enrollment, trial design and establishing trial protocols.

We may experience delays in completing our preclinical or nonclinical testing and studies and initiating or completing clinical trials. We also may experience numerous unforeseen events or circumstances during, or as a result of, any future clinical trials that we may conduct that could delay or prevent our ability to receive marketing approval or commercialize our product candidates, including:

- regulators or institutional review boards, or 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;
- we may experience delays in reaching, or fail to reach, agreement on acceptable terms with prospective trial sites and prospective CROs as the terms of these agreements can be subject to extensive negotiation and vary significantly among different CROs and trial sites;
- clinical trials of any product candidates may fail to show safety, purity or potency, or produce negative or inconclusive results, which may cause us to decide, or regulators to require us, to conduct additional nonclinical studies or clinical trials or which may cause us to decide to abandon product development programs;
- the number of patients required for clinical trials of any product candidates may be larger than we anticipate, enrollment in these clinical trials may be slower than we anticipated or participants may drop out of these clinical trials or fail to return for post-treatment follow-up at a higher rate than we anticipated;
- our CROs and other third-party contractors involved in our clinical trials may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all, or they may deviate from the clinical trial protocol or drop out of the trial, which may require that we add new clinical trial sites or investigators;
- we may elect to, or regulators, IRBs or ethics committees may require that we or our investigators, suspend or terminate clinical research or trials for various reasons, including noncompliance with regulatory requirements or a finding that participants are being exposed to unacceptable health risks;
- the cost of preclinical or nonclinical testing and studies and clinical trials of any product candidates may be greater than we anticipate;
- the potential insufficiency or inadequacy of the supply or quality of our product candidates or other materials necessary to conduct clinical trials of our product candidates;
- the potential inability to manufacture and supply product to patients consistent with clinical trial protocols;
- our product candidates may have undesirable side effects or other unexpected characteristics, causing us or our investigators, regulators, IRBs or ethics committees to suspend or terminate trials, or reports may arise from nonclinical or clinical testing of other cancer therapies that raise safety or efficacy concerns about our product candidates; and
- the FDA or other regulatory authorities may require us to submit additional data such as long-term toxicology studies, or impose other requirements on us, before permitting us to initiate a clinical trial.

We could also encounter delays if a clinical trial is suspended or terminated by us, the IRBs of the institutions in which these clinical trials are being conducted, or the FDA or other regulatory authorities, or if a clinical trial is recommended for suspension or termination by the relevant Data Safety Monitoring Board, or DSMB. 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 that results in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a product or treatment, 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 could 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. Further, the FDA or other regulatory authorities may disagree with our clinical trial design and our interpretation of data from clinical trials or may change the requirements for approval even after they have reviewed and commented on the design for our clinical trials.

Our product development costs will increase if we experience delays in conducting clinical testing or receiving marketing approvals. We do not know whether any of our preclinical or nonclinical testing and studies or clinical trials will begin as planned, will need to be restructured or will be completed on schedule, or at all. Significant preclinical or nonclinical testing and studies or clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize our product candidates and may 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, financial condition, prospects and results of operations. Any delays in our nonclinical or future clinical development programs may harm our business, financial condition, prospects and results of operations significantly.

***Neon relies on its RECON bioinformatics engine to identify neoantigen targets. Neon's competitive position could be materially harmed if its competitors develop platforms similar to RECON that they use to develop rival product candidates.***

We rely on trade secrets, unpatented know-how, inventions and other proprietary information to strengthen our competitive position. We consider know-how to be our primary intellectual property with respect to our RECON (Real-time Epitope Computation for ONcology) bioinformatics engine. The algorithms comprising RECON require accurate input data to enable the algorithms to detect patterns. Our clinical trials allow us to collect clinical data together with myriad samples of blood and tumor tissue, which we use as a feedback loop to make improvements to RECON. However, know-how protected by trade secret can be difficult to protect. In particular, we anticipate that, with respect to this platform, this know-how may over time be disseminated within the industry through independent development, the publication of journal articles describing the method and the movement of skilled personnel.

We cannot rule out that our competitors may have or obtain the knowledge necessary to analyze and characterize similar data to our known data for the purpose of identifying and developing products that could compete with our current or future product candidates. Our competitors may also have significantly greater financial, product development, technical and human resources and access to other human tumors than we do. Further, our competitors may have significantly greater experience in using translational science methods to identify and develop product candidates.

We may not be able to prohibit our competitors from using technology or methods that are the same as or similar to RECON to develop their own product candidates. If our competitors develop bioinformatics and engage in the computation and analysis of complex algorithms to identify neoantigen targets and develop associated therapies, our ability to develop and market a promising product or product candidate may diminish substantially, which could have a material adverse effect on our business, financial condition, prospects and results of operations.

Continuous and up-to-date clinical data is a key feature of RECON. We cannot guarantee that we will be permitted by regulatory authorities, or have the resources to obtain, continuous clinical data that would be input into RECON. For example, regulatory authorities may require that we refrain from inputting any additional data into RECON after we commence a pivotal clinical trial. If we are prevented or impeded from adding additional clinical data into RECON, we will not be able to advance RECON and its utility may be diminished. In addition, we cannot guarantee that any changes or additions we make to RECON will ultimately result in improved therapeutic outcomes for any product candidates that are generated as a result of RECON. As a result, our ability to develop product candidates through the use of RECON that provide therapeutic benefit may be significantly impacted, which could have a material adverse effect on our business, financial condition, prospects and results of operations.

***Neon's planned clinical trials or those of Neon's future collaborators may reveal significant adverse events not seen in Neon's preclinical or nonclinical studies and may result in a safety profile that could inhibit regulatory approval or market acceptance of any of Neon's product candidates.***

Before obtaining regulatory approvals for the commercial sale of any products, we must demonstrate through lengthy, complex and expensive preclinical studies and clinical trials that our product candidates are both safe and effective for use in each target indication. Clinical testing is expensive and can take many years to complete and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process. The results of preclinical studies and early clinical trials of our product candidates may not be predictive of the results of later-stage clinical trials. In addition, initial success in clinical trials may not be indicative of results obtained when those trials are completed. There is typically an extremely high rate of attrition from the failure of product candidates proceeding through clinical trials. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy profile despite having progressed through nonclinical studies and initial clinical trials. Companies in the biopharmaceutical industry have suffered significant setbacks in later-stage clinical trials due to lack of efficacy or unacceptable safety issues, 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.

Certain of our product candidates will be developed in combination with one or more cancer therapies. This combination may have additional side effects that were not present in initial clinical trials of our product candidates with other cancer therapies. The uncertainty resulting from the use of our product candidates in combination with other cancer therapies may make it difficult to accurately predict side effects 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 patients to our clinical trials, patients may drop out of our 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, or an IRB, may suspend clinical trials of a product candidate at any time for various reasons, including a belief that trial subjects 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 presented do not preclude the drug from obtaining or maintaining marketing approval, undesirable side effects 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, prospects and results of operations.

***If Neon encounters difficulties enrolling patients in Neon's clinical trials, Neon's clinical development activities could be delayed or otherwise adversely affected.***

We may experience difficulties in patient enrollment in our clinical trials for a variety of reasons. The timely completion of clinical trials in accordance with their protocols depends, among other things, on our ability to

enroll a sufficient number of patients who remain in the study until its conclusion. The enrollment of patients depends on many factors, including:

- the patient eligibility and exclusion criteria defined in the protocol;
- the size of the patient population required for analysis of the trial's primary endpoints;
- the proximity of patients to trial sites;
- the design of the trial;
- the ability to recruit clinical trial investigators with the appropriate competencies and experience;
- the ability to obtain and maintain patient consents; and
- the risk that patients enrolled in clinical trials will drop out of the trials before completion.

In addition, our clinical trials will compete with other clinical trials for product candidates that are similar therapeutic areas as our product candidates, which may reduce the number and types of patients available to us. 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 patients who are available for our clinical trials at those sites. Moreover, because our product candidates represent a departure from more commonly used methods for cancer treatment, potential patients and their doctors may be inclined to use conventional therapies, such as chemotherapy and bone marrow transplantation, rather than enroll patients in a clinical trial. This may be particularly true for patients with late-stage disease who may perceive that our approach is not effective for patients with that disease profile. Delays in patient enrollment may result in increased costs or may affect the timing or outcome of our planned clinical trials. These delays could also prevent completion of these trials and adversely affect our ability to advance the development of our product candidates.

***Neon expects to develop some of Neon's product candidates in combination with other therapies, and safety or supply issues with combination use products may delay or prevent development and approval of Neon's product candidates.***

We intend to develop some of our product candidates in combination with one or more approved or unapproved cancer therapies.

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 or similar regulatory authorities outside of the United States 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 or similar regulatory authorities outside of the United States 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 may also evaluate some of our product candidates in combination with one or more cancer therapies that have not yet been approved for marketing by the FDA or similar regulatory authorities outside of the United States. We will not be able to market and sell any product candidate we develop in combination with an unapproved cancer therapy if that unapproved cancer therapy does not ultimately obtain marketing approval. In addition, unapproved cancer 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 approval.

If the FDA or similar regulatory authorities outside of the United States 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 our product candidates , we may be unable to obtain approval of or market those product candidates.

***Neoantigen-targeted therapies are a novel approach and negative perception of the efficacy or safety of any of Neon's product candidates could adversely affect Neon's ability to conduct Neon's business or obtain regulatory approvals for Neon's product candidates.***

Neoantigen-targeted therapies remain novel and unproven technologies, with no neoantigen-targeted therapy approved to date in the U.S. or EU. Neoantigen T cell therapies, neoantigen vaccines or any other modality that we seek to use may not gain the acceptance of the public or the medical community. For example, earlier cancer vaccines attempted to direct the immune system against a class of molecules found predominantly, but not exclusively, at the tumor site. Since the targets of these cancer vaccines were are also found on normal cells, they were regarded as 'self', which caused the immune system to prohibit destruction of the cancerous cells. As a result, these cancer vaccines did not generate potent immune responses. Our neoantigen vaccines may be perceived to face the same challenges as the earlier cancer vaccines, which could limit our ability to enroll patients in our clinical trials or if approved, negatively impact our vaccines' market acceptance. Further, with respect to our NEO-PTC-01 program, the use of T cells as a potential cancer treatment is a recent scientific development and may not become broadly accepted by physicians, patients, hospitals, cancer treatment centers and others in the medical community.

Our success will depend upon physicians who specialize in the treatment of diseases targeted by our product candidates prescribing treatments that involve the use of our product candidates in lieu of, or in addition to, existing treatments with which they are more familiar and for which greater clinical data may be available. Adverse events in clinical trials of our product candidates or in clinical trials of others developing similar products and the resulting publicity, as well as any other adverse events in the field of neoantigen-targeted therapies cancer vaccines, or T cell therapies, could result in a decrease in demand for any product that we may develop. In addition, responses by the U.S., state or foreign governments to negative public perception may result in new legislation or regulations that could limit our ability to develop or commercialize any product candidates, obtain or maintain regulatory approval or otherwise achieve profitability. More restrictive statutory regimes, government regulations or negative public opinion would have an adverse effect on our business, financial condition, prospects and results of operations and may delay or impair the development and commercialization of our product candidates or demand for any products we may develop.

***NEO-PV-01, Neon's personal neoantigen-based cancer vaccine product candidate, includes a development-stage vaccine adjuvant, poly-ICLC. It is difficult for Neon to predict how Neon's use of poly-ICLC will be viewed by the FDA or other regulatory agencies as Neon attempts to demonstrate the safety of NEO-PV-01.***

We use an adjuvant, poly-ICLC, with our NEO-PV-01 vaccine product candidate, which makes it difficult to predict how the FDA and applicable other regulatory agencies will evaluate the safety of NEO-PV-01. Adjuvants are compounds that are added to vaccines to enhance the activation of and improve the immune response and efficacy of vaccines. Any vaccine, because of the presence of an adjuvant, may have side effects that may pose too great a safety risk to warrant approval of the vaccine. Development-stage vaccine adjuvants, such as poly-ICLC, may pose an increased safety risk to patients. Poly-ICLC has been used as an adjuvant in other investigational vaccine trials but has never been approved by the FDA for commercial use. The existence of additional trials using this adjuvant may provide support for approval of our product candidates, however, negative safety or efficacy results from other trials using poly-ICLC could similarly jeopardize the continued development of our product candidates that use poly-ICLC as an adjuvant.

***If Neon fails to comply with environmental, health and safety laws and regulations, Neon could become subject to fines or penalties or incur costs that could have a material adverse effect on the success of Neon's business.***

We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our research and development activities involve the use of biological and hazardous materials and produce hazardous waste products. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials, which could cause an interruption of our commercialization efforts, research and development efforts and business operations, as well as environmental damage that could result in costly clean-up and liabilities under applicable laws and regulations governing the use, storage, handling and disposal of these materials and specified waste products. Although we believe that the safety procedures utilized by our third-party manufacturers for handling and disposing of these types of materials generally comply with the standards prescribed by applicable laws and regulations, we cannot guarantee that this is the case or eliminate the risk of accidental contamination or injury from these types of materials. In the event of any contamination or injury, we may be held liable for any resulting damages in an amount that could potentially exceed our resources, and state or federal or other applicable authorities may curtail our use of certain materials and/or interrupt our business operations. Furthermore, environmental laws and regulations are complex, change frequently and have tended to become more stringent. We cannot predict the impact of changes to applicable laws and regulations and cannot be certain of our future compliance. 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. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

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 or other work-related injuries, this insurance may not provide adequate coverage against potential liabilities. We do not carry specific biological waste or hazardous waste insurance coverage or workers compensation or property and casualty and general liability insurance policies that include coverage for damages and fines arising from biological or hazardous waste exposure or contamination.

***Neon may incur substantial liabilities and may be required to limit commercialization of Neon's product candidates if Neon faces product liability lawsuits.***

We face an inherent risk of product liability as a result of testing our product candidates in clinical trials and will face an even greater risk if we commercialize any products. For example, we may be sued if our product candidates cause or are perceived to cause injury or are found to be otherwise unsuitable during clinical trials, manufacturing, marketing or sale. We could face product liability claims that may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability or a breach of warranties. In addition, we could face claims asserted under state consumer protection acts. If we cannot successfully defend ourselves against product liability claims or state consumer protection claims, we may incur substantial liabilities or be required to limit commercialization of our product candidates. Even the successful defense against a claim of this nature would require significant financial and management resources. Regardless of the merits or eventual outcome, claims of liability of this nature may result in:

- our inability to bring a product candidate to the market or commercialize any product candidate;
- decreased demand for our products;
- injury to our reputation;
- withdrawal of clinical trial participants and inability to continue clinical trials;
- initiation of investigations by regulators;

- costs to defend the related litigation;
- diversion of management's time and our resources;
- substantial monetary awards to trial participants or patients;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- loss of revenue;
- exhaustion of any available insurance and our capital resources;
- the withdrawal of IRB approval for the conduct of clinical trials using our product candidates; and
- a decline in our share price.

Our inability to obtain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of products we develop, alone or with collaborators. Even if our agreements with any future corporate collaborators entitle us to indemnification against losses, that indemnification may not be available or adequate should any claim arise. Although we currently carry $10.0 million in clinical trial insurance, that amount of insurance coverage may not be adequate and, in the future, we may be unable to maintain this insurance coverage or we may not be able to obtain additional or replacement insurance at a reasonable cost, if at all. Our insurance policies also have various exclusions and we may be subject to a product liability claim for which we have no coverage. We may have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay those amounts.

***The market opportunities for Neon's product candidates may be limited or small.***

The potentially addressable patient population for our product candidates may be limited or may not be amenable to treatment with our product candidates. In addition, our projections of both the number of people who have the cancers we are targeting, as well as the subset of people with these cancers in a position to receive our therapies, if approved, are based on our beliefs and estimates. These estimates have been derived from a variety of sources, including scientific literature, surveys of clinics, patient foundations, or market research, and may prove to be incorrect. Further, new studies may change the estimated incidence or prevalence of these cancers. The number of potential patients for our product candidates may turn out to be lower than expected. Even if we obtain significant market share for our product candidates, if the potential target populations are small, we may never achieve profitability without obtaining regulatory approval for additional indications.

***Neon faces significant competition from other biotechnology and pharmaceutical companies and Neon's operating results will suffer if Neon fails to compete effectively.***

The biopharmaceutical industry is characterized by intense competition and rapid innovation. Our competitors may be able to develop other compounds or drugs that are able to achieve similar or better results. Our potential competitors include major multinational pharmaceutical companies, established biotechnology companies, specialty pharmaceutical companies and universities and other research institutions. Many of our competitors have substantially greater financial, technical and other resources, such as larger research and development staff and experienced marketing and manufacturing organizations and well-established sales forces. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large, established companies. Established pharmaceutical companies may also invest heavily to accelerate discovery and development of novel therapeutics or to in-license novel therapeutics that could make the product candidates that we develop obsolete. Mergers and acquisitions in the biotechnology and pharmaceutical industries may result in even more resources being concentrated in our competitors. Competition may increase further due to advances in the commercial applicability of technologies and greater availability of capital for investment in these industries. Our competitors, either alone or with collaborative partners, may succeed in developing, acquiring or licensing on an

exclusive basis drug or biologic products that are more effective, safer, more easily commercialized or less costly than our product candidates, or they may develop proprietary technologies or secure patent protection that we may need for the development of our technologies and products. We believe the key competitive factors that will affect the development and commercial success of our product candidates are efficacy, safety, tolerability, reliability, convenience of use, price and reimbursement.

We anticipate competing with the largest pharmaceutical companies in the world, many of which are conducting research in neoantigen based therapies and all of which have greater financial and human resources than we currently have. In addition to these fully-integrated biopharmaceutical companies, we will also face competition from other immunotherapy-focused oncology companies. Further, we directly compete with a number of neoantigen therapeutics-focused companies, some of whom are developing vaccines, while others are developing T cell therapies and/or T cell receptor-based therapies. These competitors include Aduro Biotech, Inc., Achilles Therapeutics Limited, Adaptimmune Therapeutics plc, Adaptive Biosciences, Inc., Adicet Bio, Inc., Advaxis, Inc., Agenus Inc., AgenTus Therapeutics, Inc., BioNTech SE, bluebird bio, Inc., Celgene Corporation, Genocea Biosciences, Inc., Gilead Sciences, Inc., Gritstone Oncology, Inc., Immatics Biotechnologies GmbH, IMV Inc., Iovance Biotherapeutics, Inc., ISA Pharmaceuticals, B.V., Lion TCR Pte. Ltd., Marker Therapeutics, Inc., Medigene AG, Moderna, Inc., Nouscom AG, PACT Pharma, Inc., Regeneron Pharmaceuticals, Inc., TScan Therapeutics, Inc., Vaccibody AS, Zelluna Immunotherapy AS and ZIOPHARM Oncology, Inc. For further information on our potential merger with one of our competitors, BioNTech SE, please see section above titled “Risk Factors—Risks Related to Our Merger with BioNTech.”

Even if we obtain regulatory approval of our product candidates, the availability and price of our competitors’ products could limit the demand and the price we are able to charge for our product candidates. We may not be able to implement our business plan if the acceptance of our product candidates is inhibited by price competition or the reluctance of physicians to switch from existing methods of treatment to our product candidates, or if physicians switch to other new drug or biologic products or choose to reserve our product candidates for use in limited circumstances.

***Even if a product candidate Neon develops receives marketing approval, it may fail to achieve the degree of market acceptance by physicians, patients, third-party payors and others in the medical community necessary for commercial success.***

If any product candidate we develop receives marketing approval, whether as a single agent or in combination with other therapies, it may nonetheless fail to gain sufficient market acceptance by physicians, patients, third-party payors and others in the medical community. For example, other cancer treatments like chemotherapy and radiation therapy are well established in the medical community and doctors may continue to rely on these therapies. If the product candidates we develop do not achieve an adequate level of acceptance, we may not generate significant product revenues and we may not become profitable. The degree of market acceptance of any product candidate, if approved for commercial sale, will depend on a number of factors, including:

- efficacy and potential advantages compared to alternative treatments;
- price competitiveness;
- convenience and ease of administration compared to alternative treatments;
- 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;
- the ability to obtain sufficient third-party coverage and adequate reimbursement, including with respect to the use of the approved product as a combination therapy;

- adoption of a companion diagnostic and/or complementary diagnostic; and
- the prevalence and severity of any side effects.

***Neon may need to grow the size of Neon's organization and Neon may experience difficulties identifying and hiring the right employees and in managing this growth.***

Although we announced in November 2019 a 24% reduction in our headcount, it is possible that, in the future, we may experience significant growth in the number of our employees and the scope of our operations, particularly in the areas of technology research, product development and manufacturing, regulatory affairs and, if any product candidates are submitted for or receive marketing approval, sales, marketing and distribution. Future growth would impose significant added responsibilities on members of management, including:

- identifying, recruiting, integrating, maintaining and motivating additional employees;
- managing our internal development efforts effectively, including the clinical and FDA review process for our product candidates, while complying with our contractual obligations to contractors and other third parties; and
- improving our operational, financial and management controls, reporting systems and procedures.

Our future financial performance and our ability to commercialize our product candidates may depend, in part, on our ability to effectively manage any future growth and our management may also have to divert a disproportionate amount of its attention away from day-to-day activities in order to devote a substantial amount of time to managing these growth activities.

We currently rely, and for the foreseeable future will continue to rely, in substantial part on certain independent organizations, advisors, contractors and consultants to provide certain services, including substantially all aspects of regulatory approval, clinical management and manufacturing. There can be no assurance that the services of independent organizations, advisors, contractors and consultants will continue to be available to us on a timely basis when needed or that we will be able to find qualified replacements. In addition, if we are unable to effectively manage our outsourced activities or if the quality or accuracy of the services provided by independent organizations, advisors, contractors or consultants is compromised for any reason, our clinical trials may be extended, delayed or terminated and we may not be able to obtain regulatory approval of our product candidates or otherwise advance our business. There can be no assurance that we will be able to manage our existing independent organizations, advisors, contractors or consultants or find other competent resources on economically reasonable terms, or at all.

If we are not able to effectively expand our organization by hiring new employees and expanding the roster of independent organizations, advisors and consultants on whom we rely on an outsourced basis, we may not be able successfully to implement the tasks necessary to further develop and commercialize our product candidates and, accordingly, may not achieve our research, development and commercialization goals.

***Neon's corporate restructuring and the associated headcount reduction announced in November 2019 may not result in anticipated savings, could result in total costs and expenses and attrition that are greater than expected and could disrupt Neon's business.***

On November 20, 2019, we announced a 24% reduction in headcount as part of a corporate restructuring. We may not realize, in full or in part, the anticipated benefits, savings and improvements in our cost structure from our restructuring efforts due to unforeseen difficulties, delays or unexpected costs. If we are unable to realize the expected operational efficiencies and cost savings from the restructuring, our operating results and financial condition would be adversely affected. We also cannot guarantee that we will not have to undertake additional headcount reductions or restructuring activities in the future. Furthermore, our restructuring activities may be disruptive to our operations. For example, our headcount reductions could yield unanticipated

consequences, such as attrition beyond planned staff reductions, or increase difficulties in our day-to-day operations. Our headcount reductions could also harm our ability to attract and retain qualified management, scientific, clinical, manufacturing and other personnel who are critical to our business. Any failure to attract or retain qualified personnel could prevent us from successfully developing and commercializing our product candidates in the future.

***If Neon loses key management personnel, or if Neon fails to retain or recruit additional highly skilled personnel, Neon's ability to identify and develop new or next generation product candidates will be impaired, could result in loss of markets or market share and could make it less competitive.***

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 on our management, scientific and medical personnel. The loss of the services of any of our executive officers, other key employees and other scientific and medical advisors and our inability to find suitable replacements could result in delays in product development and harm our business.

We conduct our operations at our facility in Cambridge, Massachusetts. This region is home to many other biopharmaceutical companies and many academic and research institutions and competition for skilled personnel in our market is intense and may limit our ability to hire and retain highly qualified personnel on acceptable terms or at all.

Additionally, while we put in place retention arrangements at the time we effected our November 2019 corporate restructuring, the combination of having effected that restructuring and the January 2020 announcement of the planned acquisition of our company by BioNTech announced in January 2020 may make it increasingly difficult for us to retain our executive officers, other key employees and other scientific and medical advisors.

To induce valuable employees to remain at our company, in addition to salary and cash incentives, we have provided restricted stock, restricted stock units and stock options that vest over time. The value to employees of stock options that vest over time may be significantly affected by movements in our stock price that are beyond our control and may at any time be insufficient to counteract more lucrative offers from other companies. Despite our efforts to retain valuable employees, members of our management, scientific and development teams may terminate their employment with us on short notice. Although we have employment agreements with certain of our key employees, these employment agreements provide for at-will employment, which means that any of our employees could leave our employment at any time, with or without notice. We do not maintain "key man" insurance policies on the lives of these individuals or the lives of any of our other employees. Our success also depends on our ability to continue to attract, retain and motivate highly skilled junior, mid-level and senior managers, as well as junior, mid-level and senior scientific and medical personnel.

***Business disruptions could seriously harm Neon's future revenue and financial condition and increase Neon's costs and expenses.***

Our operations, and those of our CROs, CMOs and other independent organizations, advisors, contractors and consultants, could be subject to earthquakes, power shortages, telecommunications failures, water shortages, floods, hurricanes, typhoons, fires, extreme weather conditions, medical epidemics and other natural or man-made disasters or business interruptions for which we are predominantly self-insured. The occurrence of any of these business disruptions could seriously harm our operations and financial condition and increase our costs and expenses. We rely on third-party manufacturers to produce and process our product candidates on a patient-by-patient basis. Our ability to obtain clinical supplies of our product candidates could be disrupted if the operations of the suppliers of these materials are affected by a man-made or natural disaster or other business interruption.

***The COVID-19 outbreak may materially and adversely affect Neon's business and our financial results.***

The recent outbreak of COVID-19 originated in Wuhan, China in December 2019 and has since spread globally, including to the United States and Europe. In response to the spread of COVID-19, we have temporarily directed our employees to work from home unless their job responsibilities require them to be onsite to work in our research laboratories. As a result of the COVID-19 outbreak, we may experience disruptions that could severely impact our business, clinical trials and/or preclinical studies. For example, due to the COVID-19 outbreak, we may experience disruptions or delays in our ability to recruit and retain patients and principal investigators and site staff who, as healthcare providers, may have heightened exposure to COVID-19 if an outbreak occurs in their geography and delays enrollment in our clinical trials due to prioritization of hospital resources toward the outbreak and/or restrictions in travel. Further, some patients may be unwilling to enroll in our clinical trials or be unable to comply with clinical trial protocols if quarantines or travel restrictions impede patient movement or interrupt healthcare services. The COVID-19 outbreak may also negatively affect the operations of the third-party contract research organizations that we rely upon to carry out our clinical trials or the third-party manufacturers who manufacture our product candidates, which could result in delays or disruptions in the supply of our product candidates. The negative impact COVID-19 may have on patient enrollment or treatment or the timing and execution of our clinical trials could cause costly delays to our clinical trial activities, as well as in the availability of data from our clinical trials. If any of our clinical trials are delayed or suspended as a result of COVID-19 or for other reasons, we cannot provide any assurances about when they might reinitiate or commence enrollment or that their enrollment will be reinitiated at all. For our ongoing clinical trials, COVID-19 may require us to delay or pause dosing or data collection in our clinical trials as a result of negative impacts to site initiation, participant recruitment and enrollment, participant dosing, distribution of clinical trial materials, trial monitoring or data analysis. Even if we are able to collect clinical data while the outbreak is ongoing, COVID-19 may negatively affect the quality, completeness and/or interpretability of that clinical data as a result of deviations from clinical study protocols, disruptions in patient screening or dosing (for instance, as a result of delays in manufacturing) or disruptions in patient evaluations (for instance, as a result of inabilities to conduct study visits while following local public health requirements or inabilities to conduct remote assessments). Any of these effects could adversely affect our ability to obtain regulatory approval for and to commercialize our product candidates, increase our operating expenses and have a material adverse effect on our business and financial results.

In addition, COVID-19 has resulted in significant governmental measures being implemented to control the spread of the virus, including quarantines, travel restrictions and business shutdowns. We have taken temporary precautionary measures intended to help minimize the risk of the virus to our employees and community, including temporarily requiring all employees to work remotely other than those whose job responsibilities require them to be physically present in our research laboratories, suspending all non-essential travel worldwide for our employees and discouraging employee attendance at industry events, other large gatherings or in-person work-related meetings. These measures could negatively affect our business. For instance, temporarily requiring all employees to work remotely may disrupt our operations, impact our productivity or increase the risk of a cybersecurity incident. Business disruptions, including those affecting our ongoing and planned clinical studies, may negatively affect the accuracy of our estimates regarding capital requirements and needs for additional financing or our ability to produce accurate and timely financial statements. We may incur additional liabilities related to business disruptions caused by COVID-19. COVID-19 has also caused volatility in the global financial markets and threatened a slowdown in the global economy, which may negatively affect our ability to raise additional capital on attractive terms or at all. In addition, a recession, depression or other sustained adverse market event resulting from the spread of COVID-19 could materially and adversely affect our business and the value of our common stock.

The extent to which COVID-19 may impact our business will depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the duration of the outbreak, the severity of COVID-19 or the effectiveness of actions to contain and treat for COVID-19. We cannot presently predict the scope and severity of any potential business shutdowns or disruptions, including to our ongoing and planned

clinical studies. Any shutdowns or other business interruptions could result in material and negative effects to our ability to conduct our business in the manner and on the timelines presently planned, which could have a material adverse impact on our business, results of operation and financial condition.

***Neon's internal computer systems, or those used by Neon's CROs or other independent organizations, advisors, contractors or consultants, may be subject to cyber-attacks, fail or suffer security breaches.***

Despite the implementation of security measures, our internal computer systems and those of our CROs and other independent organizations, advisors, contractors and consultants are vulnerable to damage from computer viruses and unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. Because information systems, networks, web tools and other technologies are critical to many of our operating activities, shutdowns or service disruptions at our company or vendors that provide information systems, networks, web tools or other services to us pose increasing risks. Disruptions of this nature may be caused by events such as computer hacking, phishing attacks, ransomware, dissemination of computer viruses, worms and other destructive or disruptive software, denial of service attacks and other malicious activity, as well as power outages, natural disasters (including extreme weather), terrorist attacks or other similar events. In addition, outside parties may attempt to penetrate our systems or those of our vendors or fraudulently induce our personnel or the personnel of our vendors to disclose sensitive information in order to gain access to our data and/or systems. Like other companies, we have on occasion experienced, and will continue to experience, threats and incursions to our data and systems, including malicious codes and viruses, phishing, business email compromise attacks or other cyber-attacks. The number and complexity of these threats continue to increase over time. While we have not experienced any material system failure or security breach to date, if an event of that nature were to occur and cause interruptions in our operations, it could result in a material disruption of our development programs and our business operations. For example, the loss of clinical trial data from 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. Additionally, a security breach related to RECON's proprietary combination of algorithms could adversely affect our ability to apply RECON to predict therapeutically-relevant neoantigens or result in our competitors having access to these algorithms, which could adversely affect our competitive position. Likewise, we currently, and may in the future continue to, rely on third parties for the manufacture of our product candidates and to conduct clinical trials and similar events relating to their computer systems could also have a material adverse effect on our business. To the extent that any disruption or security breach were to result in a loss of, or damage to, our internal computer systems or those used by our CROs or other independent organizations, advisors, contractors or consultants, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability, suffer reputational harm and experience delays in the further development and commercialization of our product candidates.

We could be required to expend significant amounts of money and other resources to respond to these threats or breaches and to repair or replace information systems or networks. We also could suffer financial loss or the loss of valuable confidential information. In addition, we could be subject to regulatory actions and/or claims made by individuals and groups in private litigation involving privacy issues related to data collection and use practices and other data privacy laws and regulations, including claims for misuse or inappropriate disclosure of data, as well as unfair or deceptive practices. Although we develop and maintain systems and controls designed to prevent these events from occurring and we have a process to identify and mitigate threats, the development and maintenance of these systems, controls and processes is costly and requires ongoing monitoring and updating as technologies change and efforts to overcome security measures become increasingly sophisticated. Moreover, despite our efforts, the possibility of these events occurring cannot be eliminated entirely and there can be no assurance that any measures we take will prevent cyber-attacks or security breaches that could adversely affect our business.

***Continued uncertainty surrounding the implementation and effect of Brexit may cause increased economic volatility, affecting Neon's operations and business.***

In March 2017, the United Kingdom served notice to the European Council under Article 50 of the Treaty of Lisbon to withdraw membership from the EU. Such exit (Brexit) could cause disruptions to, and create uncertainty surrounding, our business in the UK and EU, including affecting our relationships with our existing and future customers, suppliers, and employees. As a result, Brexit could have an adverse effect on our future business, financial results, and operations. The UK formally left the EU on January 31, 2020, and is now in a transition period through December 31, 2020. Although the UK will remain in the EU single market and customs union during the transition period, the long-term nature of the UK's relationship with the EU is unclear and there is considerable uncertainty any agreement will be reached and implemented. The political and economic instability created by Brexit has caused and may continue to cause significant volatility in global financial markets and uncertainty regarding the regulation of data protection in the UK. In particular, although the UK enacted a Data Protection Act in May 2018 that is consistent with the EU General Data Protection Regulation, uncertainty remains regarding how data transfers to and from the UK will be regulated. Brexit could also have the effect of disrupting the free movement of goods, services, and people between the UK, the EU, and elsewhere. Brexit could lead to legal uncertainty and potentially divergent national laws and regulations as the UK determines which EU laws to replace or replicate. Further, uncertainty around these and related issues could lead to adverse effects on the economy of the UK and the other economies. There can be no assurance that any or all of these events will not have a material adverse effect on our business operations, results of operations and financial condition.

***Neon's employees, independent contractors, consultants, commercial partners and vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.***

We are exposed to the risk of fraud or other illegal activity by our employees, independent contractors, consultants, commercial partners and vendors. Misconduct by these parties could include intentional, reckless and/or negligent conduct that fails to comply with the laws enforced by the FDA and other similar foreign regulatory bodies, provide true, complete and accurate information to the FDA and other similar foreign regulatory bodies, comply with manufacturing standards we have established, comply with healthcare fraud and abuse laws in the United States and similar foreign laws, or report financial information or data accurately or to disclose unauthorized activities to us. If we obtain FDA approval of any of our product candidates and begin commercializing those products in the United States, our potential exposure under these laws will increase significantly and our costs associated with compliance with these laws are also likely to increase. These laws may impact, among other things, our current activities with principal investigators and research patients, as well as proposed and future sales, marketing and education programs.

***Neon's relationships with healthcare providers and physicians and third-party payors will be subject to applicable anti-kickback, fraud and abuse and other healthcare laws and regulations, which could expose it to criminal sanctions, civil penalties, contractual damages, reputational harm and diminished profits and future earnings.***

Healthcare providers, physicians and third-party payors in the United States and elsewhere play a primary role in the recommendation and prescription of pharmaceutical products. Arrangements with third-party payors and customers can expose pharmaceutical manufactures to broadly applicable fraud and abuse and other healthcare laws and regulations, including, without limitation, the federal Anti-Kickback Statute and the federal False Claims Act, or the FCA, which may constrain the business or financial arrangements and relationships through which companies sell, market and distribute pharmaceutical products. In particular, the promotion, sales and marketing of healthcare items and services, as well as certain business arrangements in the healthcare industry, are subject to extensive laws designed to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and

promotion, structuring and commission(s), certain customer incentive programs and other business arrangements generally. Activities subject to these laws also involve the improper use of information obtained in the course of patient recruitment for clinical trials. The applicable federal, state and foreign healthcare laws and regulations laws that may affect our ability to operate include, but are not limited to:

- the federal Anti-Kickback Statute, which prohibits, among other things, 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, to induce, or in return for, either the referral of an individual, or the purchase, lease, order or recommendation of any good, facility, item or service for which payment may be made, in whole or in part, under a federal healthcare program, such as the Medicare and Medicaid programs. A person or entity can be found guilty of violating this statute without actual knowledge of the statute or specific intent to violate it. Violations are subject to civil and criminal fines and penalties for each violation, plus up to three times the remuneration involved, imprisonment, and exclusion from government healthcare programs. In addition, a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the FCA. The Anti-Kickback Statute has been interpreted to apply to arrangements between pharmaceutical manufacturers, on the one hand, and prescribers, purchasers and formulary managers, on the other. There are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution;
- federal civil and criminal false claims laws and civil monetary penalty laws, including the FCA, which impose criminal and civil penalties, including through civil “qui tam” or “whistleblower” actions, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, false or fraudulent claims for payment to, or approval by Medicare, Medicaid, or other federal healthcare programs, knowingly making, using or causing to be made or used a false record or statement material to a false or fraudulent claim or an obligation to pay or transmit money to the federal government, or knowingly concealing or knowingly and improperly avoiding or decreasing or concealing an obligation to pay money to the federal government. Manufacturers can be held liable under the FCA even when they do not submit claims directly to government payors if they are deemed to “cause” the submission of false or fraudulent claims. The FCA also permits a private individual acting as a “whistleblower” to bring actions on behalf of the federal government alleging violations of the FCA and to share in any monetary recovery. When an entity is determined to have violated the FCA, the government may impose civil fines and penalties ranging, plus treble damages, and exclude the entity from participation in Medicare, Medicaid and other federal healthcare programs;
- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created new federal criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (e.g., public or private) and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false statements in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters. Similar to the federal Anti-Kickback Statute, a person or entity can be found guilty of violating HIPAA without actual knowledge of the statute or specific intent to violate it;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and their respective implementing regulations, which impose, among other things, requirements on certain covered healthcare providers, health plans and healthcare clearinghouses, as well as their respective business associates that perform services for them that involve the use, or disclosure of, individually identifiable health information, relating to the privacy, security and transmission of individually identifiable health information without appropriate authorization. HITECH also created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to

file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions;

- the federal Physician Payment Sunshine Act, created under the Patient Protection and Affordable Care Act, and its implementing regulations, which require manufacturers of drugs, devices, biologicals and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to the United States Department of Health and Human Services information related to payments or other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members. Effective January 1, 2022, these reporting obligations will extend to include transfers of value made to certain non-physician providers such as physician assistants and nurse practitioners;
- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers; and
- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers, and may be broader in scope than their U.S. federal equivalents; state and foreign laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare providers; state and foreign 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 and foreign laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

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 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. 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.

The failure to comply with any of these laws or regulatory requirements subjects entities to possible legal or regulatory action. Depending on the circumstances, our failure to meet applicable regulatory requirements can result in civil, criminal and administrative penalties, damages, fines, disgorgement, individual imprisonment, exclusion from participation in federal and state funded healthcare programs, contractual damages and the curtailment or restricting of our operations, as well as additional reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws. Any action for violation of these laws, even if successfully defended, could cause a pharmaceutical manufacturer to incur significant legal expenses and divert management's attention from the operation of the business. Prohibitions, restrictions on sales or withdrawal of future marketed products could materially affect a pharmaceutical manufacturer's business in an adverse way.

We have adopted a code of business conduct and ethics, a copy of which is available on the Investors section of our website. However, even after adopting and implementing appropriate corporate policies, it is not

always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent inappropriate conduct may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with applicable laws or regulations. Our efforts to ensure that our business arrangements will comply with applicable healthcare laws may involve substantial costs. It is possible that governmental and enforcement authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law interpreting applicable fraud and abuse or other healthcare laws and regulations. If any actions of this nature are instituted against us and if we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of civil, criminal and administrative penalties, damages, disgorgement, monetary fines, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings and curtailment of our operations, any of which could adversely affect our ability to operate our business, financial condition, prospects and results of operations. In addition, the approval and commercialization of any of our product candidates outside the United States will also likely subject us to foreign equivalents of the healthcare laws mentioned above, among other foreign laws.

***Neon may not be successful in Neon's efforts to identify additional product candidates. Due to Neon's limited resources and access to capital, Neon must prioritize development of certain product candidates; these decisions may prove to be wrong and may adversely affect Neon's business.***

Although we intend to explore therapeutic opportunities beyond those that we are currently developing, we may fail to identify viable new product candidates for clinical development for a number of reasons, which could result in harm to our business.

Research programs to pursue the development of our existing and planned product candidates for additional indications and to identify new product candidates and disease targets require substantial technical, financial and human resources, whether or not they are ultimately successful. Our research programs may initially show promise in identifying potential indications and/or product candidates, yet fail to yield results for clinical development for a number of reasons, including:

- the research method used may not be successful in identifying potential indications and/or product candidates;
- potential product candidates may, after further study, be shown to have harmful adverse effects or other characteristics that indicate they are unlikely to be effective therapies; or
- it may take greater human and financial resources than we will possess to identify additional therapeutic opportunities for our product candidates or to develop suitable potential product candidates through internal research programs, thereby limiting our ability to develop, diversify and expand our product portfolio.

Because we have limited financial and human resources, we intend to initially focus on research programs and product candidates for a limited set of indications. As a result, we may forego or delay pursuit of opportunities with other product candidates or for other indications that later prove to have greater commercial potential or a greater likelihood of success. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities.

Accordingly, there can be no assurance that we will ever be able to identify additional therapeutic opportunities for our product candidates or develop suitable potential product candidates through internal research programs, which could materially adversely affect our business, financial condition, prospects and results of operations. We may focus our efforts and resources on potential product candidates or other potential programs that ultimately prove to be unsuccessful.

***Neon's business could be materially and adversely affected by a variety of risks associated with marketing Neon's product candidates internationally.***

We plan to seek regulatory approval of our product candidates outside of the United States and, accordingly, if we obtain necessary approvals, we expect that we will be subject to additional risks related to operating in foreign countries, including:

- differing regulatory requirements in foreign countries, including with respect to privacy restrictions and the sharing of patient information;
- unexpected changes in tariffs, trade barriers, price and exchange controls and other regulatory requirements;
- import and export regulations;
- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- foreign taxes, including withholding of payroll taxes;
- foreign 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 foreign operations;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- potential liability under the FCPA or comparable foreign regulations;
- challenges enforcing our contractual and intellectual property rights, especially in those foreign countries that do not respect and protect intellectual property rights to the same extent as the United States;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geo-political actions, including war and terrorism.

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

***Neon currently has no marketing and sales organization and has no organizational experience marketing products. If Neon is unable to establish marketing and sales capabilities or enter into agreements with third parties to market and sell Neon's product candidates, Neon may not be able to generate product revenue.***

We currently have no sales, marketing or distribution capabilities and have no organizational experience marketing products. In the future, we may determine to develop an in-house marketing organization and sales force, which will require significant capital expenditures, management resources and time. We will have to compete with other pharmaceutical and biotechnology companies to recruit, hire, train and retain marketing and sales personnel.

In addition to establishing internal sales, marketing and distribution capabilities, we may pursue collaborative arrangements regarding the sales and marketing of our products. However, there can be no assurance that we will be able to establish or maintain these types of collaborative arrangements, or if we are able to do so, that our partners will have effective sales forces. Any revenue we receive from collaboration partners will depend upon the efforts of these third parties, which may not be successful. We may have little or no control

over the marketing and sales efforts that these third parties undertake and our revenue from product sales may be lower than if we had commercialized our product candidates ourselves. We also face competition in our search for third parties to assist us with the sales and marketing efforts of our product candidates.

There can be no assurance that we will be able to develop in-house sales and distribution capabilities or establish or maintain relationships with third-party collaborators to commercialize any, assuming they receive regulatory approval, in the United States or overseas.

***Fluctuations in foreign currency exchange rates could substantially increase Neon's development costs.***

A portion of our planned clinical trial activities and clinical product manufacturing are conducted outside of the United States, and associated costs may be incurred in the local currency of the country in which the activity is being conducted, which costs could be subject to fluctuations in foreign exchange rates. At present, we do not engage in hedging transactions to protect against uncertainty in future exchange rates between particular foreign currencies and the U.S. dollar. A decline in the value of the U.S. dollar against currencies in geographies in which we conduct clinical trials or manufacturing activities could have a negative impact on our research and development costs. We cannot predict the impact of foreign currency fluctuations, and foreign currency fluctuations in the future may adversely affect our development costs.

***Changes in tax law could adversely affect Neon's business and financial condition.***

The laws and rules dealing with U.S. federal, state and local income taxation are routinely reviewed and modified by governmental bodies, officials and regulatory agencies, including the Internal Revenue Service and the U.S. Treasury Department. Changes to tax laws (which changes may have retroactive application) could adversely affect us or holders of our common stock. Since the Company was founded in 2014, many such changes have been made and changes are likely to continue to occur in the future. For example, in December 2017, Internal Revenue Code of 1986, as amended, or the Code, was significantly reformed by the Tax Cuts and Jobs Act, or the TCJA. Changes under the TCJA included, among other things, a reduction of the U.S. federal corporate income tax rate, significant limitations on the deductibility of interest and net operating loss carryforwards, or NOLs, the ability to expense capital expenditures, and the migration from a "worldwide" system of taxation to a territorial system. It cannot be predicted whether, when, in what form, or with what effective dates, tax laws, regulations and rulings may be enacted, promulgated or issued, that could result in an increase in our or our shareholders' tax liability.

***Neon's ability to use net operating losses and research and development credits to offset future taxable income may be subject to certain limitations.***

As of December 31, 2019, we had U.S. federal net operating loss carryforwards of $153.9 million of which $79.1 million will begin to expire in 2034 and $74.8 million of which can be carried forward indefinitely. We also had state net operating loss carryforwards of $155.2 million, which begin to expire in 2034. As of December 31, 2019, we also had federal and state research and development tax credit carryforwards of $7.6 million and $2.6 million, respectively, which begin to expire in 2034 and 2029, respectively. Under the TCJA, net operating loss carryforwards generated in taxable years ending after December 31, 2017 are not subject to expiration. Our ability to utilize our net operating losses or tax credits, or NOLs or credits, is conditioned upon our attaining profitability and generating U.S. federal and state taxable income. As described above under "*Risk Factors—Risks Related to Our Business, Technology and Industry*," we have incurred significant net losses since our inception and anticipate that we will continue to incur significant losses for the foreseeable future. In addition, in general, under Sections 382 and 383 of the Code, a corporation that undergoes an "ownership change" is subject to limitations on its ability to utilize its pre-change NOLs or credits to offset future taxable income or taxes. For these purposes, an ownership change generally occurs where the aggregate stock ownership of one or more stockholders or groups of stockholders who owns at least 5% of a corporation's stock increases its ownership by more than 50 percentage points over its lowest ownership percentage within a

specified testing period. We may have experienced ownership changes in the past and we expect to experience an ownership change in the future as a result of the proposed acquisition of the Company by BioNTech (as discussed above under "*Risk Factors—Risks Related to Our Merger with BioNTech*"). Our NOLs or credits may also be impaired under state law. Accordingly, we do not know whether or when we will utilize our NOL or credit carryforwards.

*Risks Related to Government Regulation*

***The regulatory approval process for Neon's product candidates in the United States, European Union and other jurisdictions is currently uncertain and will be lengthy, time-consuming and inherently unpredictable and Neon may experience significant delays in the clinical development and regulatory approval, if any, of Neon's product candidates.***

The research, testing, manufacturing, labeling, approval, selling, import, export, marketing and distribution of drug products, including biologics, are subject to extensive regulation by the FDA in the United States and regulatory authorities in states and other countries. We are not permitted to market any biological product in the United States until we receive a biologics license from the FDA. We have not previously submitted a BLA to the FDA, or similar marketing application to comparable foreign authorities. A BLA must include extensive nonclinical and clinical data and supporting information to establish that the product candidate is safe, pure and potent for each desired indication. The BLA must also include significant information regarding the chemistry, manufacturing and controls for the product, and the manufacturing facilities must complete a successful pre-license inspection. We expect the novel nature of our product candidates to create further challenges in obtaining regulatory approval. For example, the personal T cell and vaccine product candidates that we design and manufacture are molecularly different for each patient and the FDA has not approved any personal neoantigen therapies to date. Similarly, we use data from our clinical trials to continuously improve the algorithms composing our RECON bioinformatics engine. The FDA or other regulatory authorities may require that we refrain from inputting any additional data into our RECON bioinformatics engine before we commence any pivotal clinical trials of our product candidates. As a result, our ability to develop product candidates and obtain regulatory approval may be significantly impacted.

The FDA may also require a panel of experts, referred to as an Advisory Committee, to deliberate on the adequacy of the safety and efficacy data to support approval. The opinion of the Advisory Committee, although not binding, may have a significant impact on our ability to obtain approval of any product candidates that we develop based on the completed clinical trials.

Moreover, while we are not aware of any specific genetic or biomarker diagnostic tests for which regulatory approval would be necessary in order to advance any of our product candidates to clinical trials or potential commercialization, in the future, regulatory agencies may require the development and approval of these types of tests. Accordingly, the regulatory approval pathway for our product candidates may be uncertain, complex, expensive and lengthy, and we may never obtain regulatory approval for our product candidates.

In addition, clinical trials can be delayed or terminated for a variety of reasons, including delays or failures related to:

- obtaining regulatory authorization to begin a trial;
- the availability of financial resources to begin and complete the planned trials;
- reaching agreement on acceptable terms with prospective CROs and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- obtaining approval at each clinical trial site by an independent IRB or ethics committee;
- recruiting suitable patients to participate in a trial in a timely manner;

- having patients complete a trial or return for post-treatment follow-up;
- deviations from trial protocols by clinical trial sites, noncompliance with GCP requirements or clinical trial sites dropping out of a trial;
- addressing any patient safety concerns that arise during the course of a trial;
- addressing any conflicts with new or existing laws or regulations;
- adding new clinical trial sites; or
- manufacturing qualified materials under cGMP regulations for use in clinical trials.

In December 2019, we filed a clinical trial authorization with the Dutch Health Authority for our planned trial of NEO-PTC-01 in the Netherlands in patients with metastatic melanoma who are refractory to checkpoint inhibitors. NEO-PTC-01 involves the priming, activation and expansion of neoantigen-specific T cells *ex vivo*, an approach that may be less effective than anticipated, and our planned clinical trial is subject to risks related to trial execution, including uncertainty of timing or achievement of approval from the Dutch Health Authority to conduct the trial, difficulties with patient enrollment, trial design and establishing trial protocols.

Patient enrollment is a significant factor in the timing of commencement and completion of trials and can be affected by many factors. A clinical trial may be suspended or terminated by us, the IRBs for the institutions in which such trials are being conducted, or the FDA or other regulatory authorities, or a clinical trial may be recommended for suspension or termination by the applicable DSMB, 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 from using a product candidate, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. If we experience termination of, or delays in the completion of, any clinical trial of our product candidates, the commercial prospects for our product candidates will be harmed, and our ability to generate product revenue will be delayed. In addition, any delays in completing any clinical trials will increase our costs, slow down our product development and approval process and jeopardize our ability to commence product sales and generate revenue.

***The FDA or a comparable foreign regulatory authority may disagree with Neon's regulatory plan and Neon may fail to obtain regulatory approval of Neon's product candidates.***

The general approach for FDA or comparable foreign regulatory authority approval of a new biologic or drug is to provide dispositive data from two well-controlled, Phase 3 clinical trials of the relevant biologic or drug in the relevant patient population. Phase 3 clinical trials typically involve hundreds of patients, have significant costs and take years to complete. We believe that we may be able to utilize an accelerated approval approach for our product candidates given the limited alternatives for cancer treatments, but the FDA or comparable foreign regulatory authority may not agree with our plans.

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

- the FDA or comparable foreign 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 or comparable foreign 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 or comparable foreign regulatory authorities for approval;

- we may be unable to demonstrate that our product candidates' clinical and other benefits outweigh their safety risks;
- the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from nonclinical studies or clinical trials;
- the data collected from clinical trials of our product candidates may be deemed by the FDA or comparable foreign regulatory authorities to be insufficient to support the submission of a BLA or other comparable submission in foreign jurisdictions or to obtain regulatory approval in the United States or elsewhere;
- the FDA or comparable foreign regulatory authorities may fail to approve or find deficiencies with the manufacturing processes and controls or facilities of third-party manufacturers with which we contract for clinical and commercial supplies or any facilities that we may own in the future; and
- the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner that could render our clinical data insufficient for approval.

For example, in December 2019 we filed a clinical trial authorization with the Dutch Health Authority for our planned trial of NEO-PTC-01 in the Netherlands in patients with metastatic melanoma who are refractory to checkpoint inhibitors. NEO-PTC-01 involves the priming, activation and expansion of neoantigen-specific T cells *ex vivo*, an approach that may be less effective than anticipated, and our planned clinical trial is subject to risks related to trial execution, including uncertainty of timing or achievement of approval from the Dutch Health Authority to conduct the trial, difficulties with patient enrollment, trial design and establishing trial protocols.

***Neon may rely on third parties to conduct investigator-sponsored clinical trials of Neon's product candidates. Any failure by a third party to meet its obligations with respect to the clinical development of Neon's product candidates may delay or impair Neon's ability to obtain regulatory approval for Neon's other product candidates.***

We may rely on academic and private, non-academic institutions to conduct and sponsor clinical trials relating to our product candidates. We will not control the design or conduct of these investigator-sponsored trials. It is possible that the FDA or non-U.S. regulatory authorities will not view these investigator-sponsored trials as providing adequate support for future clinical trials, whether controlled by us or third parties, for any one or more reasons, including due to elements of the design or execution of the trials, safety concerns or other trial results.

Our arrangements with academic and private, non-academic institutions will likely provide us certain information rights with respect to the investigator-sponsored trials, including access to and the ability to use and reference the data resulting from the investigator-sponsored trials, including for our own regulatory filings. However, we would not have control over the timing and reporting of the data from investigator-sponsored trials, nor would we own the data from the investigator-sponsored trials. If we are unable to confirm or replicate the results from investigator-sponsored trials or if those trials produce negative results, we would likely be further delayed or prevented from advancing further clinical development of our product candidates. Further, if investigators or institutions breach their obligations with respect to the clinical development of our product candidates, or if the data they generate prove to be inadequate compared to the first-hand knowledge we might have gained had their trials instead been sponsored and conducted by us, then our ability to design and conduct any future clinical trials ourselves may be adversely affected.

Additionally, the FDA or non-U.S. regulatory authorities may disagree with the sufficiency of our right of reference to the preclinical, manufacturing or clinical data generated by these investigator-sponsored trials, or our interpretation of preclinical, manufacturing or clinical data from these investigator-sponsored trials. If so, the FDA or other non-U.S. regulatory authorities may require us to obtain and submit additional preclinical, manufacturing, or clinical data before we may initiate our planned trials and/or may not accept such additional data as adequate to initiate our planned trials.

***Obtaining and maintaining regulatory approval of Neon's product candidates in one jurisdiction does not mean that Neon will be successful in obtaining regulatory approval of Neon's product candidates in other jurisdictions.***

Obtaining and maintaining regulatory approval of a product candidate in one jurisdiction does not guarantee that we will be able to obtain or maintain regulatory approval for that product candidate in any other jurisdiction, while a failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory approval process in others. For example, even if the FDA grants marketing approval of a product candidate, comparable regulatory authorities in foreign jurisdictions must also approve the manufacturing, marketing and promotion of the product candidate in those countries. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from, and greater than, those in the United States, including additional nonclinical studies or clinical trials as clinical trials conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions. In many jurisdictions outside the United States, a product candidate must be approved for reimbursement before it can be approved for sale in that jurisdiction. In some cases, the price that we intend to charge for our products is also subject to regulatory approval.

We may also submit marketing applications in other countries. Regulatory authorities in jurisdictions outside of the United States have requirements for approval of product candidates with which we must comply prior to marketing our product candidates in those jurisdictions. Obtaining foreign regulatory approvals and compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our products in certain countries. If we fail to comply with the regulatory requirements in international markets and/or receive applicable marketing approvals, our target market will be reduced and our ability to realize the full market potential of our product candidates will be harmed.

***Even if Neon receives regulatory approval of any product candidates or therapies, Neon will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense and Neon may be subject to penalties if Neon fails to comply with regulatory requirements or experiences unanticipated problems with Neon's product candidates.***

If any of our product candidates are approved, they will be subject to ongoing regulatory requirements for manufacturing, labeling, packaging, storage, advertising, promotion, sampling, record-keeping, conduct of post-marketing studies and submission of safety, efficacy and other post-market information, including both federal and state requirements in the United States and requirements of comparable foreign regulatory authorities. In addition, we will be subject to continued compliance with cGMP and GCP requirements for any clinical trials that we conduct post-approval.

Manufacturers and manufacturers' facilities are required to comply with extensive FDA, and comparable foreign regulatory authority requirements, including ensuring that quality control and manufacturing procedures conform to cGMP, and in certain cases, current Good Tissue Practices, or cGTP, regulations. As a result, we and our contract manufacturers, including our outsourced peptide manufacturer and vaccine adjuvant supplier, will be subject to continual review and inspections to assess compliance with cGMP and adherence to commitments made in any BLA, other marketing application, and previous responses to inspection observations. Accordingly, we and others with whom we work must continue to expend time, money and effort in all areas of regulatory compliance, including manufacturing, production and quality control.

Any regulatory approvals that we receive for our product candidates may be subject to limitations on the approved indicated uses for which the product may be marketed or to the conditions of approval or contain requirements for potentially costly post-marketing testing, including Phase 4 clinical trials and surveillance to monitor the safety and efficacy of the product candidate. The FDA may also require that we implement a risk evaluation and mitigation strategy, or REMS, program as a condition of approval of our product candidates, which could entail requirements for long-term patient follow-up, a medication guide, physician communication

plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. In addition, if the FDA or a comparable foreign regulatory authority approves our product candidates, we will have to comply with requirements including submissions of safety and other post-marketing information and reports and establishment registration.

The FDA may seek consent decrees or withdraw 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 our product candidates, including adverse events of unanticipated severity or frequency, or with our third-party manufacturers or 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 studies or clinical trials 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 our products, withdrawal of the product from the market or voluntary or mandatory product recalls;
- fines, warning or untitled letters or holds on clinical trials;
- refusal by the FDA to approve pending applications or supplements to approved applications filed by us or suspension or revocation of license approvals;
- product seizure or detention or refusal to permit the import or export of our product candidates; and
- injunctions 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. 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. The policies of the FDA and of other regulatory authorities may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability.

***Coverage and reimbursement may be limited or unavailable in certain market segments for Neon's product candidates, if approved, which could make it difficult for it to sell any product candidates or therapies profitably.***

Our ability to successfully commercialize our product candidates also will depend in part on the extent to which coverage and adequate reimbursement for these products and related treatments will be available from third-party payors, including government health care programs, private health insurers, and other organizations. Third-party payors decide which medications they will pay for and establish reimbursement levels. The availability of coverage and extent of reimbursement by governmental and private payors is essential for most patients to be able to afford treatments. Sales of these or other product candidates that we may identify will depend substantially, both domestically and abroad, on the extent to which the costs of our product candidates will be covered and reimbursed by third-party payors. If coverage and adequate 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.

Third-party payors decide which drugs and treatments they will cover and the amount of reimbursement. There is significant uncertainty related to the insurance coverage and reimbursement of newly approved products

and coverage may be more limited than the purposes for which the medicine is approved by the FDA or comparable foreign regulatory authorities. 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. CMS decides whether and to what extent a new medicine will be covered and reimbursed under Medicare and private payors tend to follow CMS to a substantial degree. Coverage and reimbursement by a third-party payor may depend upon a number of factors, including 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.

In the United States, no uniform policy of coverage and reimbursement for products exists among third-party payors. As a result, obtaining coverage and reimbursement approval 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 each payor supporting scientific, clinical and cost-effectiveness data for the use of our products, with no assurance that the payor would agree to provide coverage and adequate reimbursement. 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 and have not been approved for reimbursement in certain European countries. Moreover, eligibility for reimbursement does not imply that any drug will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale, and distribution. Interim reimbursement levels for new drugs, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Reimbursement rates may vary according to the use of the drug and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost drugs and may be incorporated into existing payments for other services. Our inability to promptly obtain coverage and profitable payment rates from both government-funded and private payors for any approved products we may develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize product candidates, and our overall financial condition. Even if we obtain coverage for a given product, the resulting reimbursement payment rates might not be adequate for us to achieve or sustain profitability or may require co-payments that patients find unacceptably high. Additionally, third-party payors may not cover, or provide adequate reimbursement for, long-term follow-up evaluations required following the use of product candidates. 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. Because our product candidates may have a higher cost of goods than conventional therapies and may require long-term follow up evaluations, the risk that coverage and reimbursement rates may be inadequate for us to achieve profitability may be greater. There is significant uncertainty related to insurance coverage and reimbursement of newly approved products. It is difficult to predict at this time what third-party payors will decide with respect to the coverage and reimbursement for our product candidates.

Payment methodologies may be subject to changes in healthcare legislation, regulatory initiatives and judicial challenges. For example, in order for a drug product to receive federal reimbursement under the Medicaid or Medicare Part B programs or to be sold directly to U.S. government agencies, the manufacturer must extend discounts to entities eligible to participate in the 340B drug pricing program. Additional state and federal healthcare reform measures are expected to be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for certain pharmaceutical products or additional pricing pressures and therefore may affect our business, financial condition, prospects and results of operations.

Moreover, increasing efforts by governmental and third-party payors in the United States and abroad to cap or reduce healthcare costs may cause public and private payor organizations to limit both coverage and the level of reimbursement for newly approved products and, as a result, they may not cover or provide adequate payment for our product candidates. There has been increasing legislative and enforcement interest in the United States with respect to specialty drug pricing practices. Specifically, there have been several recent U.S. Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs. At the federal level, Congress and the current administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs, and the current administration recently released a "Blueprint," or plan, to reduce the cost of drugs. The current administrations' Blueprint contains certain measures that the U.S. Department of Health and Human Services is already working to implement. In May 2019, CMS issued a final rule to allow Medicare Advantage Plans the option of using step therapy, a type of prior authorization, for Part B drugs beginning January 1, 2020. This final rule codified CMS's policy change that was effective January 1, 2019. While some proposed measures may require additional authorization to become effective, Congress and the Trump administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs. For example, on September 25, 2019, the Senate Finance Committee introduced the Prescription Drug Pricing Reduction Action of 2019, a bill intended to reduce Medicare and Medicaid prescription drug prices. The proposed legislation would restructure the Part D benefit, modify payment methodologies for certain drugs, and impose an inflation cap on drug price increases. An even more restrictive bill, the Lower Drug Costs Now Act of 2019, was introduced in the House of Representatives on September 19, 2019, and would require HHS to directly negotiate drug prices with manufacturers. The Lower Drugs Costs Now Act of 2019 has passed out of the House and was delivered to the Senate on December 16, 2019. However, it is unclear whether either of these bills will make it through both chambers and be signed into law, and if either is enacted, what effect it would have on our business. Individual states in the United States have also increasingly passed legislation and implemented regulations designed to control pharmaceutical 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.

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, cost containment initiatives and additional legislative changes.

***Ongoing healthcare legislative and regulatory reform measures may have a material adverse effect on Neon's business and results of operations.***

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 changes of this nature were to be imposed on us, they could adversely affect the operation of our business.

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, Congress passed the Patient Protection and Affordable Care Act, or the ACA, which substantially changes the way healthcare is financed by both governmental and private insurers, and significantly impacts the U.S. pharmaceutical industry. The ACA, among other things, subjects biological products to potential competition by lower-cost biosimilars; addresses a new method by which rebates

owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected; increases the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program and extends the rebate program to individuals enrolled in Medicaid managed care organizations; establishes annual fees and taxes on manufacturers of certain branded prescription drugs; and creates a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 70% (increased pursuant to the Bipartisan Budget Act of 2018, effective as of 2019) point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D.

Since its enactment, there have been judicial, administrative, executive and Congressional legislative challenges to certain aspects of the ACA, and we expect there will be additional challenges and amendments to the ACA in the future. For example. various portions of the ACA are currently undergoing constitutional challenges in the Fifth Circuit Court and the United States Supreme Court, and the Trump Administration has issued various Executive Orders eliminating cost sharing subsidies and various provisions 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. Additionally, Congress has introduced several pieces of legislation aimed at significantly revising or repealing the ACA. It is unclear whether the ACA will be overturned, repealed, replaced, or further amended, and we cannot predict what affect further changes to the ACA would have on our business.

Other legislative changes have been proposed and adopted in the United States since the ACA was enacted. On August 2, 2011, 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, including aggregate reductions of Medicare payments to providers of 2% per fiscal year. These reductions went into effect on April 1, 2013 and, due to subsequent legislative amendments to the statute, including the BBA, will remain in effect through 2029, unless additional congressional action is taken. On January 2, 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to several types of providers. In addition, on May 30, 2018, the Right to Try Act was signed into law. The law, among other things, provides a federal framework for certain patients to access certain investigational new drug products that have completed a Phase I clinical trial and that are undergoing investigation for FDA approval. Under certain circumstances, eligible patients can seek treatment without enrolling in clinical trials and without obtaining FDA permission under the FDA expanded access program. There is no obligation for a drug manufacturer to make its drug products available to eligible patients as a result of the Right to Try Act, but the manufacturer must develop an internal policy and respond to patient requests according to that policy.

These laws, and state and federal healthcare reform measures that may be adopted in the future, may result in additional reductions in Medicare and other healthcare funding and/or otherwise affect the prices we may obtain for any product candidates for which we may obtain regulatory approval or the frequency with which any such approved product candidate is prescribed or used. Litigation and legislative efforts to change or repeal the ACA are likely to continue, with unpredictable and uncertain results.

***European Union drug marketing and reimbursement regulations may materially affect Neon's ability to market and receive coverage for its products in the European member states.***

We intend to seek approval to market our product candidates in both the United States and in selected foreign jurisdictions. If we obtain approval for our product candidates in one or more foreign jurisdictions, we will be subject to rules and regulations in those jurisdictions. In some foreign countries, particularly those in the European Union, or the EU, 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.

Much like the Anti-Kickback Statute prohibition in the United States, 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 also prohibited in the European Union. The provision of benefits or advantages to physicians is 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 and/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 that are 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.

In addition, in most foreign countries, 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 study 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 strategic partners and the potential profitability of any of our product candidates in those countries would be negatively affected.

***European data collection is governed by restrictive regulations governing the use, processing and cross-border transfer of personal information.***

The collection and use of personal health data in the European Union is governed by the provisions of the General Data Protection Regulation (EU) 2016/679, or GDPR. This directive imposes several requirements relating to the consent of the individuals to whom the personal data relates, the information provided to the individuals, notification of data processing obligations to the competent national data protection authorities and the security and confidentiality of the personal data, and substantial fines for breaches of the data protection rules. The GDPR also imposes strict rules on the transfer of personal data out of the European Union to the United States. Failure to comply with the requirements of the GDPR and the related national data protection laws of the European Union Member States may result in fines and other administrative penalties. The GDPR also confers a private right of action on data subjects and consumer associations to lodge complaints with supervisory authorities, seek judicial remedies, and obtain compensation for damages resulting from violations of the GDPR.

In addition, the GDPR includes restrictions on cross-border data transfers. The GDPR may increase our responsibility and liability in relation to personal data that we process where such processing is subject to the GDPR, and we may be required to put in place additional mechanisms to ensure compliance with the GDPR, including as implemented by individual countries. Since we anticipate beginning our NEO-PTC-01 program in the Netherlands, our operations in the EU may be subject to the GDPR. The GDPR regulations may impose additional responsibility and liability in relation to personal data that we process and we may be required to put in place additional mechanisms ensuring compliance with these and/or new data protection rules. We may be required to obtain additional consent to process and transfer data outside the EU, which may affect our ability to enroll enough patients in our trials. These regulations may be onerous and adversely affect our business, financial condition, prospects and results of operations.

***Additional laws and regulations governing international operations may preclude Neon from developing, manufacturing or selling certain products and product candidates outside the United States, which could limit its growth potential and increase its development costs.***

If we expand our operations outside of the United States, we must dedicate additional resources to comply with numerous laws and regulations in each jurisdiction in which we plan to operate. The FCPA prohibits any U.S. individual or business from paying, offering, authorizing payment or offering of anything of value, directly or indirectly, to any foreign official, political party or candidate for the purpose of influencing any act or decision of the foreign entity in order to assist the individual or business in obtaining or retaining business. The FCPA also obligates companies whose securities are listed in the United States to comply with certain accounting provisions requiring the company to maintain books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries, and to devise and maintain an adequate system of internal accounting controls for international operations.

Compliance with the FCPA is expensive and difficult, particularly in countries in which corruption is a recognized problem. In addition, the FCPA presents particular challenges in the pharmaceutical industry, because, in many countries, hospitals are operated by the government and doctors and other hospital employees are considered foreign officials. Certain payments to hospitals in connection with clinical trials and other work have been deemed to be improper payments to government officials and have led to FCPA enforcement actions.

Various laws, regulations and executive orders also restrict the use and dissemination outside of the United States, or the sharing with certain non-U.S. nationals, of information classified for national security purposes, as well as certain products and technical data relating to those products. If we expand our presence outside of the United States, we will need to dedicate additional resources to complying with these laws, and these laws may preclude us from developing, manufacturing or selling certain products and product candidates outside of the United States, which could limit our growth potential and increase our development costs.

The failure to comply with laws governing international business practices may result in substantial civil and criminal penalties and suspension or debarment from government contracting. The U.S. Securities and Exchange Commission, or SEC, also may suspend or bar issuers from trading securities on U.S. exchanges for violations of the FCPA's accounting provisions.

***Neon is subject to certain U.S. and foreign anti-corruption, anti-money laundering, export control, sanctions, and other trade laws and regulations. Neon can face serious consequences for violations.***

Among other matters, U.S. and foreign anti-corruption, anti-money laundering, export control, sanctions, and other trade laws and regulations, which are collectively referred to as the Trade Laws, prohibit companies and their employees, agents, clinical research organizations, legal counsel, accountants, consultants, contractors, and other partners 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 the 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 also expect our non-U.S. activities to increase in time, including when and if we conduct clinical trials outside the United States. We plan to engage third parties for clinical trials and/or to obtain necessary permits, licenses, patent registrations and other regulatory approvals and we can be held liable for the corrupt or other illegal activities of our personnel, agents or partners, even if we do not explicitly authorize or have prior knowledge of such activities.

*Risks Related to Neon Intellectual Property*

***Neon's success depends in part on its ability to protect its intellectual property. It is difficult and costly to protect its proprietary rights and technology and Neon may not be able to ensure their protection.***

Our commercial success will depend in large part on obtaining and maintaining patent, trademark and trade secret protection of our proprietary technologies and product candidates, their respective components, formulations, combination therapies, methods used to manufacture them and methods of treatment, as well as successfully defending these patents against third-party challenges. Our ability to stop unauthorized third parties from making, using, selling, offering to sell or importing our product candidates is dependent upon the extent to which we have rights under valid and enforceable patents or trade secrets that cover these activities. If we are unable to secure and maintain patent protection for any product or technology we develop or if the scope of the patent protection secured is not sufficiently broad, our competitors could develop and commercialize products and technology similar or identical to ours and our ability to commercialize any product candidates we may develop may be adversely affected.

The patenting process is expensive and time-consuming and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. In addition, we may not pursue or obtain patent protection in all relevant markets. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. Moreover, in some circumstances, we may not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the patents, covering technology that we license from or license to third parties and are reliant on our licensors or licensees. Our pending and future patent applications may not result in issued patents that protect our technology or products, in whole or in part. In addition, our existing patents and any future patents we obtain may not be sufficiently broad to prevent others from using our technology or from developing competing products and technologies.

***Neon depends on intellectual property licensed from third parties and termination of any of these licenses could result in the loss of significant rights, which would harm Neon's business.***

We are dependent on patents, know-how and proprietary technology, both our own and those licensed from others. As a result, any termination of these licenses could result in the loss of significant rights and could harm our ability to commercialize our product candidates.

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 on intellectual property of the licensor that is not subject to the licensing agreement;
- our right to sublicense patent and other rights to third parties under collaborative development relationships;
- our diligence obligations with respect to the use of the licensed technology in relation to our development and commercialization of our product candidates and what activities satisfy those diligence obligations; and

- the ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our partners.

If disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on acceptable 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 or our licensors fail to adequately protect this intellectual property, our ability to commercialize products could suffer.

***If Neon fails to comply with Neon's obligations under its patent licenses with third parties, Neon could lose license rights that are important to its business.***

We are a party to license agreements with the Dana-Farber Cancer Institute, Inc., the Eli and Edythe L. Broad Institute of MIT and Harvard, and others, pursuant to which we in-license key patent and patent applications for our product candidates. These existing licenses impose various diligence, milestone payment, royalty, insurance and other obligations on us. If we fail to comply with these obligations, our licensors may have the right to terminate the license, in which event we would not be able to develop or market the products covered by the intellectual property licensed under these agreements.

We have limited control over the maintenance and prosecution of these in-licensed patents and patent applications and may have limited control over other intellectual property that may be in-licensed. For example, we cannot be certain that the maintenance and prosecution activities by these licensors have been or will be conducted in compliance with applicable laws and regulations or will result in valid and enforceable patents and other intellectual property rights. We also have limited control over the manner in which our licensors initiate an infringement proceeding against a third-party infringer of the intellectual property rights or defend certain of the intellectual property that is licensed to us. It is possible that the licensors' infringement proceedings or defense activities may be less vigorous than had we conducted them ourselves.

***Neon's proprietary position depends upon patents that are manufacturing, formulation or method-of-use patents, which may not prevent a competitor or other third party from using the same product candidate for another use.***

Composition-of-matter patents on the active pharmaceutical ingredient, or API, in prescription drug products are generally considered to be the strongest form of intellectual property protection for drug products because those types of patents provide protection without regard to any particular method of use or manufacture or formulation of the API used. We do not currently have any claims in our owned or in-licensed issued U.S. patents that cover the composition-of-matter of any of our product candidates. We are, however, pursuing claims in our pending owned or in-licensed patent applications that cover the composition-of-matter of our product candidates. 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. In addition, there are likely to be additional challenges in obtaining composition-of-matter patents for our current and future personal T cell and vaccine product candidates, given the highly bespoke nature of our personalized therapies.

Method-of-use patents protect the use of a product for the specified method and formulation patents cover formulations of the API. These types of patents do not prevent a competitor or other third party from developing or marketing an 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 prosecute. In addition, there are numerous publications and other prior art that may be relevant to our owned and in-licensed formulation and method-of-use patents and may be used to challenge the validity of these owned or in-licensed patents in litigation or other intellectual property-related proceedings. If these types of challenges are successful, our owned and in-licensed patents may be narrowed or found to be invalid and we may lose valuable intellectual property rights. Any of the foregoing could have a material adverse effect on our business, financial conditions, prospects and results of operations.

The strength of patents in the biotechnology and pharmaceutical field involves complex legal and scientific questions and can be uncertain. The patent applications that we own or in-license may fail to result in issued patents with claims that cover our product candidates or uses thereof in the United States or in foreign countries. Even if patents do successfully issue, third parties may challenge their validity, enforceability or scope, which may result in those patents being narrowed, invalidated or held unenforceable. Furthermore, even if they are unchallenged, our patents and patent applications may not adequately protect our intellectual property or prevent others from designing around our claims. If the breadth or strength of protection provided by the patent applications we hold with respect to our product candidates is threatened, it could dissuade companies from collaborating with us to develop, and threaten our ability to commercialize, our product candidates. Further, if we encounter delays in our clinical trials, the period of time during which we could market our product candidates under patent protection would be reduced. Since patent applications in the United States and other countries are confidential for a period of time after filing, at any moment in time, we cannot be certain that we were in the past or will be in the future the first to file any patent application related to our product candidates. Furthermore, for our United States patent applications in which all claims are entitled to a priority date before March 16, 2013, a third party can invoke, or the United States patent office, or USPTO, can institute an interference proceeding to determine who was the first to invent any of the subject matter covered by the patent claims included in our applications.

We cannot be certain that we are the first to invent the inventions covered by pending patent applications and, if we are not, we may be subject to priority disputes. We may be required to disclaim part or all of the term of certain patents or all of the term of certain patent applications. There may be prior art of which we are not aware that may affect the validity or enforceability of a patent claim. There also may be prior art of which we are aware, but which we do not believe affects the validity or enforceability of a claim, which may, nonetheless, ultimately be found to affect the validity or enforceability of a claim. No assurance can be given that, if challenged, our patents would be declared by a court to be valid or enforceable or that even if found valid and enforceable, a competitor's technology or product would be found by a court to infringe our patents. We may analyze patents or patent applications of our competitors that we believe are relevant to our activities and consider that we are free to operate in relation to our product candidates, but our competitors may achieve issued claims, including in patents we consider to be unrelated, that block our efforts or potentially result in our product candidates or our activities infringing those issued claims. The possibility also exists that others will develop products that have the same effect as our products on an independent basis that do not infringe our patents or other intellectual property rights or will design around the claims of patents that we have had issued that cover our products.

Past or future patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. In March 2013, under the Leahy-Smith America Invents Act, or the America Invents Act, the United States moved from a "first to invent" to a "first-to-file" patent system. Under a "first-to-file" system, assuming the other requirements for patentability are met, the first inventor to file a patent application generally will be entitled to a patent on the invention regardless of whether another inventor had made the invention earlier. The America Invents Act includes a number of other significant changes to U.S. patent law, including provisions that affect the way patent applications are prosecuted, redefine prior art and establish a new post-grant review system. The effects of these changes are currently unclear as the USPTO continues to promulgate new regulations and procedures in

connection with the America Invents Act and many of the substantive changes to patent law, including the "first-to-file" provisions, only became effective in March 2013. In addition, the courts have yet to address many of these provisions and the applicability of the act and new regulations on the specific patents discussed in this filing have not been determined and would need to be reviewed. However, 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, prospects and results of operations.

The degree of future protection for our proprietary rights is uncertain because legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep our competitive advantage. For example:

- others may be able to make or use compounds or cells that are similar to the biological compositions of our product candidates but that are not covered by the claims of our patents;
- the active biological ingredients in our current product candidates will eventually become commercially available in biosimilar drug products and no patent protection may be available with regard to formulation or method of use;
- we or our licensors, as the case may be, may fail to meet our obligations to the U.S. government regarding any in-licensed patents and patent applications funded by U.S. government grants, leading to the loss of patent rights;
- we or our licensors, as the case may be, might not have been the first to file patent applications for certain inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies;
- it is possible that our pending patent applications will not result in issued patents;
- it is possible that there are prior public disclosures that could invalidate our or our licensors' patents, as the case may be, or parts of our or their patents;
- it is possible that others may circumvent our owned or in-licensed patents;
- it is possible that there are unpublished applications or patent applications maintained in secrecy that may later issue with claims covering our products or technology similar to ours;
- the laws of foreign countries may not protect our or our licensors', as the case may be, proprietary rights to the same extent as the laws of the United States;
- the claims of our owned or in-licensed issued patents or patent applications, if and when issued, may not cover our product candidates;
- our owned or in-licensed issued patents may not provide us with any competitive advantages, may be narrowed in scope, or be held invalid or unenforceable as a result of legal challenges by third parties;
- the inventors of our owned or in-licensed patents or patent applications may become involved with competitors, develop products or processes that design around our patents or become hostile to us or the patents or patent applications on which they are named as inventors;
- it is possible that our owned or in-licensed patents or patent applications omit individual(s) that should be listed as inventor(s) or include individual(s) that should not be listed as inventor(s), which may cause these patents or patents issuing from these patent applications to be held invalid or unenforceable;
- we have engaged in scientific collaborations in the past and will continue to do so in the future and our collaborators may develop adjacent or competing products that are outside the scope of our patents;

- we may not develop additional proprietary technologies for which we can obtain patent protection;
- it is possible that product candidates or diagnostic tests we develop may be covered by third parties' patents or other exclusive rights; or
- the patents of others may have an adverse effect on our business.

***If Neon is unable to protect the confidentiality of Neon's trade secrets, its business and competitive position would be harmed.***

In addition to patent protection, we rely heavily upon know-how and trade secret protection, as well as non-disclosure agreements and invention assignment agreements with our employees, consultants and third-parties, to protect our confidential and proprietary information, especially where we do not believe patent protection is appropriate or obtainable. For example, significant elements of our research and development approaches, including aspects of sample preparations, methods of manufacturing, cell culturing conditions and computational-biological algorithms, including RECON's algorithms, and related processes and software, are based on unpatented trade secrets and know-how that are not publicly disclosed.

It is our policy to require our employees, consultants, outside scientific collaborators, sponsored researchers and other advisors to execute confidentiality agreements upon the commencement of employment or consulting relationships with us. These agreements provide that all confidential information concerning our business or financial affairs developed or made known to the individual or entity during the course of the party's relationship with us is to be kept confidential and not disclosed to third parties, except in certain specified circumstances. In the case of employees, the agreements provide that all inventions conceived by the individual and that are related to our current or planned business or research and development or made during normal working hours on our premises or using our equipment or proprietary information are our exclusive property. We have also adopted policies and conduct training that provides guidance on our expectations and our advice for best practices in protecting our trade secrets.

In addition to contractual measures, we try to protect the confidential nature of our proprietary information through other appropriate precautions, such as physical and technological security measures. These measures may not, for example, in the case of misappropriation of a trade secret by an employee or third party with authorized access, provide adequate protection for our proprietary information. Our security measures may not prevent an employee or consultant from misappropriating our trade secrets and providing them to a competitor and any recourse we might take against this type of misconduct may not provide an adequate remedy to protect our interests fully. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret can be difficult, expensive and time-consuming and the outcome is unpredictable. In addition, trade secrets may be independently developed by others in a manner that could prevent us from receiving legal recourse. If any of our confidential or proprietary information, such as our trade secrets, were to be disclosed or misappropriated, or if any of that information was independently developed by a competitor, our competitive position could be harmed.

In addition, courts outside the United States are sometimes less willing to protect trade secrets. If we choose to go to court to stop a third party from using any of our trade secrets, we may incur substantial costs. Even if we are successful, these types of lawsuits may consume our time and other resources. Although we take steps to protect our proprietary information and trade secrets, third parties may independently develop substantially equivalent proprietary information and techniques or otherwise gain access to our trade secrets or disclose our technology. As a result, we may not be able to meaningfully protect our trade secrets.

***Third-party claims of intellectual property infringement may prevent or delay Neon's product discovery and development efforts.***

Our commercial success depends in part on our ability to develop, manufacture, market and sell our product candidates and use our proprietary technologies without infringing the proprietary rights of third parties. There is

a substantial amount of litigation involving patents and other intellectual property rights in the biotechnology and pharmaceutical industries, as well as administrative proceedings for challenging patents, including interference, derivation, *inter partes* review, post grant review, and reexamination proceedings before the USPTO or oppositions and other comparable proceedings in foreign jurisdictions. We may be exposed to, or threatened with, future litigation by third parties having patent or other intellectual property rights alleging that our product candidates and/or proprietary technologies infringe their intellectual property rights. Numerous U.S. and foreign issued patents and pending patent applications that are owned by third parties, exist in the fields in which we are developing our product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our product candidates may give rise to claims of infringement of the patent rights of others. Moreover, it is not always clear to industry participants, including us, which patents cover various types of drugs, products or their methods of use or manufacture. Thus, because of the large number of patents issued and patent applications filed in our fields, there may be a risk that third parties may allege they have patent rights encompassing our product candidates, technologies or methods.

If a third party claims that we infringe its intellectual property rights, we may face a number of issues, including, but not limited to:

- infringement and other intellectual property claims that, regardless of merit, may be expensive and time-consuming to litigate and may divert our management's attention from our core business;
- substantial damages for infringement, which we may have to pay if a court decides that the product candidate or technology at issue infringes on or violates the third party's rights, and, if the court finds that the infringement was willful, we could be ordered to pay treble damages plus the patent owner's attorneys' fees;
- a court prohibiting us from developing, manufacturing, marketing or selling our product candidates, or from using our proprietary technologies, unless the third party licenses its product rights to us, which it is not required to do;
- if a license is available from a third party, we may have to pay substantial royalties, upfront fees and other amounts and/or grant cross-licenses to intellectual property rights for our products; and
- the requirement that we redesign our product candidates or processes so they do not infringe, which may not be possible or may require substantial monetary expenditures and time.

Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise the funds necessary to continue our operations or could otherwise have a material adverse effect on our business, financial condition, prospects and results of operations.

Third parties may assert that we are employing their proprietary technology without authorization. Generally, conducting clinical trials and other development activities in the United States is not considered an act of infringement. If and when any of our neoantigen-targeting therapy product candidates is approved by the FDA or a comparable foreign regulatory authority, a third party who believes that our technology infringes its patent may then be able to seek to enforce its patent by filing a patent infringement lawsuit against us. We are aware of U.S. Patent No. 10,055,540 entitled "Neoantigen Identification, Manufacture, and Use." If a claim is subsequently asserted that any of our neoantigen-targeting therapy product candidates or RECON infringes this patent, we believe that we have reasonable defenses, such as noninfringement or invalidity. There can be no assurance that these defenses will succeed. We also have patent rights in this technology space. Further, while we do not believe that any claims of other outstanding patents that could otherwise materially adversely affect commercialization of our neoantigen therapies product candidates, if approved, are valid and enforceable, we may be incorrect in this belief or we may not be able to prove that position in a litigation. In this regard, patents issued in the United States by law enjoy a presumption of validity that can be rebutted only with evidence that is "clear and convincing," a heightened standard of proof.

There may be third-party patents of which we are currently unaware with claims to materials, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our product candidates. Because patent applications can take many years to issue, there may be currently pending patent applications that 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 use of our technologies infringes upon these patents.

If any third-party patents were held by a court of competent jurisdiction to cover the manufacturing process of our product candidates, constructs or molecules used in or formed during the manufacturing process or any final product itself, the holders of those patents may be able to block our ability to commercialize our product candidate unless we obtained a license under the applicable patents or until those patents were to expire or are finally determined to be invalid or unenforceable. Similarly, if any third-party patent were held by a court of competent jurisdiction to cover aspects of our formulations, processes for manufacture or methods of use, including combination therapy or patient selection methods, the holders of that patent may be able to block our ability to develop and commercialize the product candidate unless we obtained a license or until the applicable patent expires or is finally determined to be invalid or unenforceable. In either case, a license may not be available on commercially reasonable terms, or at all, particularly if the applicable patent is owned or controlled by one of our primary competitors. If we are unable to obtain a necessary license to a third-party patent on commercially reasonable terms, or at all, our ability to commercialize our product candidates may be impaired or delayed, which could significantly harm our business. Even if we obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates.

Parties making claims against us may seek and obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize our product candidates. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee time and resources from our business. In the event of a successful claim of infringement against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, obtain one or more licenses from third parties, pay royalties or redesign our infringing products, which may be impossible or require substantial time and monetary expenditure. We cannot predict whether any license of this nature would be available at all or whether it would be available on commercially reasonable terms. Furthermore, even in the absence of litigation, we may need to obtain licenses from third parties to advance our research or allow commercialization of our product candidates and we may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all. In that event, we would be unable to further develop and commercialize our product candidates, which could significantly harm our business.

***Neon's use of open source software could impose limitations on its ability to commercialize its products.***

Our use of open source software could impose limitations on our ability to commercialize our products. Our products utilize open source software that contain modules licensed for use from third-party authors under open source licenses. In particular, some of the software that powers RECON may be provided under license arrangements that allow use of the software for research or other non-commercial purposes. As a result, in the future, as we seek to use RECON in connection with commercially available products, we may be required to license that software under different license terms, which may not be possible on commercially reasonable terms, if at all. If we are unable to license software components on terms that permit its use for commercial purposes, we may be required to replace those software components, which could result in delays, additional cost and/ or additional regulatory approvals.

Use and distribution of open source software may entail greater risks than use of third-party commercial software as open source licensors generally do not provide warranties or other contractual protections regarding infringement claims or the quality of the software code. Some open source licenses contain requirements that we make available source code for modifications or derivative works we create based upon the type of open source

software we use. If we combine our proprietary software with open source software in a certain manner, we could, under certain of the open source licenses, be required to release the source code of our proprietary software to the public. This could allow our competitors to create similar products with lower development effort and time, and ultimately could result in a loss of product sales for us. Although we monitor our use of open source software, the terms of many open source licenses have not been interpreted by U.S. courts, and there is a risk that those licenses could be construed in a manner that could impose unanticipated conditions or restrictions on our ability to commercialize our products. In that case we could be required to seek licenses from third parties in order to continue offering our products, to re-engineer our products or to discontinue the sale of our products in the event re-engineering cannot be accomplished on a timely basis, any of which could materially and adversely affect our business, financial condition, prospects and results of operations.

***Third parties may assert that Neon's employees or consultants have wrongfully used or disclosed confidential information or misappropriated trade secrets.***

As is common in the biotechnology and pharmaceutical industries, we employ individuals who were previously employed at universities or other biopharmaceutical or pharmaceutical companies, including our competitors or potential competitors. Although we there are no currently pending misappropriation or improper disclosure claims and although we try to ensure that our employees and consultants do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed intellectual property, including trade secrets or other proprietary information, of a former employer or other third parties. We may then have to pursue litigation to defend against these claims. If we fail in defending any claims of this nature, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against these types of claims, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses and could distract our technical and management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments, and, if securities analysts or investors perceive these results to be negative, that perception could have a substantial adverse effect on the price of our common stock. This type of litigation or proceeding could substantially increase our operating losses and reduce our resources available for development activities. We may not have sufficient financial or other resources to adequately conduct this type of litigation or proceedings. Some of our competitors may be able to sustain the costs of this type of litigation or proceedings more effectively than we can because of their substantially greater financial resources. Uncertainties resulting from the initiation and continuation of intellectual property litigation or other intellectual property related proceedings could adversely affect our ability to compete in the marketplace.

***Neon may not be successful in obtaining or maintaining necessary rights to product components and processes for Neon's development pipeline through acquisitions and in-licenses.***

Presently, we have intellectual property rights through licenses from third parties to develop certain of our product candidates and we have filed and may continue to file additional patent applications of our own in the future that may be directed to some or all of these or other product candidates. Because our programs may involve additional product candidates that may require the use of proprietary rights held by third parties, the growth of our business will likely depend in part on our ability to acquire, in-license or use these proprietary rights.

Our product candidates may also require specific formulations to work effectively and efficiently and these rights may be held by others. We may develop products containing our compounds and pre-existing pharmaceutical compounds. We may be required by the FDA or comparable foreign regulatory authorities to provide a companion diagnostic test or tests with our product candidates, which test or tests may be covered by intellectual property rights held by others. We may be unable to 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

or important to our business operations. In addition, we may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all, which would harm our business. Were that to happen, we may need to cease use of the compositions or methods covered by those third-party intellectual property rights and seek to develop alternative approaches that do not infringe on those intellectual property rights, which may entail additional costs and development delays, even if we were able to develop such alternatives, which may not be feasible. Even if we are able to obtain a license, it may be non-exclusive, which means that our competitors may also receive access to the same technologies licensed to us. In that event, we may be required to expend significant time and resources to develop or license replacement technology.

Additionally, we sometimes collaborate with academic institutions to accelerate our preclinical research or development under written agreements with these institutions. In certain cases, these institutions provide us with an option to negotiate a license to any of the institution's rights in technology resulting from the collaboration. Regardless of whether we hold that type of option, we may be unable to negotiate a license from the institution within the specified timeframe or under terms that are acceptable to us. If we are unable to do so, the institution may offer the intellectual property rights to others, potentially blocking our ability to pursue our program. If we are unable to successfully obtain rights to required third-party intellectual property or to maintain our existing intellectual property rights, we may have to abandon development of a program our business financial condition, prospects and results of operations could suffer.

The licensing and acquisition of third-party intellectual property rights is a competitive area and companies, that may be more established or have greater resources than we do may also be pursuing strategies to license or acquire third-party intellectual property rights that we may consider necessary or attractive in order to commercialize our product candidates. More established companies may have a competitive advantage over us due to their size, cash resources and greater clinical development and commercialization capabilities. There can be no assurance that we will be able to successfully complete these types of negotiations and ultimately acquire the rights to the intellectual property surrounding the additional product candidates that we may seek to develop or market.

***Neon may be involved in lawsuits to protect or enforce Neon's patents or the patents of its licensors, which could be expensive, time-consuming and unsuccessful.***

Competitors may infringe our patents or the patents of our licensors. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming. In addition, in an infringement proceeding, a court may decide that one or more of our patents is not valid or is unenforceable or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation or defense proceedings could put one or more of our patents at risk of being invalidated, held unenforceable or interpreted narrowly and could put our patent applications at risk of not issuing. Defense of these types of claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business.

We may choose to challenge the patentability of claims in a third party's U.S. patent by requesting that the USPTO review the patent claims in an *ex-parte* re-examination, *inter partes* review or post-grant review proceedings. These proceedings are expensive and may consume our time or other resources. We may choose to challenge a third party's patent in patent opposition proceedings in the European Patent Office, or EPO, or another foreign patent office. The costs of these opposition proceedings could be substantial, and may consume our time or other resources. If we fail to obtain a favorable result at the USPTO, EPO or other patent office then we may be exposed to litigation by a third party alleging that the patent may be infringed by our product candidates or proprietary technologies.

In addition, because some patent applications in the United States may be maintained in secrecy until the patents are issued, patent applications are typically not published in the United States until 18 months after their

respective filing dates. Further, publications in the scientific literature often lag behind actual discoveries. Consequently, we cannot be certain that others have not filed patent applications for technology covered by our owned and in-licensed issued patents or our pending applications, or that we or, if applicable, a licensor were the first to invent the technology. It is possible that our competitors may have filed, and may in the future file, patent applications covering our products or technology similar to ours and that those patent applications may have priority over our owned and in-licensed patent applications or patents, which could require us to obtain rights to issued patents covering such technologies. If another party has filed a U.S. patent application on inventions similar to those owned by or in-licensed to us, we or, in the case of in-licensed technology, the licensor may have to participate in an interference proceeding declared by the USPTO to determine priority of invention in the United States. If we or one of our licensors is a party to an interference proceeding involving a U.S. patent application on inventions owned by or in-licensed to us, we may incur substantial costs, divert management's time and expend other resources, even if we are successful.

Interference proceedings provoked by third parties or brought 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 in an interference proceeding could result in a loss of our current patent rights and 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. Litigation or interference proceedings may result in a decision adverse to our interests and, even if we are successful, may result in substantial costs and distract our management and other employees.

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. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, that perception could have a substantial adverse effect on the price of our common stock.

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

Periodic maintenance fees on any issued patent are due to be paid to the USPTO and foreign patent agencies in several stages over the lifetime of the patent. The USPTO and various foreign governmental patent agencies also require compliance with a number of procedural, documentary, fee payment and other provisions during the patent application process and following the issuance of a patent. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance 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.

Noncompliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. Were a noncompliance event to occur, our competitors might be able to enter the market, which would have a material adverse effect on our business.

***Issued patents covering Neon's product candidates could be found invalid or unenforceable if challenged in court, the USPTO or in foreign jurisdictions.***

If we or one of our licensing partners initiate legal proceedings against a third party to enforce a patent covering one of our product candidates, the defendant could counterclaim that the patent covering our product candidate, as applicable, is invalid and/or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity and/or unenforceability are commonplace and there are numerous grounds upon which a third party can assert invalidity or unenforceability of a patent. Third parties may also raise similar

claims before administrative bodies in the United States or abroad, even outside the context of litigation. These types of mechanisms include re-examination, post grant review and equivalent proceedings in foreign jurisdictions (e.g., opposition proceedings). These types of proceedings could result in revocation or amendment to our patents such that they no longer cover our product candidates. The outcome for any particular patent following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which we, our patent counsel and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, or if we are otherwise unable to adequately protect our rights, we would lose at least part, and perhaps all, of the patent protection on our product candidates. A loss of patent protection for our product candidates could have a material adverse impact on our ability to commercialize or license our technology and product candidates and, as a result, on our business, financial condition, prospects and results of operations. In 2018, one of our in-licensed European patents related to our NEO-PV-01 and NEO-PTC-01 product candidates was involved in a European opposition proceeding at the EPO involving several opponents. Following an oral hearing, the EPO decided to revoke this in-licensed patent, which is one asset within our broader intellectual property portfolio that relates to our personal neoantigen product candidates. We and our licensors filed an appeal of this decision and, over what we believe will be a multi-year period while the appeal is pending at the EPO, the claims in the originally granted patent remain effective and enforceable. If we are unsuccessful in this appeal, we will be unable to assert this patent against our competitors marketing products in relevant European countries that would have been deemed to be infringing.

Likewise, our in-licensed patents directed to our proprietary technologies and our product candidates are expected to expire in 2031, without taking into account any possible patent term adjustments or extensions. Our earliest in-licensed patents may expire before, or soon after, our first product achieves marketing approval in the United States or foreign jurisdictions. Upon the expiration of our current patents, we may lose the right to exclude others from practicing these inventions. The expiration of these patents could also have a similar material adverse effect on our business, financial condition, prospects and results of operations. We own or in-license pending patent applications directed to proprietary technologies or our product candidates that, if issued as patents, are expected to expire from 2031 through 2038, without taking into account any possible patent term adjustments or extensions. However, we cannot be assured that the USPTO or relevant foreign patent offices will grant any of these patent applications.

***Changes in patent law in the United States and in non-U.S. jurisdictions could diminish the value of patents in general, thereby impairing Neon's ability to protect its products.***

As is the case with other biopharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biopharmaceutical industry involve both technological and legal complexity and is therefore costly, time-consuming and inherently uncertain. In addition, the United States has recently enacted and is currently implementing wide-ranging patent reform legislation. 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, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future. For example, in the case, *Assoc. for Molecular Pathology v. Myriad Genetics, Inc.*, the U.S. Supreme Court held that certain claims to DNA molecules are not patentable. While we do not believe that any of our owned or in-licensed patents will be found invalid based on this decision, we cannot predict how future decisions by the courts, the U.S. Congress or the USPTO may impact the value of our patents. Any similar any adverse changes in the patent laws of other jurisdictions could also have a material adverse effect on our business, financial condition, prospects and results of operations.

***Neon has limited foreign intellectual property rights and may not be able to protect Neon's intellectual property rights throughout the world.***

We have limited intellectual property rights outside the United States. Filing, prosecuting and defending patents on 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 foreign countries do not protect intellectual property rights to the same extent as federal and state laws in 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 into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we have patent protection but where enforcement is not as strong as that in the United States. These products may compete with our products in jurisdictions where we do not have any issued patents and our patent claims 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 biopharmaceutical products, which could make it difficult for us to stop the infringement of our patents or marketing of competing products against third parties in violation of our proprietary rights generally. The initiation of proceedings by third parties to challenge the scope or validity of our patent rights in foreign jurisdictions could result in substantial cost and divert our efforts and attention from other aspects of our business. Proceedings to enforce our patent rights in foreign 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 license.

***Neon may incur substantial costs as a result of litigation or other proceedings relating to patents and Neon may be unable to protect Neon's rights to its products and technology.***

If we or our licensors choose to go to court to stop a third party from using the inventions claimed in our owned or in-licensed patents, that third party may ask the court to rule that our patents are invalid and/or should not be enforced against that third party. These types of lawsuits are expensive and would consume time and other resources even if we or our licensors, as the case may be, were successful in stopping the infringement of these patents. In addition, there is a risk that the court will decide that our patents are not valid and that we or our licensors, as the case may be, do not have the right to stop others from using the inventions in question.

There is also the risk that, even if the validity of our patents is upheld, the court will refuse to stop the third party on the ground that the third party's activities do not infringe our owned or in-licensed patents. In addition, the U.S. Supreme Court has recently changed some legal principles that affect patent applications, granted patents and assessment of the eligibility or validity of these patents. As a consequence, issued patents may be found to contain invalid claims according to the newly revised eligibility and validity standards. Some of our owned or in-licensed patents may be subject to challenge and subsequent invalidation or significant narrowing of claim scope in proceedings before the USPTO or during litigation under the revised criteria, which could also make it more difficult to obtain patents.

We or our licensors, as the case may be, may not be able to detect infringement against our owned or in-licensed patents, which may be especially difficult for manufacturing processes or formulation patents. Even if

we or our licensors detect infringement by a third party of our owned or in-licensed patents, we or our licensors, as the case may be, may choose not to pursue litigation against or settlement with the third party. If we, or our licensors later sue such third party for patent infringement, the third party may have certain legal defenses available to it that otherwise would not be available but for the delay between when the infringement was first detected and when the suit was brought. These legal defenses may make it impossible for us or our licensors to enforce our owned or in-licensed patents, as the case may be, against that third party.

If another party questions the patentability of any of our claims in our owned or in-licensed U.S. patents, the third party can request that the USPTO review the patent claims such as in an *inter partes* review, *ex parte* re-examination or post-grant review proceedings. These proceedings are expensive and may result in a loss of scope of some claims or a loss of the entire patent. In addition to potential USPTO review proceedings, we are currently, and may in the future become, party, to patent opposition proceedings at the EPO or similar proceedings in other foreign patent offices where either our owned or in-licensed foreign patents are challenged. In 2018, one of our in-licensed European patents related to our NEO-PV-01 and NEO-PTC-01 product candidates was involved in a European opposition proceeding at the EPO involving several opponents. Following an oral hearing, the EPO decided to revoke this in-licensed patent, which is one asset within our broader intellectual property portfolio that relates to the our personal neoantigen product candidates. We and our licensors filed an appeal of this decision and, over what we believe will be multi-year period while an appeal is pending at the EPO, the claims in the originally granted patent remain effective and enforceable. If we are unsuccessful in this appeal, we will be unable to assert this patent against our competitors marketing products in relevant European countries that would have been deemed to be infringing.

In the future, we may be involved in similar proceedings challenging the patent rights of others, and the outcome of that type of proceeding is highly uncertain. An adverse determination in any proceeding of that nature could reduce the scope of or invalidate our patent rights, allow third parties to commercialize our technology or products and compete directly with us without payment to us, or result in our inability to manufacture or commercialize products without infringing third-party patent rights. The costs of these opposition or similar proceedings could be substantial and may result in a loss of scope of some claims or a loss of the entire patent. An unfavorable result at the USPTO, EPO or other patent office may result in the loss of our right to exclude others from practicing one or more of our inventions in the relevant country or jurisdiction, which could have a material adverse effect on our business.

***Patent terms may be inadequate to protect Neon's competitive position on its product candidates for an adequate amount of time.***

Patents have a limited lifespan. In the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest U.S. non-provisional filing date. Various extensions may be available, but the life of a patent and the protection it affords is limited. Even if patents covering our product candidates are obtained, once the patent life has expired, we may be open to competition from competitive products, including biosimilars. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting our product candidates might expire before or shortly after we or our partners commercialize those candidates. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

***If Neon does not obtain patent term extension and data exclusivity for any product candidates Neon may develop, Neon's 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 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 per product 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, even if we were to seek a patent term extension, it may not be granted because of, for example, failing to exercise due diligence during the testing phase or regulatory review process, the failure to apply within applicable deadlines, the failure to apply prior to expiration of relevant patents or the failure otherwise to satisfy applicable requirements. Moreover, the applicable time period or the scope of patent protection afforded under an extension request could be less than we request. If we are unable to obtain patent term extension or if the term of any requested extension is less than we request, our competitors may obtain approval of competing products following our patent expiration, and our business, financial condition, prospects and results of operations could be materially harmed.

*Risks Related to Neon's Reliance on Third Parties*

***Neon will rely on third parties to conduct its clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines or comply with regulatory requirements, Neon may not be able to obtain regulatory approval of or commercialize any potential product candidates.***

We presently and, in the future, will depend upon third parties, including independent investigators, to conduct our clinical trials under agreements with universities, medical institutions, CROs, strategic partners and others. As a result, we have to negotiate budgets and contracts with CROs and trial sites, which may result in delays to our development timelines and increased costs.

We presently do, and in the future will continue to, rely heavily on third parties over the course of our clinical trials, and, as a result, will have limited control over the clinical investigators and limited visibility into their day-to-day activities, including with respect to their compliance with the approved clinical protocol. Nevertheless, our reliance on third parties does not relieve us of our regulatory responsibilities and we will be responsible for ensuring that each of our trials is conducted in accordance with the applicable protocol, legal and regulatory requirements and scientific standards. We and these third parties are required to comply with GCP requirements, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities for product candidates in clinical development. Regulatory authorities enforce these GCP requirements through periodic inspections of trial sponsors, clinical investigators and trial sites. If we or any of these third parties fail to comply with applicable GCP requirements, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to suspend or terminate these trials or perform additional nonclinical studies or clinical trials before approving our marketing applications. We cannot be certain that, upon inspection, regulatory authorities will determine that any of our clinical trials comply with the applicable GCP requirements. In addition, our clinical trials must be conducted with biologic products produced under cGMP requirements and may require a large number of patients.

Our failure or any failure by these third parties to comply with these applicable regulations or to recruit a sufficient number of patients may require us to repeat clinical trials, which would delay the regulatory approval process. Moreover, our business may be implicated if any of these third parties violates federal or state fraud and abuse or false claims laws and regulations or healthcare privacy and security laws.

The third parties who presently or may in the future conduct our clinical trials will not be our employees and, except for remedies that may be available to us under our agreements with those third parties, we cannot control whether or not they devote sufficient time and resources to our ongoing nonclinical and clinical programs. These third parties may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials or other product development activities, which could affect their performance on our behalf. If these third parties do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the

clinical data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated and we may not be able to complete development of, obtain regulatory approval of or successfully commercialize our product candidates in a timely manner or at all. As a result, our financial results and the commercial prospects for our product candidates would be harmed, our costs could increase and our ability to generate revenue could be delayed.

If any of our relationships with these third-party CROs or others terminate, we may not be able to enter into arrangements with alternative CROs or other third parties or to do so on commercially reasonable terms. Switching or adding additional CROs involves additional cost and requires management time and focus. In addition, there is a natural transition period when a new CRO begins work. As a result, delays may occur, which can materially impact our ability to meet our desired clinical development timelines. Though we carefully manage our relationships with our CROs, there can be no assurance that we will not encounter similar challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition and prospects.

***Neon expects to rely on third parties to manufacture Neon's clinical product supplies, and Neon intends to rely on third parties to produce and process its product candidates, if approved.***

We do not currently own any facility that may be used as our clinical-scale manufacturing and processing facility and expect to rely on outside vendors to manufacture supplies and process our product candidates. We have not yet caused any product candidates to be manufactured or processed on a commercial scale and may not be able to do so for any of our product candidates. We will make changes as we work to optimize the manufacturing process. For example, we may switch or be required to switch from non-cGMP materials to commercial grade materials in order to get regulatory approval of our product candidates. We cannot be sure that even minor changes in the process will result in therapies that are safe and effective and approved for commercial sale.

The facilities used by our contract manufacturers to manufacture our product candidates must be approved by the FDA or other foreign regulatory agencies following inspections that will be conducted after we submit an application to the FDA or other foreign regulatory agencies. We do not directly control the manufacturing process of, and will be completely dependent on, our contract manufacturing partners for compliance with regulatory requirements, known as cGMP requirements, for the manufacture of our product candidates. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or other regulatory authorities, they will not be able to secure and/or maintain regulatory approval for their manufacturing facilities. For instance, for NEO-PTC-01, our outside vendors will harvest T cells from a patient and then prime, activate and expand those T cells *ex vivo* to create a T cell therapy for that patient that will ultimately be infused back into the patient's body. As a result of these complexities, the cost to manufacture our product candidates is generally higher than traditional small molecule chemical compounds and the manufacturing process is less reliable and is more difficult to reproduce. In addition, we have no direct control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or a comparable foreign regulatory authority does not approve these facilities for the manufacture of our product candidates or if it finds deficiencies with or withdraws any approval in the future, 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, if approved.

***Neon's existing and future collaborations will be important to its business. If Neon is unable to enter into or maintain any of these collaborations, or if these collaborations are not successful, Neon's business could be adversely affected.***

We have limited capabilities for product development and do not yet have any capability for sales, marketing or distribution. Accordingly, we have entered into collaborations with other companies to provide us

with important technologies for our programs and technology and we expect to receive additional technologies under these and other collaborations in the future. Our existing therapeutic collaborations and any future collaborations we may enter into may pose a number of risks, including the following:

- collaborators have significant discretion in determining the efforts and resources that they will apply;
- collaborators may not perform their obligations as expected;
- 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 programs or license arrangements based on clinical trial results, changes in the collaborators' strategic focus or available funding or external factors, such as a strategic transaction that may divert resources or create competing priorities;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or 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 products and product candidates if the collaborators believe that the competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours;
- product candidates discovered in collaboration 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 commercialization of our product candidates;
- collaborators may fail to comply with applicable regulatory requirements regarding the development, manufacture, distribution or marketing of a product candidate or product;
- collaborators 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 our product or products;
- disagreements with collaborators, including disagreements over proprietary rights, contract interpretation or the preferred course of development, might cause delays or terminations of the research, development or commercialization of product candidates, might lead to additional responsibilities for us with respect to product candidates or might result in litigation or arbitration, any of which would be time-consuming and expensive;
- collaborators may not properly maintain or defend our intellectual property rights or may use our proprietary information in a manner that may invite litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential litigation;
- collaborators may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability;
- if a collaborator of ours is involved in a business combination, the collaborator might deemphasize or terminate the development or commercialization of any product candidate we licensed to it; and
- collaborations may be terminated by the collaborator, and, if terminated, we could be required to raise additional capital to pursue further development or commercialization of the applicable product candidates.

If our collaborations do not result in the successful discovery, development and commercialization of products or if one of our collaborators terminates its agreement with us, we may not receive any anticipated future benefits under the collaboration, our development of our technology and product candidates could be delayed and we may need additional resources to develop product candidates and our technology. All of the risks relating to product development, regulatory approval and commercialization described in this filing also apply to the activities of our therapeutic collaborators.

Additionally, if one of our collaborators terminates its agreement with us, we may find it more difficult to attract new collaborators as the way we are perceived in the business and financial communities could be adversely affected.

For some of our programs, we may in the future determine to collaborate with pharmaceutical and biotechnology companies for development and potential commercialization of product candidates. Collaborations are complex and time-consuming to negotiate and document. 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. We face significant competition in seeking appropriate collaborations. Our ability to 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. If we are unable to reach agreements with suitable collaborators on a timely basis, on acceptable terms, or at all, we may have to curtail the development of a product candidate, reduce or delay one or more of our other development programs, delay a product candidate's potential commercialization, reduce the scope of any sales or marketing activities or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to increase our expenditures to fund development or commercialization activities on our own, we may need to obtain additional expertise and additional capital, which may not be available to us on acceptable terms, or at all. If we fail to enter into collaborations or do not have sufficient funds or expertise to undertake the necessary development and commercialization activities, we may not be able to further develop our product candidates, bring them to market and generate revenue from sales of drugs or continue to develop our technology and our business may be materially and adversely affected.

***Neon is dependent on single-source suppliers for some of the components and materials used in and the processes required to develop Neon's product candidates.***

We currently depend on single-source suppliers for some of the components and materials used in and processes required to develop our product candidates. We cannot ensure that these suppliers or service providers will remain in business, 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. For example, we obtain our vaccine adjuvant, poly-ICLC, which is administered simultaneously with NEO-PV-01, from a single-source supplier. Additionally, we rely on a single-source supplier to manufacture our peptides and a single source for the manufacture of our T cell product candidate NEO-PTC-01. There are, in general, relatively few alternative sources of supply for substitute components. Our current 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, prospects and results of operations.

If we were to have to switch to a replacement supplier, the manufacture and delivery of our product candidates or components of our product candidates could be interrupted for an extended period, which could adversely affect our business. We may not be able to quickly establish additional or replacement suppliers for the adjuvants, peptides or any of the components or processes used in our product candidates, if required. If we are able to find a replacement supplier, the replacement supplier would need to be qualified, which might require additional regulatory authority approval, which could result in further delay. For example, the FDA or other comparable foreign regulatory authority could require additional supplemental data and clinical trial data if we rely upon a new supplier for the adjuvants and peptides used in our product candidates. 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, or at all, in a timely manner, could impair our ability to meet the demand of our customers and cause them to cancel orders.

In addition, as part of the FDA's or other regulatory authority's approval of our product candidates, we will also require FDA or other regulatory authority approval of the individual components of our process, which include the manufacturing processes and facilities of our single-source suppliers. Our current single-source suppliers have not undergone this process, nor have they had any components included in any product approved by the FDA.

Our reliance on these suppliers, service providers and manufacturers subjects us to a number of risks that could harm our reputation, business, financial condition, prospects and results of operations, 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 products 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;
- increased cost of our warranty program due to product repair or replacement based upon defects in 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, our costs could significantly increase and our ability to meet demand for our products could be impacted.

*Risks Related to Neon Common Stock*

***Neon does not know whether there will be an active, liquid and orderly trading market for Neon common stock or what the market price of its common stock will be and, as a result, it may be difficult for Neon stockholders to sell their shares of Neon common stock.***

We became a public company in June 2018 and accordingly there is only a limited history of there being a public market for shares of our common stock. An active trading market for our shares may never develop or be sustained and, as a result, you may not be able to sell your shares quickly or at the market price if trading in shares of our common stock is not active. Further, an inactive market may also impair our ability to raise capital by selling shares of our common stock and may impair our ability to enter into strategic partnerships or acquire companies or products by using our shares of common stock as consideration.

***The price of Neon's stock may be volatile and Neon stockholders could lose all or part of their investments.***

The trading price of our common stock is likely to be highly volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control, including limited trading volume. In addition to the factors discussed in this "Risk Factors" section, these factors may include:

- the commencement, enrollment or results of our ongoing clinical trials or any future clinical trials we may conduct or changes in the development status of our product candidates;
- any delay in our regulatory filings for our product candidates and any adverse development or perceived adverse development with respect to the applicable regulatory authority's review of our regulatory filings, including without limitation the FDA's issuance of a "refusal to file" letter, a clinical hold or a request for additional information;
- adverse results or delays in clinical trials;
- our decision to initiate a clinical trial, not to initiate a clinical trial or to terminate an existing clinical trial;
- adverse regulatory decisions, including failure to receive regulatory approval of our product candidates;
- changes in laws or regulations applicable to our products, including but not limited to clinical trial requirements for approvals;
- adverse developments concerning our manufacturers;
- our inability to obtain adequate product supply for any approved product or inability to do so at acceptable prices;
- our inability to establish collaborations if and when needed;
- our failure to commercialize our product candidates;
- additions or departures of key scientific or management personnel;
- serious safety concerns related to the use of our product candidates;
- introduction of new products or services offered by us or our competitors;
- announcements of significant acquisitions, strategic partnerships, joint ventures or capital commitments by us or our competitors;
- our ability to effectively manage our growth;
- the size and growth of our initial cancer target markets;
- our ability to successfully treat additional types of cancers or cancers at different stages;
- actual or anticipated variations in quarterly operating results;
- our cash position;
- our failure to meet the estimates and projections of the investment community or that we may otherwise provide to the public;
- publication of research reports about us or our industry or neoantigen-targeted therapies in particular, or positive or negative recommendations or withdrawal of research coverage by securities analysts;
- changes in the market valuations of similar companies;
- overall performance of the equity markets;
- sales of our common stock by us or our stockholders in the future;

- trading volume of our common stock;
- adoption of new accounting standards;
- ineffectiveness of our internal controls;
- disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;
- significant lawsuits, including intellectual property or stockholder litigation;
- general political and economic conditions; and
- other events or factors, many of which are beyond our control.

For instance, in January 2020, we announced entry into a definitive agreement for the acquisition of our company by BioNTech, which we expect to close in the second quarter of 2020. As a result of this announcement, the trading price of our common stock is likely to be volatile and could be subject to wide fluctuations.

In addition, the stock market in general, and the market for biopharmaceutical companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Broad market and industry factors may negatively affect the market price of our common stock, regardless of our actual operating performance. In the past, securities class action litigation has often been instituted against companies following periods of volatility in the market price of a company's securities. This type of litigation, if instituted, could result in substantial costs and a diversion of management's attention and resources, which would harm our business, financial condition, prospects and results of operations.

***Neon does not intend to pay dividends on Neon's common stock so any returns will be limited to the value of its stock.***

We currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. Any return to stockholders will therefore be limited to the appreciation of their stock.

***Neon's principal stockholders and management own a significant percentage of its stock and will be able to exert significant control over matters subject to stockholder approval.***

Our executive officers and directors and Third Rock Ventures III, L.P., a venture capital fund affiliated with certain of our directors, beneficially held, as of December 31, 2019, in the aggregate, approximately 39% of our outstanding voting stock. Therefore, these stockholders and other principal stockholders will have the ability to influence us through their ownership positions. These stockholders may be able to determine all matters requiring stockholder approval. For example, these stockholders may be able to control 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 common stock that you may feel are in your best interest as one of our stockholders.

***Neon is an emerging growth company, and Neon cannot be certain if the reduced reporting requirements applicable to emerging growth companies will make Neon's common stock less attractive to investors.***

We are an emerging growth company, as defined in the Jumpstart Our Business Startups Act, or the JOBS Act, which was enacted in April 2012. For as long as we continue to be an emerging growth company, we may

take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies, including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, as amended, or the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements and exemptions from the requirements of holding nonbinding advisory votes on executive compensation and stockholder approval of any golden parachute payments not previously approved. We could be an emerging growth company for up to five years following the year in which we complete our IPO, which occurred in June 2018, although circumstances could cause us to lose that status earlier. We will remain an emerging growth company until the earlier of (1) the last day of the fiscal year (a) following the fifth anniversary of the completion of our IPO, (b) in which we have total annual gross revenue of at least $1.07 billion or (c) in which we are deemed to be a large accelerated filer, which requires the market value of our common stock that is held by non-affiliates to exceed $700 million as of the prior June 30th, and (2) the date on which we have issued more than $1 billion in non-convertible debt during the prior three-year period. We cannot predict if investors will find our common stock less attractive because we may rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile.

Under the JOBS Act, emerging growth companies can also delay adopting new or revised accounting standards until such time as those standards apply to private companies. We have irrevocably elected not to avail ourselves of this exemption from new or revised accounting standards and, therefore, will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies. As a result, changes in rules of U.S. generally accepted accounting principles or their interpretation, the adoption of new guidance or the application of existing guidance to changes in our business could significantly affect our financial position and results of operations.

***Neon is a "smaller reporting company" and the reduced disclosure requirements applicable to smaller reporting companies may make Neon's common stock less attractive to investors.***

We are considered a "smaller reporting company" under Rule 12b-2 of the Exchange Act. We are therefore entitled to rely on certain reduced disclosure requirements, such as an exemption from providing selected financial data and executive compensation information. These exemptions and reduced disclosures in our SEC filings due to our status as a smaller reporting company also mean our auditors are not required to review our internal control over financial reporting and may make it harder for investors to analyze our results of operations and financial prospects. We cannot predict if investors will find our common stock less attractive because we may rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our common stock prices may be more volatile. We will remain a smaller reporting company until our public float exceeds $250 million or our annual revenues exceed $100 million with a public float greater than $700 million.

***Neon incurs significant costs as a result of operating as a public company and Neon's management is required to devote substantial time to new compliance initiatives.***

As a public company, and particularly after we are no longer an "emerging growth company" or a "smaller reporting company" under applicable SEC regulations, we incur and will continue to incur significant legal, accounting and other expenses. We will be subject to the reporting requirements of the Securities Exchange Act of 1934, as amended, or the Exchange Act, which will require, among other things, that we file with the SEC annual, quarterly and current reports with respect to our business and financial condition. In addition, the Sarbanes-Oxley Act, as well as rules subsequently adopted by the SEC and the Nasdaq Global Select Market to implement provisions of the Sarbanes-Oxley Act, impose significant requirements on public companies, including requiring establishment and maintenance of effective disclosure and financial controls and changes in corporate governance practices. Further, in July 2010, Congress enacted the Dodd-Frank Wall Street Reform and Consumer Protection Act, or the Dodd-Frank Act. 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 their initial public offerings. 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. If that were to happen, we would incur additional and unexpected expenses. Stockholder 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.

We expect the rules and regulations applicable to public companies to substantially increase our legal and financial compliance costs and to make some activities more time-consuming and costly. If these requirements divert the attention of our management and personnel from other business concerns, they could have a material adverse effect on our business, financial condition, prospects and results of operations. The increased costs will decrease our net income or increase our net loss and may require us to reduce costs in other areas of our business or increase the prices of our products or services. For example, we expect these rules and regulations to make it more difficult and more expensive for us to obtain director and officer liability insurance and we may be required to incur substantial costs to maintain the same or similar coverage. We cannot predict or estimate the amount or timing of additional costs we may incur to respond to these requirements. The impact of these requirements could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, our board committees or as executive officers.

***Sales of a substantial number of shares of Neon's common stock by its existing stockholders in the public market could cause its stock price to fall.***

If our pre-initial public offering stockholders sell, or indicate an intention to sell, substantial amounts of our common stock in the public market after the lapsing of any applicable legal restrictions on resale, the trading price of our common stock could decline.

Shares held by directors, executive officers and other affiliates may be subject to certain limitations of Rule 144 under the Securities Act of 1933, as amended, or the Securities Act. In addition, shares of common stock that are either subject to outstanding options or reserved for future issuance under our existing equity compensation plans will become eligible for sale in the public market to the extent permitted by the provisions of various vesting schedules, any lock-up agreements and Rule 144 under the Securities Act. If these additional shares of common stock are sold, or if it is perceived that they will be sold, in the public market, the trading price of our common stock could decline. Additionally, the number of shares of our common stock reserved for issuance under our 2018 Stock Option and Incentive Plan automatically increases on each January 1 by 4% of the outstanding number of shares of our common stock on the immediately preceding December 31 or such lesser number of shares as determined by our compensation committee. Unless our compensation committee elects not to increase the number of shares available for future grant each year, our stockholders may experience additional dilution.

Certain of our stockholders are entitled to rights with respect to the registration of their shares under the Securities Act. Registration of these shares under the Securities Act would result in the shares becoming freely tradable without restriction under the Securities Act, except for shares held by affiliates, as defined in Rule 144 under the Securities Act. Any sales of securities by these stockholders could have a material adverse effect on the trading price of our common stock.

On July 1, 2019, we 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, our common stock, convertible securities or other equity securities in one or more offerings.

We also simultaneously entered into a Controlled Equity Offering Sales Agreement, or the Sales Agreement, with Cantor Fitzgerald & Co., or the Sales Agent, to provide for the offering, issuance and sale of up to an aggregate amount of $50.0 million of our common stock from time to time in "at-the-market" offerings under the Shelf Registration Statement and subject to the limitations thereof. As of December 31, 2019, we have sold $0.4 million of our common stock in "at the market offerings" under the Shelf Registration Statement, prior to applicable commissions under the Sales Agreement. We pay to the Sales Agent cash commissions of 3.0% of the aggregate gross proceeds of sales of common stock under the Sales Agreement. Sales of common stock, convertible securities or other equity securities by us under the Shelf Registration Statement may represent a significant percentage of our common stock currently outstanding. If we sell, or the market perceives that we intend to sell, substantial amounts of our common stock under the Shelf Registration Statement or otherwise, the market price of our common stock could decline significantly.

***Neon has broad discretion in the use of Neon's existing cash, cash equivalents and marketable securities and may not use them effectively.***

Our management has broad discretion in the application of our existing cash, cash equivalents and marketable securities and you will not have the opportunity as part of your investment decision to assess whether these proceeds are being used appropriately. Because of the number and variability of factors that will determine our use of our existing cash, cash equivalents and marketable securities, their ultimate use may vary substantially from their currently intended use. Our management might not apply our existing cash, cash equivalents and marketable securities in ways that ultimately increase the value of your investment. The failure by our management to apply these funds effectively could harm our business. Pending their use, we may invest our cash in short-term, investment-grade, interest-bearing securities. These investments may not yield a favorable return to our stockholders. If we do not invest our cash in ways that enhance stockholder value, we may fail to achieve expected financial results, which could cause our stock price to decline.

***Neon's operating results may fluctuate significantly, which makes its future operating results difficult to predict and could cause its operating results to fall below expectations or its guidance.***

Our quarterly and annual operating results may fluctuate significantly in the future, which makes it difficult for us to predict our future operating results. From time to time, we may enter into license or collaboration agreements with other companies that include development funding and significant upfront and milestone payments and/or royalties, which may become an important source of our revenue. Accordingly, our revenue may depend on development funding and the achievement of development and clinical milestones under any potential future license and collaboration agreements and sales of our products, if approved. These upfront and milestone payments may vary significantly from period to period and any variance could cause a significant fluctuation in our operating results from one period to the next.

In addition, we measure compensation cost for stock-based awards made to employees at the grant date of the award, based on the fair value of the award as determined by our board of directors, and recognize the cost as an expense over the employee's requisite service period. As the variables that we use as a basis for valuing these awards change over time, our underlying stock price and stock price volatility, the magnitude of the expense that we must recognize may vary significantly.

Further, our operating results may fluctuate due to a variety of other factors, many of which are outside of our control and may be difficult to predict, including the following:

- the timing and cost of, and level of investment in, research and development activities relating to our current and any future product candidates, which will change from time to time;
- our ability to enroll patients in clinical trials and the timing of enrollment;
- the cost of manufacturing our current and any future product candidates, which may vary depending on FDA or other regulatory authority guidelines and requirements, the quantity of production and the terms of our agreements with manufacturers;

- expenditures that we will or may incur to acquire or develop additional product candidates and technologies;
- the timing and outcomes of clinical studies for our product candidates or the timing and outcomes of clinical trials for competing product candidates;
- competition from existing and potential future products that compete with our product candidates and changes in the competitive landscape of our industry, including consolidation among our competitors or partners;
- any delays in regulatory review or approval of our product candidates;
- the level of demand for our product candidates, if approved, which may fluctuate significantly and be difficult to predict;
- the risk/benefit profile, cost and reimbursement policies with respect to our products candidates, if approved, and existing and potential future products that compete with our product candidates;
- our ability to commercialize our product candidates, if approved, within and outside of the United States, either independently or working with third parties;
- our ability to adequately support our future growth;
- potential unforeseen business disruptions that increase our costs or expenses;
- future accounting pronouncements or changes in our accounting policies; and
- the changing and volatile global economic environment.

The cumulative effect of these factors could result in large fluctuations and unpredictability in our quarterly and annual operating results. As a result, comparing our operating results on a period-to-period basis may not be meaningful. Investors should not rely on our past results as an indication of our future performance. This variability and unpredictability could also result in our failing to meet the expectations of industry or financial analysts or investors for any period. If our revenue or operating results fall below the expectations of analysts or investors or below any forecasts we may provide to the market or if the forecasts we provide to the market are below the expectations of analysts or investors, the price of our common stock could decline substantially. The price of our common stock could decline even when we have met any previously publicly stated revenue and/or earnings guidance we may provide.

***Anti-takeover provisions under Neon's organizational documents and Delaware law could delay or prevent a change of control, which could limit the market price of its common stock and may prevent or frustrate attempts by its stockholders to replace or remove its current management.***

Our amended and restated certificate of incorporation and amended and restated bylaws contain provisions that could delay or prevent a change of control of our company or changes in our board of directors that our stockholders might consider favorable. Some of these provisions include:

- a board of directors divided into three classes serving staggered three-year terms, such that not all members of the board will be elected at one time;
- a prohibition on stockholder action through written consent, which requires that all stockholder actions be taken at a meeting of our stockholders;
- a requirement that special meetings of stockholders may only be called only by the chairman of the board of directors, the chief executive officer or by a majority of the total number of authorized directors;
- advance notice requirements for stockholder proposals and nominations for election to our board of directors;

- a requirement that no member of our board of directors may be removed from office by our stockholders except for cause and, in addition to any other vote required by law, upon the approval of not less than two-thirds (2/3) of all outstanding shares of our voting stock then entitled to vote in the election of directors;
- a requirement of approval of not less than two-thirds (2/3) of all outstanding shares of our voting stock to amend any bylaws by stockholder action or to amend specific provisions of our certificate of incorporation; and
- the authority of the board of directors to issue preferred stock on terms determined by the board of directors without stockholder approval, which preferred stock may include rights superior to the rights of the holders of common stock.

In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporate Law, which may prohibit certain business combinations with stockholders owning 15% or more of our outstanding voting stock. These anti-takeover provisions and other provisions in our amended and restated certificate of incorporation and amended and restated bylaws could make it more difficult for stockholders or potential acquirers to obtain control of our board of directors or initiate actions that are opposed by the then-current board of directors and could also delay or impede a merger, tender offer or proxy contest involving our company. These provisions could also discourage proxy contests and make it more difficult for you and other stockholders to elect directors of your choosing or cause us to take other corporate actions you desire. Any delay or prevention of a change of control transaction or changes in our board of directors could cause the market price of our common stock to decline.

***If securities or industry analysts do not publish research or publish inaccurate or unfavorable research about Neon's business, its stock price and trading volume could decline.***

The trading market for our common stock will depend in part on the research and reports that securities or industry analysts publish about us or our business. If one or more of the analysts who covers us downgrades our stock or publishes inaccurate or unfavorable research about our business, our stock price may decline. If one or more of these analysts ceases coverage of our company or fails to publish reports on us regularly, demand for our stock could decrease, which might cause our stock price and trading volume to decline.

***Neon's amended and restated bylaws designate specific courts as the exclusive forum for certain litigation that may be initiated by Neon's stockholders, which could limit Neon's stockholders' ability to obtain a favorable judicial forum for disputes with Neon.***

Pursuant to our amended and restated bylaws, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware is the sole and exclusive forum for state law claims for (1) any derivative action or proceeding brought on our behalf; (2) any action asserting a claim of or based on a breach of a fiduciary duty owed by any of our current or former directors, officers or other employees to us or our stockholders; (3) any action asserting a claim against us or any of our current or former directors, officers, employees or stockholders arising pursuant to any provision of the Delaware General Corporation Law, our amended and restated certificate of incorporation or our amended and restated bylaws; or (4) any action asserting a claim governed by the internal affairs doctrine (the "Delaware Forum Provision"). The Delaware Forum Provision will not apply to any causes of action arising under the Securities Act or the Exchange Act. Our amended and restated bylaws further provide that, unless we consent in writing to the selection of an alternative forum, the United States District Court for the District of Massachusetts is the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act (the "Federal Forum Provision"). We have chosen the United States District Court for the District of Massachusetts as the exclusive forum for such Securities Act causes of action because our principal executive offices are located in Cambridge, Massachusetts. In addition, our amended and restated bylaws provide that any person or entity purchasing or otherwise acquiring

any interest in shares of our common stock is deemed to have notice of and consented to the foregoing Delaware Forum Provision and Federal Forum Provision.

In *Sciabacucchi v. Salzberg*, C.A. No. 2017-0931-JTL (Del. Ch.), the Court of Chancery of the State of Delaware issued a decision declaring that federal forum selection provisions that purport to require claims under the Securities Act be brought in federal court are ineffective and invalid under Delaware law. However, that decision was appealed to the Delaware Supreme Court and on March 18, 2020, the Delaware Supreme Court reversed the Court of Chancery and ruled that such federal forum provisions are "facially valid" under Delaware law. In light of the Delaware Supreme Court's ruling, we intend to enforce our Federal Forum Provision designating the District of Massachusetts as the exclusive forum for Securities Act claims.

We recognize that the Delaware Forum Provision and the Federal Forum Provision in our amended and restated bylaws may impose additional litigation costs on stockholders in pursuing any such claims, particularly if the stockholders do not reside in or near the State of Delaware or the Commonwealth of Massachusetts, as applicable. Additionally, the forum selection clauses in our amended and restated bylaws may limit our stockholders' ability to bring a claim in a judicial forum that they find favorable for disputes with us or our directors, officers or employees, which may discourage the filing of lawsuits against us and our directors, officers and employees even though an action, if successful, might benefit our stockholders. The Federal Forum Provision may also impose additional litigation costs on stockholders who assert the provision is not enforceable or invalid. The Court of Chancery of the State of Delaware or the United States District Court for the District of Massachusetts, as applicable, may also reach different judgments or results than would other courts, including courts where a stockholder considering an action may be located or would otherwise choose to bring the action, and such judgments may be more or less favorable to us than our stockholders.

## THE NEON SPECIAL MEETING

### Date, Time and Place of the Neon Special Meeting

The Neon Special Meeting will be held on May 4, 2020, at 10:00 a.m. Eastern Time, unless the Neon Special Meeting is adjourned or postponed. In light of COVID-19 (coronavirus) and to support the well-being of our stockholders and partners, the Neon Special Meeting will be completely virtual. Stockholders can attend the Neon Special Meeting by visiting www.virtualshareholdermeeting.com/NTGN2020.

### Purpose of the Neon Special Meeting

At the Neon Special Meeting, Neon stockholders will be asked to consider and vote upon the following matters:

- the Merger Proposal; and
- the Adjournment Proposal.

### Recommendation of the Neon Board

The Neon Board unanimously: (1) determined that the Merger Agreement and the transactions contemplated thereby, including the Merger, upon the terms and subject to the conditions set forth therein, were in the best interests of Neon stockholders; (2) approved and declared advisable the Merger Agreement and the transactions contemplated thereby in accordance with the requirements of the Delaware General Corporation Law, or the DGCL; and (3) recommended that Neon stockholders approve and adopt the Merger Agreement at the Neon Special Meeting.

The Neon Board recommends that Neon stockholders vote "**FOR**" the Merger Proposal and "**FOR**" the Adjournment Proposal.

### Record Date for the Neon Special Meeting; Stock Entitled to Vote

Only holders of record of shares of Neon common stock at the close of business on the record date of March 23, 2020, will be entitled to vote at the Neon Special Meeting. Each outstanding share of Neon common stock entitles its holder to cast one vote. As of the record date, there were 28,931,978 shares of Neon common stock outstanding and entitled to vote at the Neon Special Meeting.

### Quorum; Abstentions and Broker Non-Votes

A quorum is the minimum number of shares required to be present at the Neon Special Meeting for the meeting to be properly held under Neon's bylaws and Delaware law. The presence, online or represented by proxy, of a majority of all issued and outstanding shares of Neon common stock entitled to vote at the Neon Special Meeting will constitute a quorum at the meeting. In the absence of a quorum, the chairperson of the Neon Special Meeting or the affirmative vote of the holders of Neon common stock entitled to vote at the Neon Special Meeting, present in person or represented by proxy, will have the power to adjourn the Neon Special Meeting. As of the record date for the Neon Special Meeting, 14,465,990 shares of Neon common stock will be required to achieve a quorum.

Holders of shares of Neon common stock present online at the Neon Special Meeting but not voting, and shares of Neon common stock for which Neon has received proxies indicating that their holders have abstained, will be counted as present at the Neon Special Meeting for purposes of determining whether a quorum is established.

Under the rules that govern brokers who have record ownership of shares that are held in street name for their clients, the beneficial owners of the shares, brokers have discretion to vote these shares on routine matters

but not on non-routine matters. The approval of the Merger Proposal is not considered a routine matter. Accordingly, brokers will not have discretionary voting authority to vote on that matter at the Neon Special Meeting. A broker non-vote occurs when brokers do not have discretionary voting authority and have not received instructions from the beneficial owners of the shares on a particular non-routine matter. A broker will not be permitted to vote on the Merger Proposal without instruction from the beneficial owner of the shares of Neon common stock held by that broker. Accordingly, a broker non-vote will have the same effect as a vote "**AGAINST**" the Merger Proposal but will have no effect on the Adjournment Proposal. If you hold shares of Neon common stock through a broker, bank or other organization with custody of your shares, follow the voting instructions you receive from that organization.

**Vote Required**

Approval of the Merger Proposal requires the affirmative vote of the holders of a majority of the outstanding shares of Neon common stock entitled to vote on such matter. Accordingly, a Neon stockholder's failure to submit a proxy card or to vote online at the Neon Special Meeting, an abstention from voting, or the failure of a Neon stockholder who holds his or her shares in "street name" through a broker or other nominee to give voting instructions to such broker or other nominee, will have the same effect as a vote "**AGAINST**" the proposal to approve the Merger Agreement.

Approving the Adjournment Proposal (if it is necessary or appropriate to solicit additional proxies if there are not sufficient votes to approve the Merger Agreement) requires the affirmative vote of the holders of a majority of the shares of outstanding Neon common stock entitled to vote, online or represented by proxy, at the Neon Special Meeting and entitled to vote on the Adjournment Proposal. Accordingly, abstentions will have no effect on the outcome of the Adjournment Proposal and shares not in attendance at the Neon Special Meeting will have no effect on the outcome of the Adjournment Proposal.

**Neon Voting Agreements**

On January 15, 2020, concurrently with the execution and delivery of the Merger Agreement, certain directors and executive officers of Neon and certain of their respective affiliates, entered into voting agreements with BioNTech, pursuant to which such stockholders have agreed, among other things, to vote their respective shares of Neon common stock in favor of the Merger Agreement and the transactions contemplated thereby. As of the public announcement of the Merger, those certain directors and executive officers who signed the Neon voting agreements owned an aggregate of approximately 36% in voting power of the outstanding shares of Neon common stock. As of the record date for the Neon Special Meeting, the directors and executive officers of Neon who signed the Neon voting agreements owned an aggregate of approximately 39% of the voting power of the outstanding Neon common stock. The form of Neon voting agreements is attached to this proxy statement/prospectus as **Annex B**.

**How to Vote**

Neon stockholders may vote using any of the following methods:

***By Telephone or on the Internet***

Neon stockholders can vote by calling the toll-free telephone number on their proxy card. Please have your proxy card handy when you call. Easy-to-follow voice prompts allow you to vote your shares and confirm that your instructions have been properly recorded.

The website for Internet voting is www.proxyvote.com. Please have your proxy card handy when you go online. As with telephone voting, you can confirm that your instructions have been properly recorded.

Telephone and Internet voting facilities for Neon stockholders of record will be available 24 hours a day beginning on or about April 3, 2020, and will close at 11:59 p.m. Eastern Time on May 3, 2020. The availability

of telephone and Internet voting for beneficial owners will depend on the voting processes of your bank, broker or other holder of record. Therefore, Neon recommends that you follow the voting instructions in the materials you receive.

***By Mail***

Neon stockholders may complete, sign and date the proxy card or voting instruction card mailed to them and return it in the prepaid envelope.

***Online at the Neon Special Meeting***

You may attend the Neon Special Meeting, submit questions and vote your shares electronically during the meeting via live webcast by visiting www.virtualshareholdermeeting.com/NTGN2020. You will need the control number that is printed on your proxy card to enter the Neon Special Meeting. We recommend that you log in at least 15 minutes before the Neon Special Meeting to ensure you are logged in when the meeting starts. Please note that you will not be able to attend the Neon Special Meeting in person.

**Voting of Proxies**

**Shares will be voted in accordance with the instructions provided by a Neon stockholder who has voted by Internet, by telephone or by completing, signing, dating and mailing a proxy card or voting instruction card. If you are a Neon stockholder of record and you sign, date and return your proxy card but do not indicate how you want to vote or do not indicate that you wish to abstain, your shares will be voted "FOR" the Merger Proposal and "FOR" the Adjournment Proposal, and in the discretion of the proxyholders on any other matter that may properly come before the Neon Special Meeting at the discretion of the Neon Board.**

**Revoking Your Proxy**

Neon stockholders may revoke a proxy at any time before it is voted at the Neon Special Meeting. To do this, you must:

- enter a new vote by telephone or over the Internet by the date and time indicated on the applicable proxy card or voter instruction form;
- deliver another duly executed proxy card or voter instruction form bearing a later date to the addressee named in the proxy card or voter instruction form;
- provide written notice of the revocation to Neon's Corporate Secretary at 40 Erie Street, Suite 110, Cambridge, MA 02139; or
- attend the Neon Special Meeting and vote online (your attendance at the meeting will not, by itself, revoke your proxy; you must vote online at the meeting).

If your shares are held in "street name," you must contact your broker, bank or nominee to revoke and vote your proxy. If you have questions about how to vote or revoke your proxy, you should contact Neon's proxy solicitor, Innisfree, toll-free at (888) 750-5834.

**Attending the Neon Special Meeting**

Neon stockholders as of the record date, or their duly appointed proxies, may attend the Neon Special Meeting. If you hold shares of Neon common stock in your name as a stockholder of record and you wish to attend the Neon Special Meeting, you must present evidence of your stock ownership, such as your most recent account statement, at the Neon Special Meeting. You should also bring valid picture identification.

If your shares of Neon common stock are held in "street name" in a stock brokerage account or by a broker, bank or other nominee and you wish to attend the Neon Special Meeting, you need to bring a copy of a bank or brokerage statement to the Neon Special Meeting reflecting your stock ownership as of the record date. You should also bring valid picture identification. Please note that if you plan to attend the Neon Special Meeting online and would like to vote at the Neon Special Meeting, you will need to bring a legal proxy from your broker, bank or other holder of record as explained above.

**Adjournments and Postponements**

Although it is not currently expected, the Neon Special Meeting may be adjourned or postponed for the purpose of, among other things, soliciting additional proxies. Neon may adjourn the Neon Special Meeting without notice if announced at the Neon Special Meeting at which the adjournment is taken and if the adjournment is to a date that is not greater than 30 days after the original date fixed for the Neon Special Meeting and no new record date is fixed for the adjourned meeting. Any signed proxies received by Neon prior to the Neon Special Meeting in which no voting instructions are provided on such matter will be voted "**FOR**" the Adjournment Proposal of the Neon Special Meeting, if necessary or appropriate. Any adjournment or postponement of the Neon Special Meeting will allow Neon stockholders who have already sent in their proxies to revoke them at any time prior to their use at the Neon Special Meeting as adjourned or postponed.

If, at the Neon Special Meeting, the number of shares of Neon common stock present online or represented by proxy and voting in favor of the Merger Proposal is not sufficient to approve that proposal, Neon may move to adjourn the Neon Special Meeting in order to enable the Neon Board to solicit additional proxies for the approval of the Merger Proposal. In that event, Neon will ask its stockholders to vote only upon the adjournment proposal, and not the Merger Proposal. The Adjournment Proposal relates only to an adjournment or postponement of the Neon Special Meeting occurring for purposes of soliciting additional proxies for approval of the Merger Proposal in the event that there are insufficient votes to approve that proposal. Neon retains full authority to the extent set forth in its bylaws and Delaware law to adjourn the Neon Special Meeting for any other purpose, or to postpone the Neon Special Meeting before it is convened, without the consent of any Neon stockholders.

**Householding of Stockholder Materials**

Neon has adopted a procedure called "householding," which the SEC has approved. Under this procedure, Neon will deliver a single copy of proxy materials to multiple stockholders who share the same address unless Neon receives contrary instructions from one or more of the stockholders. This procedure reduces printing costs, mailing costs, and fees. Neon stockholders who participate in householding will continue to be able to access and receive separate proxy cards. Upon written or oral request, Neon will deliver promptly a separate copy of the proxy statement/prospectus and related proxy materials to any stockholder at a shared address to which Neon delivered a single copy of any of these documents. To receive a separate copy, or, if you are receiving multiple copies, to request that Neon only send a single copy of proxy materials, stockholders may contact Neon as follows: Neon Therapeutics, Inc., Attention: Corporate Secretary, 40 Erie Street, Suite 110, Cambridge, MA 02139 or by calling (617) 337-4701. Neon stockholders who hold shares in street name may contact their brokerage firm, bank, broker-dealer, or other similar organization to request information about householding.

**Solicitation of Proxies**

Neon is soliciting proxies for the Neon Special Meeting from Neon stockholders. Neon has also retained Innisfree to solicit proxies for the Neon Special Meeting from Neon stockholders for a fee of approximately $15,000 plus expenses. Neon will bear the entire cost of soliciting proxies from Neon stockholders, and Neon will pay all expenses incurred in connection with the printing and mailing of this proxy statement/prospectus. In addition to this mailing, Neon's directors, officers and employees (who will not receive any additional compensation for such services) may solicit proxies. Solicitation of proxies may be undertaken through the mail, in person, by telephone, the Internet or other means.

## PROPOSALS SUBMITTED TO NEON STOCKHOLDERS

### PROPOSAL 1: THE MERGER PROPOSAL

Neon is asking its stockholders to approve and adopt the Merger Agreement. For a detailed discussion of the terms of the Merger Agreement, see "The Merger Agreement." As discussed in "The Merger—Neon's Reasons for the Merger" located elsewhere in this proxy statement/prospectus after careful consideration, the Neon Board unanimously: (1) determined that the Merger Agreement and the transactions contemplated thereby, including the Merger, upon the terms and subject to the conditions set forth therein, were in the best interests of Neon stockholders; (2) approved and declared advisable the Merger Agreement and the transactions contemplated thereby in accordance with the requirements of the Delaware General Corporation Law; and (3) recommended that Neon stockholders approve and adopt the Merger Agreement at the Neon Special Meeting. **The Neon Board unanimously recommends that Neon stockholders vote "FOR" the Merger Proposal and "FOR" the Adjournment Proposal.**

Approval of the Merger Proposal is a condition to the closing of the Merger. If the Merger Proposal is not approved, the Merger will not occur. For a detailed discussion of the terms and conditions of the Merger, see "The Merger Agreement—Conditions to Closing."

**Required Vote**

Approval of the Merger Proposal requires the affirmative vote of the holders of a majority of the outstanding shares of Neon common stock entitled to vote on such matter. For purposes of this vote, an abstention or a failure to vote will have the same effect as a vote "**AGAINST"** the Merger Proposal.

**The Neon Board unanimously recommends Neon stockholders vote "FOR" the Merger Proposal.**

### PROPOSAL 2: THE ADJOURNMENT PROPOSAL

Neon stockholders are being asked to approve the adjournment of the Neon Special Meeting, if necessary or appropriate, to solicit additional proxies in favor of approval of the Merger Proposal.

If, at the Neon Special Meeting, the number of shares of Neon common stock present or represented and voting in favor of the Merger Proposal is insufficient to approve such proposal, Neon may move to adjourn the Neon Special Meeting in order to enable the Neon Board to solicit additional proxies for approval of the Merger Proposal.

Neon is asking its stockholders to authorize the holder of any proxy solicited by the Neon Board to vote in favor of granting discretionary authority to the proxy holders, and each of them individually, to adjourn the Neon Special Meeting to another time and place for the purpose of soliciting additional proxies. If the Neon stockholders approve this proposal, Neon could adjourn the Neon Special Meeting and any adjourned session of the Neon Special Meeting and use the additional time to solicit additional proxies, including the solicitation of proxies from Neon stockholders who have previously voted.

**Required Vote**

Approval of the Adjournment Proposal requires the affirmative vote of a majority of the shares of outstanding Neon common stock present at the Neon Special Meeting in person or by proxy. If a quorum is not present, the holders of shares of Neon common stock entitled to vote at the Neon Special Meeting, present online or by proxy, may adjourn the meeting.

**The Neon Board unanimously recommends that Neon stockholders vote "FOR" the Adjournment Proposal.**

**Other Business**

At this time, Neon does not intend to bring any other matters before the Neon Special Meeting, and Neon does not know of any matters to be brought before the Neon Special Meeting by others. If, however, any other matters properly come before the Neon Special Meeting, the persons named in the enclosed proxy, or their duly constituted substitutes, acting at the Neon Special Meeting or any adjournment or postponement thereof will be deemed authorized to vote the shares of Neon common stock represented thereby in accordance with the judgment of management on any such matter.

## THE MERGER

*The following discussion contains important information relating to the Merger. This summary does not purport to be complete and may not contain all of the information about the Merger that is important to you. You are urged to read this discussion together with the Merger Agreement and the related documents attached as annexes to this proxy statement/prospectus before voting.*

### Summary of the Merger

On January 15, 2020, BioNTech, Neon and Endor Lights, Inc., or Merger Sub, BioNTech's direct, wholly owned subsidiary, entered into an Agreement and Plan of Merger, or the Merger Agreement, pursuant to which, subject to the satisfaction or waiver of the conditions therein, Merger Sub will merge with and into Neon, with Neon surviving as a wholly owned subsidiary of BioNTech. Subject to the terms of the Merger Agreement, at the Effective Time, each share of Neon common stock, excluding shares owned by the parties to the Merger Agreement, that are issued and outstanding immediately prior to the Effective Time shall automatically be cancelled and converted into the right to receive the Merger Consideration.

As of immediately following the Effective Time, former Neon stockholders are expected to own approximately 0.85% of the outstanding equity interests of the Combined Company on an undiluted basis. No fractional BioNTech ADSs will be issued in the Merger. Each holder of Neon common stock converted pursuant to the Merger who would otherwise have been entitled to receive a fraction of a BioNTech 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 BioNTech ADS multiplied by the volume weighted average price of one BioNTech ADS for the ten trading days immediately prior to the second business day prior to the date of the closing of the Merger, starting with the opening of trading on the first trading day to the closing of the second to last trading day prior to the date of closing of the Merger, as reported by Bloomberg.

BioNTech and Neon currently anticipate that the Merger will occur during the second quarter of 2020. However, neither BioNTech nor Neon can predict the exact timing of the completion of the Merger because the Merger is subject to certain other conditions to closing as set forth in the Merger Agreement. See "—Conditions to Closing" located elsewhere in this proxy statement/prospectus.

### Background of the Merger

*The following chronology summarizes the key meetings and events that led to the signing of the Merger Agreement. The following chronology does not purport to catalogue every conversation among the Neon Board, the Special Committee (as defined below), members of Neon management or Neon's representatives and other parties.*

As part of the continuous evaluation of Neon's pre-clinical and clinical programs and financing needs, the Neon Board and senior management regularly considered a variety of potential strategic options and transactions in a continued effort to capitalize the company and enhance stockholder value. Over the past several years, the Neon Board, together with Neon's senior management and with the assistance of Neon's advisors, considered potential financings, partnership opportunities and strategic alternatives presented or potentially available to Neon, as well as the opportunities and risks associated with Neon continuing to operate as an independent company.

On July 15, 2019, Neon presented data from its NT-001 clinical trial that demonstrated that NEO-PV-01, Neon's personal neoantigen-based cancer vaccine, in combination with a checkpoint inhibitor, broadens the immune response to specific new cancer targets. When presented, this data was the first demonstration of improved clinical durability for a personal neoantigen-based therapy in the metastatic cancer setting. Following the presentation of this data, Neon sought to conduct an equity financing with the goal of securing sufficient

capital to advance NEO-PV-01 and extend Neon's cash runway. However, due to economic conditions and market feedback, Neon was ultimately not able to consummate an equity financing of this nature. After reaching this conclusion, the Neon Board and senior management commenced a process to evaluate the options available to support Neon's continued development and operations.

On August 1, 2019, the Neon Board held a regularly-scheduled meeting at the offices of Goodwin Procter LLP, or Goodwin, Neon's outside legal counsel, during which the Neon Board, together with senior management, discussed, among other things, financing options available to Neon following the release of data from its NT-001 clinical trial and business development and partnering opportunities. In addition, at this meeting, the Neon Board and senior management also conducted a comprehensive strategic review of Neon's programs and product candidates, as well as the risks and challenges of seeking to capitalize the company to pursue the breadth of its programs and product candidates. Following discussion, the Neon Board and senior management aligned on the need to refocus the company on a smaller set of programs and product candidates, namely, Neon's T cell program and product candidates.

On August 27, 2019, the Neon Board held a telephonic meeting, at which members of senior management were present and, at the invitation of the Neon Board, representatives of a nationally recognized investment bank that was later engaged by Neon, or the Financing Advisor, joined for a portion of the meeting. At this meeting, the Neon Board discussed, among other things, Neon's strategic and business development options and a potential restructuring of the company. Representatives of the Financing Advisor discussed with the Neon Board matters related to a potential equity financing, including investor messaging, targeting and timing. Following this discussion, the Neon Board and senior management discussed the need to engage a financial advisor to assist the company with capital raising efforts and a separate strategic advisor to assist the company in evaluating its broader strategic options. The Neon Board discussed potential financial and strategic advisors that might be retained to assist the company.

During the balance of the third fiscal quarter and into the fourth fiscal quarter of 2019, the Neon Board, together with Neon's senior management and with the assistance of Neon's advisors, explored an equity financing with the goal of securing sufficient capital to advance Neon's T cell product candidates into an initial clinical trial and capitalize the company to pursue further operations. In parallel, the Neon Board, together with Neon's senior management and with the assistance of Neon's advisors, also began to explore whether a potential strategic transaction would be in the best interests of Neon stockholders.

During the summer of 2019 and through mid-November 2019, Hugh O'Dowd, the President and Chief Executive Officer of Neon (and also a member of the Neon Board) and the chief executive officer of another publicly traded biotechnology company, "Party A", informally and on a periodic basis discussed topics related to the industry and their respective businesses, including the possibility of a potential strategic transaction involving the two companies. In support of advancing these conversations to include consideration of a potential strategic transaction, on July 30, 2019, Neon and Party A entered into a confidentiality agreement, which included customary non-disclosure and "standstill" provisions that included the ability of Party A to make confidential proposals to Neon at any time following Neon's public announcement of its entry into a definitive agreement with a third party to acquire Neon. Ultimately, discussions with Party A did not mature to the point where Party A submitted a proposal.

During the fall of 2019 and through mid-November 2019, Mr. O'Dowd also met with the chief executive officer of another publicly traded biotechnology company, "Party B." During the course of these discussions, the chief executive officer of Party B indicated a possible interest in pursuing a strategic transaction with Neon. Neither party made any proposals or otherwise discussed the specific terms of a potential transaction during the course of these discussions.

On September 4, 2019, in furtherance of the discussions occurring between Neon and Party B, Neon executed a confidentiality agreement with Party B, which included customary non-disclosure and standstill

provisions that included the ability of Party B to make confidential proposals to Neon at any time following Neon's public announcement of its entry into a definitive agreement with a third party to acquire Neon.

On September 5, 2019, the Neon Board held a telephonic meeting at which members of management and representatives of Goodwin were present. At this meeting, the Neon Board discussed, among other things, potential advisors to assist the Neon Board in evaluating strategic alternatives.

On September 17, 2019, the Neon Board held a telephonic meeting at which members of senior management and representatives of Goodwin were present to discuss, among other things, potential restructuring scenarios and management's recommendations for financial and strategic advisors. Based upon the knowledge and experience of certain directors and upon the recommendation of management, the Neon Board ratified the engagement of the Financing Advisor to advise on a potential equity financing and the engagement of Ondra Partners, or Ondra, to serve as a strategic advisor to the Neon Board. The Neon Board engaged each of the Financing Advisor and Ondra based on its qualifications, experience and reputation within the industry in which Neon operates. With the Financing Advisor's assistance, during the third and fourth fiscal quarters of 2019, Neon pursued an equity financing transaction. With Ondra's assistance, during the third and fourth fiscal quarters of 2019, the Neon Board and senior management evaluated strategic alternatives, including potential opportunities for licensing arrangements, partnering opportunities, mergers and business combinations, sales of part or all of Neon's assets, a sale of the whole company and other strategic transactions.

On October 2, 2019, the Neon Board held a telephonic meeting at which members of senior management, representatives of Goodwin and, for portions of the meeting, representatives of the Financing Advisor and Ondra were present. During this meeting, representatives of the Financing Advisor provided an update on investor outreach activities and representatives of Ondra discussed with the Neon Board potential strategic options, including timing of potential outreach.

On October 11, 2019, the Neon Board held a telephonic meeting at which members of senior management, representatives of Goodwin, and, for portions of the meeting, representatives of the Financing Advisor and Ondra were present. At this meeting, representatives of the Financing Advisor provided an update on the status of Neon's equity financing efforts, noting levels of engagement, investor education on Neon's science and progress, investor feedback, status of confidentiality agreements, timing and investor perception of Neon's capital requirements. During this meeting, representatives of Ondra outlined Neon's outreach plans with potential target companies, as well as the anticipated timing of additional outreach activities in light of the potential timing of a restructuring announcement if the Neon Board were to determine to go forward with a restructuring.

On October 25, 2019, the Neon Board held a telephonic meeting at which members of senior management, representatives of Goodwin and, for portions of the meeting, representatives of the Financing Advisor and representatives of Ondra were present. At this meeting, representatives of the Financing Advisor provided an update on the status of Neon's equity financing efforts, including discussion of a potential lead investor and the potential timing for closing a transaction. The Neon Board also discussed with representatives of the Financing Advisor other mechanisms to bring in additional capital to fund Neon's business. As part of this discussion, the Neon Board determined that it would be prudent to reactivate the Neon Board's pricing committee, or the Pricing Committee, for the purpose of evaluating and approving the terms of any potential financing. The Pricing Committee consisted of Neon Board members, Mr. O'Dowd, Cary Pfeffer, M.D. (Chairman of the Neon Board), Robert Bazemore, Stephen Sherwin, M.D. and Meryl Zausner.

On October 29, 2019, the Pricing Committee held a telephonic meeting, at which members of management and representatives of the Financing Advisor were present. At this meeting, representatives of the Financing Advisor provided an update on Neon's equity financing efforts, including feedback received from a potential lead investor on the potential size and terms of an equity financing.

On October 31, 2019, the Neon Board held a telephonic meeting at which members of senior management, representatives of Goodwin and, for a portion of the meeting, representatives of the Financing Advisor were

present. At this meeting, representatives of the Financing Advisor provided an update on the status of Neon's equity financing efforts. The Neon Board also discussed, among other things, Neon's plans for securing necessary funding, as well as potential plans to reduce Neon's cost structure and extend Neon's cash runway.

On November 1, 2019, the Pricing Committee held a telephonic meeting at which senior management, representatives of Goodwin and, for a portion of the meeting, representatives of the Financing Advisor were present. At this meeting, representatives of the Financing Advisor provided an update on the status of Neon's equity financing efforts, describing the process and anticipated timeline for the proposed lead investor to complete its due diligence efforts.

On November 11, 2019, the Neon Board held a telephonic meeting at which members of senior management, representatives of Goodwin, and, for a portion of the meeting, representatives of the Financing Advisor and Ondra were present. At this meeting, representatives of the Financing Advisor provided an update on the status of Neon's equity financing efforts, noting that the investor who had been considering leading the financing had determined not to do so, but had indicated a willingness to participate in an equity financing if one were to go forward. With the assistance of the Financing Advisor, the Neon Board discussed ways in which Neon might be able to consummate an equity financing without a lead investor. Following discussion, the Neon Board expressed support for Neon's continued efforts, with the representatives of the Financing Advisor, to pursue an equity financing.

Also at the November 11, 2019 meeting, representatives of Ondra discussed with the Neon Board strategic alternatives available to Neon, including other types of transactions such as a sale of the company or asset sales. The Neon Board also discussed the potential that Neon might receive an offer from Party A, Party B or other parties and that, because one of these parties had relationships with a private investment firm with representatives serving on the Neon Board, and also for purposes of efficiency, it would be advisable to form a special committee of independent and disinterested directors to evaluate any such offers and to consider Neon's strategic alternatives to remaining as an independent public company. Following this discussion and as a result of the preliminary expressions of interest by Party A and Party B as mentioned above and the potential for further discussions with those parties regarding a potential strategic transaction, the Neon Board established a special committee, or the Special Committee, consisting of independent and disinterested directors. The Special Committee was authorized to consider and evaluate any proposals that Neon might receive regarding a potential strategic transaction, participate in and direct the negotiation of the material terms and conditions of any such transaction, and recommend to the Neon Board the advisability of entering into any such transaction or pursuing another strategic alternative. The Special Committee initially consisted of Robert Bazemore and Meryl Zausner. Throughout the Special Committee's evaluation of a potential strategic transaction involving Neon, the Special Committee conducted formal meetings, to which other directors were invited to attend, and had regular discussions with Neon's senior management and advisors and among themselves. The Special Committee on a number of occasions also met in executive session with only the independent directors and, at times, also with legal counsel present. In addition, from time to time members of the Special Committee had discussions with Neon's management, financial advisors and legal counsel.

Shortly after the November 11, 2019 Neon Board meeting and following outreach to interested investors, representatives of the Financing Advisor informed Neon that it was unable to secure sufficient interest from prospective investors to enable Neon to effect an equity financing. Based on this feedback, Neon thereafter terminated its efforts to effect an equity financing.

On November 12, 2019, certain members of Neon's senior management held an in-person meeting with Party A and its representatives at Neon's offices in Cambridge, Massachusetts to discuss the potential synergies that may be achieved if Neon and Party A were to combine.

On November 13, 2019 and following solicitation and receipt of input from the Special Committee, Mr. O'Dowd sent to the chief executive officer of Party A a process letter, which included a proposed timeline,

of entering into a strategic transaction with Party A by the end of 2019, with a view to closing that transaction by the end of the first quarter of 2020.

On November 14, 2019, the Special Committee held a telephonic meeting at which other directors, members of senior management and representatives of Ondra and Goodwin were present. At the meeting, the Special Committee discussed, among other things, the status of Neon's discussions with Party A, the potential benefits of a transaction with Party A, confirmation of the independence of the Special Committee members and potential parties to be contacted in the strategic process.

On November 14, 2019, Party A informed Neon that it was no longer interested in exploring a potential strategic transaction with Neon. Party A did not make any proposal or otherwise discuss the specific terms of a potential transaction prior to dropping out of the process. Following the termination of discussions between Neon and Party A, the directors, including the members of the Special Committee, met together at meetings duly called for the Neon Board and, on certain occasions, the Special Committee met separately, serving as a subset of the Neon Board to facilitate continual updates to and involvement from members of the Neon Board.

On November 18, 2019, the Neon Board held a telephonic meeting at which members of senior management and representatives of Goodwin were present. At this meeting, the Neon Board approved a corporate restructuring and strategic reprioritization, the result of which was that Neon would restructure its workforce and focus its efforts on the advancement of both personal and precision neoantigen-targeted T cell therapy candidates and cease undertaking additional spending commitments related to its cancer vaccine programs, NEO-PV-01 and NEO-SV-01. The Neon Board acknowledged Neon's inability to secure a partnership transaction or licensing arrangement that would enable Neon to continue to support its business plan. As part of this discussion, the Neon Board concluded that, given the challenges faced by Neon, including the difficulties in capitalizing Neon to pursue further operations, a sale of Neon or a sale of Neon's assets would best lead to an opportunity to enhance stockholder value out of the various alternatives available to Neon.

On November 20, 2019, Neon publicly announced the strategic reprioritization and corporate restructuring approved at the November 18, 2019 Neon Board meeting, which included a reduction in its headcount by approximately 24%. Neon's public announcement also included a statement that Neon was exploring its strategic options. The closing price per share of Neon common stock on that day was $1.43.

On November 21, 2019, the Neon Board held a regularly-scheduled meeting at Neon's offices in Cambridge, Massachusetts at which members of senior management, representatives of Ondra and Goodwin were present to discuss, among other things, the status of Neon's T cell therapy program and product candidates. At this meeting, the Neon Board also approved adding Dr. Pfeffer, the Chairman of the Neon Board, as an independent and disinterested member to the Special Committee.

Following a discussion of the challenges faced by Neon, including the inability to secure equity financing or a business development or partnering transaction, at the November 21, 2019 meeting, the Neon Board again determined, with the assistance of Ondra, that a sale of Neon or a sale of Neon's assets would best lead to an opportunity to enhance stockholder value. In furtherance of this objective, the Neon Board and senior management and representatives of Ondra then discussed the universe of parties that they believed would be most likely to have an interest in acquiring Neon or one or more of its assets. The Neon Board considered such factors as it deemed relevant, including the parties' likely interest in acquiring companies or assets in Neon's industry and their perceived strategic priorities, as well as the potential strategic fit provided by Neon's platforms, programs and product candidates. At the conclusion of this discussion, the Neon Board approved a list of approximately 65 companies (which included BioNTech and Party B) and authorized and directed representatives of Neon's Board, senior management or representatives of Ondra, as appropriate, to contact each of these companies to gauge the third party's interest in a potential acquisition of Neon or other strategic transaction involving Neon.

Following the November 21, 2019 Neon Board meeting, representatives of Neon's Board, senior management and representatives of Ondra, at the direction of the Neon Board, commenced outreach to the approximately 65 identified parties. Following initial contact, if the potential counterparty expressed interest in learning more, representatives of Ondra sent the potential counterparty an initial bid instruction letter on behalf of Neon setting forth the timing and procedures for submitting preliminary offers to engage in a strategic transaction with Neon. The initial bid process letter, at the direction of the Neon Board, requested that preliminary non-binding offers be submitted by 5 p.m. Eastern Time on December 18, 2019, and address, among other things, proposed economics, transaction scope, financing sources, business rationale, due diligence requirements, required approvals, timing and material conditions to a sale transaction.

On November 25, 2019, Neon's President of Research and Development, Dr. Richard Gaynor, had an introductory telephone conversation with BioNTech's Chief Executive Officer, Professor Ugur Sahin, M.D. Neither party made any proposals during this meeting or otherwise discussed the specific terms of a potential transaction.

On November 25, 2019, representatives of Ondra provided certain publicly available, introductory information concerning Neon and its business to the chief operating officer of a publicly traded biotechnology company, "Party C."

Later during the week of November 25, 2019, Party B indicated to representatives of Ondra that it would consider whether to participate in Neon's strategic process. Following this communication, no further discussions took place between Neon and Party B regarding a potential transaction. Party B did not make any proposals or otherwise discuss the specific terms of a potential transaction prior to dropping out of the process.

Between November 26 and December 18, 2019, 17 parties, including each of BioNTech (on December 6, 2019), a publicly traded biotechnology company, "Party D," (on November 26, 2019) and Party C (on December 13, 2019), executed a confidentiality agreement with Neon, which included customary non-disclosure and standstill provisions that included the ability of the bidder to make confidential proposals to Neon at any time following Neon's public announcement of its entry into a definitive agreement with a third party to acquire Neon.

On November 26, 2019, the Special Committee held a meeting to receive an update on the strategic transaction process, at which other directors, members of senior management and representatives of Ondra and Goodwin were also present. During this meeting, representatives of Ondra provided an update on the status of the outreach to potential counterparties.

Early on December 3, 2019, Dr. Gaynor had a breakfast meeting with Prof. Sahin in Cambridge, Massachusetts. Following this meeting, representatives of Ondra provided representatives of BioNTech with a bid process letter and a confidentiality agreement, which included customary non-disclosure and standstill provisions that included the ability of BioNTech to make confidential proposals to Neon at any time following Neon's public announcement of its entry into a definitive agreement with a third party to acquire Neon.

Later on December 3, 2019, the Special Committee held a meeting at which other directors, members of senior management, representatives of Goodwin, and, for a portion of the meeting, representatives of Ondra were present. At this meeting, representatives of Ondra provided an update to the Special Committee regarding the status of its outreach to prospective parties. The Special Committee also discussed, in a portion of the meeting at which the representatives of Ondra were not present, a potential amendment to the terms of Ondra's engagement letter to extend the term of Ondra's engagement and provide for a success fee.

On December 4, 2019, Mr. O'Dowd, Dr. Gaynor, Prof. Sahin, Mr. Sean Marett, Chief Business Officer and Chief Commercial Officer of BioNTech, and Mr. Ryan Richardson, SVP Corporate Development and Strategy of BioNTech, spoke by telephone to discuss the potential benefits of a business combination between the parties.

On December 5, 2019, representatives of Party C discussed with Mr. O'Dowd their interest in a potential transaction with Neon. Neither party made any proposals during this meeting or otherwise discussed the specific terms of a potential transaction.

Also on December 5, 2019, the Special Committee held a meeting to receive an update on the strategic process at which other directors, members of senior management and representatives of Ondra and Goodwin were also present.

Also on December 5, 2019, representatives of Ondra and Mr. Richardson spoke by telephone to discuss the status of Neon's process and its timing expectations for bidders.

Also on December 5, 2019, Mr. O'Dowd and the chief executive officer of Party D met in person to discuss the general status of discussions between the parties. Thereafter, representatives of Neon and Party D met in person to discuss scientific due diligence matters.

On December 9, 2019, Neon granted BioNTech and its representatives access to its electronic data room to permit BioNTech to perform more extensive due diligence on Neon.

Later on December 9, 2019, Mr. O'Dowd had a meeting with the chief executive officer and chief operating officer of Party D to discuss Neon's business and related diligence matters.

On December 10, 2019, representatives of Party D, senior management and Ondra met at Ondra's offices in New York to discuss the general status of discussions between the parties.

On December 10, 2019, the Special Committee held a meeting to receive an update on the strategic process at which other directors, members of senior management and representatives of Ondra and Goodwin were also present. Members of senior management and representatives of Ondra provided updates regarding the strategic process and the perceived levels of interest from the interested parties. The Special Committee discussed the advisability of retaining a financial advisor with significant expertise in rendering fairness opinions. The Board of Directors and the Special Committee discussed the engagement of various financial advisory firms and authorized management to interview members of Duff & Phelps to provide such services and review Duff & Phelps' relationships with each of BioNTech, Party C and Party D.

On December 12, 2019, representatives of Neon and BioNTech continued to engage in due diligence discussions regarding intellectual property and finance matters.

Also on December 12, 2019, the Special Committee held a meeting at which other directors, members of senior management, representatives of Goodwin, and for a portion of the meeting, representatives of Ondra were present. During this meeting, the Special Committee discussed the status of Neon's outreach activities and the engagement of various third parties in this process. Further, during a portion of the meeting at which representatives of Ondra were not present, the Special Committee discussed a potential amendment to the terms of Ondra's engagement letter to extend the term of Ondra's engagement and provide for a success fee.

On December 13, 2019, Neon received a preliminary non-binding indication of interest letter from Party D indicating that Party D would be interested in acquiring Neon in a stock-for-stock transaction for a total purchase price of $45 million, or approximately $1.59 per fully-diluted share of Neon common stock, representing an approximate 38% premium to the closing price per share of Neon common stock on December 12, 2019 of $1.15. Prior to this date, Party D had not made any proposals or otherwise discussed the specific terms of a potential transaction.

On December 17, 2019, representatives of BioNTech, including Prof. Sahin and Mr. Richardson, participated in a management meeting at Neon's office in Cambridge, Massachusetts to discuss Neon's business and the rationale for the proposed combination.

Also on December 17, 2019, representatives of Neon and Party C had an in-person meeting to discuss a potential transaction involving the two companies and the synergies that might be achieved.

On December 18, 2019, BioNTech and Party C each submitted a non-binding indication of interest to Neon. Prior to this date, neither BioNTech nor Party C had made any proposal or otherwise discussed the specific terms of a potential transaction. BioNTech's indication of interest provided for a stock-for-stock acquisition of Neon based on an exchange ratio of 0.055 BioNTech ADSs to each share of Neon common stock, representing a fully diluted equity value of $40.9 million. Party C's indication of interest provided for an acquisition of Neon's RECON® bioinformatics engine, NEO-STIM™ (Neon's proprietary method of generating antigen-specific T cells and TCRs), and certain of Neon's identified TCRs for an upfront payment of $4-8 million with an opportunity to earn $66-$70 million in additional milestone payments. The closing price per share of Neon common stock on December 18, 2019 was $1.15.

Later on December 18, 2019, Ondra sent the initial bid instruction letter and other introductory materials to a newly formed private biotechnology company, "Party E," following a conversation between Mr. O'Dowd and a representative of Party E during which Party E expressed interest in better understanding Neon's business. Party E was not included at the start of the process given its early stage and the perception that other parties presented a stronger perceived rationale.

On December 19, 2019, the Neon Board held a meeting to discuss the status and results of the strategic transaction process at which members of senior management and representatives of Ondra and Goodwin were also present. At this meeting, the Neon Board, with the assistance of representatives of Ondra and Goodwin, discussed the three preliminary indications of interest received between December 13 and December 18, 2019. The Neon Board also reviewed its prior evaluation of strategic alternatives and again concluded that the most compelling alternative at that time was to create value for stockholders through a sale of the entire company if Neon was able to receive a valuation superior to the value that the Neon Board believed could be achieved if Neon remained an independent, stand-alone company especially given its inability to secure the necessary financing through an equity financing or partnering transaction or to fund the company's refocus on its T cell programs. Representatives of Ondra discussed preliminary financial matters regarding the initial indications of interest, including with respect to the value offered by each bidder. The Neon Board and senior management reviewed the possibility of a business combination with each of Party D and BioNTech, including strategic fit, long-term growth platform, short- and long-term financial benefits, cultural fits and views of the strengths of the various companies, and other factors affecting whether to invite either or both of these companies to the next phase of the strategic process. The Neon Board considered the advantages and disadvantages of receiving stock of BioNTech or Party D as consideration (where Neon stockholders would benefit from appreciation of the BioNTech's shares issued in the form of BioNTech ADSs or Party D common stock, as applicable, but would also bear the risk of any decreases in the value of such stock), and the execution risks associated with the proposals, including the risks associated with the time to obtain approval from Neon stockholders to consummate the transaction. The Neon Board and senior management also discussed the viability of Party C's offer for an asset purchase transaction and the potential value to Neon stockholders of that transaction, which value would only be realized upon the achievement of certain clinical and regulatory milestones, as compared to a sale of the entire company. During this meeting representatives of Goodwin also reviewed with the Neon Board its fiduciary duties in the context of evaluating the preliminary indications of interest in the context of a possible business combination involving Neon or sale of certain of its assets.

At the December 19, 2019 meeting, the Neon Board also discussed how best to further enhance stockholder value through the next phase of the strategic process. Following this discussion, the Neon Board directed representatives of Ondra to encourage each of Party D and BioNTech to increase the value of its respective offer and, assuming satisfactory responses, to advance each of Party D and BioNTech to the next phase of the strategic process during which stage, each party would be provided with access to additional diligence materials to facilitate the party's submission of a final, binding bid. At the same time, the Neon Board determined that Party C's asset purchase offer was not compelling because the total value of Party C's offer was contingent upon the

achievement of certain clinical and regulatory milestones. As a result, the Neon Board determined that a sale of the whole company would create more value for Neon stockholders and also because Party C indicated to Neon that it would not be able to prioritize a potential transaction until the middle of January 2020. The Neon Board concluded that it would be in the best interests of Neon stockholders to continue to engage primarily with BioNTech, Party D and, if it were to prove seriously interested, Party E. The Neon Board directed representatives of Ondra to indicate to BioNTech and Party D that their indications of interest were not compelling and that they would need to increase their offer prices in order to proceed to the second round of the process. The Neon Board also instructed representatives of Ondra to inform Party C that it would be open to continuing conversations in 2020, but that Neon was focused on executing a whole company transaction. In addition, the Neon Board instructed representatives of Ondra to encourage Party E to participate in the strategic process and, if they were interested in moving forward, to be in a position to make a proposal on the same date that Party D and BioNTech would be asked to make their final proposals in the next phase of the strategic process. Representatives of Ondra discussed with the Neon Board the potential timetable for BioNTech, Party D and, if interested, Party E to conduct confirmatory diligence and submit proposals in the next phase of the strategic process. The Neon Board directed representatives of Ondra to set a second round bid deadline of 12 p.m. Eastern Time on January 8, 2020. During this meeting, the Neon Board ratified the engagement of Duff & Phelps to deliver a financial analysis to the Neon Board in connection with a strategic transaction. Finally, the Neon Board also ratified an amendment to Ondra's engagement letter to extend the term of Ondra's engagement and provide for a success fee, a portion of which would be paid upon announcement of a strategic transaction and the remainder would be paid upon consummation of such transaction.

After the Neon Board meeting on December 19, 2019, Ondra sent a management presentation and second round process letter to Party E and Party E executed a confidentiality agreement with Neon, which included customary non-disclosure and standstill provisions that included the ability of the bidder to make confidential proposals to Neon at any time following Neon's public announcement of its entry into a definitive agreement with a third party to acquire Neon. Party E was also provided access to Neon's electronic data room.

In addition, on December 19, 2019 and during the weeks that followed leading up to the delivery of its final opinion on January 15, 2020, representatives of Duff & Phelps held diligence calls with representatives of Neon to discuss the history of Neon, the process it had undergone to achieve liquidity, Neon's current business strategy and the Neon Projections. See "*—Certain Prospective Financial Information Reviewed by the Neon Board and Neon's Financial Advisor*".

On December 20, 2019, representatives of Ondra, at the direction of the Neon Board, spoke telephonically with the chief executive officer and chief operating officer of Party D to inform them that Party D's initial indication of interest was not competitive and that they would need to put forward a more compelling offer price in order to proceed to the second round of the process. During this conversation, the representatives of Party D noted that Party D would need approval from its board of directors in order to increase its offer, but that they believed they would receive that approval for an increased offer of $55 million. Based on the expectation that Party D would revert to its board of directors and receive such approval, Party D was included in the second phase of this process.

Also on the morning of December 20, 2019, representatives of Ondra had a telephone conversation with Mr. Marett and Mr. Richardson of BioNTech, during which they conveyed that BioNTech's initial indication of interest was not compelling enough to proceed to the second round of the strategic process.

Later in the day on December 20, 2019, BioNTech verbally submitted a non-binding indication of interest with an equity value range of $58 to 65 million. On this basis, BioNTech was included in the second phase of this process.

On December 20, 2019, at the direction of the Neon Board, representatives of Ondra distributed an instruction letter regarding the receipt of final bids and a draft merger agreement to each of BioNTech and Party

D. The bid process letter indicated a deadline for submitting final, binding written proposals by 12 p.m. Eastern Time on January 8, 2020 and also requested comments from each of the bidders on Neon's proposed form of merger agreement by that same date.

On December 20, 2019, representatives of Party E participated in a due diligence call with representatives of Neon.

On December 22, 2019, Dr. Gaynor spoke telephonically with a representative of Party E to discuss Neon's platforms, programs and product candidates.

On December 23, 2019, Neon engaged in further due diligence discussions with Party E.

Also on December 23, 2019, Party D indicated to Neon that, due to other business endeavors, it would be unable to meet Neon's proposed timeline. Party D requested that Ondra contact them in the event Neon's strategic process became delayed.

On December 24, 2019, BioNTech was provided access to the second phase of Neon's electronic data room in order to continue its due diligence investigation.

On December 24, 2019, Party E indicated to representatives of Ondra that it was no longer interested in pursuing a strategic transaction with Neon, citing an inability to finish its due diligence investigation in accordance with Neon's proposed timeline. Party E did not make any proposals or otherwise discuss the specific terms of a potential transaction prior to dropping out of the process.

On January 2, 2020, BioNTech's and Neon's respective tax advisors had due diligence discussions. In addition, representatives of BioNTech and Ondra had a telephone conversation to discuss the next phase of the process.

Also on January 2, 2020, Party C contacted Ondra to discuss next steps regarding future diligence discussions and the proposed timeline.

On January 7, 2020, representatives of BioNTech participated in a second management meeting at Neon's office in Cambridge, Massachusetts to continue due diligence and further discuss Neon's business and the rationale for a strategic transaction involving the companies. Mr. Marett and Mr. Richardson of BioNTech met with Mr. O'Dowd, Dr. Yasir Al-Wakeel, Chief Financial Officer of Neon, Ms. Jolie Siegel, Vice President, General Counsel of Neon, Dr. Gaynor and Michiel Bröker of Ondra to discuss these topics.

On January 8, 2020, Party C indicated that it would not be able to submit an offer, citing an inability to complete due diligence in accordance with Neon's proposed timetable. Party C expressed that they would, however, be interested in reengaging in discussions with Neon if Neon's strategic process did not move forward or if the successful bidder wanted to explore discussions regarding a licensing transaction after closing.

Early on January 8, 2020, representatives of BioNTech notified representatives of Ondra that it would not be able to submit a final bid by the requested 12 p.m. Eastern Time deadline, but committed to submitting a final bid by the morning of January 9, 2020.

Later on January 8, 2020, the Neon Board held a telephonic meeting at which members of senior management and representatives of Ondra and Goodwin were also present. At this meeting, the Neon Board reviewed and discussed the status and timing for receipt of final, binding offers and, based on the previously received information from BioNTech, determined to adjourn the meeting until the next day. The Neon Board also confirmed its approval of the long-term financial forecast materials that had been previously provided to and reviewed by the Neon Board, which comprise the Neon Projections (see "*—Certain Prospective Financial*

*Information Reviewed by the Neon Board and Neon's Financial Advisor*"). The Neon Board also confirmed its agreement with the Neon Projections and, among other things, authorized Duff & Phelps to use the Neon Projections in preparing its financial analysis.

Later in the evening of January 8, 2020, BioNTech submitted to representatives of Ondra a written offer letter outlining BioNTech's offer to acquire Neon in a stock-for-stock acquisition based on an exchange ratio of 0.066 BioNTech ADSs for each share of Neon common stock, representing an approximate 74% to 78% premium to Neon's 30-day volume weighted average share price of $1.19 for the period ending January 6, 2020 and to Neon's closing stock price of $1.15, or the January 8 Proposal. BioNTech also submitted initial comments to the draft merger agreement provided by Neon, which, among other things, also contemplated voting agreements being executed between BioNTech and certain stockholders of Neon, including Neon's directors and officers and Neon's largest investor, Third Rock Ventures. The closing price per share of Neon common stock on January 8, 2020 was $1.19.

On January 9, 2020, the Neon Board reconvened its meeting to discuss the status of the strategic process with members of senior management and representatives of Ondra and Goodwin also present. The Neon Board, with the assistance of Ondra, discussed the January 8 Proposal. The Neon Board also received updates as to the status of ongoing negotiations of the terms of the proposed transaction with BioNTech and discussed further various pricing methodologies. During this meeting, representatives of Goodwin also provided an overview of the material terms of the draft merger agreement provided by BioNTech. The Neon Board also discussed the fact that Neon's management should be restricted from having discussions with any bidders regarding their roles, compensation, retention or investment arrangements in connection with a proposed transaction until after Neon and BioNTech had completed valuation discussions.

On January 9, 2020, in response to BioNTech's due diligence enquiries, representatives of Ondra contacted representatives of BioNTech to better understand which assumed costs related to Neon's restructuring, transaction fees and certain other costs had been incorporated into the exchange ratio offered in the January 8 Proposal to ensure that such exchange ratio reflected reasonable cost estimates.

On January 10, 2020, representatives of Ondra again spoke with representatives of BioNTech to clarify the mechanics of the exchange ratio offered and to answer questions and discuss certain transaction-related expenses that were incorporated by BioNTech into its analysis of the value it could pay to acquire Neon, as set forth in BioNTech's January 8 Proposal. Following this call, representatives of BioNTech verbally indicated to representatives of Ondra that BioNTech was decreasing its proposal to an exchange ratio of 0.061 BioNTech ADSs to each share of Neon common stock to account for certain transaction-related expenses that BioNTech had not incorporated into its financial model when it arrived at the January 8 Proposal.

Later on January 10, 2020, Mr. O'Dowd and Mr. Marett spoke by telephone. On this call, Messrs. O'Dowd and Marett discussed BioNTech's proposed exchange ratio and following this discussion, Mr. Marett verbally agreed to offer a higher exchange ratio than that which representatives of BioNTech had verbally indicated to representatives of Ondra earlier that day. At the conclusion of this discussion, Mr. Marett informed Mr. O'Dowd that BioNTech was committed to proceeding with an acquisition of Neon based on a fixed exchange ratio of 0.063 BioNTech ADSs to each share of Neon common stock.

From January 10 through January 15, representatives of Goodwin and BioNTech's outside legal counsel, Covington and Burling LLP, or Covington, exchanged drafts and engaged in discussions regarding the terms of the proposed merger agreement. Issues discussed between the parties included the scope of and qualifications to Neon's representations and warranties and operating covenants between signing and closing, the scope of post-closing benefits for Neon's employees, Neon's obligation to "bring down" its representations and warranties at closing, the scope of the "material adverse effect" closing condition, exceptions to the definition of "material adverse effect" (which generally defines the standard for closing risk), Neon's ability to respond to unsolicited inquiries following the announcement of a transaction and Neon's right to terminate the proposed merger

agreement to accept a superior proposal. The parties also discussed the amount of the termination fee to be paid under such circumstances, which BioNTech proposed should be an amount equal to 4.75% of the total value of the transaction.

On January 12, 2020, the Neon Board held a telephonic meeting at which certain members of senior management and representatives of Ondra, Duff & Phelps and Goodwin were present. During the meeting, representatives of Ondra provided an update regarding the status of discussions with BioNTech. Thereafter, representatives of Goodwin reviewed the key terms of the proposed merger agreement relating to deal certainty and certain open issues between the parties, including the size of the termination fee potentially payable by Neon and termination rights in connection with accepting a superior proposal from a third party, the definition of "material adverse effect" and certain obligations under the interim operating covenants. Thereafter, representatives of Duff & Phelps reviewed with the Neon Board matters relating to, among other things, the exchange ratio and implied price per share offered by BioNTech and reviewed preliminary financial analyses of the proposed exchange ratio. Duff & Phelps stated at the end of its discussion that, based on its analysis of the proposed exchange ratio, it expected to be able to render a fairness opinion based on the proposed exchange ratio offered by BioNTech. Following this review and after further discussion by the Neon Board, the Neon Board determined that the value offered to Neon stockholders pursuant to BioNTech's proposed offer was more favorable to Neon stockholders than the alternative of remaining a stand-alone public company, and directed Neon's senior management, Ondra and Goodwin to continue negotiations of the proposed merger agreement and related documentation on the terms discussed by the Neon Board.

On January 13, 2020, Goodwin provided a revised draft of the merger agreement and proposed draft of the form of voting agreement to Covington.

Also on January 13, 2020, representatives of Neon and Ondra discussed with representatives of and advisors to BioNTech, including Covington, support calculations for certain transaction-related expenses.

Early on January 15, 2020, Covington, on behalf of BioNTech, provided Goodwin with a revised draft of the merger agreement and, during the day on January 15, 2020, Mr. O'Dowd and Mr. Marett, further negotiated and ultimately reached resolution on the remaining open points of the proposed merger agreement, which included issues with respect to the size of the termination fee (4.75% of the equity value of the transaction), exceptions to the definition of "material adverse effect," Neon's obligation to hold a stockholder meeting in the event the Neon Board changes its recommendation in favor of a superior proposal, obligations under the interim operating covenants, conditions precedent to BioNTech's obligation to proceed with closing and regulatory matters. Neon also facilitated final due diligence inquiries from BioNTech and Covington.

Later on January 15, 2020, following the close of markets in the United States, the Neon Board held a telephonic meeting to discuss the final terms of the proposed transaction with BioNTech. Members of Neon's senior management and representatives of Ondra, Duff & Phelps and Goodwin were also present at this meeting. During this meeting, representatives of Ondra provided an update on the discussions with BioNTech since the last Neon Board meeting. Representatives of Goodwin also provided an overview of the negotiation process to date with BioNTech's representatives, as well as a presentation regarding the terms of the final proposed merger agreement.

Also at this meeting, representatives of Duff & Phelps rendered an oral opinion to the Neon Board, which was subsequently confirmed by delivery of a written opinion immediately after the meeting on January 15, 2020, to the effect that, as of that date, the exchange ratio provided for in the proposed transaction was fair, from a financial point of view, to the holders of shares of Neon common stock (without giving effect to any impact of the proposed transaction on any particular stockholder other than in its capacity as a stockholder). The written opinion delivered by Duff & Phelps is attached to this proxy/prospectus as Annex C. After further discussing the advantages and risks of the proposed transaction, including the factors that are described in "—Reasons for Recommendation of the Neon Board," located elsewhere in this proxy statement/prospectus and based on the

discussions and deliberations at the January 12 and January 15 meetings, the Neon Board unanimously: (1) determined that the Merger Agreement and the transactions contemplated thereby, including the Merger, upon the terms and subject to the conditions set forth therein, were in the best interests of Neon stockholders; (2) approved and declared advisable the Merger Agreement and the transactions contemplated thereby in accordance with the requirements of the Delaware General Corporation Law; and (3) recommended that Neon stockholders approve and adopt the Merger Agreement at the Neon Special Meeting.

Later on January 15, 2020, after approval by Merger Sub, BioNTech and Neon, the parties finalized, executed and delivered the Merger Agreement and the Neon Voting Agreements.

On the morning of January 16, 2020, before the opening of the U.S. stock markets, Neon and BioNTech issued a joint press release announcing the execution of the Merger Agreement.

**Neon's Reasons for the Merger**

In evaluating the Merger Agreement and the transactions contemplated thereby, including the Merger, the Neon Board consulted with Neon's management and legal and financial advisors. In the course of reaching its determination that the terms of the Merger are advisable and in the best interests of Neon and its stockholders and to recommend that Neon stockholders approve and adopt the Merger Agreement at the Neon Special Meeting, the Neon Board reviewed, evaluated, and considered a significant amount of information and numerous factors and benefits of the Merger, which the Neon Board believed supported its unanimous determination and recommendation. As a result, for the reasons set forth below (which are not listed in any relative order of importance), the Neon Board recommends that Neon stockholders approve and adopt the Merger Agreement at the Neon Special Meeting:

*Exchange Ratio*. The Neon Board considered:

- the fact that the exchange ratio is fixed and will not fluctuate based upon changes in the stock price of Neon or BioNTech prior to completion of the Merger;
- the fact that the BioNTech ADSs to be received by the Neon stockholders will be received in an exchange that is intended to be tax free within in the meaning of Section 368(a) of the Code and will be registered under U.S. federal securities laws and be freely tradeable for Neon stockholders who are not affiliates of BioNTech; and
- the Neon Board's belief, based upon the negotiations with BioNTech, that the form and the amount of consideration to be paid by BioNTech is the most that BioNTech was willing to pay for Neon and that the terms of the Merger Agreement include the most favorable terms to Neon to which BioNTech was willing to agree.

*Neon's Operating and Financial Condition and Prospects*. The Neon Board considered Neon's operating and financial performance and its prospects, including certain prospective forecasts for Neon prepared by Neon's senior management, which reflect an application of various assumptions of senior management. The Neon Board considered the inherent uncertainty of achieving management's prospective forecasts, as set forth under "—*Certain Prospective Financial Information Reviewed by the Neon Board and Neon's Financial Advisor*," located elsewhere in this proxy statement/prospectus and that as a result Neon's actual financial results in future periods could differ materially from senior management's prospective forecasts.

*Strategic Alternatives*. The Neon Board considered, after a thorough review of Neon's long-term strategic goals and opportunities and discussions with Neon's senior management and outside legal and financial advisors, the challenges and risks of continuing as a stand-alone public company, including the difficulties in capitalizing Neon to pursue further operations and the potential strategic alternatives available to Neon. Following such review, the Neon Board determined that the value offered to Neon stockholders pursuant to the Merger Agreement is more favorable to Neon stockholders than the alternative of remaining a stand-alone public company.

*Negotiation Process*. The Neon Board actively sought proposals from other parties it believed were logical potential buyers (as more fully described above under "—Background of the Merger" located elsewhere in this proxy statement/prospectus). The Neon Board considered the fact that the terms of the Merger Agreement were the result of robust arm's-length negotiations conducted by Neon, with the knowledge and at the direction of the Neon Board and with the assistance of independent financial and legal advisors.

*Potentially Interested Counterparties*. The Neon Board considered the process conducted by the Neon Board, with the assistance of representatives of Ondra, to identify potential buyers, taking into account their expected interest, their financial capability to pursue a transaction with Neon and their ability to move quickly and efficiently in a transaction process. The Neon Board also considered the fact that, should any potential counterparty be interested in pursuing a transaction on terms more favorable to Neon and its stockholders than those contemplated by the Merger Agreement, Neon would be able to withdraw its recommendation of the Merger.

*Duff & Phelps' Opinion*. The Neon Board considered the oral opinion of Duff & Phelps rendered to the Neon Board on January 15, 2020, which was subsequently confirmed by delivery of a written opinion dated January 15, 2020 to the effect that, as of the date of such opinion and based upon and subject to the various assumptions made, procedures followed, matters considered and limitations and qualifications on the scope of the review undertaken by Duff & Phelps in preparing its opinion, as set forth in its written opinion, the exchange ratio provided for in the proposed transaction was fair, from a financial point of view, to the holders of shares of Neon common stock (without giving effect to any impact of the proposed transaction on any particular stockholder other than its capacity as a stockholder) as more fully described in "The Merger—Opinion of Neon's Financial Advisor."

*Likelihood of Completion*. The Neon Board considered the likelihood that the proposed transaction would be consummated in light of the conditions to the closing set forth in the Merger Agreement.

*Business Reputation of BioNTech*. The Neon Board considered the business reputation and capabilities of BioNTech and its management and the substantial financial resources of BioNTech and, by extension, Merger Sub, which the Neon Board believed supported the conclusion that a transaction with BioNTech and Merger Sub could be completed relatively quickly and in an orderly manner.

In the course of its deliberations, the Neon Board also considered a variety of material risks and other countervailing factors related to entering into the Merger Agreement, including, but not limited to, the following:

- the belief that a combination between Neon and BioNTech would enable the combined company to continue to build a business that provides immunotherapy products for the treatment of cancer and other serious diseases;
- the effect of the public announcement of the Merger Agreement, including effects on Neon's relationship with its partners and other business relationships and Neon's ability to attract and retain key management and personnel;
- the fact that the Merger Agreement precludes Neon from actively soliciting alternative transaction proposals and requires payment by Neon of a $3.2 million termination fee under certain circumstances, including in the event that the Neon Board withdraws its recommendation of the Merger and BioNTech terminates the Merger Agreement;
- the fact that, because the exchange ratio is fixed, if BioNTech's stock price declines and does not recover prior to the Effective Time, the value of consideration received by Neon stockholders in connection with the Merger would also decline;
- the risks associated with integrating businesses upon completion of the Merger, including risks of employee disruption, risks relating to melding of company cultures and retention risks relating to key management and employees;

- the possibility that the Merger will not be consummated and the potential negative effects on Neon's business, operations, financial results and stock price;
- the restrictions imposed by the Merger Agreement on the conduct of Neon's business prior completion of the Merger, which could delay or prevent Neon from undertaking some business opportunities that may arise during that time, including Neon's ability to capitalize the company to continue operations;
- the risk of litigation;
- the interests that certain directors and executive officers of Neon may have with respect to the Merger that may be different from, or in addition to, their interests as stockholders of Neon or the interests of Neon's other stockholders generally, as described under "—Interests of Neon's Directors and Executive Officers in the Merger" located elsewhere in this proxy statement/prospectus; and
- the various other applicable risks associated with Neon, BioNTech and the Merger, including the risks described in "Cautionary Statement Regarding Forward-Looking Statements" and "Risk Factors" located elsewhere in this proxy statement/prospectus.

The foregoing discussion of the information and factors considered by the Neon Board in reaching its conclusions and recommendations is not, and is not intended to be, exhaustive. In view of the wide variety of reasons and factors considered, the Neon Board did not find it practicable to, and did not, quantify or otherwise attempt to rank or assign relative or specific weights to the various factors considered in reaching its determination and making its recommendation. In addition, the Neon Board did not undertake to make any specific determination as to whether any particular factor, or any aspect of any particular factor, was favorable or unfavorable to the ultimate determination of the Neon Board, but rather the Neon Board conducted an overall analysis of the factors described above, including discussions with and questioning of our senior management, legal counsel and financial advisors. reach any specific conclusion with respect to any of the factors or reasons considered. Instead, the Neon Board conducted an overall review of the factors and reasons described above and determined that, in the aggregate, the potential benefits considered outweighed the potential risks or possible negative consequences of the Merger.

The foregoing discussions of the reasoning of the Neon Board and certain information presented in this section is forward-looking in nature and, therefore, the information should be read in light of the factors discussed in "Cautionary Statement Regarding Forward-Looking Statements." For the reasons described above, and in light of other factors that the Neon Board believed were appropriate to consider, the Neon Board approved the Merger Agreement and the transactions contemplated thereby, including the Merger, and unanimously recommends that Neon stockholders approve and adopt the Merger Agreement at the Neon Special Meeting.

**Certain Prospective Financial Information Reviewed by the Neon Board and Neon's Financial Advisor**

As a matter of course, Neon does not publicly disclose long-term projections of future financial performance due to among other things, the inherent difficulty of predicting financial performance for future periods and the likelihood that the underlying assumptions and estimates may not be realized. However, in connection with the exploration of strategic alternatives as described in this proxy statement/prospectus, including the proposals from BioNTech, Neon management prepared certain non-public, unaudited projections of financial performance for Neon for the fiscal years ending December 31, 2020 through 2044, or the Management Projections, based on its view of the prospects of Neon, and risk-adjusted these projections for Neon's principal programs consisting of (i) Neon's two lead T cell programs, NEO-PTC-01, or PTC, and NEO-STC-01, or STC, and, together with PTC, the T cell Therapies, and (ii) Neon's two vaccine programs, NEO-PV-01, or PV, and NEO-SV-01, or SV, and, together with PV, the Vaccines. In addition, Duff & Phelps prepared extrapolations of the Management Projections for the fiscal years ending December 31, 2045 through 2050, or the Extrapolated Projections and, together with the Management Projections, the Neon Projections, based upon the guidance and direction of Neon management. The Neon Projections were used to calculate cash flows for the fiscal years 2020 through 2050 for purposes of Duff & Phelps' discounted free cash flow analysis, as described under the "—Opinion of Neon's

Financial Advisor." The Neon Projections were based on certain internal assumptions about the probability of technical success and regulatory approval, launch timing, epidemiology, pricing, sales ramp, market growth, market share, competition, and other relevant factors relating to the commercialization of Neon's product candidates.

The Neon Projections were developed under the assumption of continued standalone operation and did not give effect to any changes or expenses as a result of the Merger or any other effects of the Merger or any impact should the Merger fail to be consummated. The Neon Projections were prepared solely for internal use and are subjective in many respects. As a result, there can be no assurance that the forecasted results will be realized or that actual results will not be significantly higher or lower than estimated. Since the unaudited forecasted financial information covers multiple years, such information, by its nature, becomes less predictive with each successive year. The estimates and assumptions underlying the unaudited forecasted financial information involve judgments with respect to, among other things, future economic, competitive, regulatory and financial market conditions that may not materialize and are inherently subject to significant uncertainties and contingencies, all of which are difficult to predict and many of which are beyond Neon's control. The Neon Projections also reflect assumptions as to certain business decisions that are subject to change. Important factors that may affect actual results and cause the Neon Projections to not be achieved include, but are not limited to: (1) conditions in the financing markets and access to sufficient capital; (2) the timing of regulatory approvals and introduction of new products; (3) the market acceptance of new products; (4) the success of clinical testing; (5) the availability of third-party reimbursement; (6) the impact of competitive products and pricing; (7) the effect of regulatory actions; (8) the effect of global economic conditions; (9) changes in applicable laws, rules and regulations; (10) the early development stage of Neon's product candidates and the corresponding time horizons to reach market and (11) other risk factors described in Neon's Annual Report on Form 10-K for the fiscal year ended December 31, 2018 and Current Reports on Form 8-K, as well as "Cautionary Statement Regarding Forward-Looking Statements" located elsewhere in this proxy statement/prospectus. In addition, the Neon Projections may be affected by Neon's ability to achieve strategic goals, objectives and targets over the applicable period. Accordingly, there can be no assurance that the Neon Projections will be realized and actual results may vary materially from those shown.

The prospective financial information included in this proxy statement/prospectus was not prepared with a view toward public dissemination or compliance with published guidelines of the SEC or established by the American Institute of Certified Public Accountants for preparation and presentation of prospective financial information or generally accepted accounting principles, or GAAP, but, in the view of Neon's management, was prepared on a reasonable basis, reflected, at the time the prospective financial information was prepared, the best currently available estimates and judgments, and presented, to the best of Neon management's knowledge and belief at that time, the expected course of action and the expected future financial performance of Neon. However, this information is not fact and should not be relied upon as being necessarily indicative of future results and readers of this proxy statement/prospectus are cautioned not to place undue reliance, if any, on the prospective financial information.

The tables below present a summary of the Neon Projections. The summary below is included solely to give Neon's stockholders access to certain long-term financial analyses and forecasts that were made available to the Neon Board and Duff & Phelps for purposes of performing analyses underlying Duff & Phelps' opinion, and is not included in this proxy statement/prospectus to influence a Neon stockholder's decision whether to vote for the Merger Proposal or for any other purpose. The inclusion of a summary of the Neon Projections in this document does not constitute an admission or representation that the information is material. The inclusion of a summary of the Neon Projections should not be regarded as an indication that Neon and/or its affiliates, officers, directors, advisors or other representatives consider the Neon Projections to be necessarily predictive of actual future events and this information should not be relied upon as such. None of Neon and/or its affiliates, officers, directors, advisors or other representatives gives any stockholder of Neon or any other person any assurance that actual results will not differ materially from the Neon Projections.

The Neon Projections do not take into account any circumstances, transactions or events occurring after the date on which they were prepared. Some or all of the assumptions underlying the Neon Projections may have changed since the date the Neon Projections were prepared.

NEON HAS NOT UPDATED AND DOES NOT INTEND TO UPDATE OR OTHERWISE REVISE THE UNAUDITED FORECASTED FINANCIAL INFORMATION TO REFLECT CIRCUMSTANCES EXISTING AFTER THE DATE WHEN MADE OR TO REFLECT THE OCCURRENCE OF FUTURE EVENTS, EVEN IN THE EVENT THAT ANY OR ALL OF THE ASSUMPTIONS UNDERLYING SUCH PROSPECTIVE FINANCIAL INFORMATION ARE NO LONGER APPROPRIATE.

Certain of the measures included in the Neon Projections may be considered non-GAAP financial measures, including free cash flow. Non-GAAP financial measures should not be considered in isolation from, or as a substitute for, financial information presented in compliance with GAAP, and non-GAAP financial measures as used by Neon may not be comparable to similarly titled amounts used by other companies.

Financial measures provided to a financial advisor are excluded from the definition of non-GAAP financial measures and therefore, are not subject to SEC rules regarding disclosures of non-GAAP financial measures, which would otherwise require a reconciliation of a non-GAAP financial measure to a GAAP financial measure. Reconciliations of non-GAAP financial measures were not relied upon by Duff & Phelps for purposes of its financial analysis as described above in “—Opinion of Neon’s Financial Advisor” located elsewhere in this proxy statement/prospectus or by the Neon Board in connection with its consideration of the Merger. Accordingly, Neon has not provided a reconciliation of the non-GAAP financial measures included in the Neon Projections.

For the foregoing and other reasons, readers of this proxy statement/prospectus are cautioned that the inclusion of a summary of the Neon Projections in this proxy statement/prospectus should not be regarded as a representation or guarantee that the targets will be achieved nor that they should place undue reliance, if any, on the Neon Projections. The Neon Projections constitute forward-looking statements and are subject to risks and uncertainties that could cause actual results to differ materially from the projected results. See also “Cautionary Statement Regarding Forward-Looking Statements” located elsewhere in this proxy statement/prospectus.

*Summary of the Neon Projections*

Set forth below is a summary of the Neon Projections. The Neon Projections reflect: (1) Neon management's assessment of the probability of success for the T cell Therapies and the Vaccines based on *Hay et al. Clinical development success rates for investigations drugs. (2014) Nature Biotechnology*; (2) Neon's existing and future net operating loss, or NOL, carryforwards, estimated using the limitations set forth under Section 382 of the Code; (3) Neon's estimated operational costs, including research and development and general and administrative costs; (4) a blended tax rate of 25.9% for Neon; (5) estimated royalties and milestone payments for Neon and (6) capital expenditure and working capital estimates for Neon. The Neon Projections included in this proxy statement/prospectus have been prepared by, and are the responsibility of, Neon's management. PricewaterhouseCoopers LLP, or PwC, has not audited, reviewed, examined, compiled nor applied agreed-upon procedures with respect to the accompanying Neon Projections and, accordingly, PwC does not express an opinion or any other form of assurance with respect thereto. The PwC report included in this proxy statement/prospectus relates to Neon's previously issued financial statements. It does not extend to the Neon Projections and should not be read to do so.

*($ in thousands)*

| | 2020 P | 2021 P | 2022 P | 2023 P | 2024 P | 2025 P | 2026 P | 2027 P | 2028 P | 2029 P | 2030 P | 2031 P | 2032 P | 2033 P | 2034 P | 2035 P |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Revenue | $ 0 | $ 0 | $ 0 | $ 0 | $ 0 | $ 0 | $ 4,207 | $ 24,608 | $ 70,851 | $129,017 | $198,836 | $272,327 | $329,791 | $371,053 | $403,236 | $420,555 |
| EBITDA(1) | (46,494) | (44,007) | (78,798) | (57,399) | (32,301) | (26,921) | (14,892) | (15,098) | (7,397) | 25,132 | 62,126 | 109,912 | 138,303 | 156,087 | 168,980 | 179,162 |
| Earnings Before Interest and Taxes | ($ 46,494) | ($ 44,007) | ($ 78,798) | ($ 57,399) | ($ 32,301) | ($ 27,220) | ($ 15,595) | ($ 16,042) | ($ 8,395) | $ 24,082 | $ 61,076 | $108,862 | $137,253 | $155,014 | $167,906 | $178,088 |
| Net Operating Profit After Tax | $ (46,494) | $ (44,007) | $ (78,798) | $ (57,399) | $ (32,301) | $ (27,220) | $ (15,595) | $ (16,042) | $ (8,395) | $ 22,835 | $ 57,912 | $103,223 | $130,143 | $118,683 | $124,419 | $131,964 |
| Free Cash Flow(2) | ($ 46,494) | ($ 44,007) | ($ 78,798) | ($ 57,399) | ($ 32,301) | ($ 38,590) | ($ 30,769) | ($ 25,107) | ($10,884) | $ 20,099 | $ 56,868 | $102,068 | $129,469 | $117,625 | $124,526 | $132,517 |

| | 2036 P | 2037 P | 2038 P | 2039 P | 2040 P | 2041 P | 2042 P | 2043 P | 2044 P | 2045 P | 2046 P | 2047 P | 2048 P | 2049 P | 2050 P |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Revenue | $437,824 | $449,440 | $453,024 | $429,989 | $399,252 | $359,170 | $320,855 | $284,136 | $229,898 | $183,995 | $144,664 | $114,350 | $91,034 | $73,031 | $59,081 |
| EBITDA(1) | 188,433 | 194,775 | 203,446 | 209,164 | 197,669 | 177,920 | 158,727 | 142,413 | 106,833 | 84,576 | 69,273 | 51,986 | 40,603 | 31,885 | 25,192 |
| Earnings Before Interest and Taxes | $187,360 | $193,702 | $202,373 | $208,091 | $196,596 | $176,847 | $157,654 | $141,340 | $105,760 | $ 83,503 | $ 68,200 | $ 50,913 | $39,530 | $30,811 | $24,119 |
| Net Operating Profit After Tax | $138,834 | $143,533 | $149,958 | $154,195 | $145,677 | $131,043 | $116,822 | $104,733 | $ 78,368 | $ 61,876 | $ 50,536 | $ 37,727 | $29,291 | $22,831 | $17,872 |
| Free Cash Flow(2) | $139,389 | $144,258 | $150,924 | $155,960 | $147,673 | $133,319 | $119,044 | $106,907 | $ 81,068 | $ 64,326 | $ 52,789 | $ 39,709 | $31,064 | $24,444 | $19,364 |

(1) EBITDA is defined as Neon's earnings before interest, taxes, depreciation and amortization and excludes stock-based compensation expense.
(2) Free cash flow is defined as Neon's free cash flow before interest payments and is calculated as earnings before interest, taxes, depreciation and amortization, less capital expenditures, less increases in net working capital and less tax expense.

**Opinion of Neon's Financial Advisor**

On December 17, 2019, Neon engaged Duff & Phelps, LLC to serve as an independent financial advisor to the Neon Board (solely in their capacity as members of the Neon Board) to provide an opinion as to the fairness, from a financial point of view, to the holders of shares of Neon common stock of the Exchange Ratio provided for in the Merger (without giving effect to any impact of the Merger on any particular Neon stockholder other than in its capacity as a Neon stockholder).

Neon retained Duff & Phelps based on Duff & Phelps' qualifications, reputation, experience in the valuation of businesses and their securities, and its experience in valuing companies in the biotechnology and biopharmaceutical industry. Duff & Phelps is a premier global valuation and corporate finance advisor that is regularly engaged to provide financial advisory services, including fairness opinions and valuation advice in connection with mergers and acquisitions, related party transactions and recapitalization transactions.

On January 12, 2020, Duff & Phelps delivered to the Neon Board a written presentation and an oral opinion, which was subsequently confirmed in writing by delivery of a written opinion dated January 15, 2020, or the Duff & Phelps Opinion, to the Neon Board that, as of that date thereof, the Exchange Ratio provided for in the Merger was fair, a financial point of

view, to the holders of shares of Neon common stock (without giving effect to any impact of the Merger on any particular Neon stockholder other than in its capacity as a Neon stockholder).

**The full text of the Duff & Phelps Opinion that Duff & Phelps delivered to the Neon Board, which sets forth, among other things, certain assumptions made, certain matters considered, and certain limitations on the review undertaken in connection with the Duff & Phelps Opinion, is attached as Annex C and is incorporated herein by reference. We urge you to read the Duff & Phelps Opinion carefully and in its entirety. The summary of the Duff & Phelps Opinion set forth in this proxy statement/prospectus is qualified in its entirety by reference to the full text of the Duff & Phelps Opinion.**

Duff & Phelps provided the Duff & Phelps Opinion for the use and benefit of the Neon Board in connection with its consideration of the Merger. The Duff & Phelps Opinion: (i) did not address the merits of the underlying business decision to enter into the Merger versus any alternative strategy or transaction; (ii) did not address any transaction related to the Merger; (iii) was not a recommendation as to how the Neon Board or any Neon stockholder should vote or act with respect to any matters relating to the Merger or otherwise, or whether to proceed with the Merger or any related transaction, and (iv) does not indicate that the Exchange Ratio in the Merger is the best possibly attainable under any circumstances; instead, it merely states whether the Exchange Ratio is within a range suggested by certain financial analyses. The decision as to whether to proceed with the Merger or any related transaction may depend on an assessment of factors unrelated to the financial analysis on which the Duff & Phelps Opinion was based.

The Duff & Phelps Opinion was only one of many factors taken into consideration by the Neon Board in making its determination with respect to the Merger. The Duff & Phelps Opinion should not be construed as creating any fiduciary duty on the part of Duff & Phelps to any party. Duff & Phelps has not undertaken, and is under no obligation, to update, revise, reaffirm or withdraw the Duff & Phelps Opinion, or otherwise comment on or consider events occurring or coming to its attention after the date of the Duff & Phelps Opinion.

In connection with the Duff & Phelps Opinion, Duff & Phelps made such reviews, analyses and inquiries as it deemed necessary and appropriate under the circumstances. Duff & Phelps also took into account its assessment of general economic, market and financial conditions, as well as its experience in securities and business valuation, in general, and with respect to similar transactions, in particular. Duff & Phelps' procedures, investigations, and financial analyses with respect to the preparation of the Duff & Phelps Opinion included, but were not limited to, the items summarized below:

1. Reviewed the following documents:
    a. Neon's annual reports and audited financial statements on Form 10-K filed with the SEC for the year ended December 31, 2018 and Neon's unaudited interim financial statements for the nine months ended September 30, 2019 included in Neon's Form 10-Q filed with the SEC;
    b. Financial projections for Neon's neoantigen, T cell-focused programs NEO-PTC-01 and NEO-STC-01 and for Neon's vaccine programs NEO-PV-01 and NEO-SV-01 for the years ending December 31, 2020 through 2050, (which consist of projections for fiscal years ending December 31, 2020 through 2044 provided by Neon management and extrapolated by Duff & Phelps for fiscal years ending December 31, 2045 through 2050), reflecting the probability of success specified by management of Neon (see "– *Certain Prospective Financial Information Reviewed by the Neon Board and Neon's Financial Advisor*" located elsewhere in this proxy statement/prospectus);
    c. License agreement by and between The Broad Institute, Inc. and Neon, dated November 13, 2015;
    d. Other internal documents relating to the history, current operations, and probable future outlook of Neon, provided to us by management of Neon;
    e. Documents related to the Merger, including the draft Merger Agreement dated January 15, 2020;

2. Discussed the information referred to above and the background and other elements of the Merger with management of Neon and representatives and their investment bank Ondra;

3. Reviewed the historical trading price and trading volume of Neon common stock and BioNTech ADSs and the publicly traded securities of certain other companies that Duff & Phelps deemed relevant;

4. Performed certain valuation and comparative analyses using generally accepted valuation and analytical techniques consisting of a discounted cash flow analysis; and

5. Conducted such other analyses and considered such other factors as Duff & Phelps deemed appropriate.

No limits were placed on Duff & Phelps by Neon in terms of the information to which it had access or the matters it could consider.

In performing its analyses and rendering the Duff & Phelps Opinion with respect to the Merger, Duff & Phelps, with Neon's consent:

1. Relied upon the accuracy, completeness, and fair presentation of all information, data, advice, opinions and representations obtained from public sources or provided to it from private sources, including management of Neon, and did not independently verify such information;

2. Relied upon the fact that the Neon Board and Neon have been advised by counsel as to all legal matters with respect to the Merger, including whether all procedures required by law to be taken in connection with the Merger have been duly, validly and timely taken;

3. Assumed that any estimates, evaluations, forecasts and projections furnished to Duff & Phelps were reasonably prepared and based upon the best currently available information and good faith judgment of the person furnishing the same, and Duff & Phelps expresses no opinion with respect to such projections or the underlying assumptions;

4. Assumed that information supplied and representations made by management of Neon are substantially accurate regarding Neon and the Merger;

5. Assumed, at the direction of management of Neon, that the Exchange Ratio is equal to 0.063 and will not be adjusted pursuant to the Merger Agreement;

6. Assumed, with management of Neon's consent, that the trading price for the BioNTech ADSs is a reliable reflection of its fair market value;

7. Assumed that the representations and warranties made in the Merger Agreement are substantially accurate;

8. Assumed that the final versions of all documents reviewed by Duff & Phelps in draft form conform in all material respects to the drafts reviewed;

9. Assumed that there has been no material change in the assets, liabilities, financial condition, results of operations, business, or prospects of Neon or BioNTech since the date of the most recent financial statements and other information made available to Duff & Phelps, and that there is no information or facts that would make the information reviewed by Duff & Phelps incomplete or misleading;

10. Assumed that all of the conditions required to implement the Merger will be satisfied and that the Merger will be completed in accordance with the Merger Agreement without any amendments thereto or any waivers of any terms or conditions thereof; and

11. Assumed that all governmental, regulatory or other consents and approvals necessary for the consummation of the Merger will be obtained without any adverse effect on Neon.

To the extent that any of the foregoing assumptions or any of the facts on which the Duff & Phelps Opinion is based prove to be untrue in any material respect, the Duff & Phelps Opinion cannot and should not be relied

upon. Furthermore, in Duff & Phelps' analysis and in connection with the preparation of the Duff & Phelps Opinion, Duff & Phelps has made numerous assumptions with respect to industry performance, general business, market and economic conditions and other matters, many of which are beyond the control of any party involved in the Merger.

The Duff & Phelps Opinion was delivered to the Neon Board on and is dated January 15, 2020. The Duff & Phelps Opinion was necessarily based upon market, economic, financial and other conditions as they existed and could be evaluated as of that date, and Duff & Phelps disclaims any undertaking or obligation to advise any person of any change in any fact or matter affecting the Duff & Phelps Opinion which may come or be brought to the attention of Duff & Phelps after January 15, 2020. In the event of any such change prior to the completion of the Merger, Duff & Phelps reserves the right to change, modify or withdraw the Duff & Phelps Opinion.

In rendering the Duff & Phelps Opinion, Duff & Phelps did not express any opinion as to the market price or value of Neon common stock or BioNTech ADS (or anything else) after the announcement or the consummation of the Merger. The Duff & Phelps Opinion should not be construed as a valuation opinion, credit rating, solvency opinion, an analysis of Neon's credit worthiness, as tax advice, or as accounting advice. Duff & Phelps has not made, and assumes no responsibility to make, any representation, or render any opinion, as to any legal matter.

In rendering the Duff & Phelps Opinion, Duff & Phelps did not express any opinion with respect to the amount or nature of any compensation to any of Neon's officers, directors, or employees, or any class of such persons, relative to the Exchange Ratio provided for in the Merger, or with respect to the fairness of any such compensation.

***Summary of Financial Analysis by Duff & Phelps***

Set forth below is a summary of the material financial analyses performed by Duff & Phelps in connection with the preparation of the Duff & Phelps Opinion. The information set forth below summarizes the material financial and comparative analyses performed by Duff & Phelps, but does not purport to be a complete description of the financial analyses performed by Duff & Phelps or the data considered by it in connection with the Duff & Phelps Opinion. The preparation of a financial opinion involves various subjective determinations as to the most appropriate and relevant methods of financial analysis and the application of these methods to particular circumstances. In arriving at the Duff & Phelps Opinion, Duff & Phelps considered a number of analytical methodologies. Each analytical technique has inherent strengths and weaknesses, and the nature of the available information may further affect the strengths and weaknesses of any particular technique. The conclusion reached by Duff & Phelps was based on all analyses and factors taken, as a whole, and also on application of Duff & Phelps' own experience and judgment. No one method of analysis should be regarded as critical to the overall conclusion. Accordingly, Duff & Phelps believes that its analyses must be considered as a whole, and that selecting portions of its analyses and of the factors considered by it, without considering all analyses and factors, could create a misleading or incomplete view of the evaluation process underlying the Duff & Phelps Opinion.

Although these paragraphs include some information in tabular format, those tables are not intended to stand alone and must be read together with the full text of each summary and the limitations and qualifications in the Duff & Phelps Opinion.

***Discounted Cash Flow Analysis***.

A discounted cash flow, or DCF, analysis is designed to provide insight into the intrinsic value of a business based on its projected earnings and capital requirements as well as the net present value of projected free cash flows. Duff & Phelps performed a DCF analysis of Neon to calculate the estimated present value of the standalone, after-tax free cash flows that Neon was forecasted to generate during fiscal years ending

December 31, 2020 through 2050, based on the Neon Projections, which consist of projections for fiscal years ending December 31, 2020 through 2044 provided by Neon management and extrapolated by Duff & Phelps for fiscal years ending December 31, 2045 through 2050 based on assumptions provided by the management of Neon (see "*—Certain Prospective Financial Information Reviewed by the Neon Board and Neon's Financial Advisor*" located elsewhere in this proxy statement/prospectus). The Neon Projections included estimates of revenues and gross profit for each product in Neon's pipeline, adjusted by the probability of success specified by management.

Duff & Phelps assumed that Neon's projected losses in fiscal years ending December 31, 2020 through 2028 would be able to offset Neon's taxable income in fiscal years ending December 31, 2029 through 2033, as well as the existing net operating loss, subject to a Section 382 limitation. Duff & Phelps tax effected Neon's pretax earnings using a 25.9% tax rate, based on Neon's projected tax rate provided by Neon management, to calculate net operating profit after tax.

Duff & Phelps then calculated the projected standalone, after-tax free cash flows of Neon, which were calculated by adding the estimated tax depreciation expense to net operating profit after tax, subtracting projected capital expenditures and changes in working capital to arrive at projected free cash flow. All of the assumptions and estimates used to determine Neon's free cash flows were provided by or discussed with and approved by Neon management. Duff & Phelps assumed that there was no terminal/continuing value at the end of the projection period (2050) because Neon's two programs were expected to have limited lives and were not expected to generate revenues past 2050.

Duff & Phelps then discounted the projected free cash flows for fiscal years ending December 31, 2020 through 2050 for Neon using discount rates ranging from 12.5% to 13.5%. The discount rates were selected upon the application of Duff & Phelps' professional judgment and experience and were based on discount rates for selected publicly traded companies, including Neon, in the biotechnology, biopharmaceutical, and immuno-oncology industries used by equity analysts in their research reports regarding such companies. Duff & Phelps also considered calculations of Neon's estimated weighted average cost of capital using the Capital Asset Pricing Model and information derived from the selected public companies as well as an estimate of the capital structure as exhibited by the selected public companies.

The selected public companies utilized in Duff & Phelps' selection of its discount rate range were companies: (i) that operated primarily in the biotechnology, biopharmaceutical, and immuno-oncology industries; (ii) with drug pipelines containing Neoantigen Cell Therapies, TCR and T-Cell Therapies, or Neoantigen Vaccines; and (iii) with drug development in the pre-clinical or early-stages. The selected companies consisted of:

- Adaptimmune Therapeutics plc
- Atara Biotherapeutics, Inc.
- Bellicum Pharmaceuticals, Inc.
- Genocea Biosciences, Inc.
- Gritstone Oncology, Inc.
- Iovance Biotherapeutics, Inc.
- Marker Therapeutics, Inc.
- ZIOPHARM Oncology, Inc.
- Adaptive Biotechnologies Corp.
- Aduro BioTech, Inc.
- Advaxis, Inc.
- Agenus Inc.
- BioNTech SE
- bluebird bio, Inc,
- Incyte Corporation
- Intellia Therapeutics, Inc.
- Moderna, Inc.
- Novartis AG

None of the selected public companies utilized was identical to Neon. The analysis of the selected public companies involved complex and subjective considerations and judgments.

The DCF analysis resulted in estimated total enterprise values for Neon ranging from ($3.5) million to $26.2 million. From these estimated enterprise values, Duff & Phelps added cash and equivalents, and subtracted

management's estimated working capital net deficit and other liabilities, each estimated by Neon management as of December 31, 2019, and subtracted Duff & Phelps' estimated value of outstanding Neon Options, to arrive at estimated equity values for Neon ranging from $18.1 million –$47.3 million. Duff & Phelps then calculated estimated per share equity values for Neon ranging from $0.59–$1.54 per share, based on 30,778,000 fully diluted shares outstanding, which included approximately 995,000 annual performance grants to be issued before the close of the Merger, per Neon management, and compared the range to the implied value of the consideration to be paid in the transaction of $2.04–$2.73 per share.

Duff & Phelps next divided the estimated $0.59–$1.54 per share equity value range for Neon by BioNTech's 30-day volume weighted average price of $32.41 per BioNTech ADS as of January 9, 2020 and the closing price of $43.27 per BioNTech ADS as of January 9, 2020 to arrive at implied exchange ratio ranges of 0.018-0.047 (based on the 30-day volume weighted average price as of January 9, 2020) and 0.014-0.036 (based on the January 9, 2020 closing price), and compared these ranges to the 0.063 Exchange Ratio in the Merger.

The implied values of the consideration to be paid in the Merger were based on the Exchange Ratio, as well as BioNTech's closing price as of January 9, 2020 of $43.27 per BioNTech ADS, in each case multiplied by the Exchange Ratio of 0.063.

The DCF analysis, like any other analytical technique used by Duff & Phelps, has inherent strengths and weaknesses. The range of valuation indications resulting from any particular technique, including the DCF analysis, should not be taken in isolation to be Duff & Phelps' view of the valuation for Neon. Accordingly, the valuation range derived from the DCF analysis was not necessarily indicative of Neon's present or future value.

***Other Factors***

Duff & Phelps also noted certain additional factors that were not considered part of Duff & Phelps' financial analyses with respect to its opinion but were referenced for informational purposes, including, among other things, the following:

*Historical Premium Analysis.* For reference only, and not as a component of its fairness analysis, Duff & Phelps reviewed premiums paid in certain acquisitions of publicly traded pre-revenue and revenue generating companies that met the following criteria: (1) the target company operated in the biotechnology, gene research and development, rDNA pharmaceuticals, protein and genome sequence products, biotechnology research equipment manufacturers, microbiology, in vivo diagnostic substances, biological products or drug delivery technologies industries, (2) the transaction involved the acquisition of a majority stake in the target, (3), the transaction was announced between December 20, 2014 and December 31, 2019, (4) the target was primarily operating in the United States and/or Canada, and (5) the total transaction value was greater than $2.5 million. Per share premiums paid in these acquisitions relative to closing share prices as of one-day prior to announcement, one-week prior to announcement and one-month prior to announcement were analyzed and compared to the implied premiums in the Merger shown below. Duff & Phelps' historical premium analysis is summarized in the following table:

| | Premium as a % of | | |
|---|---|---|---|
| | One-Day Prior to Announcement Date | One-Week Prior to Announcement Date | One-Month Prior to Announcement Date |
| **Pre-Revenue Biotechnology Companies** | | | |
| Median | 73% | 81% | 88% |
| Number of Transactions—15 | | | |
| **Revenue-Generating Biotechnology Companies** | | | |
| Median | 44% | 51% | 59% |
| Number of Transactions—52 | | | |
| **Neon(1)** | 74% | 77% | 89% |
| **Neon(2)** | 133% | 137% | 153% |

(1) *Based on the 30-day volume weighted average price of BioNTech ADSs as of January 9, 2020 and the Exchange Ratio relative to Neon's closing stock prices as of January 9, 2020, January 2, 2020, and December 9, 2019, respectively.*
(2) *Based on BioNTech ADSs' closing price as of January 9, 2020 and the Exchange Ratio relative to Neon's closing stock prices as of January 9, 2020, January 2, 2020, and December 9, 2019, respectively.*

*Historical Stock Trading Analysis*. For reference only, and not as a component of its fairness analysis, Duff & Phelps reviewed the historical trading prices and volume of Neon common stock between June 15, 2018 and January 9, 2020. As part of its review, Duff & Phelps noted that during the 30-day period ending January 9, 2020, Neon's closing stock price ranged from a low of $1.08 per share, to a high of $1.36 per share, and closed on January 9, 2020 at $1.17 per share.

***Miscellaneous***

The issuance of the Duff & Phelps Opinion was approved by Duff & Phelps' fairness opinion review committee. During the two years preceding the date of the Duff & Phelps Opinion, Duff & Phelps has not been engaged to provide financial advisory services or other services to Neon, and Duff & Phelps has not received any compensation from Neon during such period. During the two years preceding the date of its opinion, Duff & Phelps has provided valuation and other financial advisory services to BioNTech, for which it received aggregate fees that were less than 1% of Duff & Phelps' revenues, as well as customary expense reimbursement and indemnification rights. Duff & Phelps may provide financial advisory and other services to or with respect to Neon or BioNTech or their respective affiliates in the future, for which Duff & Phelps may receive compensation.

Pursuant to Neon's engagement letter with Duff & Phelps, Neon agreed to pay Duff & Phelps a fee of $250,000 for its services, $125,000 of which became payable upon signing the engagement letter and $125,000 became payable upon Duff & Phelps informing the Neon Board that it was prepared to deliver its opinion. Neon also agreed to reimburse Duff & Phelps for its reasonable out-of-pocket expenses incurred in connection with its engagement and to indemnify Duff & Phelps, its affiliates, and each of their respective directors, officers, attorneys and other agents, stockholders, employees and controlling persons against certain liabilities, including liabilities under the federal securities laws, relating to or arising out of Duff & Phelps' engagement.

**Board of Directors and Senior Management of the Combined Company**

The Supervisory Board (*Aufsichtsrat*) and Management Board (*Vorstand*) of the Combined Company will be comprised of the Supervisory Board (*Aufsichtsrat*) and Management Board (*Vorstand*) of BioNTech prior to the Effective Time.

Dr. Ulrich Wandschneider and Mr. Michael Motschmann qualify as "independent directors" as such term is defined in Rule 10A-3 under the Exchange Act and Nasdaq Rule 5605.

**Accounting Treatment**

The Merger will be accounted for in accordance with International Financial Reporting Standards, or IFRS, as issued by the International Accounting Standards Board, or IASB, and in particular, with IFRS 3, *Business Combinations*, or IFRS 3, under which the Merger qualifies since the acquisition of Neon by BioNTech fulfills the definition of a business. On the date of the acquisition, the identifiable assets and liabilities of Neon will be recorded by BioNTech at their respective acquisition-date fair values. Any excess of the purchase price over the net acquisition-date fair value of the identifiable assets acquired and liabilities assumed will be recognized as goodwill.

**Interests of Neon's Directors and Executive Officers in the Merger**

In considering the recommendation of the Neon Board to approve and adopt the Merger Agreement, Neon stockholders should be aware that some of the Neon directors and executive officers have interests in the Merger and have arrangements that are different from, or in addition to, those of Neon stockholders generally. These interests and arrangements may create potential conflicts of interest. The Neon Board was aware of these potential conflicts of interest and considered them, among other matters, in reaching its decision to approve and declare advisable the Merger Agreement and recommend that the Neon stockholders adopt and approve the Merger Agreement.

*Executive Employment Agreements with Executive Officers*

Neon previously entered into Executive Employment Agreements with each of Mr. O'Dowd, Dr. Al-Wakeel, and Dr. Gaynor, effective June 29, 2018, and with Ms. Siegel, effective August 13, 2018, in each case, as amended by retention letter agreements on November 18, 2019, or the Neon Executive Employment Agreements, and each of Mr. O'Dowd, Dr. Al-Wakeel, Dr. Gaynor, and Ms. Siegel are referred to as the Neon executive officers. The Merger will constitute a change in control under each of the Neon Executive Employment Agreements, and we expect that each Neon executive officer will be eligible to receive certain severance payments and other benefits in connection with a termination by Neon without "cause" or the executive's resignation for "good reason" (as such terms are defined in the respective Neon Executive Employment Agreement, and each such termination, a "qualifying termination") occurring on, immediately prior to, or within 12 months following the Merger.

Pursuant to the terms of each Neon Executive Employment Agreement, upon a qualifying termination and subject to the execution and non-revocation of a separation agreement with a general release of claims, each of the Neon executive officers are eligible to receive (i) a lump sum cash payment equal to 1.5 times (in the case of Mr. O'Dowd) or one times (in the case of each other Neon executive officer) the sum of his or her then-current base salary (or his or her base salary in effect immediately prior to the change in control, if higher) plus his or her target bonus in effect immediately prior to the change in control (or his or her target bonus in effect immediately prior to the change in control, if higher), (ii) if he or she is participating in Neon's group health, dental or vision plans immediately prior to his or her termination and elects COBRA health continuation, continuation of such group health coverage at the same rate as if he or her were an active employee, for up to 18 months (in the case of Mr. O'Dowd) and 12 months (in the case of each other Neon executive officer), and (iii) full acceleration of all time-based equity awards held by the executive officer. The estimated value of potential cash severance payments and health continuation is set forth in the table below, assuming each Neon executive officer is participating in the Neon health plan immediately prior to the termination and elects COBRA health continuation.

| Name | Cash Severance ($) | Health Continuation ($) |
|---|---|---|
| Hugh O'Dowd | 1,278,945 | 34,971 |
| Yasir Al-Wakeel | 574,042 | 23,233 |
| Richard Gaynor | 616,014 | 23,233 |
| Jolie Siegel | 534,643 | 8,032 |

*Retention Bonuses*

Pursuant to the retention letter agreements entered into with each of the Neon executive officers on November 18, 2019, each Neon executive officer is eligible to receive a retention bonus equal to 25% of his or her then-current annual base salary if he or she remains employed by Neon through and until the closing of the Merger. Each Neon executive officer's eligibility for this retention bonus is dependent on the satisfaction of the following criteria: (a) his or her performance has been satisfactory, as determined in Neon's sole discretion, through the end of the retention period; (b) he or she is employed by Neon on the last day of the retention period;

(c) on or before the last day of the retention period, he or she has not given notice of resignation of employment with Neon; and (d) on or before the last day of the retention period, Neon has not given him or her notice of the intent to terminate his or her employment. The table below sets forth the amount of the retention bonus each Neon executive officer is expected to receive upon the closing of the Merger:

| Name | Retention Bonus ($) |
|---|---|
| Hugh O'Dowd | 137,521 |
| Yasir Al-Wakeel | 102,508 |
| Richard Gaynor | 110,003 |
| Jolie Siegel | 99,008 |

*Indemnification of Directors and Officers; Directors' and Officers' Insurance*

The Merger Agreement provides that, for a period of six years from the Effective Time of the Merger, BioNTech shall cause the surviving corporation to: (i) indemnify and hold harmless each current or former director or officer of Neon or of a subsidiary of Neon for any and all costs and reasonable expenses imposed upon or reasonably incurred by such person in connection with or arising out of any legal proceeding (A) by reason of such person's being or having been a director or officer or an employee or agent of Neon or any subsidiary of Neon or otherwise in connection with any action taken or not taken at the request of Neon or any subsidiary of Neon or (B) arising out of such person'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 Neon or any subsidiary of Neon; and (ii) fulfill and honor in all respects the obligations of Neon and its subsidiaries pursuant to: (A) each indemnification agreement in effect between the Company or any of its subsidiaries and any current or former director or officer of Neon as of the date of the Merger Agreement; and (B) any indemnification provision and any exculpation provision set forth in the certificate of incorporation or bylaws of Neon as in effect on the date of the Merger Agreement.

The Merger Agreement also provides that, for a period of six years from the Effective Time of the Merger, BioNTech shall cause the surviving corporation to maintain officers' and directors' liability insurance in respect of acts or omissions occurring prior to the Effective Time of the Merger covering each person currently covered by Neon'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 of the Merger Agreement.

*Outstanding Neon Equity Awards Held by Executive Officers and Directors*

Neon's executive officers and directors hold Neon Restricted Stock and Neon Units, which, pursuant to the Merger Agreement, will be treated as set forth in "Treatment of Neon Equity Awards" located elsewhere in this proxy statement/prospectus. The table below sets forth the information with respect to the Neon restricted stock and Neon Units held by each of Neon's executive officers and directors assuming the completion of the Merger occurred on April 30, 2020 and that the per share price of Neon common stock is $1.75 (the average closing market price of Neon common stock over the first five business days following the public announcement on January 16, 2020 of the entry into the Merger Agreement). While each of the Neon executive officers and non-employee directors holds outstanding Neon Options that will become fully vested and exercisable in connection with the Merger, the option exercise price per share of each such Neon stock option exceeds the per share price of Neon common stock is $1.75 (the average closing market price of Neon common stock over the first five business days following the public announcement on January 16, 2020 of the entry into the Merger Agreement).

| | Accelerated Neon Restricted Stock | | Accelerated Neon Units | | |
|---|---|---|---|---|---|
| | Aggregate Number of Accelerated Shares of Neon Restricted Stock | Aggregate Value of Accelerated Shares of Neon Restricted Stock ($) | Aggregate Number of Accelerated Neon Units | Aggregate Value of Accelerated Neon Units ($) | Total ($) |
| **Executive Officers** | | | | | |
| Hugh O'Dowd | 44,480 | 77,840 | 306,667 | 536,667 | 614,507 |
| Yasir Al-Wakeel | 0 | 0 | 154,584 | 270,522 | 270,522 |
| Richard Gaynor | 3,500 | 6,125 | 159,584 | 279,272 | 285,397 |
| Jolie Siegel | 0 | 0 | 141,250 | 247,188 | 247,188 |
| **Directors** | | | | | |
| Robert Bazemore | 0 | 0 | 0 | 0 | 0 |
| Robert Kamen, Ph.D. | 0 | 0 | 0 | 0 | 0 |
| Eric S. Lander, Ph.D. | 30,000 | 52,500 | 0 | 0 | 52,500 |
| Stephen A. Sherwin, M.D. | 0 | 0 | 0 | 0 | 0 |
| Robert Tepper, M.D. | 0 | 0 | 0 | 0 | 0 |
| Cary G. Pfeffer, M.D. | 0 | 0 | 0 | 0 | 0 |
| Meryl Zausner | 0 | 0 | 0 | 0 | 0 |

*Former Executive Officers*

Robert Ang, Neon's former Chief Business Officer and a former executive officer, resigned in July 2019. Except for continued indemnification as a former officer as set forth in "Indemnification of Directors and Officers; Directors' and Officers' Insurance" located elsewhere in this proxy statement/prospectus, Dr. Ang will not receive consideration in connection with the Merger that is different from, or in addition to, those of Neon stockholders generally.

**Treatment of Neon Options, Neon Units and Neon Restricted Stock**

*Neon Options*

The Merger Agreement provides that at the Effective Time, each Neon Option will be automatically cancelled and converted 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 equal to (i) the excess, if any, of the Cash Merger Consideration over the applicable per-share exercise price of such cancelled Neon Option, multiplied by (ii) the number of shares of Neon common stock subject to such Neon Option immediately prior to such cancellation. Each Neon Option that has a per-share exercise price that equal to or greater than the Cash Merger Consideration shall be cancelled at the Effective Time for no consideration. No Neon Options will remain outstanding following the consummation of the Merger. As of March 26, 2020, there were 3,181,796 outstanding Neon Options.

*Neon Units*

Prior to the Effective Time, Neon shall issue and deliver to the Company Trust such number of shares of Neon common stock as is necessary to satisfy the obligations under all Neon Units outstanding as of immediately prior to the Effective Time. The Merger Agreement provides that at the Effective Time each outstanding Neon Unit shall vest in full and be cancelled and converted 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 for each share of Neon common stock underlying each such Neon Unit. No Neon Units will remain outstanding following the consummation of the Merger. As of March 26, 2020, there were 1,790,519 unvested and outstanding Neon Units.

*Neon Restricted Stock*

The Merger Agreement also provides that at the Effective Time, each share of Neon Restricted Stock, which is outstanding immediately prior to the Effective Time, shall vest in full and be cancelled and converted into the right to receive the Merger Consideration in the same manner as other outstanding shares of Neon common stock. As of March 26, 2020, there were 2,847,358 shares of Neon Restricted Stock, of which 248,625 were unvested as of such date.

**BioNTech's Reasons for the Merger**

At each of their respective meetings on January 15, 2020, the BioNTech Supervisory Board and the BioNTech Management Board approved the provisions of the Merger Agreement and the transactions provided for therein as well as the execution and implementation of the Merger Agreement, the execution of any other necessary or useful agreements, and all declarations and acts in connection with the performance of the Merger Agreement.

In reaching their respective decisions to approve the Merger Agreement and transactions provided for therein, the BioNTech Supervisory Board and BioNTech Management Board evaluated the Merger and the Merger Agreement in consultation with BioNTech's senior management and outside financial, legal and other advisors, reviewed various financial data and due diligence information, and considered a variety of factors, including the following, which are not intended to be exhaustive and are not presented in any relative order of importance.

Neon brings 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 engine, and NEO-STIM™, its proprietary process to directly prime, activate and expand neoantigen-targeting T cells *ex vivo*.

The Merger would expand BioNTech's cell therapy pipeline through the addition of neoantigen specific cell therapies which are complementary to BioNTech's pipeline and focus on solid tumors. These include an adoptive T cell therapy targeting individual neoantigens, and a T cell therapy targeting shared RAS oncogenes. Moreover, the Merger would accelerate BioNTech's strategy to expand its capabilities and build BioNTech's presence in the United States by creating a U.S. hub for research and clinical development. Finally, BioNTech believes the acquisition will create long-term value for BioNTech and Neon shareholders by combining capabilities, intellectual property and synergistic pipeline programs.

**Listing of the BioNTech ADSs**

Pursuant to the Merger Agreement, BioNTech has agreed, among other things, to use its reasonable best efforts to cause the BioNTech ADSs to be issued in the Merger to be listed on Nasdaq. The approval for listing of the BioNTech ADSs, subject only to official notice of issuance, is a condition to the obligations of BioNTech and Neon to complete the Merger. BioNTech has applied to list the BioNTech ADSs on Nasdaq. BioNTech expects that the BioNTech ADSs will trade on Nasdaq under the symbol "BNTX." BioNTech ADSs will trade, and be quoted, in U.S. dollars.

**Delisting and Deregistration of Neon Common Stock**

When the Merger is completed, the shares of Neon common stock currently listed on Nasdaq will cease to be quoted on Nasdaq and will be deregistered under the Exchange Act.

**Restrictions on Sales of BioNTech ADSs Received in the Merger**

The BioNTech ADSs to be issued in connection with the Merger will be freely transferable under the Securities Act and the Exchange Act, except for BioNTech ADSs issued to any holder who may be deemed to be an "affiliate" of BioNTech for purposes of Rule 144 under the Securities Act. Persons who may be deemed to be affiliates include individuals or entities that control, are controlled by, or are under common control with BioNTech and may include the senior management, directors and significant stockholders of BioNTech. Securities held by an affiliate of BioNTech may be resold or otherwise transferred without registration in compliance with the volume limitations, manner of sale requirements, notice requirements and other requirements of Rule 144 under the Securities Act or as otherwise permitted under the Securities Act. This proxy statement/prospectus does not cover resales of BioNTech ADSs, or the underlying BioNTech Shares, received upon completion of the Merger by any person, and no person is authorized to make any use of this proxy statement/prospectus in connection with an resale.

**Regulatory Approvals Requried for the Merger**

In connection with the issuance of BioNTech ADSs in the Merger, pursuant to the Merger Agreement, as a condition to the closing of the Merger, BioNTech must file a registration statement with the SEC under the Securities Act, of which this proxy statement/prospectus forms a part, that is declared effective by the SEC.

**Appraisal Rights**

Under Delaware law, the Neon stockholders are not entitled to appraisal rights in connection with the Merger or any other transaction contemplated by the Merger Agreement.

**Litigation Related to the Merger**

It is a condition to the Merger that no temporary restraining order, preliminary or permanent injunction or any other order precluding, restraining, enjoining, prohibiting, suspending or making illegal the consummation of the Merger nor any law that precludes, restrains, enjoins or prohibits the consummation of the Merger have been issued by any governmental entity or a court of competent jurisdiction. 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.

## THE MERGER AGREEMENT

*The following discussion summarizes material provisions of the Merger Agreement entered into by BioNTech, Merger Sub and Neon. This summary does not propose to be complete and is qualified in its entirety by reference to the complete copy of the Merger Agreement which is attached as Annex A to this proxy statement/prospectus. The rights and obligations of the parties are governed by the express terms and conditions of the Merger Agreement and not by this summary. The Merger Agreement should not be read alone, but should instead be read in conjunction with the other information provided elsewhere in this proxy statement/prospectus, including the annexes before making any decisions regarding the Merger.*

*The Merger Agreement is described in this proxy statement/prospectus only to provide you with information regarding its terms and conditions and this summary is not intended to provide any factual information about BioNTech, Neon or their respective businesses. The representations, warranties and covenants contained in the Merger Agreement have been made solely for the benefit of the parties to the Merger Agreement. In addition, such representations, warranties and covenants: (1) have been made only for purposes of the Merger Agreement; (2) have been qualified by certain disclosures made by the parties to one another not reflected in the text of the Merger Agreement; (3) may be subject to materiality qualifications contained in the Merger Agreement which may differ from what may be viewed as material by you; (4) were made only as of January 15, 2020 or other specific dates; and (5) have been included in the Merger Agreement for the purpose of allocating risk between the contracting parties rather than establishing matters as facts. Accordingly, the summary of the Merger Agreement is included in this proxy statement/prospectus only to provide you with information regarding the terms of the Merger and not to provide you with any other factual information regarding BioNTech, Neon or their respective businesses. You should not rely on the representations, warranties and covenants or any descriptions thereof as characterizations of the actual state of facts or conditions of BioNTech, Neon or any of their respective subsidiaries or affiliates. Moreover, information concerning the subject matter of the representations, warranties and covenants may have changed since January 15, 2020, or may in the future change, which subsequent information may or may not be fully reflected in BioNTech's or Neon's public disclosures.*

### The Merger

On January 15, 2020, BioNTech, Neon and Merger Sub entered into the Merger Agreement, pursuant to which, subject to the satisfaction or waiver of the conditions therein, Merger Sub will merge with and into Neon, with Neon surviving as a wholly owned subsidiary of BioNTech. Each of the BioNTech Supervisory Board, the BioNTech Management Board and the Neon Board has unanimously approved the Merger Agreement.

After completion of the Merger, the certificate of incorporation and the bylaws of Merger Sub, each as in effect immediately prior to completion of the Merger, will be the certificate of incorporation and bylaws, respectively, of the surviving corporation in the Merger, in each case, as amended to change the name of the surviving corporation and to comply with the indemnification obligations provided in the Merger Agreement. The directors and officers of the surviving corporation immediately following completion of the Merger will be the directors and officers, respectively, of Merger Sub, and such directors and officers shall hold office in accordance with and subject to the certificate of incorporation and bylaws of the surviving corporation.

### Merger Consideration

At the Effective Time, each share of Neon common stock, excluding shares owned by the parties to the Merger Agreement, that is issued and outstanding immediately prior to the Effective Time will be automatically cancelled and converted using the Exchange Ratio, with each BioNTech ADS representing one BioNTech Share, without interest but subject to any withholding required under applicable law. If, prior to the Effective Time, the outstanding BioNTech Shares underlying the BioNTech ADSs 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, any appropriate and proportionate adjustment shall be made to the Exchange Ratio. The BioNTech ADSs issued pursuant to and subject to the aforementioned two sentences is referred to as the "Merger Consideration".

*Fractional Shares*

No fractional BioNTech ADSs will be issued in the Merger. Each holder of Neon common stock converted pursuant to the Merger who would otherwise have been entitled to receive a fraction of a BioNTech 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 BioNTech ADS multiplied by the volume weighted average price of one BioNTech ADS for the ten trading days immediately prior to the second business day prior to the date of the closing of the Merger, starting with the opening of trading on the first trading day to the closing of the second to last trading day prior to the date of closing of the Merger, as reported by Bloomberg, or the Fractional Share Consideration.

**Treatment of Neon Options, Neon Units, Neon Restricted Stock and the Neon ESPP**

*Neon Options*

The Merger Agreement provides that at the Effective Time each Neon Option will be automatically cancelled and converted 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 equal to (i) the excess, if any, of the Cash Merger Consideration over the applicable per-share exercise price of such cancelled Neon Option, multiplied by (ii) the number of shares of Neon common stock subject to such Neon Option immediately prior to such cancellation. Each Neon Option that has a per-share exercise price equal to or greater than the Cash Merger Consideration shall be cancelled at the Effective Time for no consideration. No Neon Options will remain outstanding following the consummation of the Merger.

*Neon Units*

Prior to the Effective Time, Neon shall issue and deliver to the Company Trust such number of shares of Neon common stock as is necessary to satisfy the obligations under all Neon Units outstanding as of immediately prior to the Effective Time. The Merger Agreement further provides that at the Effective Time each outstanding Neon Unit shall vest in full and be cancelled and converted 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 for each share of Neon common stock underlying each such Neon Unit. No Neon Units will remain outstanding following the consummation of the Merger.

*Neon Restricted Stock*

The Merger Agreement also provides that at the Effective Time, each share of Neon Restricted Stock, which is outstanding immediately prior to the Effective Time, shall vest in full and be cancelled and converted into the right to receive the Merger Consideration in the same manner as other outstanding shares of Neon common stock.

*The Neon ESPP*

The Merger Agreement provides that the Neon 2018 Employee Stock Purchase Plan, or the Neon ESPP, will terminate conditioned upon, and effective immediately after, the Effective Time. The offering period in progress as of January 15, 2020, will be the final offering period under the Neon ESPP and no offering period shall be extended after such date. If the Effective Time occurs during this final offering period, such offering period will be terminated no later than three business days prior to the Effective Time, and the accumulated payroll

deductions of each participant under the Neon ESPP will be returned to such participant without the issuance of any shares of Neon common stock. No new participants have enrolled or will be permitted to enroll in the Neon ESPP after January 15, 2020, and no existing participants in the Neon ESPP have been or will be permitted to increase their payroll deductions after such date.

**Closing and Effective Time**

The parties are obligated to effect the Merger only if all of the conditions to the closing of the Merger under the Merger Agreement are either satisfied or waived at or prior to the Effective Time.

The Merger will become effective at such time as the Certificate of Merger is duly filed with the Secretary of State of the State of Delaware on the date of the closing of the Merger, or at such subsequent date or time as BioNTech and Neon and specify in the Certificate of Merger.

In the Merger Agreement, BioNTech and Neon have agreed that the date of the closing of the Merger shall be no later than the second business day following the satisfaction or waiver of the last of the conditions to the closing of the Merger (other than those conditions that by their nature are to be satisfied at the closing of the Merger, but subject to the satisfaction or waiver of those conditions), or at such other date and time as BioNTech and Neon agree in writing.

It is currently anticipated that the Effective Time will occur during the second quarter of 2020.

**Conversion of Shares**

The conversion of each share of Neon common stock into the right to receive the Merger Consideration will occur automatically at the Effective Time. BioNTech is in the process of engaging BNY Mellon to act as the contribution agent, or the Contribution Agent, and the exchange agent, or the Exchange Agent, in connection with the Share Exchange (as described below) and to perform other duties pursuant to the Merger Agreement.

In addition, the Merger Agreement provides that BioNTech will cause a facility to be established with a depositary for the purpose of issuing the BioNTech ADSs, and that BioNTech will enter into a deposit agreement with such depositary. BioNTech has appointed The Bank of New York Mellon to act as depositary.

**Share Exchange; Letter of Transmittal**

As soon as possible following the Effective Time, BioNTech shall, among other things: (i) effect the increase of its stated share capital and use the authorized share capital to issue new BioNTech Shares underlying the Merger Consideration to the Contribution Agent for the benefit of the former holders of shares of Neon common stock against the prior contribution by the Contribution Agent to BioNTech of all of the issued and outstanding shares of common stock of the surviving corporation by contribution-in-kind; (ii) see 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 BioNTech by the Contribution Agent; (iii) issue the new BioNTech Shares underlying the Merger Consideration to the Contribution Agent for the benefit of the former holders of shares of Neon common stock; (iv) cause the Contribution Agent to deposit with the depositary, for the benefit of the holders of shares of Neon common stock, the BioNTech Shares underlying the Merger Consideration; (v) cause the depositary to issue to the Exchange Agent the BioNTech ADSs comprising the Merger Consideration and (vi) cause the Exchange Agent to deliver the BioNTech ADSs reflecting the Merger Consideration to the former holders of shares of Neon common stock (such BioNTech ADSs, together with any dividends or distributions with respect thereto, being referred to as the “Exchange Fund”) and any cash in lieu of fractional BioNTech ADSs (the actions described in clauses (i) through (vi) above, collectively, the “Share Exchange”). BioNTech shall cause the Exchange Agent to, pursuant to irrevocable instructions, deliver the BioNTech ADSs contemplated to be issued out of the Exchange Fund in accordance with the aforementioned actions. The Exchange Fund shall not be used for any other purpose.

As promptly as practicable following the Effective Time (but in no event later than five business days thereafter), BioNTech 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 of Neon common stock whose shares were converted into the right to receive the Merger Consideration a letter of transmittal. This mailing will contain instructions for use in effecting the surrender of the certificates in exchange for the Merger Consideration and any amounts payable in respect of the Fractional Share Consideration and dividends or other distributions on BioNTech ADSs. Upon surrender of a certificate to the Exchange Agent, 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 of Neon common stock previously represented by such certificate, plus any Fractional Share Consideration that such holder has the right to receive and any amounts that such holder has the right to receive in respect of dividends or other distributions on BioNTech ADSs 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.

If any certificate representing shares of Neon comment stock has 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 BioNTech 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.

No dividends or other distributions with respect to BioNTech ADSs or BioNTech 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 BioNTech ADSs or BioNTech Shares issuable under the Merger Agreement, and all such dividends and other distributions shall be paid by BioNTech 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 the Merger 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 BioNTech ADSs to which such holder is entitled pursuant to the Merger 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 BioNTech ADSs.

**Withholding**

Each of the Exchange Agent, BioNTech and the surviving corporation of the Merger, will be entitled to deduct and withhold from any consideration payable pursuant to the Merger Agreement to any holder of shares of Neon common stock or Neon equity awards, such amounts as are required to be deducted or withheld from such consideration under applicable law. To the extent such amounts are so deducted or withheld, and paid over to the appropriate governmental entity, such amounts shall be treated for all purposes under the Merger Agreement as having been paid to the person to whom such amounts would otherwise have been paid.

**Dividends and Distributions**

The Merger Agreement provides during the period commencing on January 15, 2020 and ending at the earlier of the termination of the Merger Agreement and the Effective Time, neither BioNTech nor Neon may declare, set aside or pay any dividends on, or make any other distributions, in respect of any shares of their respective capital stock. Neither BioNTech nor Neon currently pays regular dividends.

**Representations and Warranties of BioNTech, Merger Sub and Neon**

The Merger Agreement contains representations and warranties made by BioNTech, Merger Sub and Neon to, and solely for the benefit of, each other. You should not rely on the representations and warranties in the Merger Agreement as characterizations of the actual state of facts relating to BioNTech or Neon, and should instead read the information provided elsewhere in this proxy statement/prospectus for information regarding BioNTech and Neon and their respective businesses.

The Merger Agreement contains customary representations and warranties made by BioNTech, Merger Sub and Neon relating to their respective businesses regarding, among other things:

- corporate matters, including organization and power to conduct business, good standing, and qualifications of subsidiaries;
- organizational documents;
- capitalization;
- reports and financial statements, including (in the case of Neon) their preparation in accordance with U.S. GAAP, their filing or furnishing with the relevant governmental entities or regulatory authorities, and compliance with the relevant laws and regulations, and that such reports and financial statements fairly present, in all material respects, the relevant financial position and results of operations;
- in the case of Neon, maintenance of disclosure controls and procedures, internal control over financial reporting, the absence of off-balance sheet partnerships or arrangements, and the absence of outstanding or unresolved or outstanding comments in comment letters from the SEC regarding SEC filings;
- with respect to Neon, the determination that Neon does not produce, design, test, manufacture, fabricate or develop “critical technologies”, is not a “pilot program U.S. business”;
- the absence of certain changes since June 30, 2019, with respect to Neon and its subsidiaries, and since December 31, 2018, with respect to BioNTech and its subsidiaries, that have had or would reasonably be expected to have, individually or in the aggregate, a material adverse effect or that, without BioNTech’s consent, would constitute a breach of certain clauses of Neon’s interim operating covenants;
- in the case of Neon, ownership of or right to intellectual property, absence of infringement, in-licensing and out-licensing, and confirmation that all of Neon’s officers, employees, consultants who are involved in the development of owned or co-owned Neon intellectual property have signed confidentiality and invention-assignment agreements;
- in the case of Neon, title to assets;
- in the case of Neon, title and rights to real property;
- in the case of Neon, the existence of, and compliance with, material contracts;
- compliance with laws and government regulations, including drug regulatory and healthcare laws and regulations;
- the possession of material permits and compliance with their terms;
- in the case of Neon, compliance with certain anti-corruption-related laws;
- in the case of Neon, the preparation and timely filing of taxes and the accuracy and completeness of certain tax matters;
- in the case of Neon, the existence of employee benefit plans;
- in the case of Neon, compliance with applicable laws related to employee benefits and the Employment Retirement Income Security Act;

- in the case of Neon, the absence of collective bargaining agreements and other employment and labor matters;
- in the case of Neon, compliance with applicable environmental laws;
- in the case of Neon, the existence and maintenance of insurance and compliance with insurance policies;
- the absence of certain material litigation, pending or threatened claims, and binding judgments, decrees or other governmental orders;
- in the case of Neon, compliance with privacy and information security laws, including laws related to the treatment and disclosure of personally identifiable information;
- corporate authorizations and approvals relative to execution, delivery and performance of the Merger Agreement;
- the requisite vote of stockholders and shareholders;
- the absence of contraventions or conflicts with organizational documents, contracts or applicable laws as a result of the Merger;
- the absence of undisclosed liabilities;
- confirmation that the F-4 and proxy statement filed in connection with the Merger will not contain any untrue or omitted statements of material fact;
- in the case of Neon, confirmation that the Neon Board has received a fairness opinion affirming the fairness of the Exchange Ratio;
- the absence of undisclosed investment banker, broker or finder fees payable in connection with the Merger;
- in the case of BioNTech and Merger Sub, confirmation that the Merger is not contingent upon their receipt of any funds or financing;
- in the case of BioNTech and Merger Sub, confirmation that neither BioNTech nor any of its subsidiaries has been an “interested stockholder” under Delaware law during any time in the three years prior to the Merger;
- in the case of BioNTech and Merger Sub, confirmation that Merger Sub was formed solely to engage in the Merger and the other transactions contemplated by the Merger Agreement; and
- in the case of BioNTech and Merger Sub, confirmation that neither BioNTech nor Merger Sub has taken or agreed to take any action, nor does BioNTech know of any circumstance, that would be reasonably expected to prevent the Merger from qualifying for the intended tax treatment.

The representations and warranties in the Merger Agreement do not survive the Effective Time.

Each of BioNTech’s, Merger Sub’s and Neon’s representations and warranties are qualified by the information included in confidential disclosure schedules delivered concurrently with the execution of the Merger Agreement on January 15, 2020.

Various of the representations and warranties made by each of BioNTech, Merger Sub and Neon are qualified by a “knowledge,” “materiality” or “material adverse effect” standard (that is, they will not be deemed untrue or incorrect unless their failure to be true or correct, individually or in the aggregate, has had or would reasonably be expected to have a material adverse effect). Certain of the representations and warranties are qualified by a general materiality standard or by a knowledge standard. For the purpose of the Merger Agreement, a “material adverse effect” has the meaning set forth below under “Material Adverse Effect.”

**Material Adverse Effect**

***Neon Material Adverse Effect***

The Merger Agreement provides that, in the case of Neon, a "material adverse effect" means any event, condition, change, occurrence or development, that, 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 on either (i) the business, assets, liabilities (contingent or otherwise), condition (financial or otherwise) or results of operations of Neon and its subsidiaries, taken as a whole, or (ii) Neon's ability to consummate the Merger or any of the other transactions contemplated by the Merger Agreement prior to the End Date. When determining whether a material adverse effect has occurred with respect to Neon, none of the following may be taken into account:

- the execution, announcement, pendency or consummation of the Merger or any of the other transactions contemplated by the Merger Agreement (including any litigation or loss of or adverse change in the relationship of Neon and its subsidiaries with their respective employees, contractors, lenders, customers, partners, suppliers, vendors or other third parties related thereto, other than termination of certain material agreements, or Neon having received formal written notification of termination from any of the parties to such material agreements);
- the identity of BioNTech or any of its affiliates as the acquirer of Neon;
- general business, economic or political conditions, or the capital, banking, debt, financial or currency markets, or changes therein;
- general conditions in an industry in which Neon and its subsidiaries operate or in any specific jurisdiction or geographical area in the United States or elsewhere in the world where Neon or its subsidiaries operate, or changes therein;
- changes in GAAP or applicable law, or the enforcement or interpretation thereof, including the adoption, implementation, repeal, modification or reinterpretation of any law, regulation or policy by any governmental entity;
- the taking of any action, or the failure to take any action, in each case at the written direction of BioNTech or Merger Sub;
- 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;
- any claim or legal proceeding involving Neon, Neon's Board of Directors, or any committee thereof relating to the Merger or the other transactions contemplated by the Merger Agreement, or any related transaction;
- any failure by Neon to meet internal or analysts' estimates, projections, expectations, budgets or forecasts of financial performance measures, or any decline in the price or change in trading volume of shares of Neon;
- the matters expressly set forth in Neon's disclosure schedule (except for (i) any material worsening of a matter disclosed therein, and (ii) matters included in Neon's disclosure schedule in response to listing requirements);

except, in the case of the effects, changes, events, circumstances or developments referred to in the third, fourth, fifth and seventh bullets in the immediately preceding list, to the extent materially disproportionately affecting Neon and its subsidiaries, taken as a whole, as compared to other participants in the industries in which Neon and its subsidiaries operate.

The definition of "material adverse effect" with respect to Neon, is subject to various other exceptions and qualifications agreed by Neon and BioNTech, and is described in more detail in the Merger Agreement.

***BioNTech Material Adverse Effect***

The Merger Agreement provides that, in the case of BioNTech, a "material adverse effect" means any event, condition, change, occurrence or development that, individually or in the aggregate with all other events, conditions, changes, occurrences or developments, has had a material adverse effect on the ability of BioNTech or Merger Sub to consummate the Merger or any of the other transactions contemplated by the Merger Agreement prior to the End Date.

**Restrictions on Neon's Business Pending the Closing of the Merger**

Neon has agreed that, except as (i) required under the Merger Agreement, (ii) required by applicable law, (iii) consented to by BioNTech in writing (which consent shall not be unreasonably withheld, conditioned or delayed, solely with respect to certain restrictions), or (iv) set forth in Neon's disclosure schedule, Neon will, in the period prior to closing of the Merger: (A) conduct its business and operations in the ordinary course of business consistent with past practice; (B) use 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, (3) maintain all governmental authorizations, (4) maintain satisfactory relationships with customers, lenders, suppliers, licensors, licensees, distributors, and others with material business relationships with Neon; and (5) not, directly or indirectly:

- 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;
- redeem, repurchase or otherwise acquire, or offer to redeem, repurchase or otherwise acquire, directly or indirectly, any of its capital stock or other securities;
- sell, issue, grant or authorize the issuance or grant of (1) any capital stock or other security of Neon, (2) 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 Neon, or (3) any instrument convertible into or exchangeable for any capital stock or other security of Neon (in each of clauses (1) through (3), other than (x) the issuance of shares upon exercise of Neon Options granted pursuant to the terms of award agreements outstanding as of the date of the Merger Agreement or in accordance with the terms of the Neon ESPP, and (y) grants or awards of shares (including Neon Restricted Stock and Neon Units) or Neon Options required to be made under the Neon ESPP pursuant to the existing offering period in effect as of January 15, 2020 and listed on Neon's disclosure schedule);
- split, combine or reclassify its outstanding shares of capital stock of Neon or enter into any agreement with respect to voting of any of the capital stock of any of the capital stock of Neon or any securities convertible into or exchangeable for such capital stock;
- except as required by the Merger Agreement, applicable law, or a Neon employee benefit plan as in effect prior to January 15, 2020, (1) 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 Neon or its subsidiaries, (2) grant or increase any severance, change of control, retention, termination or similar pay to any such individual; (3) enter into, establish, adopt, modify, amend or terminate any Neon employee benefit plan (or any arrangement that would constitute a benefit plan if in effect on January 15, 2020); (4) 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 Neon benefit plan; (5) terminate the employment or services of any employee, officer, director or consultant of Neon or its subsidiaries, other than terminations for cause in the ordinary course of business consistent with past practice; (6) hire, or engage any new employee, officer, director or consultant of Neon or its subsidiaries; (7) recognize any new union, works council or similar employee representative with respect to any employee of Neon or its subsidiaries; or (8) implement or announce any plant closing or employee layoff that would reasonably be expected to implicate the WARN Act;

- commence any offering or offering period under the ESPP or extend any offering period under the ESPP in effect as of January 15, 2020;
- amend, modify, waive, rescind or otherwise change Neon's organizational documents;
- incur or assume any long-term or short-term indebtedness, other than indebtedness owing by any subsidiary of Neon to Neon;
- make any capital expenditures in excess of $100,000 individually, or $250,000 in the aggregate;
- 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 such rights, assets, or securities to any other person, or waive or relinquish, abandon, allow to lapse or encumber (except for any permitted encumbrance) any such rights, assets, or securities, except for sales of inventory or dispositions of obsolete or worthless equipment in the ordinary course of business consistent with past practice;
- change any of its methods of accounting or accounting practices in any material respect unless required by GAAP or applicable law;
- 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;
- issue or forgive any loans, advances or capital contributions to any other person;
- enter into any transactions or contracts with any affiliates or other persons that would be required to be disclosed under Item 404 or Regulation S-K of the SEC;
- form any subsidiary;
- 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;
- settle or compromise any material tax liability, agree to any extension or waiver of the limitations period applicable to any material taxes or material tax returns, or make any material tax election;
- write up, write down, or write off the book value of any assets, except in accordance with GAAP;
- compromise, settle, or offer or propose to settle any legal proceeding or other claim, other than immaterial routine matters in the ordinary course of business consistent with past practice that do not involve payments in excess of $50,000;
- initiate or settle any intellectual property disputes (whether such intellectual property is owned by Neon or a third party);
- terminate, cancel, assign, renew or agree to any material amendment of, change in, or waiver under, any existing Neon material contract, enter into any contract that would be a Neon material contract if existing on January 15, 2020, or amend or modify any existing contract such that, upon amendment, the contract would be a Neon material contract;
- convene any regular or special meeting (or any adjournment or postponement thereof) of Neon's stockholders other than the Neon Special Meeting;
- fail to keep in full force and effect Neon's insurance policies or revised provisions providing insurance coverage in a manner consistent with past practice with respect to assets, operations and activities of Neon or its subsidiaries as are currently in effect;
- take any action that would reasonably be expected to prevent or materially impede, interfere with, hinder or delay the consummation by BioNTech or its subsidiaries of the Merger or the other transactions contemplated by the Merger Agreement;

- implement or announce any material employee layoffs;
- commence any clinical study of which BioNTech has not been informed prior to January 15, 2020, or discontinue terminate or suspend (i) any ongoing clinical study unless mandated by any governmental entity or necessary to protect the health and well-being of clinical study subjects or (ii) any ongoing IND-enabling preclinical study without first consulting BioNTech in good faith; or
- agree, resolve or commit to do any of the foregoing.

These restrictions, which are subject to various exceptions and qualifications agreed by Neon and BioNTech, are described in more detail in the Merger Agreement. In addition, some of the restrictions on Neon's business are qualified by confidential disclosures made by Neon to BioNTech.

**Restrictions on BioNTech's Business Pending the Closing of the Merger**

BioNTech has agreed that, except as (i) required under the Merger Agreement, (ii) required by applicable law or (iii) consented to by Neon in writing (which consent shall not be unreasonably withheld, delayed or conditioned), in the period prior to the closing of the Merger, it will use commercially reasonable efforts to not, directly or indirectly:

- declare, set aside or pay any dividends on, or make any other distributions (whether in cash, stock, property or any combination thereof) in respect of, any of its capital stock;
- amend the certificate of incorporation or bylaws of BioNTech or its subsidiaries, in any manner that would adversely affect the consummation of the Merger or affect the holders of shares of Neon common stock whose shares are converted into BioNTech ADSs at the Effective Time in a manner different from holders of BioNTech ADSs prior to the Effective Time;
- take or omit to take any action to cause the BioNTech ADSs to cease to be eligible for listing on Nasdaq; or
- agree, resolve or commit to do any of the foregoing.

These restrictions, which are subject to various exceptions and qualifications agreed by BioNTech and Neon, are described in more detail in the Merger Agreement. In addition, some of the restrictions on BioNTech's business are qualified by confidential disclosures made by BioNTech to Neon.

**Agreement Not to Solicit Other Offers**

Subject to the exceptions described below and in the Merger Agreement, Neon has agreed, among other things, that it will not, directly or indirectly:

- 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;
- 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 Neon 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;
- 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);
- approve, endorse or recommend any proposal that constitutes or could reasonably be expected to lead to any acquisition proposal;

- enter into any letter of intent, agreement, contract, commitment or agreement in principle (other than a customary confidentiality agreement on terms not less favorable in the aggregate to Neon than the terms of the existing confidentiality agreements between BioNTech and Neon) with respect to an acquisition proposal or enter into any agreement, contract or commitment requiring Neon to abandon, terminate or fail to consummate, or that could otherwise materially impede the ability of BioNTech and Merger Sub to consummate, the Merger or the other transactions contemplated by the Merger Agreement; or
- propose, resolve or agree to do any of the foregoing.

Neon has further agreed (1) to immediately cease and terminate any existing solicitations, encouragements, facilitations, discussions or negotiations with any third party with respect to any acquisition proposal, and (2) promptly 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 Neon or any of its subsidiaries to any third party or representative to be returned or destroyed in accordance with the applicable confidentiality agreement.

However, at any time prior to the approval and adoption of the Merger Agreement by Neon stockholders, Neon receives an unsolicited written *bona fide* acquisition proposal from a third party, which did not result from a breach of provisions of the Merger Agreement related to unsolicited proposals and adverse board recommendation changes, and the Neon 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 failure to take the following actions would be inconsistent with fiduciary duties under applicable law, then Neon may:

- furnish information and data with respect to Neon 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 Neon and its subsidiaries; and
- 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;

provided, however, that Neon will not furnish any non-public information except pursuant to a customary confidentiality agreement on terms not less favorable in the aggregate to Neon than the terms of the existing confidentiality agreement between BioNTech and Neon and Neon will concurrently provide to BioNTech any information concerning Neon or its subsidiaries provided to such third party which was not previously provided to BioNTech.

Notwithstanding the foregoing, Neon and its representatives may, 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 in order to permit the Neon 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 direct any persons to the Merger Agreement.

The Merger Agreement provides that the term “acquisition proposal” means, with respect to Neon, 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 Neon, 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 Neon, (ii) any merger, amalgamation, consolidation, share exchange, asset acquisitions, business combination, joint venture, license, collaboration, research and development or other similar transaction involving Neon or any of

its subsidiaries, the business of which constitutes 15% or more of the net revenues, net income or assets of Neon and its subsidiaries, taken as a whole, (iii) any liquidation, dissolution, recapitalization, extraordinary dividend or other significant corporate reorganization of Neon or any of its subsidiaries, the business of which constitutes 15% or more of the net revenues, net income or assets of Neon and its subsidiaries, taken as a whole, or (iv) any combination of the foregoing.

The Merger Agreement provides that the term "superior proposal" means any *bona fide* written acquisition proposal made after the date hereof that the Neon 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 BioNTech in response to such proposal pursuant to the provisions of the Merger Agreement related to adverse board recommendation changes, which (a) would, if consummated, result in a transaction that is more favorable from a financial point of view to Neon'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%".

**Neon's Board Recommendation**

Subject to the exceptions described below and in the Merger Agreement, Neon has agreed to recommend that the Neon stockholders approve and adopt the Merger Agreement at the Neon Special Meeting, such recommendation referred to as the Neon Board Recommendation.

Notwithstanding the above, the Neon 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 an adverse board recommendation change, provided that:

- Neon shall have provided at least four business days' prior written notice to BioNTech advising BioNTech that the Neon Board intends to make an adverse board 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;
- during such notice period, Neon shall, and shall cause its representatives to, to the extent requested by BioNTech, negotiate with BioNTech in good faith to make such adjustments to the terms and conditions of the Merger Agreement as would enable the Neon Board to maintain the Neon Board Recommendation; and
- taking into account all adjustments to the terms of the Merger Agreement that may be irrevocably offered in writing by BioNTech as described above, the Neon Board (no earlier than the end of such four business day notice period) 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 an adverse board recommendation change would be inconsistent with its fiduciary duties under applicable law.

Nothing described in the bullets above shall be deemed to modify or otherwise affect the obligation of Neon to submit the adoption of the Merger Agreement and the approval of the Merger to the Neon stockholders and to seek the Neon Stockholder Approval at the Neon Special Meeting.

Notwithstanding the above, the Neon Board may fail to (i) make, withdraw, amend, modify, or materially qualify, in a manner adverse to BioNTech or Merger Sub, or otherwise make any statement or proposal inconsistent with, the Neon Board Recommendation; (ii) include the Neon Board Recommendation in the proxy

statement that is mailed to Neon stockholders; or (iii) reaffirm (publicly, if so requested by BioNTech) the Neon Board Recommendation within ten business days after the date any acquisition proposal (or material modification thereto) is first publicly disclosed by Neon or the person making such acquisition proposal, each following the occurrence of an intervening event, if the Neon 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 that:

- Neon shall have provided at least four business days' prior written notice to BioNTech advising BioNTech that the Neon Board intends to make an adverse board recommendation change and specifying the material facts underlying the determination by the Neon Board that an intervening event has occurred and the reason for such adverse board recommendation change, in reasonable detail (a "Notice of Intervening Event");
- during such notice period, Neon shall, and shall cause its representatives to, to the extent requested by BioNTech, negotiate with BioNTech in good faith to make such adjustments to the terms and conditions of the Merger Agreement as would enable the Neon Board to maintain the Neon Board Recommendation; and
- taking into account all adjustments to the terms of the Merger Agreement that may be irrevocably offered in writing by BioNTech as described above, the Neon Board (no earlier than the end of such four business day notice period) determines in good faith after consultation with its financial advisor and outside legal counsel that the failure to effect an adverse board recommendation change would be inconsistent with its fiduciary duties under applicable law.

The Merger Agreement provides that the term "intervening event" means, with respect to Neon, 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 Neon Board, as of or prior to January 15, 2020, affecting the business, assets or operations of Neon, 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 Neon Board after the date hereof and prior to the time of obtaining the Neon 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 of Neon common stock, (iv) any change, in and of itself, in the market price or trading volume of the BioNTech ADSs, (v) the fact that Neon 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 Neon (or to be refrained from being taken by Neon) pursuant to, the Merger Agreement.

**Preparation of the Form F-4 and the Proxy Statement; Neon Special Meeting**

Neon has agreed to prepare and file with the SEC the proxy statement, and BioNTech has agreed to prepare and file with the SEC the Form F-4 (which shall include a prospectus with respect to the BioNTech ADSs issuable in the Merger and the proxy statement to be sent to the stockholders of Neon).

Neon has agreed to use reasonable best efforts to cause this proxy statement to be mailed to Neon's stockholders as promptly as practicable following the date this Form F-4 is declared effective under the Securities Act. Neon has agreed to duly call, give notice of, convene and hold the Neon Special Meeting for the purpose of obtaining the Neon Stockholder Approval as soon as reasonably practicable following the date this Form F-4 is declared effective.

Neon has agreed to use reasonable best efforts to solicit from the holders of shares of Neon common stock proxies in favor of the adoption of the Merger Agreement and approval of the Merger.

**Indemnification and Insurance**

BioNTech has agreed to, and has agreed to cause the surviving corporation to, maintain officers' and directors' liability insurance in respect of acts or omissions occurring prior to the Effective Time for six years after the Effective Time covering each person currently covered by Neon'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 January 15, 2020; provided, however, that in satisfying this obligation, neither BioNTech nor the surviving corporation shall be obligated to pay annual premiums in excess of 300% of the amount per annum Neon paid in its last full fiscal year prior to January 15, 2020, or 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 Neon 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 Merger or the other transactions contemplated by the Merger Agreement; 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 BioNTech 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.

The Merger Agreement provides that, from and after the Effective Time, BioNTech 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 Neon or of a subsidiary of Neon 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 such individual shall have made an undertaking to repay such expenses if it is ultimately determined that such individual was not entitled to indemnification under the Merger Agreement), judgments, fines, penalties or liabilities (including amounts paid in settlements or compromises) imposed upon or reasonably incurred by such individual 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 individual 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) (A) by reason of such individual's being or having been a director or officer or an employee or agent of Neon or any subsidiary of Neon or otherwise in connection with any action taken or not taken at the request of Neon or any subsidiary of Neon or (B) arising out of such individual'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 Neon or any subsidiary of Neon (including in any capacity with respect to any employee benefit plan), in each of clause (A) or (B) whether or not such individual continues in such position at the time such legal proceeding is brought or threatened and at, or at any time prior to, the Effective Time (including any legal proceeding relating in whole or in part to the Merger or the other transactions contemplated by the Merger Agreement or relating to the enforcement of this provision or any other indemnification or advancement right of any such individual), to the fullest extent permitted under applicable law; and (ii) fulfill and honor in all respects the obligations of Neon and its subsidiaries pursuant to: (x) each indemnification agreement in effect between Neon or any of its subsidiaries and any such individual as of January 15, 2020; and (y) any indemnification provision (including advancement of reasonable expenses) and any exculpation provision set forth in the certificate of incorporation or bylaws of Neon as in effect on January 15, 2020. BioNTech shall cause the surviving corporation to pay all reasonable expenses, including reasonable attorneys' fees, that may be incurred by such individuals in connection with their enforcement of their aforementioned rights. BioNTech'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.

The Merger Agreement also provides that these obligations of BioNTech and the surviving corporation shall not be terminated or modified in such a manner as to adversely affect the rights of any such indemnified individual unless (x) such termination or modification is required by applicable law or (y) the affected indemnified individual shall have consented in writing to such termination or modification.

**Regulatory Filings**

The Merger Agreement requires each party to 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 Merger and the other transactions and actions contemplated to be consummated by the Merger Agreement as expeditiously as practicable and to ensure that the conditions set forth in the Merger Agreement are satisfied. Without limiting the generality of the foregoing, the parties have agreed to furnish to the other parties such necessary information and reasonable assistance as the other parties may reasonably request in connection with the foregoing.

In case at any time after the Effective Time any further action is necessary to carry out the purposes of the Merger Agreement, the parties have agreed to 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 for such purposes or otherwise to consummate the Merger and the other transactions and actions contemplated to be consummated by the Merger Agreement.

The parties have further agreed that, other than in connection with the matters contemplated by the Merger Agreement, 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 Merger and the other transactions and actions contemplated to be consummated by the Merger Agreement, any contact by a party with any governmental entity or the staff or regulators of any governmental entity relating to the Merger and the other transactions and actions contemplated to be consummated by the Merger Agreement 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 related to the preparation of the proxy statement/prospectus, interactions between BioNTech or Neon 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 Merger and the other transactions and actions contemplated to be consummated by the Merger Agreement 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 Merger and the other transactions and actions contemplated to be consummated by the Merger Agreement.

**Other Agreements**

The Merger Agreement also contains other covenants and agreements, including with respect to access to information of Neon, public announcements with respect to the transactions contemplated by the Merger Agreement, compliance by Neon with its employment, change of control and similar agreements, and obtaining third party consents under Neon's business contracts.

**Conditions to Closing**

Each party's obligation to effect the Merger is subject to satisfaction at or prior to the Effective Time of each of the following conditions (which may be waived in whole or in part by such party):

- the Neon Stockholder Approval shall have been obtained;

- no law shall have been enacted 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;
- no order (whether temporary, preliminary or permanent) of a governmental entity or court of competent jurisdiction is in effect precluding, restraining, enjoining, prohibiting, suspending or making illegal the consummation of the Merger;
- 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;
- the BioNTech ADSs issued in the Merger shall have been approved for listing on Nasdaq, subject to official notice of issuance; and
- as required by German law, a draft of the determination of adequacy of the contribution-in-kind by the German court-appointed accounting firm shall confirm such adequacy.

The obligations of BioNTech and Merger Sub to effect the Merger are further subject to the satisfaction or waiver of BioNTech at or prior to the Effective Time of the following conditions:

- the representations and warranties of Neon in the Merger Agreement (without giving effect to any references therein to material adverse effect or other materiality qualifiers), other than the representations and warranties related to capitalization, due organization, absence of changes, authority and the binding nature of the Merger Agreement, takeover statutes, the fairness opinion and the financial advisor, will be true and correct in all respects as of January 15, 2020 and as of the date of the closing of the Merger 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 Neon to be so true and correct, individually or in the aggregate, has not had and would not reasonably be expected to have a material adverse effect with respect to Neon;
- the representations and warranties relating to capitalization will be true and correct in all respects (except to a *de minimis* extent) as of January 15, 2020 and as of the date of the closing of the Merger as though made on and as of such date and time;
- the representations and warranties relating to due organization, absence of changes, authority and the binding nature of the Merger Agreement, takeover statutes, the fairness opinion and the financial advisor will be true and correct in all material respects as of January 15, 2020 and as of the date of the closing of the Merger 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);
- Neon shall have performed or complied in all material respects with all of the obligations, agreements and covenants required to be performed or complied with by Neon under the Merger Agreement at or prior to the closing of the Merger;
- BioNTech shall have received a closing certificate signed by an authorized executive officer of Neon, dated as of the date of the closing of the Merger to the effect that certain conditions in the Merger Agreement have been satisfied;
- since January 15, 2020, a material adverse effect with respect to Neon shall not have occurred;
- no more than 30 days prior to the closing of the Merger, Neon shall have delivered to BioNTech a certificate(in form and substance reasonably satisfactory to BioNTech) pursuant to Treasury

Regulations Section 1.1445-2(c)(3), stating that Neon is not and has not been a United States real property holding corporation (as defined in Section 897(c)(2) of the Internal Revenue Code) during the applicable period specified in Section 897(c)(1)(A)(ii) of the Internal Revenue Code; and

- BioNTech shall have received its counsel's tax opinion, dated as of the date of the closing of the Merger.

Neon's obligation to effect the Merger is further subject to the satisfaction or waiver of Neon at or prior to the Effective Time of the following conditions:

- the representations and warranties of BioNTech and Merger Sub in the Merger Agreement (without giving effect to any references therein to material adverse effect or other materiality qualifiers), other than the representations and warranties related to capitalization, due organization, SEC filings and financial statements, absence of changes, authority and the binding nature of the Merger Agreement, and the financial advisor, will be true and correct in all respects as of January 15, 2020 and as of the date of the closing of the Merger 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 BioNTech 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 material adverse effect with respect to BioNTech;
- the representations and warranties relating to capitalization will be true and correct in all respects (except to a *de minimis* extent) as of January 15, 2020 and as of the date of the closing of the Merger as though made on and as of such date and time;
- the representations and warranties relating to due organization, SEC filings and financial statements, absence of changes, authority and the binding nature of the Merger Agreement, and the financial advisor will be true and correct in all material respects as of January 15, 2020 and as of the date of the closing of the Merger 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);
- BioNTech and Merger Sub shall have performed or complied in all material respects with all of the obligations, agreements and covenants required to be performed or complied with by BioNTech and Merger Sub under the Merger Agreement at or prior to the closing of the Merger;
- Neon shall have received a closing certificate signed by an authorized executive officer of BioNTech, dated as of the date of the closing of the Merger to the effect that certain conditions in the Merger Agreement have been satisfied; and
- Neon shall have received its counsel's tax opinion, dated as of the date of the closing of the Merger.

Unless otherwise specified in the Merger Agreement, any or all of the conditions described above may be waived in writing, in whole or in part, by BioNTech or Neon, to the extent permitted by applicable law.

**Termination Events**

The Merger Agreement may be terminated at any time prior to the Effective Time by mutual written consent of BioNTech and Neon, and either party may terminate the Merger Agreement in the following circumstances:

- if the Merger shall not have been consummated by October 15, 2020, or the End Date,, except that the right to terminate the Merger Agreement on this basis shall not be available to any party whose breach of any representation, warranty, covenant, or agreement set forth in the Merger Agreement has been the cause of, or resulted in, the failure of the Merger to be consummated on or before the End Date;

- 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 Merger or the other transactions contemplated by the Merger Agreement and such law or order shall have become final and nonappealable; provided, however, the right to terminate the Merger Agreement on this basis shall not be available to any party whose breach of any representation, warranty, covenant, or agreement set forth in the Merger Agreement has been the cause of, or resulted in, the issuance, promulgation, enforcement, or entry of any such law or order; or
- if the Merger Agreement has been submitted to the Neon stockholders for adoption at a duly convened Neon stockholders' meeting and the Neon Stockholder Approval shall not have been obtained at such meeting (unless such Neon stockholders' meeting has been adjourned or postponed, in which case at the final adjournment or postponement thereof).

BioNTech may terminate the Merger Agreement at any time prior to the Effective Time as follows:

- if an adverse board recommendation change shall have occurred or Neon shall have materially breached its obligations under the Merger Agreement related to unsolicited proposal and adverse board recommendation changes;
- if there shall have been a breach by Neon of any representation, warranty, covenant, or agreement on the part of Neon set forth in the Merger Agreement such that the conditions to the closing of the Merger set forth in the Merger Agreement 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 BioNTech stating BioNTech's intention to terminate the Merger Agreement on this basis and (ii) three business days before the End Date;

Neon may terminate the Merger Agreement at any time prior to the Effective Time as follows:

- if there shall have been a breach by BioNTech or Merger Sub of any representation, warranty, covenant or agreement on the part of BioNTech or Merger Sub set forth in the Merger Agreement such that the conditions to the closing of the Merger set forth in the Merger Agreement 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 with the earlier of (i) 30 calendar days after the receipt of written notice thereof from Neon stating Neon's intention to terminate the Merger Agreement and (ii) three business days before the End Date.

**Termination Fees**

Neon will be required to pay to BioNTech a termination fee of $3,200,000 by wire transfer of immediately available funds if the Merger Agreement is terminated as follows:

- by BioNTech in the event that an adverse board recommendation change shall have occurred or Neon shall have materially breached its obligations under the Merger Agreement related to unsolicited proposal and adverse board recommendation changes;
- by BioNTech in the event that there shall have been a breach by Neon of any representation, warranty, covenant, or agreement on the part of Neon set forth in the Merger Agreement such that the conditions to the closing of the Merger set forth in the Merger Agreement 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 BioNTech stating BioNTech's intention to terminate the Merger Agreement on this basis and (ii) three business days before the End Date, an acquisition proposal is made or communicated to Neon or is publicly disclosed and not withdrawn before such termination, and during the period from January 15, 2020 through twelve months after such termination, Neon consummates an acquisition

proposal or enters into a definitive agreement in respect of an acquisition proposal, which acquisition proposal is subsequently consummated; or

- by BioNTech or Neon in the event that the Merger Agreement has been submitted to the Neon stockholders for adoption at a duly convened Neon stockholders' meeting and the Neon Stockholder Approval shall not have been obtained at such meeting, an acquisition proposal is made or communicated to Neon or is publicly disclosed and not withdrawn before the Neon Special Meeting, and during the period from January 15, 2020 through twelve months after such termination, Neon consummates an acquisition proposal or enters into a definitive agreement in respect of an acquisition proposal, which acquisition proposal is subsequently consummated.

**Effect of Termination**

In the event of a termination as described above under "—Termination Events," the Merger Agreement will be of no further force or effect without liability of any party (or any representative of such party) except for certain sections of the Merger Agreement, including provisions regarding termination, termination fees, confidentiality and miscellaneous provisions and any of the applicable definitions thereto. None of the parties will be relieved or released from any liabilities or damages arising out of their knowing or intentional material breach of any provision of the Merger Agreement or any other agreement delivered in connection with the Merger Agreement or any fraud, except that the failure of any party to consummate the Merger by the time specified in the Merger Agreement after all conditions 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 in the Merger Agreement notwithstanding any termination of the Merger Agreement.

**Expenses**

Other than as described above, or as otherwise provided in the Merger Agreement, all expenses incurred in connection with the Merger Agreement, the Merger, and the other transactions contemplated by the Merger Agreement will be paid by the party incurring such fees and expenses.

**Amendment**

The Merger 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 the Merger Agreement or, in the case of a waiver, by each party against whom the waiver is to be effective, provided, however, that following receipt of the Neon Stockholder Approval, there shall be no amendment or supplement to the provisions of the Merger 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 of Neon common stock without such approval.

**Governing Law; Jurisdiction; Waiver of Trial by Jury**

The Merger Agreement, and all claims or causes of action that may be based upon, arise out of or relate to the Merger Agreement or the negotiation, execution or performance of the Merger Agreement, will 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 to the Merger Agreement have agreed and consented 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 have waived 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. Merger Agreement further provides a waiver of trial by jury.

**Specific Performance**

The parties to the Merger Agreement have agreed 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 the Merger Agreement were not performed in accordance with their specific terms or were otherwise breached. The parties have accordingly agreed that each party shall be entitled to an injunction or injunctions to prevent breaches or threatened breaches of the Merger Agreement and to enforce specifically the terms and provisions of the Merger Agreement in a court of competent jurisdiction as set forth in the Merger Agreement, and, in any action for specific performance, each of the parties has waived the defense of adequacy of a remedy at law and any requirement for the securing or posting of any bond in connection with such remedy.

## BUSINESS OF BIONTECH AND CERTAIN INFORMATION ABOUT BIONTECH

### 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 eight 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, Pfizer Inc., or Pfizer, and Shanghai Fosun Pharmaceutical (Group) Co., Ltd., or Fosun Pharma. 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, the University of Pennsylvania, Genevant and Fosun Pharma, we are also leveraging our mRNA technology beyond oncology to treat influenza, other infectious diseases 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 three product candidates into the clinic in 2020, with six clinical trial updates 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 provide non-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 eight pharmaceutical companies, which comprise Genentech, Sanofi, Genmab, Genevant, Eli Lilly, Bayer, Pfizer and Fosun Pharma. 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 and Pfizer and Fosun Pharma to develop a COVID-19 vaccine, each through our mRNA-based immunotherapy technology. We also 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. Ryan Richardson, our Chief Strategy Officer, joined BioNTech from J.P. Morgan Securities LLC, where he served as the Executive Director, Healthcare Investment Banking. 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 1H 2020; start registrational phase 2 in 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 2H 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) | Enrollment update 2020[4]; Interim data update in 2021<br>Data update 2020; two phase 2 trials planned in adjuvant indications in 2020 |
| | | | Multiple solid tumors | | | | | | |
| | Intratumoral Immunotherapy | SAR441000 (BNT131) | Solid tumors (*IL-12sc, IL-15sushi, GM-CSF, IFNα*) | | | | | Sanofi (global profit/ loss share) | Data update 2H 2020[5] |
| | RiboMabs (mRNA-encoded antibodies) | BNT141 | Multiple solid tumors | | | | | Global | Phase 1 start 2H 2021 |
| | | BNT142 | Multiple solid tumors (*CD3×CLDN6*) | | | | | Global | Phase 1 start 1H 2021 |
| | RiboCytokines (mRNA-encoded cytokines) | BNT151 | Multiple solid tumors (Optimized *IL-2*) | | | | | Global | Phase 1 start 1H 2021 |
| | | BNT152, BNT153 | Multiple solid tumors (*IL-7, IL-2*) | | | | | Global | Phase 1 start 1H 2021 |
| Engineered Cell Therapies | CAR-T Cells | BNT211 | Multiple solid tumors (*CLDN6*) | | | | | Global | Phase 1/2 start 1H 2020 |
| | | BNT212 | Pancreatic, other cancers (*CLDN18.2*) | | | | | Global | |
| | TCRs | Undisclosed | Solid tumors | | | | | Eli Lilly | |
| | | 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[7] | Toll-Like Receptor Binding | BNT411 | Solid tumors (*TLR7*) | | | | | Global | Phase 1 start 2H 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 H1 2021 |
| | | BNT162 | COVID-19 | | | | | Fosun Pharma (China), BioNTech (Global, except China) | Start first study late April 2020 |
| | | To be selected | Up to 10 indications | | | | | Penn[8] | 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[9] | BNT171 | Not disclosed | | | | | Genevant (global 50:50 profit/loss share) | First Phase 1 trial to start 1H 2021 |
| | | To be selected | 4 more rare disease indications | | | | | | |

***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 and investigators 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 with registrational potential for BNT111 in metastatic melanoma 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 with registrational potential 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-α 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 (sLea), 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 Phase 1 trials for our first two RiboMab product candidates, BNT141 and BNT142, in the first half of 2021.
- *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 half of 2021.
- *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 second 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 first half of 2021, 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.

In response to the coronavirus global pandemic, we are developing a potential vaccine based on mRNA technology to induce immunity and prevent COVID-19 infection in response to the growing global health threat posed by the disease. We intend to initiate clinical testing for the product candidate, BNT162, in late April 2020, subject to regulatory approval, as part of a global clinical development program in Europe (commencing in Germany), the United States and China.

In March 2020, we entered into a strategic alliance with Fosun Pharma to co-develop a COVID-19 vaccine in China. Upon regulatory approval, Fosun Pharma will commercialize the vaccine in China, while we retain the full rights to develop and commercialize the vaccine in the rest of the world.

Building on our existing collaboration with Pfizer, in March 2020, we signed a letter of intent to co-develop and distribute a COVID-19 vaccine outside of China. We have also executed a Material Transfer and Collaboration Agreement to enable immediate collaboration.

***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 first half of 2021.

## 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 eight 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 have to-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 four 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 six clinical programs by the end of 2020; and
  - advancement of up to three 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). We expect to initiate a clinical trial for our lead CAR T product candidate, as well as BNT162 for COVID-19, in the first half of 2020, and our small molecule product candidate in the second half of 2020. We also expect to initiate a clinical trial for our RiboMab and RiboCytokine product candidates in the first half of 2021.
- 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 collaborations with Pfizer focused on influenza, influenza and COVID-19 and Fosun Pharma for COVID-19. 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 comprehensive in-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 and investigators are conducting five 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 with registrational potential 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 have expanded our footprint in the United States, and will continue to do so with the acquisition of Neon, if consummated, creating a U.S. research and development hub.

***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.***

- 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.

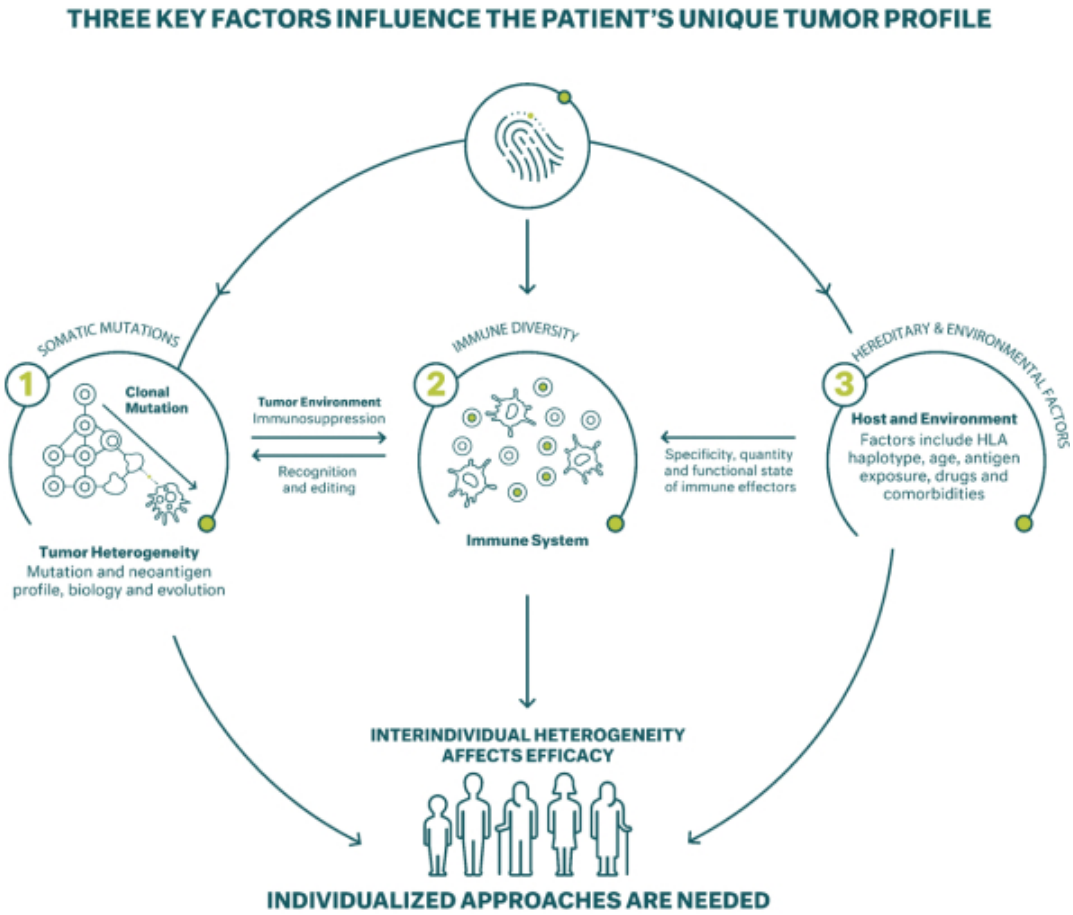
**V. Challenges and Opportunities of Cancer Therapies**

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 clones co-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.

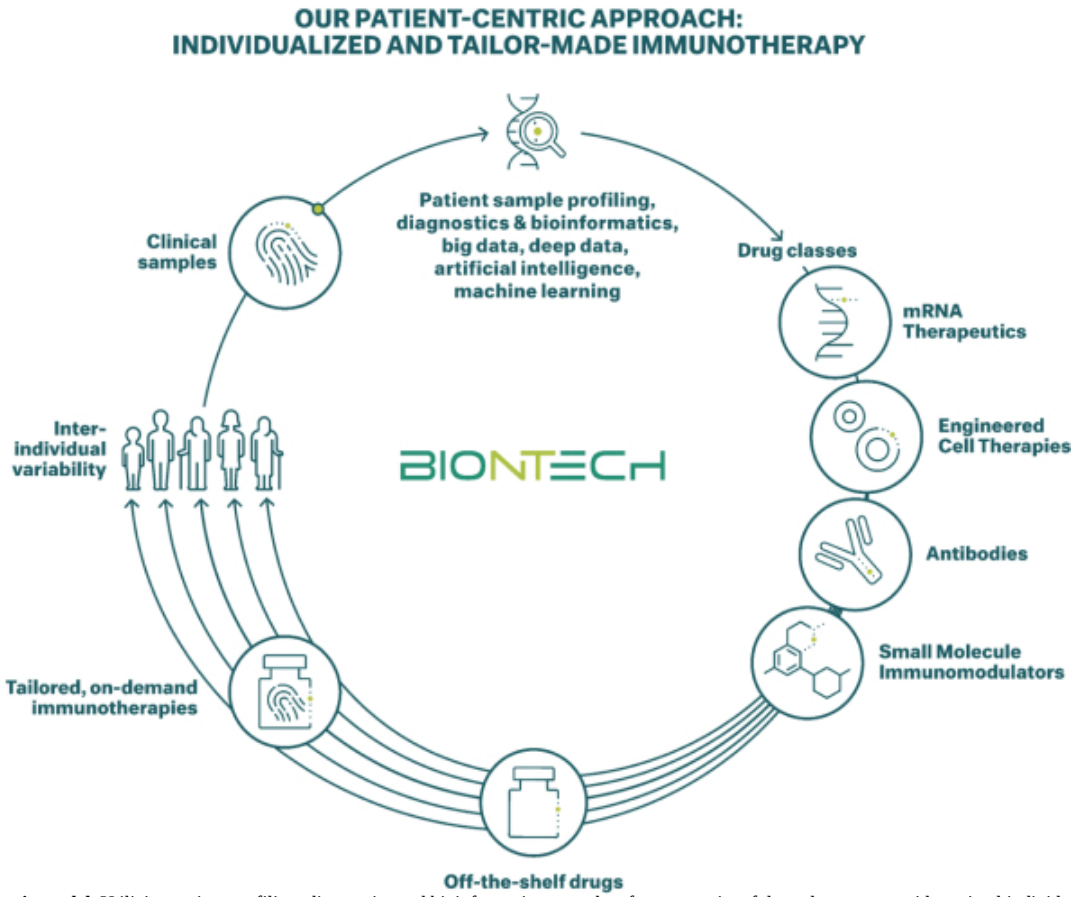
We believe this technology-agnostic range of platforms and product candidates positions us to remain at the forefront of the shift toward an individually tailored, patient-centric therapeutic approach in oncology.

***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.

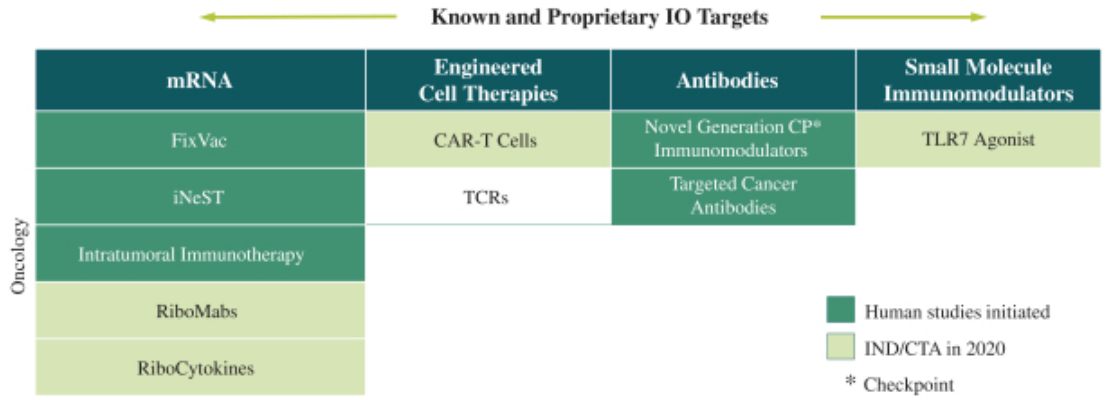
2. We have developed and are iteratively optimizing next-generation therapeutic platforms leveraging four drug classes. Each therapeutic platform bundles innovations designed to deliver a distinct mode of action with high-precision targeting, high potency and efficacy. Each platform is being developed 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 TME[1] | • ***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*** |

[1]Tumor microenvironment

**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***

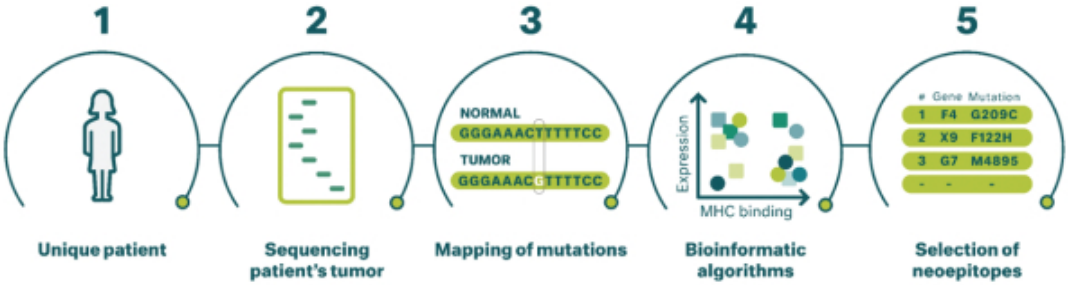
Immunostimulatory approaches are directed against receptors known to directly activate immune cells. Examples of these targets include co-stimulatory molecules such as CD40 and 4-1BB or cytokine receptors such as IL-2R, IL-7R and IL-12R. Immunostimulatory approaches provide a powerful opportunity to 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.




**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.

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

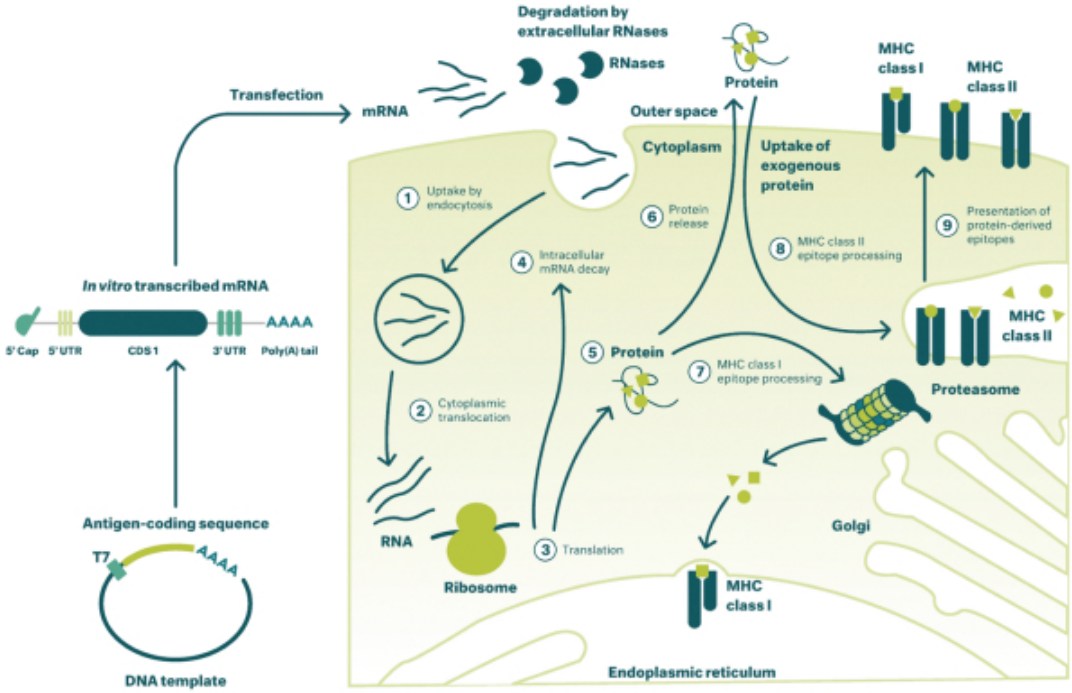
As a drug, manufactured mRNA provides instructions to a target cell to produce a desired therapeutic protein. The mRNA drug will temporarily change the status of the target cell where these instructions are translated into proteins. Based on the information encoded by the mRNA, the proteins will be either 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

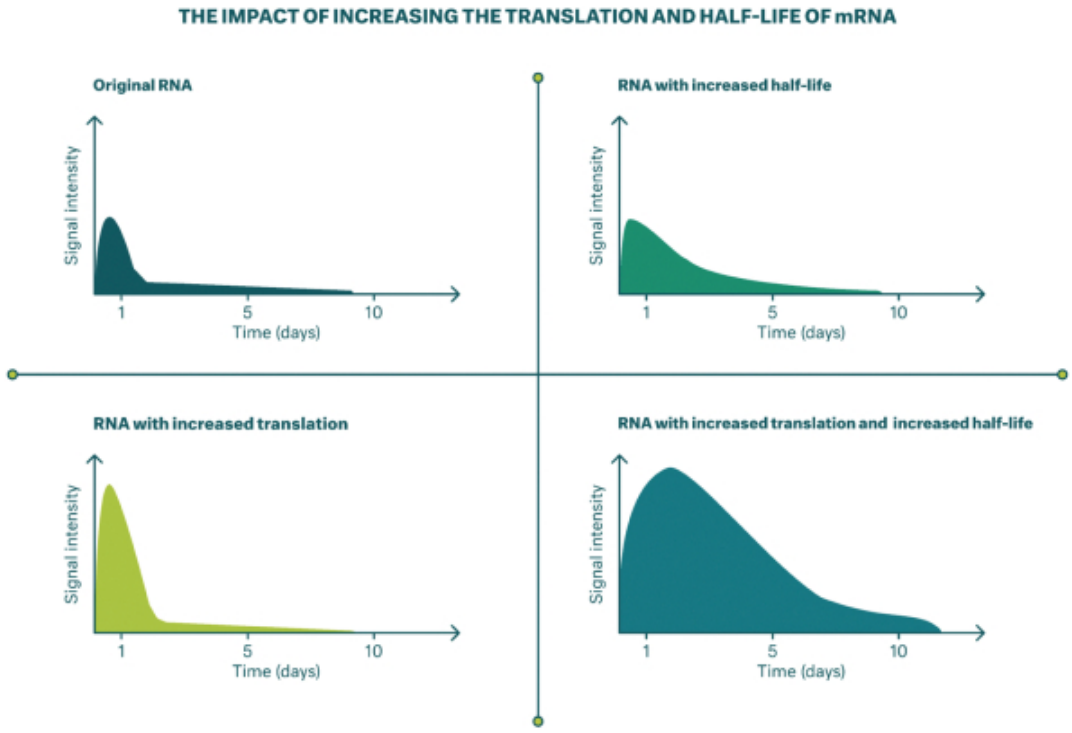
- the cap and the poly(A) tail, which are the two terminal structures of the linear mRNA, and are responsible for increased stability and translational efficiency of mRNA.

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.

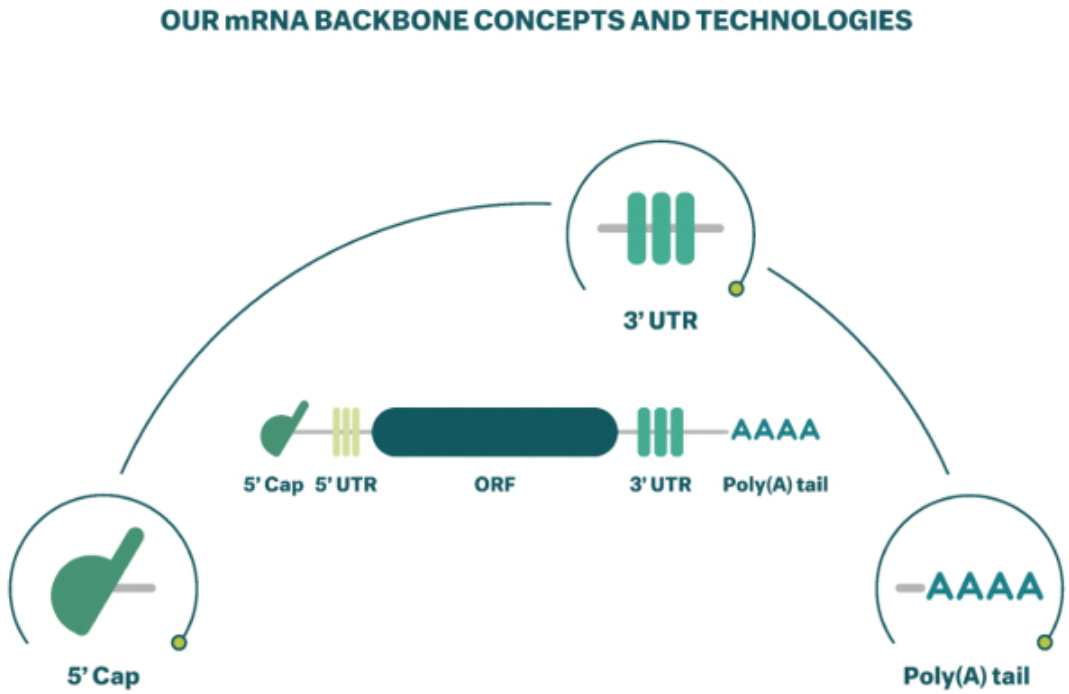
The structural elements of the mRNA have an impact on its performance. This includes potential immunogenicity, efficacy of translation and stability of the molecule. We leverage our extensive experience to design, synthesize, manufacture and formulate our therapeutic mRNA, and adapt its composition to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

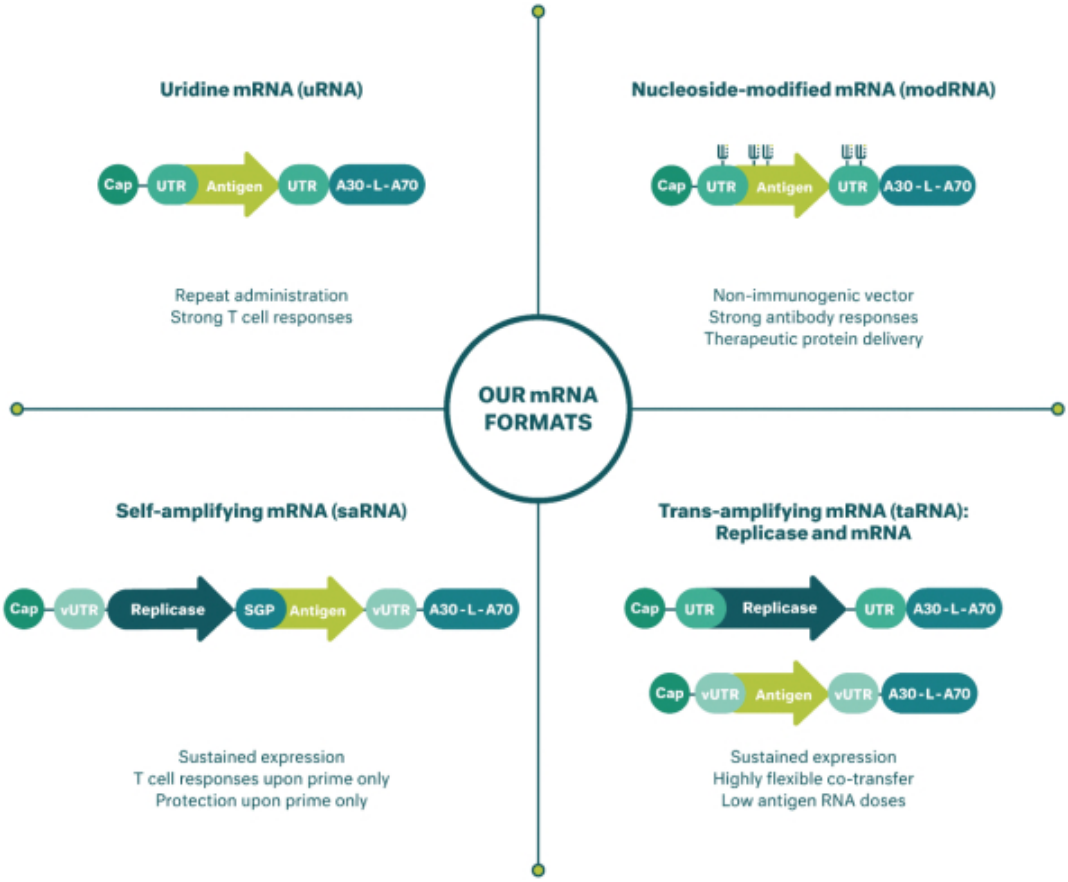
**B. Our mRNA Backbone Concepts and Technologies**

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)*

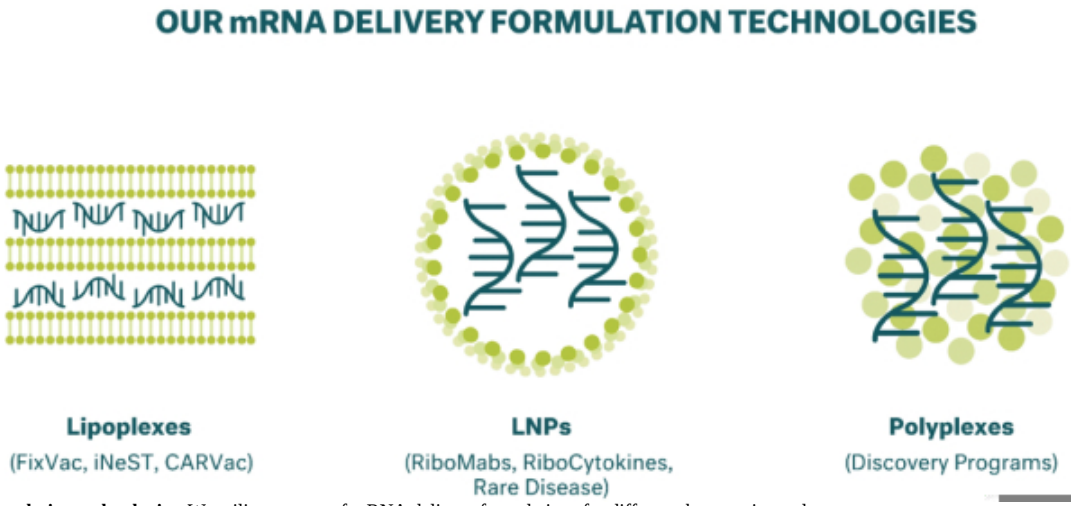
Our self-amplifying mRNA, or saRNA, drugs use the concept of viral replication, while not being an infectious, disease-causing agent itself. saRNA resembles conventional mRNA encoding the protein of interest, but also encoding a polymerase, called replicase, that multiplies part of the mRNA within the 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.

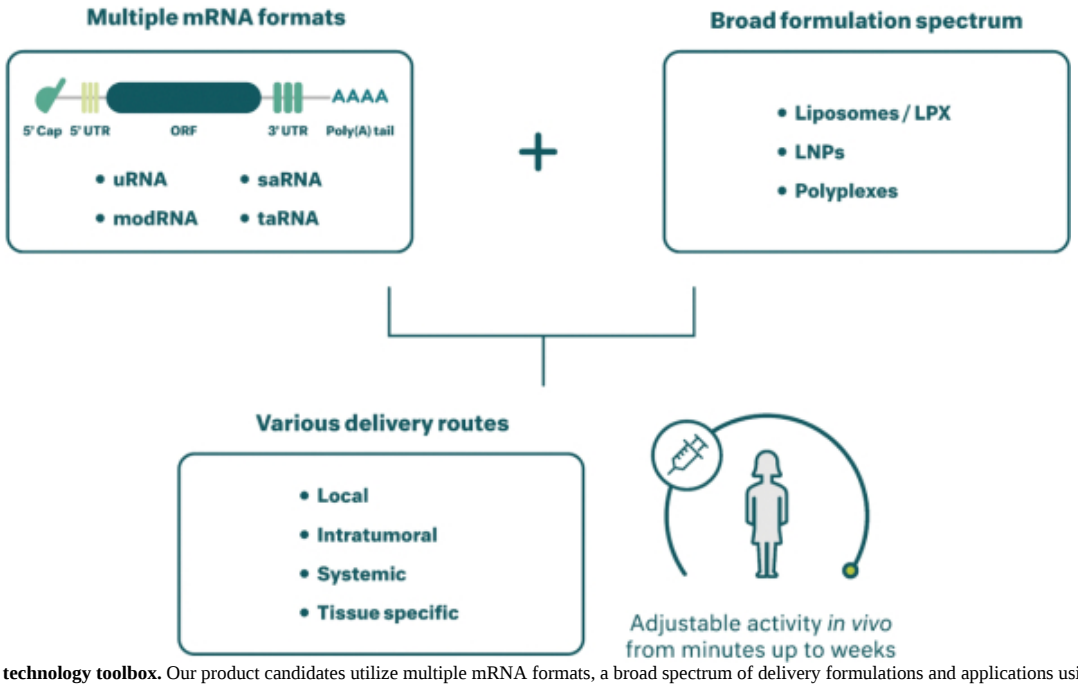



**Our mRNA delivery formulation technologies**. We utilize a range of mRNA delivery formulations for different therapeutic needs.

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.

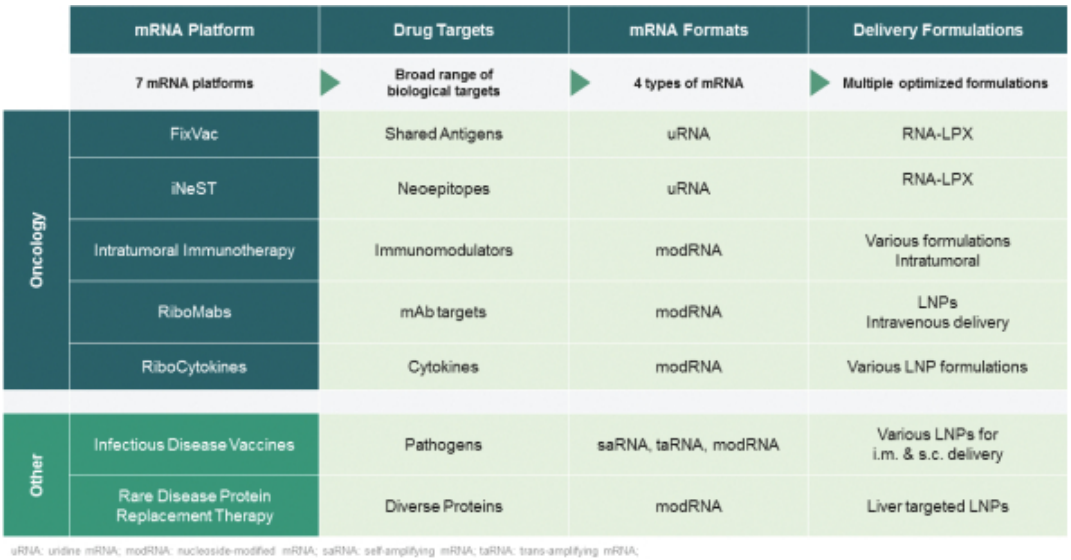



**Our therapeutic mRNA technology toolbox.** Our product candidates utilize multiple mRNA formats, a broad spectrum of delivery formulations and applications using various delivery routes.

### 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.




**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.

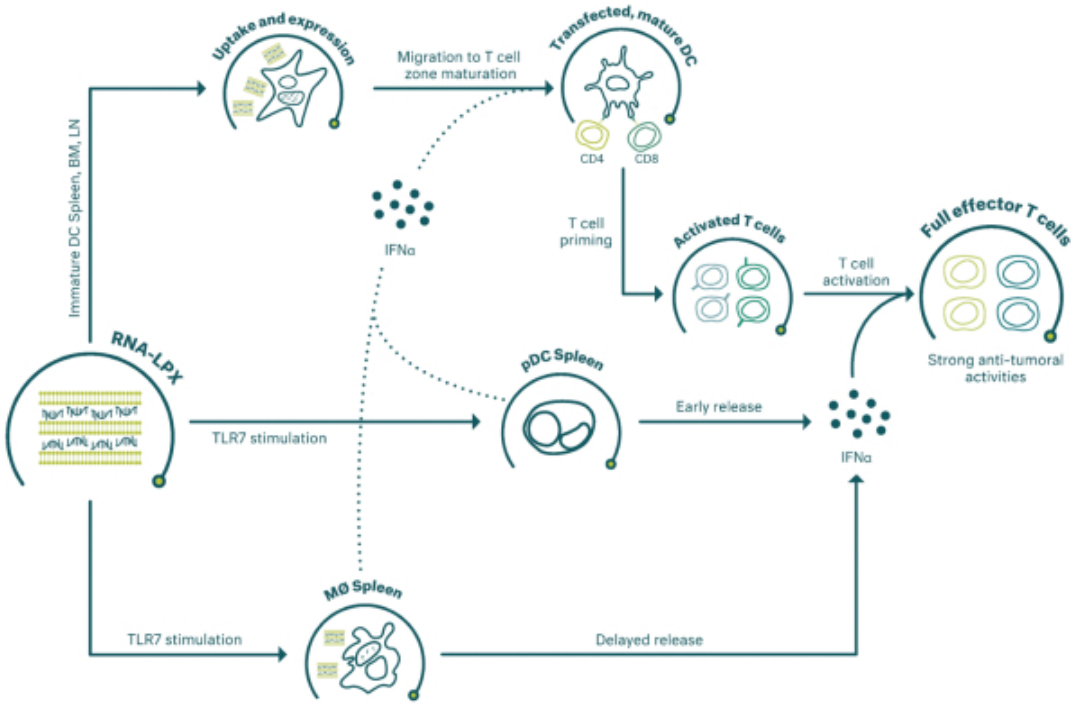
***RNA-LPX Technology***

***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.

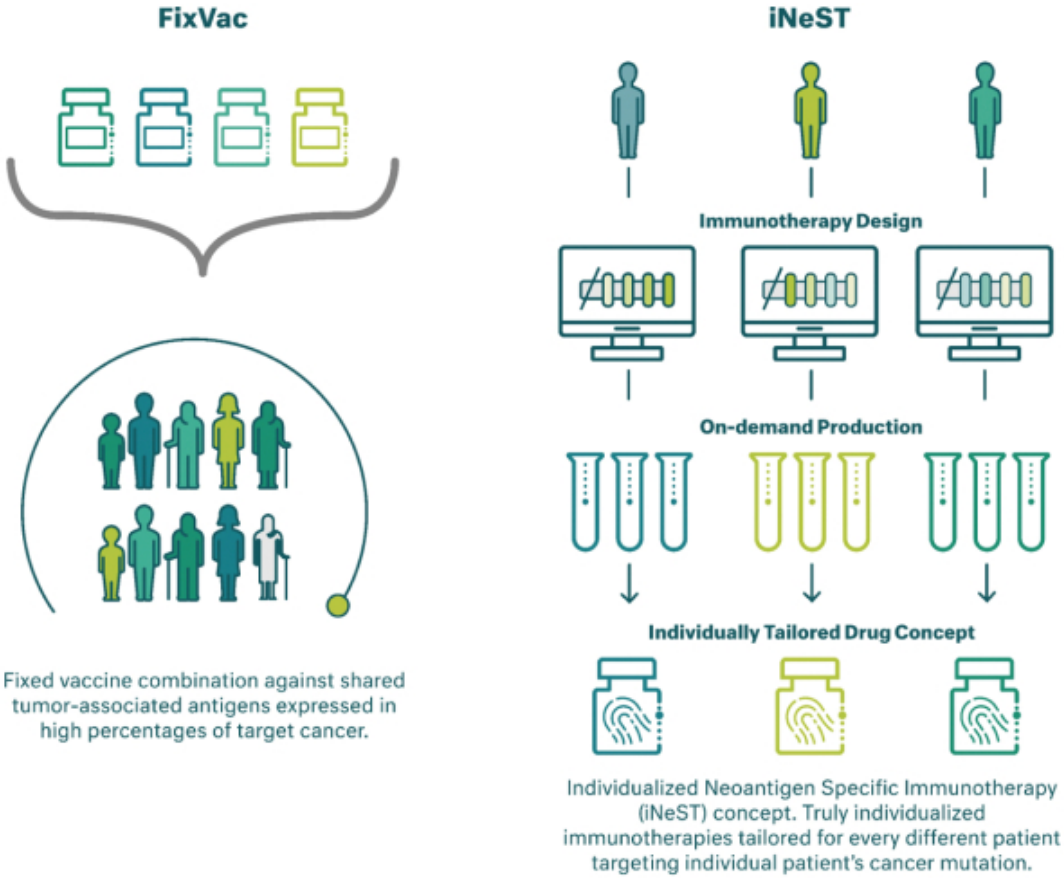
To advance from local to systemic dendritic cell, or DC, targeting, we developed an innovative liposome- based RNA-lipoplex formulation, RNA-LPX, that allows for intravenous administration of our mRNA cancer immunotherapies. We have demonstrated in the clinic that systemic DC targeting by mRNA cancer 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-α thereby promoting the activation of DCs and the induction of strong T cell responses. Abbreviations: BM, bone marrow; LN, lymph node; DC, dendritic cell; pDC, plasmacytoid dendritic cell; Mø, macrophage; IFN-α, interferon alpha.

RNA-LPX protects mRNA from degradation outside of the cell and mediates its efficient uptake and expression of encoded antigens in various dendritic cell populations.

Our RNA-LPX technology is designed to target a wide variety of antigens and address cancer patients with all possible HLA haplotypes. Utilizing RNA-LPX, we can target fixed groups of known shared antigens with our FixVac platform and a whole new class of patient-specific neoantigen targets with our iNeST platform.




***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, one complete response 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 with registrational potential 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 with registrational potential 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 in 1H 2020; initiate Phase 2 trial with registrational potential 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 with registrational potential in 2H 2020 |
| BNT114 | Selected breast cancer-specific antigens | Phase 1: TNBC | Report data update in 2H 2020 and assess antigen immunogenicity |
| BNT115 | Selected ovarian cancer-specific antigens | Phase 1 | — |
| BNT116 | Non-small cell lung cancer | Preclinical | — |

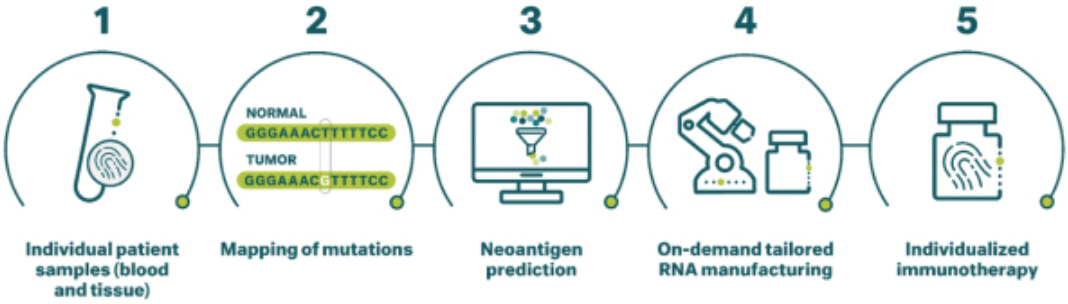
***b) Individualized Neoantigen Specific Immunotherapy (iNeST)***

***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.

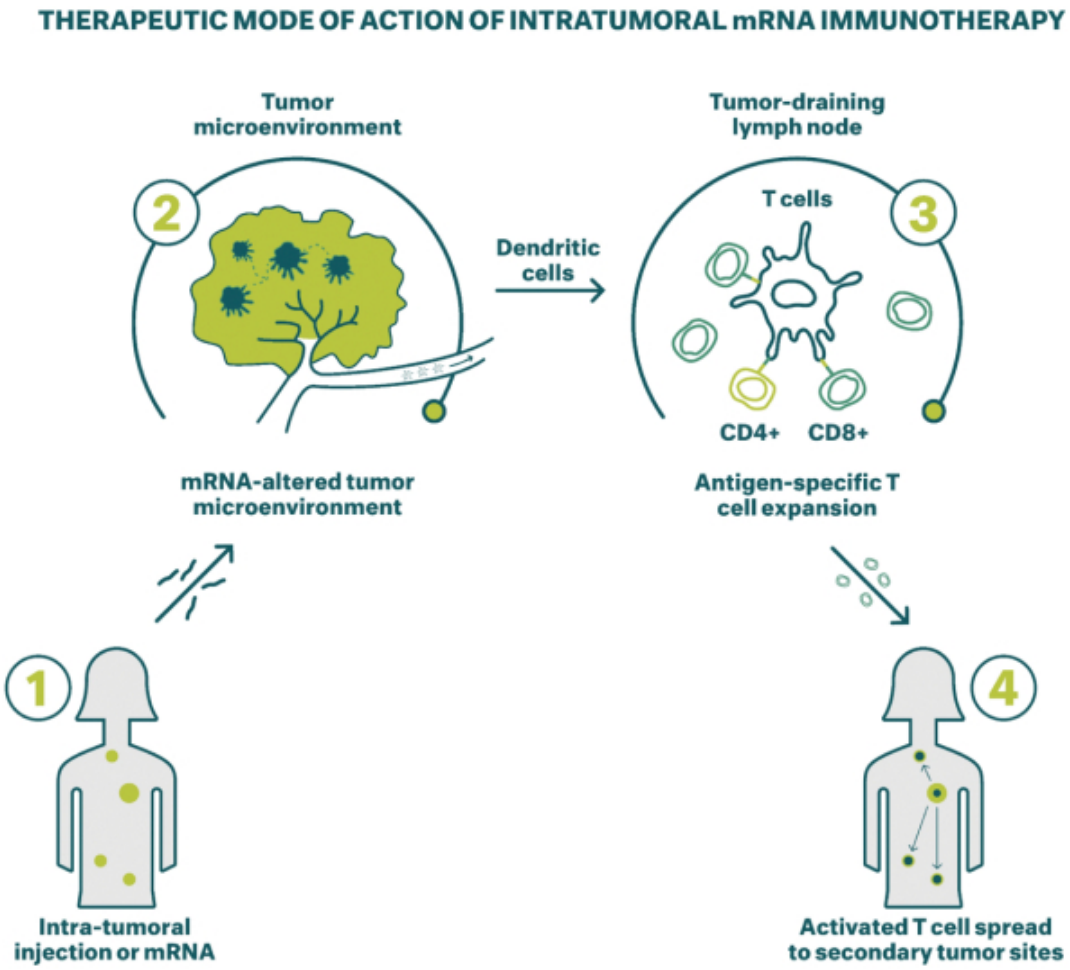
***c) Intratumoral mRNA Immunotherapy***

***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:** Modified 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 in the first half of 2021.

***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.

We are also developing a potential vaccine based on our mRNA technology to induce immunity and prevent COVID-19 infection. We intend to initiate clinical testing for the product candidate, BNT162, in late April 2020, subject to regulatory approval, as part of a global clinical development program in Europe (commencing in Germany), the United States and China.

In March 2020, we entered a strategic alliance with Fosun Pharma to advance BNT162 and jointly develop the COVID-19 vaccine in China. Upon regulatory approval, Fosun Pharma will commercialize the vaccine in China, while we retain the full rights to develop and commercialize the vaccine in the rest of the world.

Additionally, in March 2020, we signed a letter of intent with Pfizer to co-develop and distribute a COVID-19 vaccine outside of China. We have also executed a Material Transfer and Collaboration Agreement to enable immediate collaboration.

***3. mRNA-based Protein Replacement Platform for Rare Diseases***

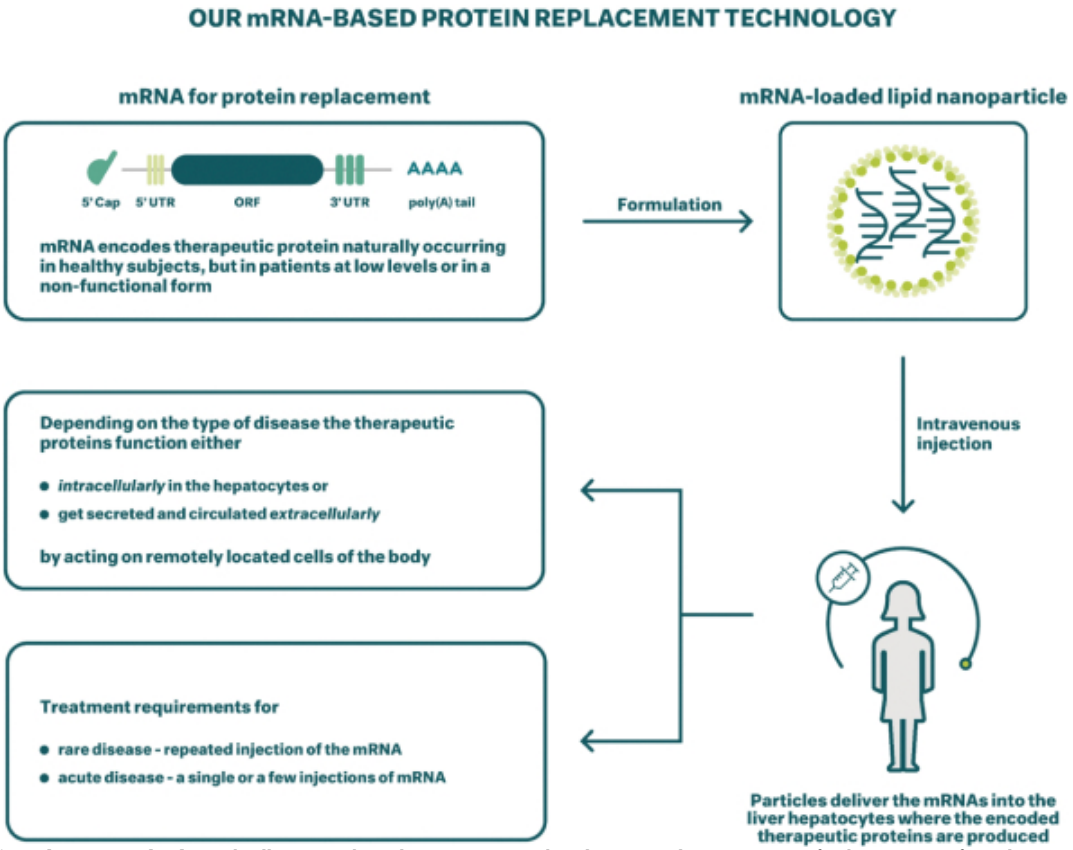
***At a glance: Our Protein Replacement Platform for Rare Diseases***

- **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 first half of 2021.

***4. RiboMabs***

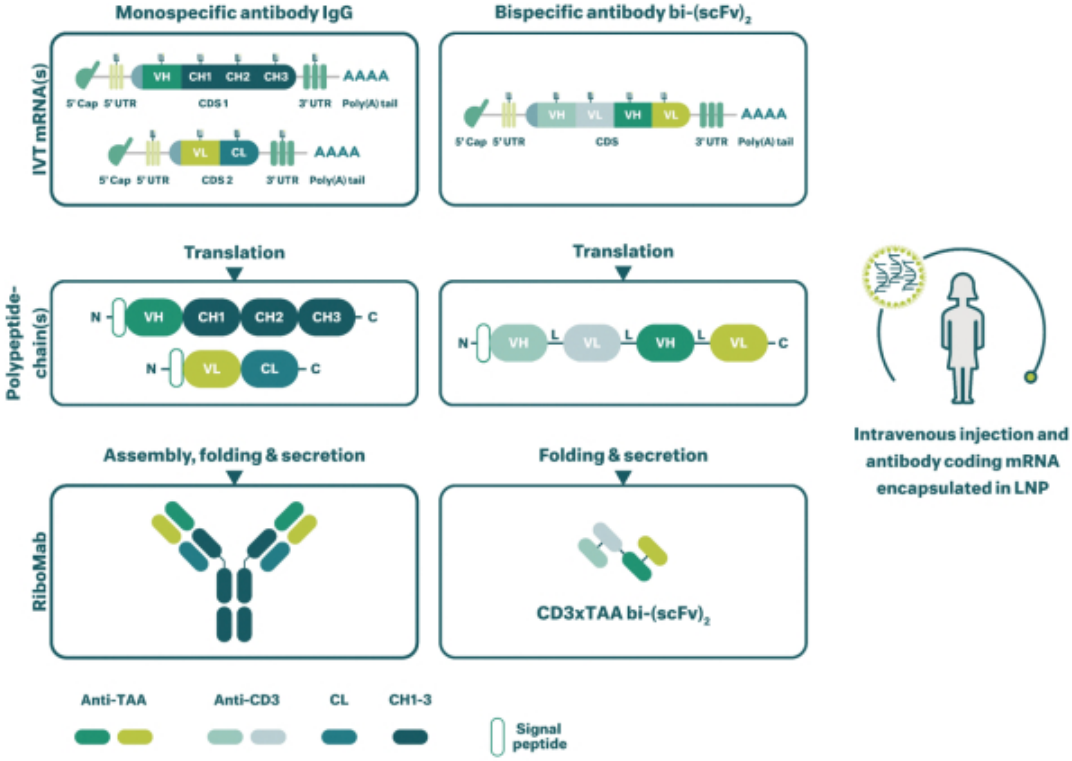
***At a glance: Our RiboMab Platform***

- **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; m1Y, 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 first half of 2021 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 1H 2021 |
| BNT142 (bispecific) | CD3xCLDN6 | Preclinical | Initiate Phase 1/2 trial in 1H 2021 |

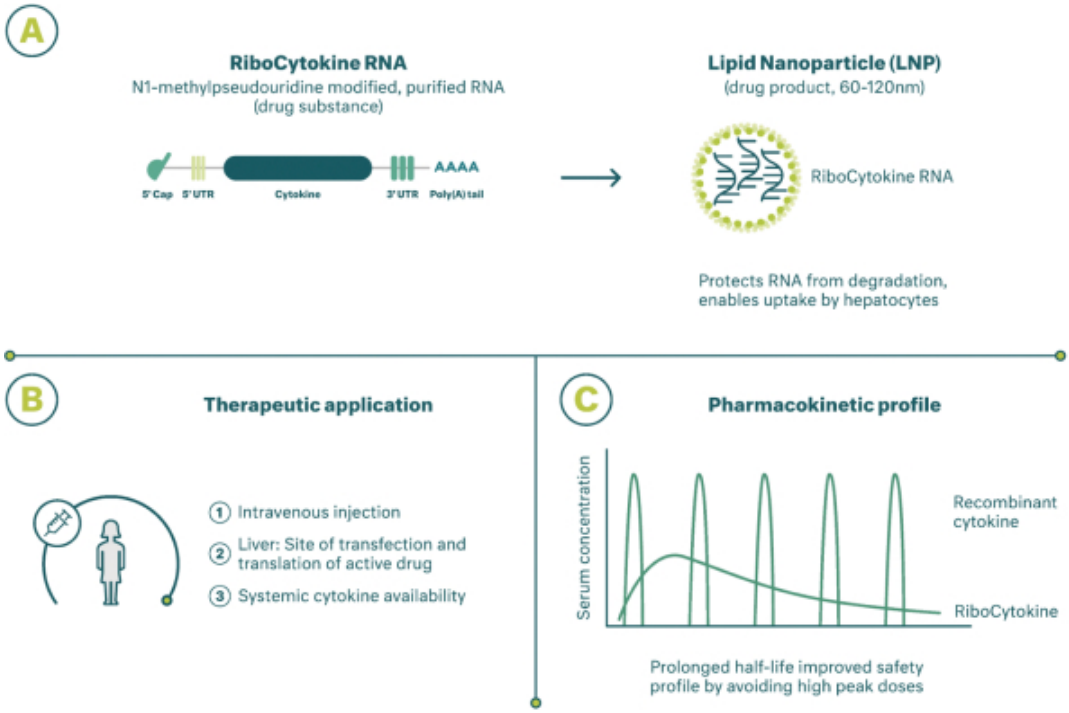
***5. RiboCytokines***

***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 of 2021 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 2021 |
| 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.

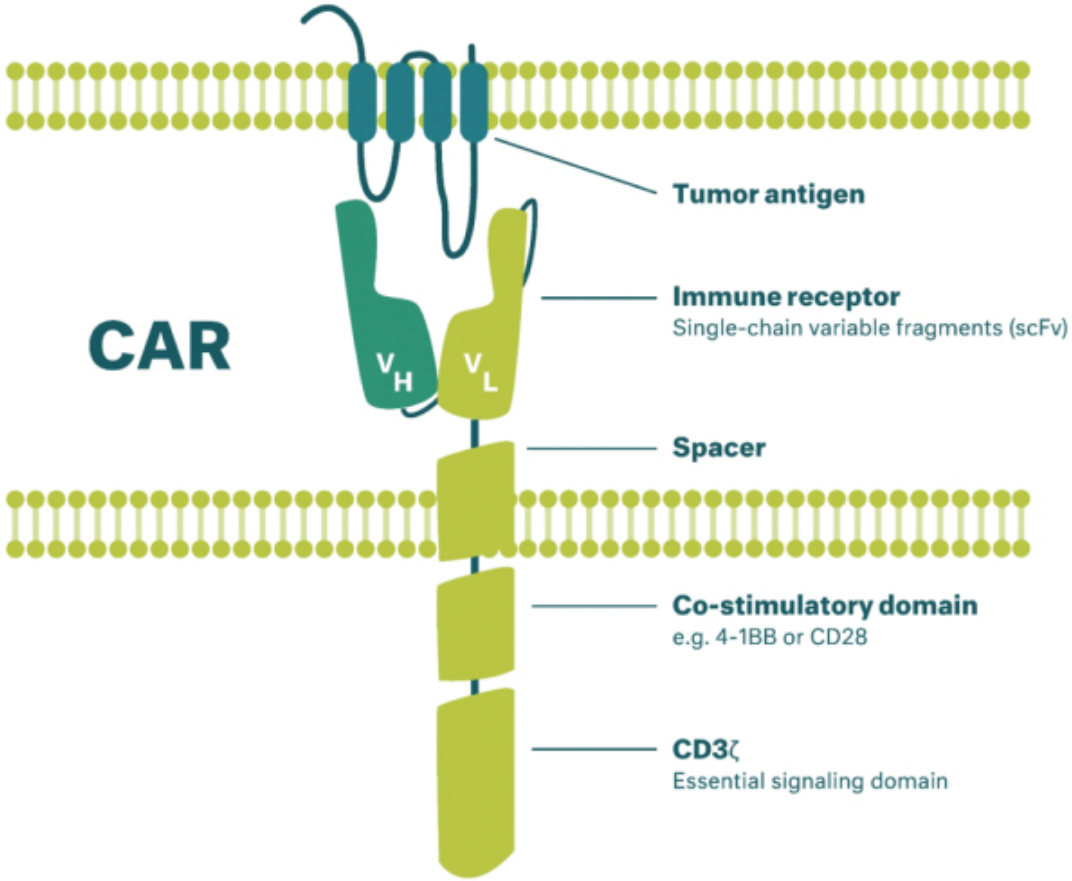
**A. CAR-T Cells**

***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.

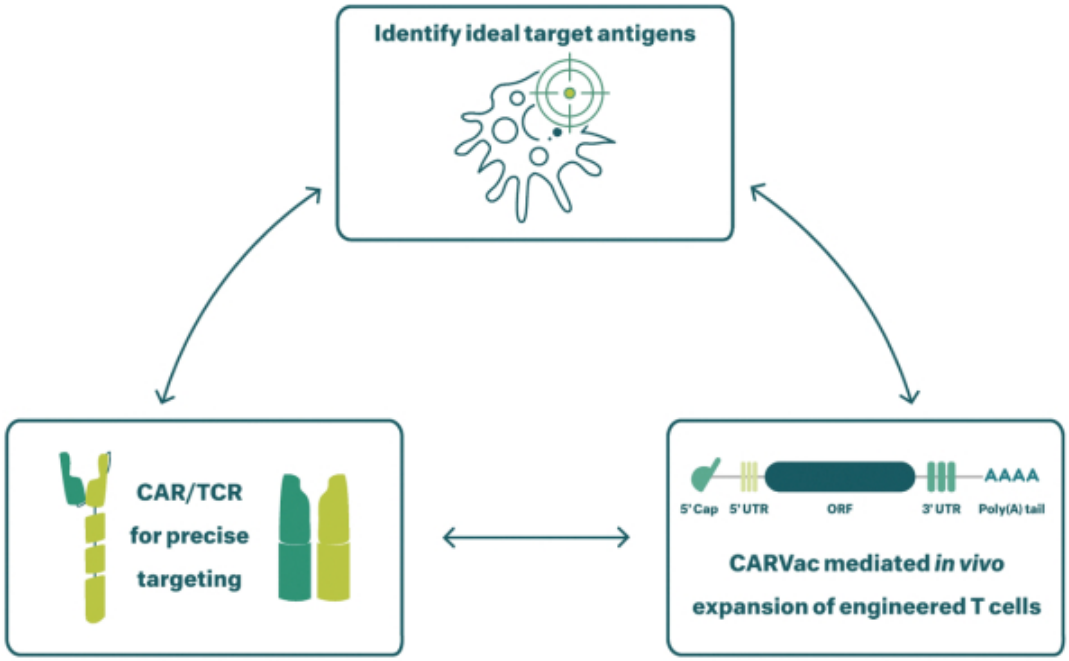
While CAR T therapy has shown potent anti-tumor responses in patients with B cell malignancies, clinical efficacy in solid tumors so far is limited. The main hurdles for application of CAR T therapies in solid tumors are:

- 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.

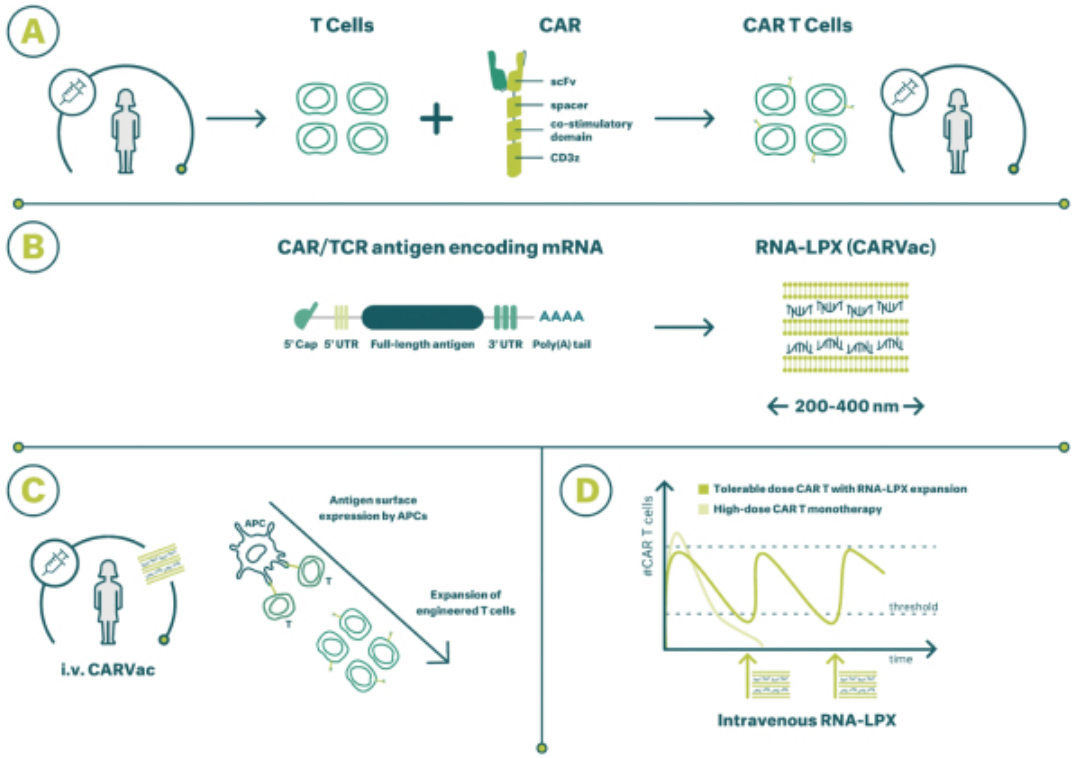
CLDN6 is an oncofetal cell surface antigen expressed in embryonic stem cells during fetal development. The gene encoding CLDN6 is strictly silenced and not expressed in healthy adult tissues but re-activated in different cancers with a high medical need including ovarian, endometrial, testicular and 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***

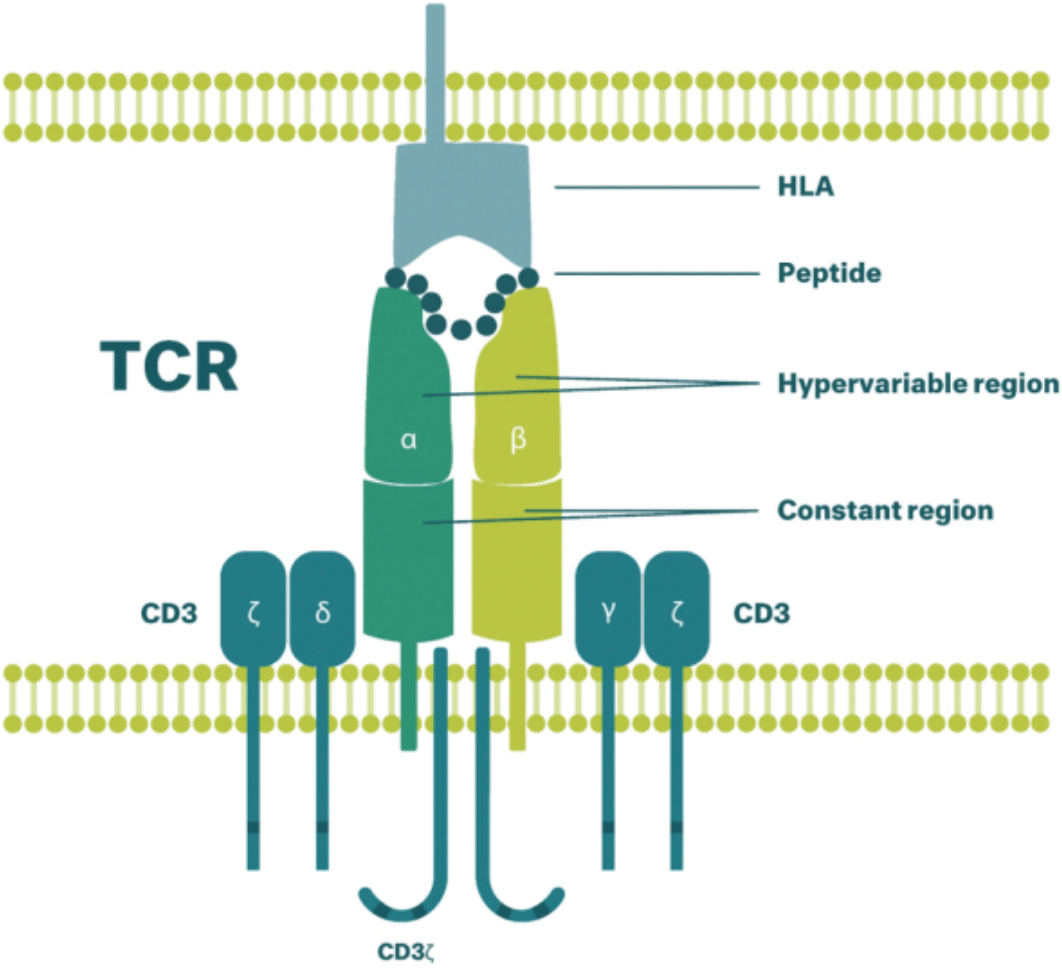
Our first CAR T product candidate, BNT211, includes a second-generation CAR directed against CLDN6. Our second product candidate is BNT212, which includes a CLDN18.2-targeting CAR. We expect to initiate a

Phase 1/2 basket trial of our novel combination CLDN6 CAR-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 TCR α 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***

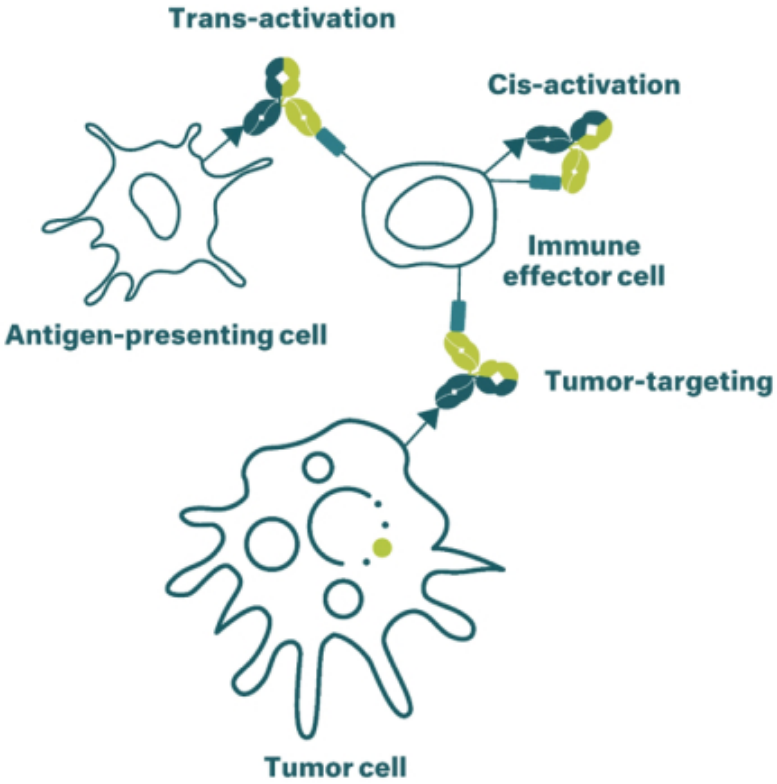
- **Concept:** Bispecific antibodies for dual immunomodulation, initially targeting 4-1BB, an immune checkpoint that is expressed on T cells and NK cells and can enhance immune cell proliferation and activation, in combination with simultaneous checkpoint inhibition.
- **Mechanism:** Conditional activation of 4-1BB 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 targeting CTLA-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.

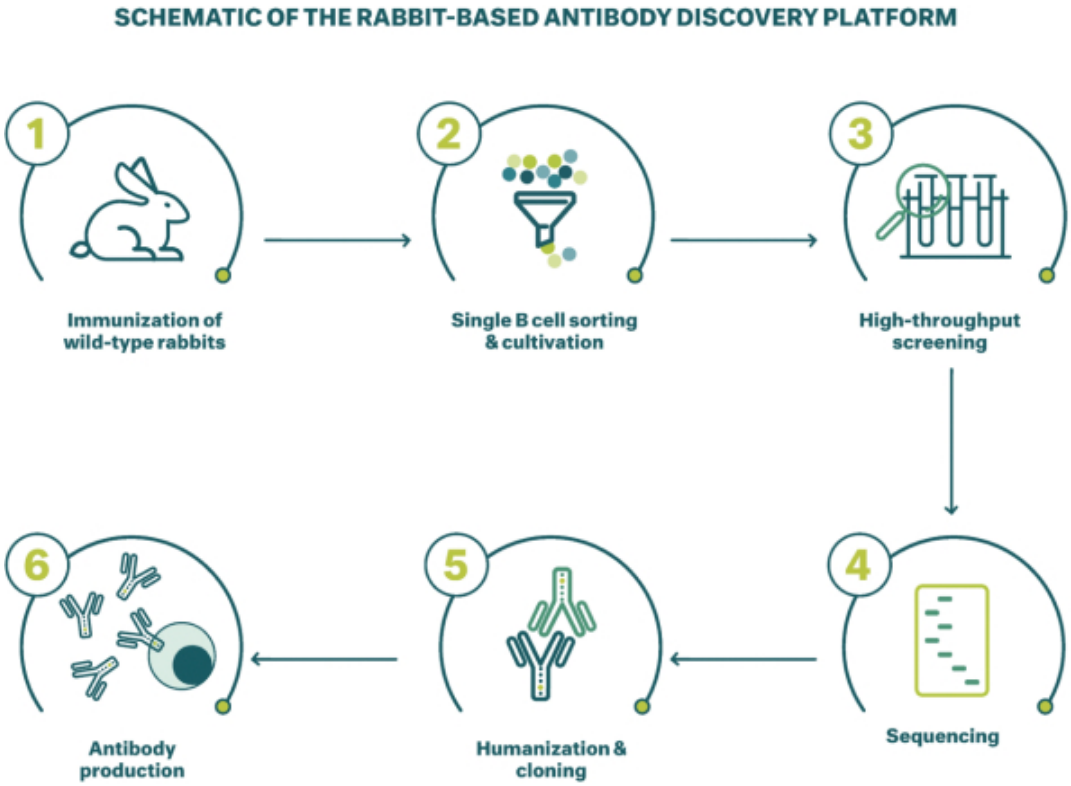
| Candidate | Targets | Development Phase | Next Potential Milestone |
|---|---|---|---|
| GEN1046 (BNT311) | PD-L1x4-1BB | Phase 1/2a trial in multiple solid tumors | Data update in 2H 2020 |
| GEN1042 (BNT312) | CD-40x4-1BB | Phase 1/2a trial in multiple solid tumors | — |

**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.



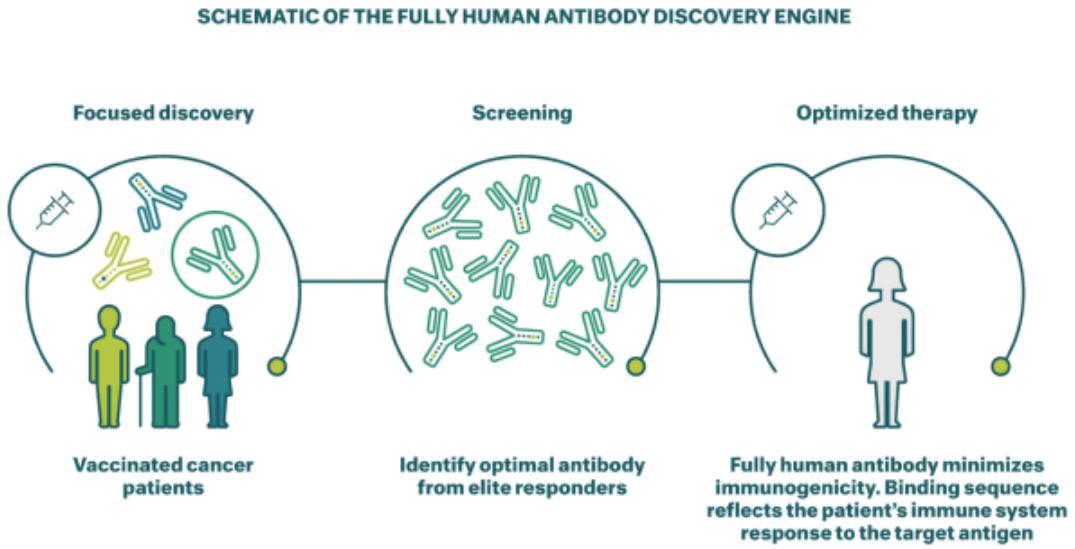

**Our rabbit-based antibody discovery engine.** The figure above depicts our semi-automated process for the discovery and production of high-affinity rabbit mAbs.

***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-α 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 2H 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.

## 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 1H 2020; start registrational phase 2 in 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 2H 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) | Enrollment update 2020[4]; Interim data update in 2021<br>Data update 2020; two phase 2 trials planned in adjuvant indications in 2020 |
| | | | Multiple solid tumors | | | | | | |
| | Intratumoral Immunotherapy | SAR441000 (BNT131) | Solid tumors (*IL-12sc, IL-15sushi, GM-CSF, IFNα*) | | | | | Sanofi (global profit/ loss share) | Data update 2H 2020[5] |
| | RiboMabs (mRNA-encoded antibodies) | BNT141 | Multiple solid tumors | | | | | Global | Phase 1 start 2H 2021 |
| | | BNT142 | Multiple solid tumors (*CD3×CLDN6*) | | | | | Global | Phase 1 start 1H 2021 |
| | RiboCytokines (mRNA-encoded cytokines) | BNT151 | Multiple solid tumors (Optimized *IL-2*) | | | | | Global | Phase 1 start 1H 2021 |
| | | BNT152, BNT153 | Multiple solid tumors (*IL-7, IL-2*) | | | | | Global | Phase 1 start 1H 2021 |
| Engineered Cell Therapies | CAR-T Cells | BNT211 | Multiple solid tumors (*CLDN6*) | | | | | Global | Phase 1/2 start 1H 2020 |
| | | BNT212 | Pancreatic, other cancers (*CLDN18.2*) | | | | | Global | |
| | TCRs | Undisclosed | Solid tumors | | | | | Eli Lilly | |
| | | 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[7] | Toll-Like Receptor Binding | BNT411 | Solid tumors (*TLR7*) | | | | | Global | Phase 1 start 2H 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 H1 2021 |
| | | BNT162 | COVID-19 | | | | | Fosun Pharma (China), BioNTech (Global, except China) | Start first study late April 2020 |
| | | To be selected | Up to 10 indications | | | | | Penn[8] | 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[9] | BNT171 | Not disclosed | | | | | Genevant (global 50:50 profit/loss share) | First Phase 1 trial to start 1H 2021 |
| | | To be selected | 4 more rare disease indications | | | | | | |

### 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%.

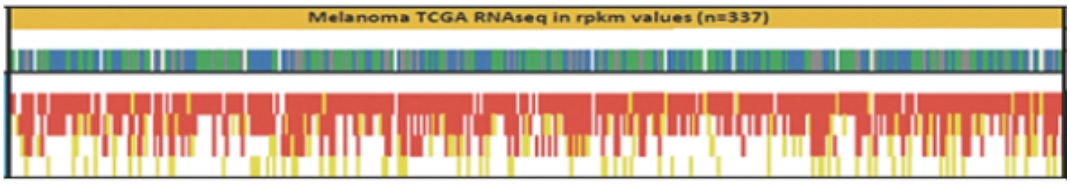
The current treatment regimen involves surgical removal for earlier stages, while a number of targeted therapies, such as BRAF and MEK inhibitors, and checkpoint inhibitors, or CPIs, are approved for advanced disease. CPIs include nivolumab (Opdivo) for advanced or metastatic melanoma after resection, 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 e*x 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, 50µg 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 new non-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 with registrational potential for BNT111 in the second half of 2020.

**b) BNT112: Our FixVac Cancer Immunotherapy for the Treatment of Prostate Cancer**

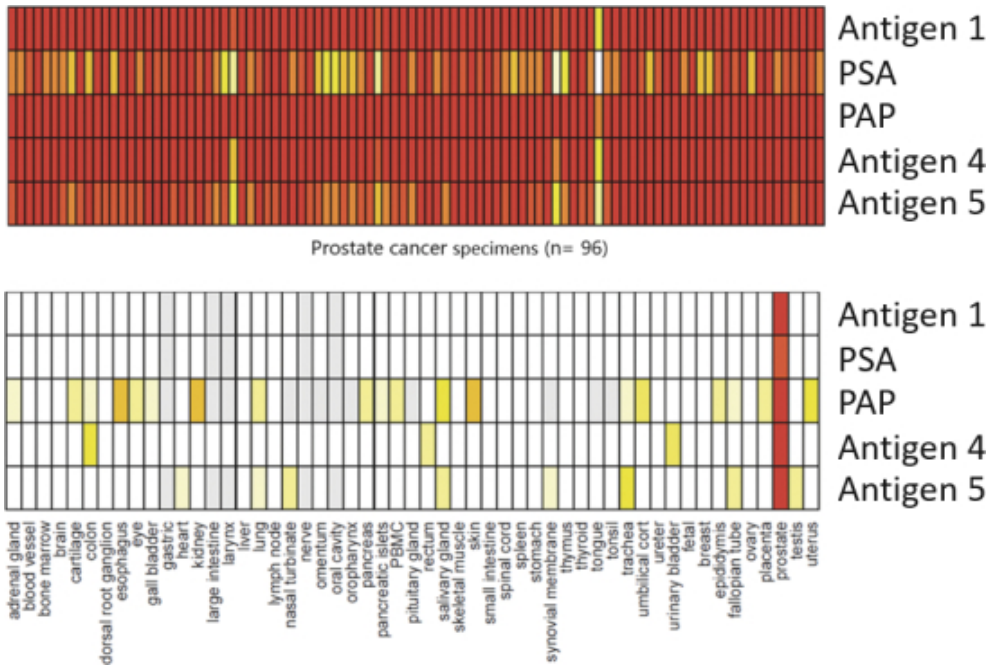
We are developing BNT112 for the treatment of prostate cancer.

***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 a 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 with registrational potential 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 a three-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 second half of 2020 and assess the immunogenicity of the selected antigens.

**e) BNT115: Our FixVac Cancer Immunotherapy for the Treatment of Ovarian 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*

The iNeST Phase 1a (monotherapy)/1b (in combination with atezolizumab) trial is a non-registrational, signal seeking study recruiting patients with locally advanced or metastatic solid tumors, including patients with melanoma, non-small cell lung cancer, bladder cancer, colorectal cancer, TNBC, renal cancer, head and neck cancer and sarcomas. The study is designed to enroll both patients with and without prior checkpoint inhibitor regimens.

The primary objective of the study was to assess safety (including dose-limiting toxicities), and additional objectives included evaluation of immunogenicity and preliminary assessment of anti-tumor activity. The trial included a Phase 1a (monotherapy) dose escalation, a Phase 1b (combination) dose escalation, and multiple Phase 1b expansion cohorts. Patients received nine doses of the vaccine administered i.v. in weekly and bi-weekly intervals during the induction phase and every eight cycles during the maintenance phase. In the Phase 1b portion of the trial, atezolizumab was administered on day one of each 21-day cycle.

BNT122 was manufactured on a per-patient basis including in-house determination of cancer mutation profiles, computational prediction of neoantigens, design, and manufacturing of the iNeST vaccine based on liposomally formulated RNA (RNA-LPX). Each vaccine contained up to 20 patient-specific neoepitopes. Importantly, the manufacturing of BNT122 for individual patients within clinical practice compatible turn-around times was shown to be feasible using clinical biopsies or routine clinical specimens across a range of tumor types including those with low or intermediate tumor mutational burden.

We and our collaborator, Genentech, have assessed preliminary clinical results from 29 patients in the Phase 1a trial and 132 patients in the Phase 1b trial. Phase 1a patients had received a median of 5 prior therapies (range 1-17), and Phase 1b patients had received a median of 3 prior therapies (range 1-11). BNT122, both with and without atezolizumab, has a manageable safety profile with predominantly transient and reversible grade 1 and grade 2 adverse events such as infusion related reaction/cytokine release syndrome manifesting as fever and chills. Analyses with complementary quantitative immunoassays showed that BNT122, both with and without atezolizumab, induces strong neoepitope-specific immune responses, including in patients with tumors of low and intermediate mutational burden. Vaccine-induced neo-antigen specific T cells were detected in post-vaccine biopsies. We observed a best response of stable disease in almost half of BNT122 treated patients, including

objective responses in a limited number of patients, including both patients with and without prior checkpoint inhibitor regimens. This indicates a level of clinical activity for BNT122 in combination with atezolizumab, however randomized data is needed to assess the individual contribution of BNT 122 on top of a checkpoint inhibitor. A randomized Phase 2 trial testing BNT122 plus pembrolizumab vs pembrolizumab alone is currently ongoing and intended to evaluate clinical efficacy of iNeST in patients with previously untreated advanced melanoma.

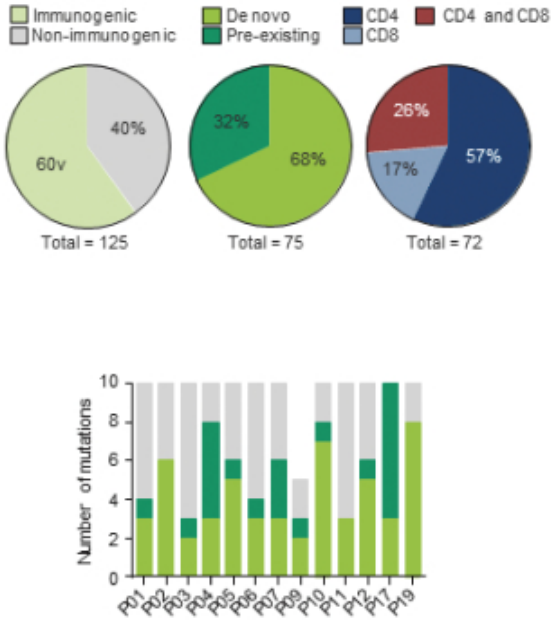
Moreover, based on data from our study of BNT121 as an adjunct to surgery in patients with metastatic melanoma, we believe that BNT122 is potentially well suited to control metastatic relapses in patients with a lower tumor burden. Accordingly, we and our collaborator, Genentech, intend to initiate two additional randomized Phase 2 trials in the adjuvant setting in solid cancer indications in the second half of 2020.

*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.

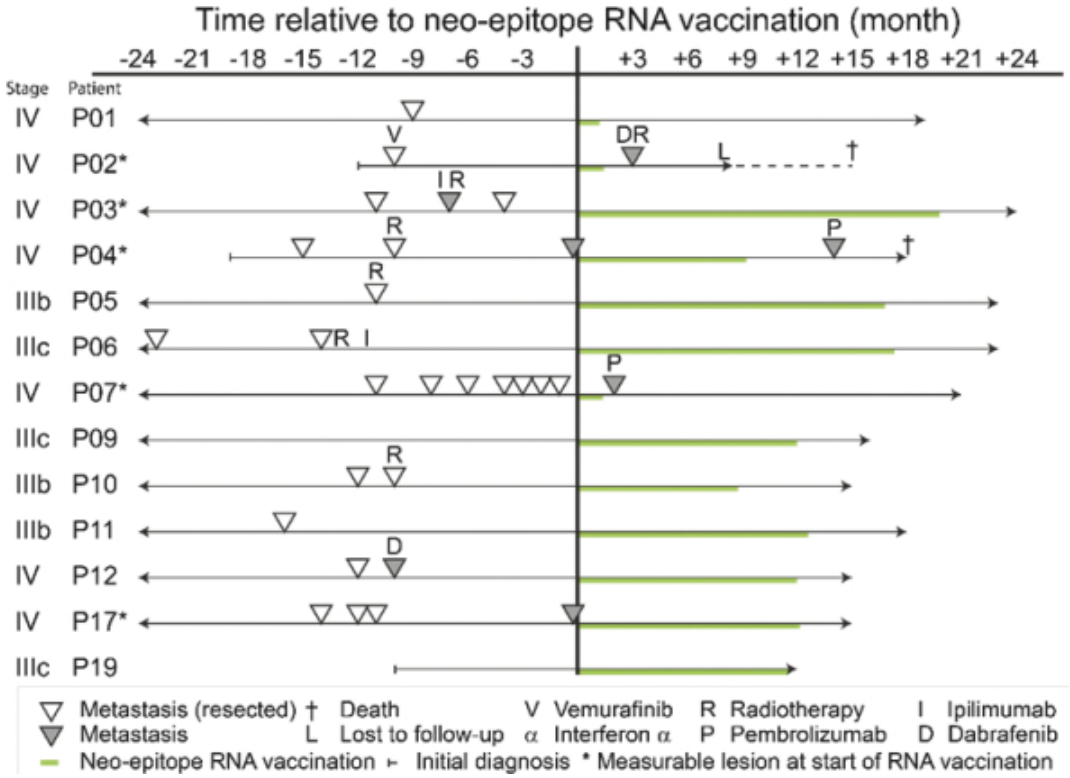
All 13 patients developed T cell immune responses against multiple immunotherapy neoepitopes at up to high single-digit percentages. As shown below, 60% of the selected neoepitopes elicited a T cell response. The detected immune response was elicited by both CD4+ and CD8+ T cells and the majority was 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 included flu-like symptoms.



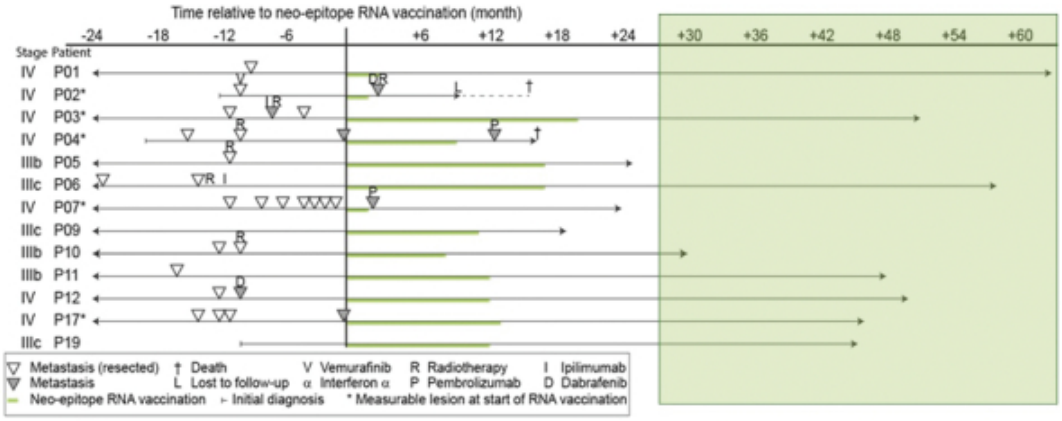

**Immune responses documented in our prior BNT121 study**. Patients showed immune responses, including both CD4+ and CD8+ responses, against multiple neoantigens. Source: Nature 547, 222-226 (13 July 2017)**.**

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 whole follow-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***

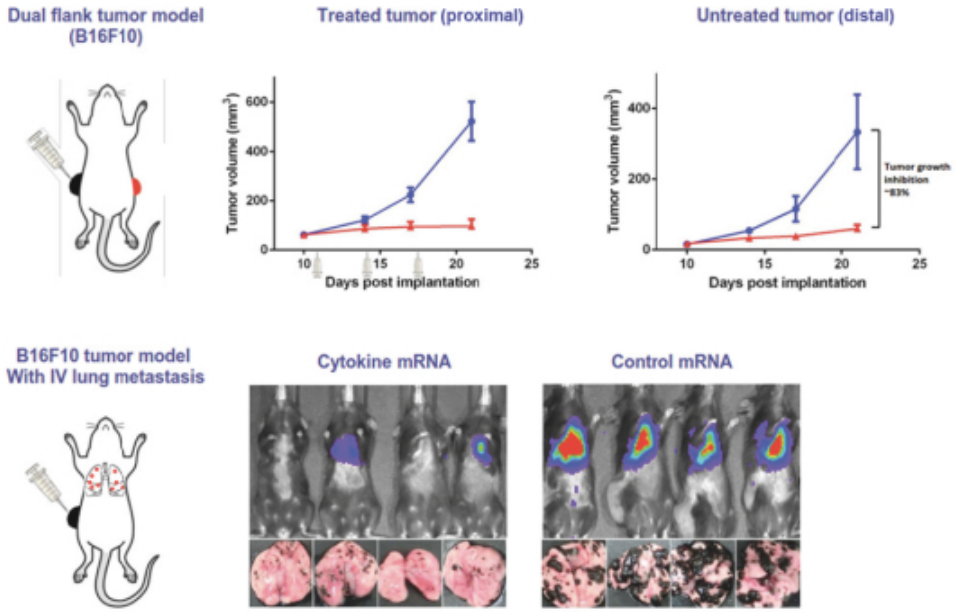
*Ongoing Phase 1 Clinical Trial*

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 recombinant 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 first half of 2021.

**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.

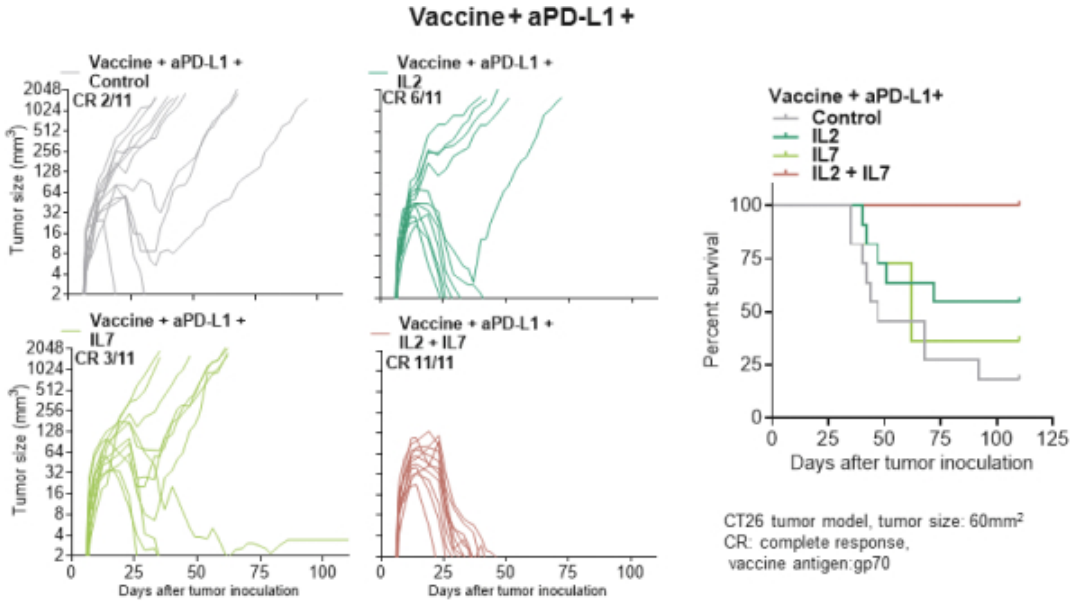
***Next Steps***

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 human interleukin-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 2021.

**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.

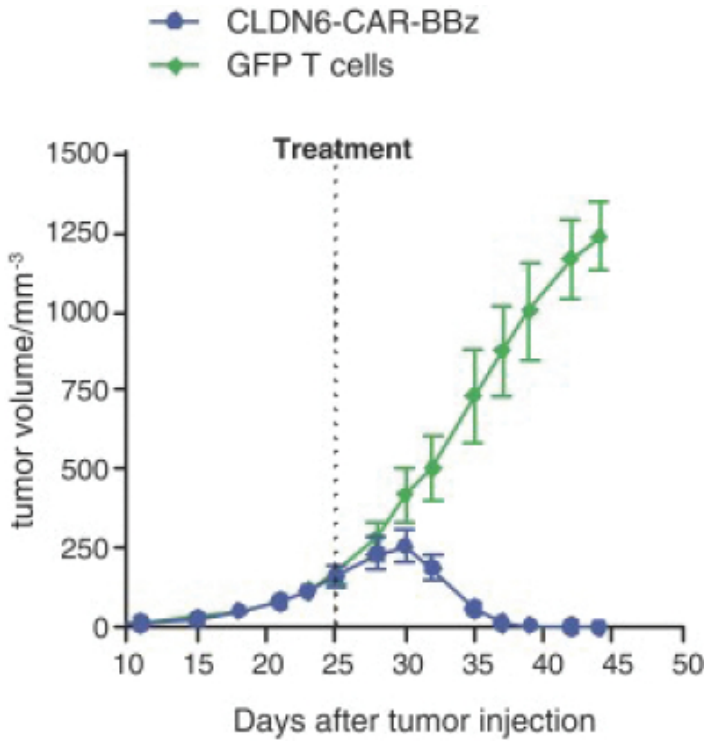
***Our BNT211 Trials***

**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 for CAR-T cells targeting the pan-cancer antigen CLDN18.2 and CD19, the target of approved CAR-T cell therapies. The combination of CAR-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 through 4-1BB stimulation which is dependent on simultaneous binding to PD-L1. In addition, the PD-L1-specific arm of DuoBody-PD-L1x4-1BB functions as a classical immune checkpoint inhibitor by blocking the PD-1/PD-L1 axis, also in the absence of 4-1BB binding. PD-L1 is a validated target that is expressed on tumor cells. 4-1BB is a trans-membrane receptor belonging to the TNF 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 through 4-1BB stimulation which is dependent on simultaneous binding to PD-L1. In addition, the PD-L1-specific arm of DuoBody-PD-L1x4-1BB functions as a classical immune checkpoint inhibitor by blocking the PD-1/PD-L1 axis.

***Next Steps***

We expect to report a data update for our ongoing Phase 1/2 trial in the second half of 2020.

**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 cross-linked 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***

In 2019, the American Cancer Society estimated that approximately 56,770 people will be diagnosed with pancreatic cancer in the United States annually. 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 (sLea), an epitope on CA19-9 that is expressed in pancreatic and other gastrointestinal cancers that plays a role in tumor adhesion and metastasis formation, and is a marker of an aggressive cancer phenotype.

***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.

We have resumed this trial and dosing has begun.

**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.

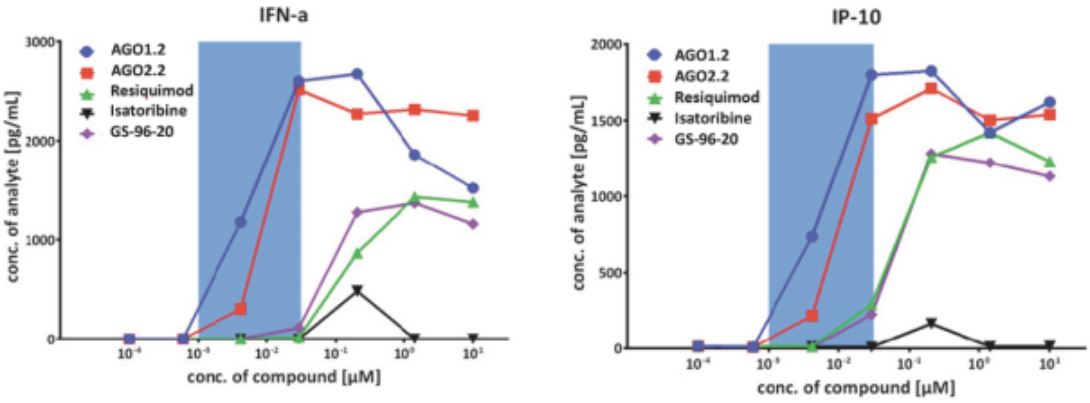
***Our BNT411 Target***

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 of IFN-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-α, 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 second 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, BNT161, will encode influenza virus antigens selected by the WHO in advance of the flu season.

***Next Steps***

We anticipate beginning a first clinical trial for BNT161 in the first half of 2021.

***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.

We also have two collaborations to develop a potential vaccine based on our mRNA technology to induce immunity and prevent COVID-19 infection. We intend to initiate clinical testing for the product candidate, BNT162, in late April 2020, subject to regulatory approval, as part of a global clinical development program in Europe (commencing in Germany), the United States and China.

In March 2020, we entered a strategic alliance with Fosun Pharma to advance BNT162 and jointly develop the COVID-19 vaccine in China. Upon regulatory approval, Fosun Pharma will commercialize the vaccine in China, while we retain the full rights to develop and commercialize the vaccine in the rest of the world.

Additionally, in March 2020, we signed a letter of intent with Pfizer to co-develop and distribute a COVID-19 vaccine outside of China. We have also executed a Material Transfer and Collaboration Agreement to enable immediate collaboration.

***Next Steps***

We expect to initiate our first Phase 1 clinical trial under the Penn collaboration in the first half of 2021, and clinical trials for BNT162 in late April 2020.

**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 first half of 2021. 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 laboratory as well as manufacturing operations to support our research and development as well as 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 laboratory and 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;
- an expansion of our JPT facility, which is designed to more than double our capacity; and
- an expansion of our laboratory space for research and development on our Mainz campus.

**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) possible co-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 Genmab Back-up Candidate has been developed would require the other party's prior written consent.

Each party has the right to discontinue its participation in the further development and commercialization of a Genmab Collaboration Product at two points: (i) when an IND submission package has been agreed upon by the parties and (ii) when the draft clinical trial report from the first Phase 1/2 clinical trial becomes available. The party that wishes to opt out of such further development and commercialization may choose to permit the other party to continue the development and commercialization of the Genmab Collaboration Product or divest its interest in such Genmab Collaboration Product. If the opt-out party permits continued development and commercialization, the other party may elect to pursue development and commercialization of such Genmab Collaboration Product alone as a Unilateral Product, at its sole cost and subject to pre-defined milestone and royalty payments and certain additional pre-defined terms. If the other party wishes to not pursue such continued development and commercialization on such pre-defined payment and additional terms, then the parties will jointly divest their interest in such Genmab Collaboration Product to a third party, and if such divestiture fails, the parties will cease all development and commercialization of such Genmab Collaboration Product. Alternatively, if the opt-out party seeks to unilaterally divest its interest in the applicable Genmab Collaboration Product, the other party has the right of first exclusive negotiation to obtain exclusive, worldwide rights to develop and commercialize such Genmab Collaboration Product. If such unilateral divestiture fails after the other party's exercise of its right of first exclusive negotiation, the opt-out party may either continue development and commercialization of such Genmab Collaboration Product or offer the other party to continue such development and commercialization on such pre-defined payment and additional terms as set forth above.

The Genmab Agreement will remain in effect until the later of (i) the expiration of the last-to-expire royalty term for any Unilateral Product 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 BioNTech 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 property in-licensed by us from third parties, to use, research, develop, manufacture, commercialize and otherwise exploit candidates and products selected under the Pfizer Agreement. We 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 BioNTech 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 infrastructure build-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 of Co-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 the Co-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 of Co-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 annual re-assessment procedure. Continuation of the authorization is linked to the annual reassessment and a negative assessment could potentially result in the marketing authorization being suspended or revoked. The renewal of the marketing authorization of a medicinal product under exceptional circumstances follows the same rules as a "normal" marketing authorization. After five years, the marketing authorization will then be renewed under exceptional circumstances for an unlimited period, unless the EMA decides, on justified grounds, to proceed with one additional five-year renewal.

The European Commission may also grant a so-called "conditional marketing authorization" prior to obtaining the comprehensive clinical data required for an application for a full marketing authorization. Such conditional marketing authorizations may be granted for product candidates (including medicines designated as orphan medicinal products) 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 BioNTech’s Business—Risks Related to BioNTech’s 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 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 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 proxy statement/prospectus, we have collaborated with third parties, including Pfizer, Penn and Fosun Pharma, 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, or CAR-, T cell or individualized T cell receptors for oncology therapy. Our patent filings relevant to these platforms and product

candidates, or the CAR T/TCR Filings, are generally co-owned by BioNTech 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 the mid- 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-Specific CAR-T Cell Filings have, and the pending Claudin-Specific CAR-T Cell Filings, if issued, would have, 20-year terms extending into the mid-2030s. 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 and IND-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 new co-owner to the other co-owners. However, in case of an assignment of such share to a third party (except in case of a material asset sale), the assigning party must obligate the assignee to comply with the terms of the TRON License Agreement and the assigning party will remain bound by the obligations of the TRON License Agreement unless the other co-owners have consented to discharge the assigning party from such obligations.

The parties to the TRON License Agreement grant licenses to each other under their shares in the Development Results substantially as follows. Ganymed is exclusively entitled to use the Development Results for certain antibodies and antibody fragments that bind to certain defined targets, or the Ganymed Field of Use. We are exclusively entitled to use the Development Results in any other field of use (including immunological therapeutics, small molecule compounds, 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 two MRT-CellScript Sublicenses discussed above. Together, the MRT-CellScript Sublicenses grant BioNTech RNA worldwide, non-exclusive sublicenses under the Penn

Modified mRNA Patent Rights (as defined in the MRT-CellScript Sublicenses) to research, develop, make, import, use and commercialize products for *in vivo* uses in humans and non-human animals, including therapeutic and prophylactic applications, and for certain uses in the diagnostic and prognostic field of use and certain laboratory research or screening uses. Under these sublicenses, BioNTech RNA has the right to grant sublicenses to affiliates and third parties.

BioNTech RNA must use reasonable efforts to develop and commercialize products under the sublicenses. Furthermore, BioNTech RNA is obliged to pay MRT and CellScript development milestone payments of up to approximately $26 million as well as royalties in the low to mid-single digits on net sales of licensed products, depending on the field of use.

The agreements continue until the expiration or abandonment of the last licensed patent to expire or be abandoned. BioNTech RNA may terminate the agreement for convenience with respect to all or certain patent rights with 60 days' prior written notice. MRT or CellScript may terminate the respective sublicense agreement for payment default, uncured material breach or the bankruptcy of BioNTech RNA.

**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 confidential know-how and continuing technological innovation to develop and maintain our competitive position. We protect certain of our technologies, including, in particular, certain proprietary manufacturing processes and technologies and/or neoantigen prediction technologies, as trade secrets. However, trade secrets and confidential know-how are difficult to protect. We seek to protect our proprietary information, in part, by using confidentiality agreements with any future collaborators, scientific advisors, employees and consultants, and invention assignment agreements with our employees. We also have agreements requiring assignment of inventions with selected consultants, scientific advisors and collaborators. These agreements may not provide meaningful protection. These agreements may also be breached, and we may not have an adequate remedy for any such breach. In addition, our trade secrets and/or confidential know-how may become known or be independently developed by a third party, or misused by any collaborator to whom we disclose such information. Despite any measures taken to protect our intellectual property, unauthorized parties may attempt to copy aspects of our products or to obtain or use information that we regard as proprietary. Although we take steps to protect our proprietary information, third parties may independently develop the same or similar proprietary information or may otherwise gain access to our proprietary information. As a result, we may be unable to meaningfully protect our trade secrets and proprietary information. See "Risk Factors—Risks Related to BioNTech's Business—Risks Related to BioNTech's 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, Germany (Headquarters) | 952 |
| Munich, Germany | 42 |
| Idar-Oberstein, Germany | 212 |
| Berlin, Germany | 101 |
| United States | 3 |
| **TOTAL** | **1,310** |

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 31, 2027, but which we have the option to extend until October 2042.

- 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, outside Munich, 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, outside Munich, 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.

## BIONTECH 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 | Term expires | Position |
|---|---|---|---|
| Prof. Ugur Sahin, M. D. | 54 | 2022 | Chief Executive Officer |
| Sean Marett | 54 | 2022 | Chief Business Officer and Chief Commercial Officer |
| Dr. Sierk Poetting | 46 | 2022 | Chief Financial Officer and Chief Operating Officer |
| Dr. Özlem Türeci | 52 | 2022 | Chief Medical Officer |
| Ryan Richardson | 40 | 2022 | 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 financing 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. Motschmann co-founded MIG Verwaltungs AG, or MIG, in 2004, where he serves on the Management Board and as Head of Equity Investments. In his role with MIG, 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 2004 to 2016 Dr. Wandschneider served as Chief Executive Officer first of Mediclin AG and later of Asklepios Kliniken GmbH & Co. KGaA. Dr. Wandschneider currently serves on various supervisory and advisory boards.

**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, as a general rule, no direct recourse against the members of our Management Board or the members of our Supervisory Board in the event that they are believed to have

breached their duty of loyalty and care to us. Apart from when we are unable to fulfill our third party obligations, tortious conduct of board members or other special circumstances, only we have the right to claim damages against the members of our two boards.

We may waive these claims to damages or settle these claims only if at least three years have passed since a claim associated with any violation of a duty has arisen and only if our shareholders approve the waiver or settlement at a shareholders' meeting with a simple majority of the votes cast, provided that no shareholders who in the aggregate hold one-tenth or more of our share capital oppose the waiver or settlement and have their opposition formally recorded in the meeting's minutes.

**Supervisory Board**

German law requires that the Supervisory Board consists of at least three members, while a company's articles of association may stipulate a certain higher number. Our Supervisory Board currently consists of 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 in Rule 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.

| *(in thousands)* | Helmut Jeggle | Michael Motschmann | Prof. Dr. Christian Huber, M.D. | Dr. Ulrich Wandschneider |
|---|---|---|---|---|
| **2019** | **€ 150** | **€ 50** | **€ 50** | **€ 95** |
| **2018** | **€ 31** | **€ 16** | **€ 46** | **€ 7** |

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.

There are no arrangements or understandings between us and any member of our Supervisory Board providing for benefits upon termination of their service as director.

**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. In December 2019, the Management Board members, Prof. Ugur Sahin, Sean Marett, Dr. Sierk Poetting and Dr. Özlem Türeci, were each awarded a cash bonus of €50,000, to be paid in 2020.

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 BioNTech 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 our initial public offering.

The service agreements of our Management Board provide for long-term incentive compensation in terms of a yearly grant of options to purchase BioNTech 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.

There are no arrangements or understandings between us and any member of our Management Board providing for benefits upon termination of their service as director.

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 €19.7 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. Ölem Türeci(1) |
|---|---|---|---|---|
| Fixed Compensation | | | | |
| 2018 | 210 | 315 | 283 | 175 |
| 2019 | 311 | 423 | 370 | 370 |
| Fringe Benefits(2) | | | | |
| 2018 | 1 | 12 | 11 | — |
| 2019 | 5 | 12 | 11 | — |
| ESOP Plan Granted(3) | | | | |
| 2018 | 442 | 147 | 147 | 5,426 |
| 2019 | 6,748 | 1,180 | 1,180 | 9,043 |
| **Total** | | | | |
| **2018** | 653 | 474 | 441 | 5,601 |
| **2019** | 7,064 | 1,615 | 1,561 | 9,413 |

(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 the pro-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 BioNTech 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 BioNTech 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. The version currently in effect, dated December 16, 2019, was published in the German Federal Gazette (*Bundesanzeiger*) on March 20, 2020. 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.

There is no obligation to comply with the recommendations or suggestions of the Corporate Governance Code. The German Stock Corporation Act (*Aktiengesetz*) requires only that the management board and supervisory board of a German company listed on a trading facility (such as a stock exchange) which is regulated and supervised by government authorities issue an annual declaration that either (i) states that the company has complied with the recommendations of the Corporate Governance Code or (ii) lists the recommendations that the company has not complied with and explains its reasons for deviating from the recommendations of the Corporate Governance Code (*Entsprechenserklärung*). In addition, a listed company is also required to state in this annual declaration whether it intends to comply with the recommendations or list the recommendations it does not plan to comply with in the future. These declarations must be made accessible to shareholders at all times. If the company changes its policy on certain recommendations between such annual declarations, it must disclose this fact and explain its reasons for deviating from the recommendations. Non-compliance with suggestions contained in the Corporate Governance Code need not be disclosed.

While in our opinion it is doubtful whether the above legal requirements and hence the Corporate Governance Code will apply following our listing on Nasdaq, 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.

**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 proxy statement/prospectus and our website address is included in this proxy statement/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 Nasdaq, for domestic issuers, we follow 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 BioNTech 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 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 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 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 Nasdaq corporate governance rules, we comply with 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.

## BENEFICIAL OWNERSHIP OF CERTAIN SHAREHOLDERS OF BIONTECH AND THE BIONTECH BOARD

The following table presents information, as of February 14, 2020, regarding the beneficial ownership of BioNTech Shares for:

- each person, or group of affiliated persons, known by us to own beneficially 5% or more of outstanding BioNTech 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 BioNTech 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 BioNTech Shares over which the individual has sole or shared voting power or investment power as well as any BioNTech Shares that the individual has the right to acquire within 60 days of February 10, 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 BioNTech Shares held by that person. All of the BioNTech Shares vote on an equal basis.

The percentage of outstanding BioNTech Shares is computed on the basis of 226,779,744 BioNTech Shares outstanding as of February 14, 2020. This amount excludes 5,524,506 shares held in treasury. Unless otherwise indicated, the address for each beneficial owner is An der Goldgrube 12, D-55131 Mainz, Germany.

| Name of Beneficial Owner | Number of Shares Beneficially Owned | Percentage Beneficially Owned |
|---|---|---|
| **5% Shareholders:** | | |
| AT Impf GmbH(1) | 114,141,520 | 50.33% |
| Medine GmbH(2) | 41,690,970 | 18.38% |
| MIG Verwaltungs AG(3) | 13,556,106 | 5.98% |
| Entities affiliated with FMR LLC | 12,718,257 | 5.61% |
| **Members of the Supervisory Board and the Management Board:** | | |
| Prof. Ugur Sahin, M.D.(4) | 41,690,970 | 18.38% |
| Sean Marett(5) | 1,091,502 | * |
| Dr. Sierk Poetting(6) | 711,828 | * |
| Dr. Özlem Türeci | — | |
| Ryan Richardson | — | |
| Helmut Jeggle(7) | 116,798,941 | 51.50% |
| Michael Motschmann | — | |
| Prof. Christoph Huber, M.D.(8) | 2,552,040 | 1.13% |
| Dr. Ulrich Wandschneider(9) | 4,680 | * |
| **All members of our Supervisor Board and Management Board, as a group** | **162,849,961** | **71.81%** |

* Less than one percent

(1) Information herein is based upon a Schedule 13G jointly filed with the SEC on February 12, 2020 by ATHOS KG, AT Impf GmbH, Helmut Jeggle and Thomas Maier. Consists of 114,141,520 ordinary shares held by AT Impf GmbH. The sole member of AT Impf GmbH is ATHOS KG, and, as a result, ATHOS KG

is deemed to be the beneficial owner of the securities held by AT Impf GmbH. Helmut Jeggle and Thomas Maier are each general partners (*komplementär*) of ATHOS KG and may be deemed to be beneficial owners of the securities held by AT Impf GmbH. Each of Messrs. Jeggle and Maier disclaim beneficial ownership of such shares except to the extent of their pecuniary interest therein.

(2) Information herein is based upon a Schedule 13G jointly filed with the SEC on February 13, 2020 by Medine GmbH and Prof. Sahin. The sole shareholder of Medine GmbH is Prof. Sahin, and, as a result, Prof. Sahin is deemed to be the beneficial owner of the securities held by Medine GmbH.

(3) Information herein is based upon a Schedule 13G jointly filed with the SEC on February 14, 2020 by MIG Verwaltungs AG, MIG GmbH & Co. Fonds 7 KG, MIG GmbH & Co. Fonds 8 KG and MIG GmbH & Co. Fonds 9 KG, Munich. 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.

(4) Consists of the shares described in note 2 above. Prof. Sahin is the sole shareholder of Medine GmbH.

(5) Consists of 1,091,502 ordinary shares held by RLG GmbH. Mr. Marett is the sole shareholder of RLG GmbH.

(6) 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.

(7) Consists of (a) the shares described in note 1 above, (b) 332,316 ordinary shares held directly by Mr. Jeggle, (c) 2,273,886 ordinary shares held by Salvia GmbH and (d) 51,219 ordinary shares held by Nils GmbH. Mr. Jeggle has no voting or dispositive power with regard to such shares described in note 1 above 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) Consts of 4,680 shares held by Tofino GmbH.

**Holdings by U.S. Shareholders**

BioNTech estimates that as of February 14, 2020 approximately 14.24% of its outstanding ordinary shares were held by 29 U.S. record holders.

## 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. Prof. Ugur Sahin, M.D., our co-founder and Chief Executive Officer, owns a significant amount of shares in TRON.

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 the year ended December 31, 2019, the aggregate value of transactions related to these agreements with TRON amounted to €10.0 million. During the year ended December 31, 2018 the aggregate value was €6.6 million.

### 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 the years ended December 31, 2019 and 2018, the aggregate value of transactions with Santo Service amounted to €2.0 million and €1.2 million, respectively, pursuant to these agreements.

### 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 2018 Financing

In February 2018, we issued an aggregate of 22,587,912 of BioNTech 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 BioNTech Shares that we issued and sold in this transaction to our related parties and the aggregate purchase price for such shares:

| PARTICIPANTS | BIONTECH SHARES (#) | AGGREGATE PURCHASE PRICE ($) |
|---|---|---|
| AT Impf GmbH(1) | 5,002,812 | 59,997,612.58 |

(1) See "Beneficial Ownership of Certain Shares of BioNTech and the BioNTech Board" in this proxy statement/prospectus for additional information about shares held by this entity or the parent company of this entity.

### Series B 2019 Financing

In June and August 2019, we issued an aggregate of 12,465,288 of BioNTech Shares (excluding 5,524,506 BioNTech 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 BioNTech 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 "Beneficial Ownership of Certain Shares of BioNTech and the BioNTech Board" in this proxy statement/prospectus for additional information about shares held by this entity or the parent company of this entity.

**Initial Public Offering**

In October 2019, we sold 10,517,408 ADSs representing 10,517,408 of BioNTech 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 "Beneficial Ownership of Certain Shares of BioNTech and the BioNTech Board" in this proxy statement/prospectus for additional information about shares held by this entity, the parent company of this entity or Supervisory Board member.

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

*You should read the following discussion and analysis of our financial condition and results of operations together with the information in "Selected Consolidated Financial Information of BioNTech" and our financial statements and related notes included elsewhere in this proxy statement/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 proxy statement/prospectus. Please also see "Cautionary Statement 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 eight 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, Pfizer Inc., or Pfizer, and Shanghai Fosun Pharmaceutical (Group) Co., Ltd., or Fosun Pharma. 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 €179.2 million and €48.3 million for the years ended December 31, 2019 and 2018, respectively. As of December 31, 2019 our accumulated losses were €424.8 million. 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 shows our consolidated statements of operations for each period presented:

| | Years ended December 31, | | |
|---|---|---|---|
| *(in thousands)* | **2019** | **2018** | **2017** |
| Revenues from contracts with customers | € 108,589 | € 127,575 | € 61,598 |
| Cost of sales | (17,361) | (13,690) | (9,318) |
| **Gross profit** | **€ 91,228** | **€ 113,885** | **€ 52,280** |
| Research and development expenses | (226,466) | (143,040) | (85,496) |
| Sales and marketing expenses | (2,718) | (3,041) | (6,603) |
| General and administrative expenses | (45,547) | (26,334) | (23,520) |
| Other operating income | 2,724 | 5,396 | 2,349 |
| Other operating expenses | (739) | (720) | (288) |
| **Operating loss** | **€(181,518)** | **€ (53,854)** | **€ (61,277)** |
| Finance income | 4,122 | 8,046 | 2,133 |
| Finance expenses | (326) | (48) | (26,007) |
| Interest expense related to lease liability | (1,718) | (1,721) | (676) |
| Share of loss of equity method investees | — | (84) | (78) |
| **Loss before tax** | **€(179,440)** | **€ (47,662)** | **€ (85,905)** |
| Income taxes | 268 | (600) | (45) |
| **Loss for the period** | **€(179,172)** | **€ (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)* | Years ended December 31, 2019 | 2018 | 2017 |
|---|---|---|---|
| **Revenues from contracts with customers** | | | |
| Revenues resulting from collaboration and license agreements | € 84,428 | € 101,837 | € 42,333 |
| Revenues from other sales transactions | 24,161 | 25,738 | 19,265 |
| **Total revenues from contracts with customers** | **€ 108,589** | **€ 127,575** | **€ 61,598** |

The following table summarizes our collaboration revenue for the periods indicated:

| *(in thousands)* | Years ended December 31, 2019 | 2018 | 2017 |
|---|---|---|---|
| **Revenues resulting from collaboration and license agreements** | | | |
| Genentech Inc. | €64,026 | € 49,536 | €27,829 |
| Pfizer Inc. | 14,348 | 7,174 | — |
| Sanofi S.A. | 4,233 | 41,712 | 5,665 |
| Genmab A/S | — | 2,740 | 6,765 |
| Eli Lilly and Company | 1,821 | 676 | 2,074 |
| **Total revenues resulting from collaboration and license agreements** | **€84,428** | **€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 proxy statement/prospectus. From the year ended December 31, 2018 to the year ended December 31, 2019 the total revenues resulting from collaboration and license agreements decreased from €101.8 million to €84.4 million. From the year ended December 31, 2017 to the year ended December 31, 2018 the total revenues resulting from collaboration and license agreements increased from €42.3 million to €101.8 million. The revenue recognized in the year ended December 31, 2018 included an amount of €33.2 million collaboration revenue from our Sanofi collaboration for a reimbursement of 50% of CellScript sublicense costs pursuant to a separate sub-sublicense agreement dated December 22, 2018. This transaction only occurred in the year ended December 31, 2018. Our collaborations with Bayer and Genevant did not result in any revenue in the years ended December 31, 2019, December 31, 2018 and December 31, 2017.

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 periods indicated:

| | Year ended December 31, | | |
|---|---|---|---|
| *(in thousands)* | 2019 | 2018 | 2017 |
| **Cost of sales:** | | | |
| Wages, benefits and social security expense | € 7,206 | € 6,726 | €6,105 |
| Laboratory supplies | 3,845 | 1,368 | 2,849 |
| Purchased services | 1,986 | 2,514 | — |
| Depreciation and amortization | 1,467 | 1,367 | — |
| Other | 2,857 | 1,715 | 364 |
| **Total cost of sales** | **€17,361** | **€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 periods indicated:

| *(in thousands)* | Year ended December 31, 2019 | 2018 | 2017 |
|---|---|---|---|
| **Research and development expenses:** | | | |
| Wages, benefits and social security expenses | € 83,213 | € 45,668 | €31,970 |
| Purchased services | 65,552 | 42,079 | 22,686 |
| Laboratory supplies | 37,218 | 22,921 | 15,762 |
| Depreciation and amortization | 27,533 | 18,312 | 9,859 |
| Lease and lease related cost | 2,527 | 2,404 | 3,475 |
| IT costs | 3,800 | 1,572 | 366 |
| Travel costs | 1,546 | 1,281 | 776 |
| Transport costs | 1,081 | 668 | 396 |
| Job advertisement expenses | 1,040 | 352 | — |
| Other | 2,956 | 7,783 | 206 |
| **Total research and development expenses** | **€226,466** | **€143,040** | **€85,496** |

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. 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.

Research and development expenses increased from €143.0 million during the year ended December 31, 2018 to €226.5 million during the year ended December 31, 2019 mainly due to an increase in wages, benefits and social security expenses due to an increase in headcount and the full-year reflection of the ESOP program expenses during the year ended December 31, 2019 as well as higher development expenses spent on purchased services and laboratory supplies.

Research and development expenses increased from €85.5 million during the year ended December 31, 2017 to €143.0 million during the year ended December 31, 2018, which was mainly due to an increase in wages, benefits and social security expenses and higher development expenses spent especially on purchased services and laboratory supplies.

***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.

Our sales and marketing expenses amounted to €2.7 million in the year ended December 31, 2019, €0.2 million of which constituted expenses for purchased services. Sales and marketing expenses amounted to €3.0 million in the year ended December 31, 2018, €0.8 million of which constituted expenses for purchased services.

Sales and marketing expenses amounted to €6.6 million in the year ended December 31, 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 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 periods indicated:

| | Years ended December 31, | | |
|---|---|---|---|
| | 2019 | 2018 | 2017 |
| *(in thousands)* | | | |
| **General and administrative expenses** | | | |
| Wages, benefits and social security expense | €19,122 | € 8,582 | € 9,861 |
| Purchased services | 6,419 | 5,177 | 3,544 |
| IT and office equipment | 4,573 | 3,774 | 2,706 |
| Depreciation and amortization | 4,855 | 2,284 | 630 |
| Lease and lease related cost | 1,715 | 1,012 | 1,611 |
| Travel costs | 1,391 | 1,043 | 247 |
| Insurance premiums | 1,061 | 145 | 99 |
| Laboratory supplies | 785 | 456 | 63 |
| Job advertisement expenses | 548 | 861 | 719 |
| Other | 5,078 | 3,000 | 4,039 |
| **Total general and administrative expenses** | **€45,547** | **€26,334** | **€23,520** |

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.

General and administrative expenses increased from €26.3 million during the year ended December 31, 2018 to €45.5 million during the year ended December 31, 2019. This increase was mainly influenced by an increase in headcount and the full year reflection of the ESOP program expenses during the year ended December 31, 2019 as well as a charge of €2.6 million in connection with certain withholding tax payments for intellectual property licenses related to prior years that was recorded during the year ended December 31, 2019 but not during the year ended December 31, 2018.

General and administrative expenses increased from €23.5 million during the year ended December 31, 2017 to €26.3 million during the year ended December 31, 2018. The relatively small increase is influenced by offsetting effects. Whereby the costs for purchased services as well as IT and office equipment increased, the costs of wages, benefits and social security expenses, as well as office costs, decreased.

***Other Operating Income (Expenses)***

Our other operating income consists primarily of government grants. In the year ended December 31, 2019, our other operating income amounted to €2.7 million, €1.5 million of which constituted government grants. In the year ended December 31, 2018, our other operating income amounted to €5.4 million, €4.2 million of which constituted government grants. In the year ended December 31, 2017, our other operating income amounted to €2.3 million, most of which was attributable to government grants.

***Finance Income (Expenses)***

Our finance income consists of interest income on cash and foreign exchange gains. In the year ended December 31, 2019, our finance income amounted to €4.1 million, €2.3 million of which were attributable to unrealized foreign exchange gains. In the year ended December 31, 2018, our finance income amounted to €8.0 million, €6.1 million of which were attributable to unrealized foreign exchange gains. In the year ended December 31, 2017, no foreign exchange gains were reported under finance income and our finance income amounted to €2.1 million.

In the year ended December 31, 2019, our finance expense amounted to €0.3 million. In the year ended December 31, 2018, our finance expense amounted to €48 thousand. In both years, no foreign exchange losses were reported under finance expense. In the year ended December 31, 2017, our finance expense amounted to €26.0 million, most 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 December 31, 2019, our accumulated tax losses amounted to €356.0 million with respect to corporate tax and €352.3 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.

Deferred tax assets on tax losses have not been capitalized as there is not 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 as at December 31, 2019 relate to Germany and the United States (as at December 31, 2018 and December 31, 2017: Germany). There is no expiration date for any of the accumulated tax losses under German or U.S. tax law.

**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.

**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:

| | Years ended December 31, | | |
|---|---|---|---|
| | 2019 | 2018 | 2017 |
| *(in thousands)* | | | |
| Revenues | € 85,122 | € 108,662 | € 42,657 |
| Cost of sales | — | (40) | — |
| **Gross profit** | **€ 85,122** | **€ 108,622** | **€ 42,657** |
| Research and development expenses | (226,305) | (142,448) | (83,583) |
| Sales and marketing expenses | (1,302) | (2,106) | (4,904) |
| General and administrative expenses | (42,577) | (23,791) | (21,094) |
| Other result | 1,514 | 4,065 | 1,598 |
| **Operating loss** | **€(183,548)** | **€ (55,659)** | **€(65,326)** |

***Comparison of the year ended December 31, 2019 and year ended December 31, 2018***

***Revenue***

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

| | Years ended December 31, | | Change | |
|---|---|---|---|---|
| *(in thousands)* | 2019 | 2018 | € | % |
| **Revenues** | | | | |
| Clinical | €33,493 | € 36,750 | € (3,257) | (9) |
| Technology Platform | 2,839 | 46,235 | (43,396) | (94) |
| Manufacturing | 48,790 | 25,635 | 23,155 | 90 |
| Business Service | — | 42 | (42) | (100) |
| **Total unit revenues** | **€85,122** | **€108,662** | **€(23,540)** | **(22)** |

Revenue of our biotech business unit decreased by €23.5 million, or 22%, to €85.1 million in the year ended December 31, 2019 from €108.7 million in the year ended December 31, 2018. The decrease was primarily driven by the decline of revenues of the Technology Platform segment which was partially offset by the increase in collaboration revenue generated in the Manufacturing segment.

The decrease in revenue in our Clinical segment of €3.3 million from €36.8 million in the year ended December 31, 2018, to €33.5 million in the year ended December 31, 2019, was due to decreased collaboration revenue with Genmab due to the fact that the remaining upfront payments received were completely recognized as revenue during the year ended December 31, 2018 with an amount of €2.7 million. The collaboration revenue generated from the Pfizer agreement increased by €7.2 million in the year ended December 31, 2019 compared to the year ended December 31, 2018 given that twelve months compared to six months straight-line allocation of revenue were generated from the upfront payment received under this collaboration. Nevertheless, this increase was offset by a decrease in collaboration revenue generated with Genentech of €8.7 million.

The decrease in revenue in our Technology Platform segment of €43.4 million from €46.2 million in the year ended December 31, 2018, to €2.8 million in the year ended December 31, 2019, was primarily due to a reimbursement of 50% of CellScript sublicense costs in the year ended December 31, 2018 (€33.2 million) pursuant to a separate sub-sublicense agreement dated December 22, 2018 and the occurrence of the Transfer and License Agreement with Ganymed for Bispecific Antibodies in the year ended December 31, 2018 (€3.9 million), which both did not reoccur in the year ended December 31, 2019.

The increase in revenue in our Manufacturing segment of €23.2 million from €25.6 million in the year ended December 31, 2018, to €48.8 million in the year ended December 31, 2019, was driven by our collaboration agreement with Genentech. Given that the respective revenues are recognized based on costs, the increase is due to higher manufacturing costs of the investigational medicinal product that correlate with higher patient enrollment in the ongoing clinical trials.

**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)* | Years ended December 31, 2019 | 2018 | Change € | Change % |
|---|---|---|---|---|
| **Research and development expenses** | | | | |
| Clinical | € 91,516 | € 48,641 | € 42,875 | 88 |
| Technology Platform | 79,119 | 60,320 | 18,799 | 31 |
| Manufacturing | 50,478 | 31,508 | 18,970 | 60 |
| Business Service | 5,192 | 1,979 | 3,213 | 162 |
| **Total unit research and development expenses** | **€ 226,305** | **€ 142,448** | **€ 83,857** | **59** |

Research and development expenses of our biotech business unit increased by €83.9 million, or 59%, to €226.3 million in the year ended December 31, 2019 from €142.4 million in the year ended December 31, 2018. This increase was due to an increase in headcount, the full-year reflection of the ESOP program and higher expenses incurred in our collaboration agreements.

The following table summarizes our clinical research and development expenses, broken down by drug class and selected platforms, for each period presented:

| *(in thousands)* | Years ended December 31, 2019 | 2018 | Change € | Change % |
|---|---|---|---|---|
| **Clinical research and development expenses** | | | | |
| mRNA | | | | |
| FixVac | €11,025 | € 3,018 | € 8,007 | 265 |
| iNeST | 23,730 | 13,335 | 10,395 | 78 |
| Other mRNA | 25,110 | 9,441 | 15,669 | 166 |
| Total mRNA | 59,865 | 25,794 | 34,071 | 132 |
| Engineered Cell Therapies | 1,616 | 653 | 963 | 147 |
| Antibodies | 18,010 | 14,353 | 3,657 | 25 |
| Small Molecule Immunomodulators | 2,303 | 1,497 | 806 | 54 |
| Other | 9,722 | 6,344 | 3,378 | 53 |
| **Total clinical research and development expenses** | **€91,516** | **€48,641** | **€42,875** | **88** |

The €15.7 million increase in other mRNA clinical research and development expenses mainly relates to collaboration agreements and license programs with partners that were initiated in the fourth quarter of 2018 and therefore affected the year ended December 31, 2019 for twelve months compared to three months in the year ended December 31, 2018. Other mRNA expenses for the year ended December 31, 2019 was primarily comprised of €7.0 million RiboCytokines project costs, €4.8 million Infectious Disease Vaccines costs, €4.7 million Intratumoral Immunotherapy costs, €3.5 million RiboMabs platforms costs and €2.0 million Protein Replacement Therapy costs. Other mRNA expenses for the year ended December 31, 2018 was primarily comprised of €2.8 million Intratumoral Immunotherapy costs, €2.6 million RiboCytokines project costs, €2.1 million 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***

Sales and marketing expenses of our biotech business unit decreased by €0.8 million, or 38%, to €1.3 million in the year ended December 31, 2019 from €2.1 million in the year ended December 31, 2018. This decrease was primarily due to a reduction of purchased sales and marketing services.

***General and Administrative Expenses***

General and administrative expenses of our biotech business unit increased by €18.8 million, or 79%, to €42.6 million in the year ended December 31, 2019 from €23.8 million in the year ended December 31, 2018. This increase was due to an increase in headcount, the full year reflection of expenses recognized from the granting of options under the ESOP program, expense for withholding tax related to prior years, increased purchased administrative services and insurance premiums as well as increased depreciation.

***Other Result***

The other result of our biotech business unit decreased by €2.6 million, or 63%, to €1.5 million in the year ended December 31, 2019 from €4.1 million in the year ended December 31, 2018. This decrease was primarily attributable to a decrease in government grants.

***Comparison of the year ended December 31, 2018 and December 31, 2017***

***Revenue***

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

| | Years ended December 31, | | Change | |
|---|---|---|---|---|
| *(in thousands)* | 2018 | 2017 | € | % |
| **Revenues** | | | | |
| 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 Service | 42 | — | 42 | — |
| **Total unit revenues** | **€108,662** | **€42,657** | **€66,005** | **155** |

Revenue of our biotech business unit increased by €66.0 million, or 155%, to €108.7 million in the year ended December 31, 2018 from €42.7 million in the year ended December 31, 2017. This increase was 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, the revenue recorded during the year ended December 31, 2018 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)* | Years ended December 31, 2018 | 2017 | Change € | Change % |
|---|---|---|---|---|
| **Research and development expenses** | | | | |
| 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 Service | 1,979 | 6,701 | (4,722) | (70) |
| **Total unit research and development expenses** | **€142,448** | **€83,583** | **€58,865** | **70** |

Research and development expenses of our biotech business unit increased by €58.9 million, or 70%, to €142.4 million in the year ended December 31, 2018 from €83.6 million in the year ended December 31, 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 each period presented:

| *(in thousands)* | Years ended December 31, 2018 | 2017 | Change € | Change % |
|---|---|---|---|---|
| **Clinical research and development expenses** | | | | |
| mRNA | | | | |
| FixVac | € 3,018 | € 2,539 | € 479 | 19 |
| iNeST | 13,335 | 17,223 | (3,888) | (23) |
| Other mRNA | 9,441 | 3,124 | 6,317 | 202 |
| Total mRNA | 25,794 | 22,886 | 2,908 | 13 |
| Engineered Cell Therapies | 653 | 2,213 | (1,560) | (70) |
| Antibodies | 14,353 | — | 14,353 | — |
| Small Molecule Immunomodulators | 1,497 | — | 1,497 | — |
| Other | 6,344 | — | 6,344 | — |
| **Total clinical research and development expenses** | **€48,641** | **€25,099** | **€23,542** | **94** |

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***

Sales and marketing expenses of our biotech business unit decreased by €2.8 million, or 57%, to €2.1 million in the year ended December 31, 2018 from €4.9 million in the year ended December 31, 2017. This decrease was primarily due to a reduction of purchased sales and marketing services.

***General and Administrative Expenses***

General and administrative expenses of our biotech business unit increased by €2.7 million, or 13%, to €23.8 million in the year ended December 31, 2018 from €21.1 million in the year ended December 31, 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 €4.1 million in the year ended December 31, 2018 from €1.6 million in the year ended December 31, 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:

| | Years ended December 31, | | |
|---|---|---|---|
| | 2019 | 2018 | 2017 |
| *(in thousands)* | | | |
| Revenues | € 23,467 | € 18,914 | €18,941 |
| Cost of sales | (16,923) | (13,358) | (9,318) |
| **Gross profit** | **€ 6,544** | **€ 5,556** | **€ 9,623** |
| Research and development expenses | (600) | (884) | (1,912) |
| Sales and marketing expenses | (1,415) | (935) | (1,698) |
| General and administrative expenses | (2,970) | (2,542) | (2,427) |
| Other result | 468 | 559 | 463 |
| **Operating income** | **€ 2,027** | **€ 1,753** | **€ 4,049** |

Our external services business unit's operating income increased by €0.2 million, or 11%, to €2 million in the year ended December 31, 2019 from €1.8 million in the year ended December 31, 2018. This increase was mainly due to an increase in revenues. Our external services business unit's operating income decreased by €2.2 million, or 55%, to €1.8 million in the year ended December 31, 2018 from €4.0 million in the year ended December 31, 2017. The decrease in operating income was primarily attributable to an increase in cost of sales by €4.1 million, or 44%, 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 Resources**

We have historically funded our operations primarily from private placements of BioNTech Shares, proceeds from collaborators and services and proceeds from secured bank loans. As of December 31, 2019, we had cash and cash equivalents of €519.1 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 loans 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 December 31, 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 €7.6 million as of December 31, 2019. The loan is repayable by quarterly installments of €286.4 thousand commencing on September 30, 2020. The loan is drawn on predetermined dates. Each of these facilities is secured by liens over our property.

In December 2019, we have signed 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 million 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 million 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 million that may be drawn in a maximum of four tranches each of which must be for a minimum of €5 million 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 million 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:

| | Years ended December 31, | | |
|---|---|---|---|
| *(in thousands)* | **2019** | **2018** | **2017** |
| **Net cash flows from (used in):** | | | |
| Operating activities | € (198,537) | € (58,877) | € (52,562) |
| Investing activities | (77,115) | (66,452) | (52,549) |
| Financing activities | 383,290 | 365,177 | (1,643) |
| Exchange rate differences | 16 | (459) | (24,820) |
| **Total cash inflow** | **€ 107,654** | **€ 239,389** | **€ (131,574)** |

***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 year ended December 31, 2019 was €198.5 million, comprising a loss before tax of €179.4 million, non-cash adjustments of €65.0 million, and a net negative change in assets and liabilities of €83.4 million. Non-cash items primarily included depreciation and amortization as well as share-based compensation expenses. The net negative change in assets and liabilities was primarily due to a decrease in contract liabilities and trade payables.

Net cash used in operating activities for the year ended December 31, 2018 was €58.9 million, comprising a loss before tax of €47.7 million, non-cash adjustments of €29.9 million, and a net negative change in assets and liabilities of €41.1 million. Non-cash items primarily included depreciation and amortization as well as 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.

The increase in net cash used in operating activities from the year ended December 31, 2018 to the year ended December 31, 2019 was primarily due to an increase in amounts spent for wages, benefits and social security expenses as headcount increases and higher research and development expenditures.

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 million, non-cash adjustments of €39.9 million, and a net negative change in assets and liabilities of €8.0 million. Non-cash items primarily included depreciation and amortization as well as share-based compensation expenses. 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 year ended December 31, 2019 was €77.1 million, of which €32.5 million was attributable to the purchase of intangible assets, including the final installment payment for the license agreement for the CellScript patent, €38.6 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 k€21 and €6.1 million were attributable to the acquisition of MAB Discovery GmbH's operational antibody generation unit based near Munich, Germany.

Net cash used in investing activities for the year ended December 31, 2018 was €66.5 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 €29.9 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 k€705.

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 year ended December 31, 2019, we generated cash from financing activities of €383.3 million, primarily from proceeds from the issuance of shares in the amount of €375.4 million and proceeds from loans and borrowings in the amount of €11.0 million, partially offset by the payment of finance lease liabilities in the amount of €3.1 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 during the year ended December 31, 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 €424.8 million as of December 31, 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. 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 will be sufficient to fund our operating expenses and capital expenditure requirements into the third quarter of 2021.

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 may in-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 do not have any off-balance sheet arrangements.

### Tabular Disclosure of Contractual Obligations

The following table summarizes our contractual obligations as of December 31, 2019 and the effects that such obligations are expected to have on our liquidity and cash flows in future periods:

**Year ended December 31, 2019**

| *(in thousands)* | Less than 1 year | 1 to 3 years | 3 to 5 years | More than 5 years | Total |
|---|---|---|---|---|---|
| Interest bearing loans and borrowings | € 2,220 | € 5,448 | € 5,245 | € 8,355 | € 21,268 |
| Lease liabilities | 5,176 | 9,712 | 8,170 | 55,852 | 78,910 |
| **Total** | **€ 7,396** | **€ 15,160** | **€ 13,415** | **€ 64,207** | **€100,178** |

We have lease agreements for land and buildings in all of our locations, which will expire from 2021 to 2042. In addition, we have various leases for equipment and cars which will expire from 2020 to 2022. The amounts in the table above represent our fixed undiscounted contractual lease obligations and do not include the optional extensions.

### Impact of COVID-19

We are closely monitoring the potential impact of COVID-19 on our business. The COVID-19 pandemic could affect our ability to enroll patients in clinical studies and complete clinical trials on the timelines we currently anticipate. In addition, our suppliers, licensors, CROs and collaborators could also be disrupted by conditions related to COVID-19, possibly resulting in disruption to our supply chain, clinical trials, partnerships or operations. Our operations, including research and manufacturing, could also be disrupted due to the potential of the impact of staff absences as a result of self-isolation procedures or extended illness. It is not possible at this time to predict the likelihood, timing or severity of the aforementioned direct and indirect impacts of COVID-19 on our business.

**Critical Accounting Policies and Use of Estimates**

Our consolidated financial statements for the years ending December 31, 2019 and 2018 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 of BioNTech and Certain Information About BioNTech—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 proxy statement/prospectus.

***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 operations 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***

*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 December 31, 2019, we had options outstanding representing 11,796,894 BioNTech Shares with a weighted-average exercise price of 10.23.

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 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 | Grant date December 1, 2019 |
|---|---|---|---|---|
| Weighted average fair value | € 7.41 | € 6.93 | € 7.04 | € 9.49 |
| Weighted average share price | € 14.40 | € 15.72 | € 16.03 | € 19.84 |
| Exercise price | € 10.14 | € 15.03 | € 15.39 | € 15.82 |
| Expected volatility (%) | 46.0% | 46.0% | 46.0% | 46.0% |
| Expected life (years) | 5.84 | 6.00 | 6.00 | 5.50 |
| Risk-free interest rate (%) | 0.05% | 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 option holder behavior for employee options.

*2019 Chief Executive Officer Grant*

In September 2019, we agreed to grant Prof. Ugur Sahin, M.D. an option to purchase 4,374,963 of BioNTech 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. The option rights can be exercised at the latest ten years after the allocation date. If they have not been exercised by that date, they will lapse without compensation.

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 | € 5.63 |
| (Weighted average) share price | € 13.60 |
| Exercise price | € 13.60 |
| Expected volatility (%) | 41.42% |
| Expected life (years) | 5.37 |
| Risk-free interest rate BioNTech (%) | 1.52% |

The options' per share exercise price is the Euro translation of the public offering price from 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.

***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.

We have 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, we have determined that we cannot recognize deferred tax assets on the tax losses carried forward.

For further disclosures relating to deferred taxes, see Note 8 of our consolidated financial statements included elsewhere in this proxy statement/prospectus.

**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 5% against the Euro, cash and cash equivalents as of December 31, 2019 would decrease by €10.2 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. However, our lack of sufficient accounting and supervisory personnel also means there has also been a lack of supervision over external consultants providing technical accounting services. 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 "—Risks Factors Related to the BioNTech ADSs."

**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 OF NEON AND CERTAIN INFORMATION ABOUT NEON

### Overview

We are 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. Genetic mutations, which are a hallmark of cancer, can result in specific immune targets called neoantigens. The presence of neoantigens in cancer cells and their absence in normal cells makes them compelling, untapped targets for cancer therapy. By directing the immune system towards these targets, we believe our neoantigen-targeted therapies will offer a new level of patient and tumor specificity in the field of cancer immunotherapy that will drive a strong risk-benefit profile to dramatically improve patient outcomes.

We aim to lead a paradigm shift in the treatment of cancer patients towards an era of truly personal immuno-oncology therapies. Our founders have done pioneering work in immuno-oncology, including work that resulted in a class of immunotherapy known as checkpoint inhibitors, which aim to reactivate the immune system to kill cancer cells. Checkpoint inhibitors have demonstrated potent efficacy in cancers with higher rates of genetic mutations, or mutational burden, which provide a greater diversity of neoantigen targets. However, even in these tumor types, the majority of patients do not respond to treatment and new treatment strategies are needed. We seek to address this unmet need by leveraging the T cell modality to target neoantigens with the potential to unlock the potency of cell therapies in solid tumors.

We have deep expertise in the development of neoantigen therapies, with both T cell and vaccine modalities. We are leveraging over a decade of insights from our founders to develop neoantigen-targeted therapies that use two distinct approaches: the first approach utilizes fully personal therapies that target neoantigens specific to each individual, and the second approach utilizes therapies that target neoantigens that are shared across subsets of patients or tumor types. Both the personal neoantigen approach and the shared neoantigen approach focus on targeting a prioritized set of what we believe are the most therapeutically-relevant neoantigens.

Our most advanced T cell program is NEO-PTC-01, our personal neoantigen adoptive T cell therapy, which consists of multiple T cell populations that are generated to target each individual patient’s unique set of neoantigens. Data presented at the Society for Immunotherapy of Cancer meeting in November 2019, as well as our ongoing research, give us confidence that we can reliably generate multiple enriched neoantigen-specific T cell populations at a therapeutic manufacturing scale that are capable of killing tumor cells. Importantly, we showed that NEO-PTC-01-induced T cell cultures directly recognize autologous patient tumor material. We believe NEO-PTC-01 has several significant advantages that could overcome the challenges of other cell therapies in the solid tumor setting. To this end, we are focusing the initial clinical development of NEO-PTC-01 in solid tumors for patients who are refractory to checkpoint inhibitors. In December 2019, we announced that we filed a clinical trial application, or CTA, with the Dutch Health Authority to evaluate NEO-PTC-01 in a first-in-human clinical trial. We plan to initiate a Phase 1 dose escalation clinical trial in metastatic melanoma in collaboration with the Netherlands Cancer Institute in the third quarter of 2020. The second planned indication for NEO-PTC-01 is metastatic ovarian cancer, with the potential to both expand to other solid tumor types and pursue clinical development in the United States.

We are also advancing a T cell therapy program targeting shared neoantigens in genetically defined patient populations to direct the immune system towards prevalent mutations that are shared across patients in specific tumor types. We intend to develop product candidates targeting shared neoantigens using both non-engineered and engineered T cell modalities. Our first product candidate using the shared neoantigen approach, NEO-STC-01, is a non-engineered adoptive T cell therapy that targets RAS mutations prevalent across many solid tumors. We are focusing our initial efforts with NEO-STC-01 on the treatment of pancreatic ductal adenocarcinoma, or PDAC, as over 84% of PDAC tumors have a RAS mutation and there is a significant unmet medical need for PDAC therapies. We have also assembled libraries of high-quality T cell receptors, or TCRs,

against various shared neoantigens across common human leukocyte antigens, or HLAs, which are suitable for an engineered TCR-T cell therapy approach.

Finally, we also have two neoantigen vaccines in our portfolio, NEO-PV-01, a fully personal neoantigen cancer vaccine, custom-designed and manufactured for each individual patient's tumor mutations, and NEO-SV-01, a neoantigen vaccine for the treatment of a subset of hormone receptor-positive breast cancer. NEO-PV-01 is in Phase 1b clinical development in metastatic disease settings, with three ongoing trials. In November 2019, we reported top line results from the first trial, NT-001, at the Society of Immunotherapy for Cancer 2019 meeting. In November 2019, we also announced the cessation of additional spending commitments related to our cancer vaccine programs, NEO-PV-01 and NEO-SV-01. We will continue to conduct follow-up from our ongoing 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 initial clinical data from this trial in the second half of 2020. We have also ceased enrollment in our NT-003 trial in metastatic melanoma.

In developing all of our therapeutic product candidates, we leverage our proprietary neoantigen platform, which continuously improves as our product candidates generate data. This platform comprises two key elements: our Real-time Epitope Computation for ONcology, or RECON, bioinformatics engine, and our combined T cell biology and immune-monitoring expertise, in particular NEO-STIM, our proprietary antigen-specific T cell induction protocol.

Our RECON bioinformatics engine utilizes a proprietary combination of algorithms designed to predict the most therapeutically-relevant neoantigen targets associated with each patient's tumor. As detailed in our February 2017 and October 2019 papers in *Immunity*, our approach to bioinformatics uses a proprietary allele-specific, or mono-allelic, approach that allows us to predict neoantigens that are presented by specific Class I and Class II HLA alleles relevant for each patient. Using this approach and with our growing proteomic database of greater than 1.7 million unique HLA bound peptides, we have generated high quality datasets that have resulted in positive predictive values greater than 50%, exceeding standard approaches by greater than ten times for Class I HLAs and by greater than sixty times for Class II HLAs when using a recall-based measurement of performance. We intend to continue to strengthen our leading position in bioinformatics and identification of therapeutic neoantigens by using data generated from our ongoing and future clinical trials, coupled with our machine learning expertise, to continue to refine RECON's neoantigen prediction algorithms.

Our combined T cell biology and immune-monitoring expertise allows us to elicit neoantigen-specific immune responses, both *in vivo* and *ex vivo*, and to evaluate these responses in patients. We have developed a proprietary method for *ex vivo* T cell stimulation, which we call NEO-STIM, that allows us to directly prime, activate and expand antigen-specific T cells. In addition, we have built up immune profiling capabilities using a state-of-the-art toolkit that allows us to understand the antigen-specific immune responses to our therapies, thereby providing a key feedback loop that further enables improvements in research and development of our programs.

***Recent Corporate Updates***

On November 20, 2019, we announced that, as part of a new strategic focus, we were reducing our workforce by approximately 24% of our then current headcount. This corporate restructuring was substantially completed during the fourth quarter of 2019. We also announced the cessation of additional spending commitments related to our cancer vaccine programs, as detailed above.

After a comprehensive review of strategic alternatives, on January 15, 2020, we entered into an agreement with BioNTech SE, or BioNTech, pursuant to which, if all of the conditions to closing are satisfied or waived, we will become a wholly-owned subsidiary of BioNTech, or the Merger Agreement and such transaction, the Merger. The Merger Agreement was unanimously approved by the members of our board of directors, or the Board, and the Board resolved to recommend approval of the Merger Agreement to our shareholders. The closing

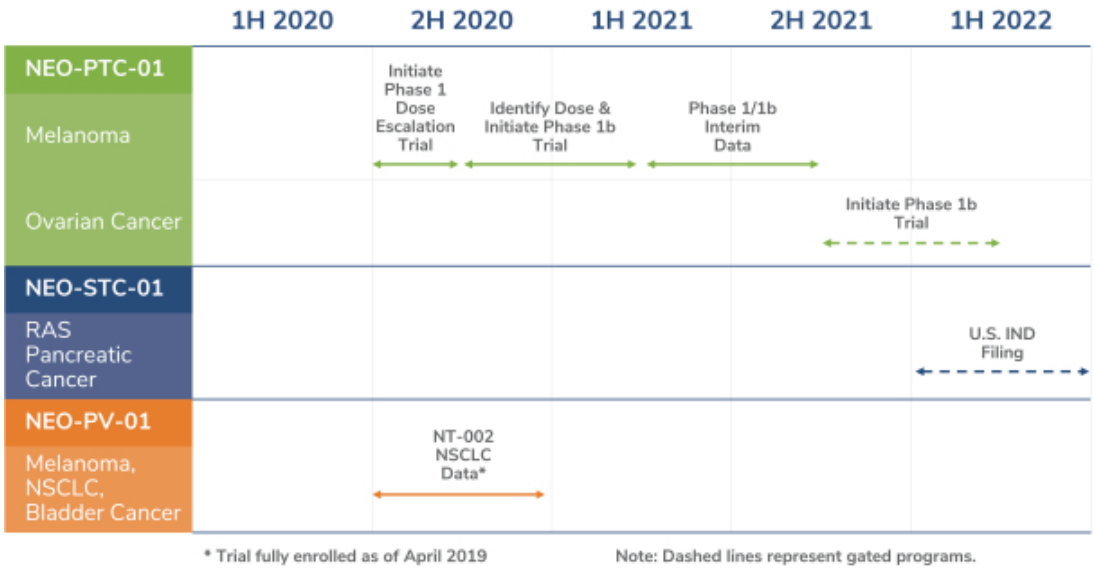
of the Merger is subject to approval of our shareholders and the satisfaction of customary closing conditions. Certain of our stockholders who collectively own approximately 36% of the outstanding shares of our common stock have entered into voting agreements, pursuant to which they have agreed, among other things, and subject to the terms and conditions of the agreements, to vote in favor of the Merger.

Subject to the terms of the Merger Agreement, at the effective time of the Merger, or the Effective Time, each share of our common stock issued and outstanding immediately prior to the Effective Time shall automatically be canceled and converted (without interest but subject to any withholding required under applicable law) into the right to receive 0.063 of an American Depositary Share of BioNTech, or Parent ADS, with each Parent ADS representing one ordinary share of BioNTech.

The transaction is expected to close in the second quarter of 2020.

***Neon's Approaches and Product Candidates***

The following diagram summarizes the current status of our product development pipeline:




*Neon's Personal Neoantigen Approach*

NEO-PTC-01 is a personal neoantigen adoptive T cell therapy that consists of multiple T cell populations targeting what we predict to be the most therapeutically-relevant neoantigens from each patient's tumor. T cells are a type of white blood cell that play a central role in the immune system, including both detecting and killing cancer cells. NEO-PTC-01 uses T cells from the periphery of each patient that we then specifically prime, activate and expand to generate a therapy that specifically targets that patient's personal neoantigens. We believe that NEO-PTC-01 will allow us to drive a robust and persistent anti-tumor response and could be applicable across a broad range of both hematological and solid tumors. NEO-PTC-01 is currently in preclinical development. We filed a CTA with the Dutch Health Authority in December 2019 to evaluate NEO-PTC-01 in solid tumors in patients that are refractory to checkpoint inhibitors. Our first clinical trial of NEO-PTC-01 will be in metastatic melanoma and is expected to start in the third quarter of 2020.

*Neon's Shared Neoantigen Approach*

Our shared neoantigen programs take a precision medicine approach to neoantigen-targeted therapies. We are seeking to discover, validate and develop therapies directed towards shared neoantigens, which are neoantigen targets that are shared across subsets of patients or tumor types. Our proprietary shared neoantigen targets will be developed as adoptive T cell therapies. Our lead shared neoantigen product candidate is NEO-STC-01, a neoantigen adoptive T cell therapy for the treatment of cancers driven or mediated by RAS mutations. We believe NEO-STC-01 has the potential to be used across multiple different tumor types harboring RAS mutations. We also continue to make significant progress with respect to shared neoantigen discovery and validation and have assembled libraries of high-quality TCRs against various shared neoantigens across common HLAs.

**Neon's Strategy**

To fulfill our mission, we are developing neoantigen-targeted therapies that we believe have the potential to lead a paradigm shift in the treatment of cancer patients. Key elements of our strategy include:

- *Advance product candidates using multiple T cell therapies across a broad array of patient populations.*
- *Develop NEO-PTC-01 to leverage the potency of cell therapies to target neoantigens specific to each individual.*
- *Develop shared neoantigen T cell therapies for patients who share specific neoantigens.*
- *Strengthen our leading position in the neoantigen field through ongoing investment in our platform technologies.*
- *Discover and validate a pipeline of TCRs than can effectively target tumor antigens across common HLAs and are suitable for an engineered TCR-T cell therapy approach.*

**Neon's Neoantigen Platform**

We have pioneered a proprietary neoantigen platform that we are using to develop neoantigen-targeted therapies. We believe that directing the immune system towards neoantigen targets is fundamental to driving effective cancer immunotherapies. Accordingly, our platform seeks to identify and harness the most therapeutically relevant neoantigens present within each patient's tumor.

Our platform comprises two key elements that form an iterative feedback loop: our RECON bioinformatics engine, which is designed to predict the most therapeutically-relevant neoantigen targets and our combined T cell biology and immune-monitoring expertise, in particular NEO-STIM, our proprietary antigen-specific T cell induction protocol. We are using our platform to develop product candidates across several neoantigen-targeting non-engineered and engineered T cell therapies using two distinct approaches:

- Our personal medicine approach enables neoantigen-targeted therapies that are tailored for the individual profile of each patient's tumor.
- Our precision medicine approach enables neoantigen therapies that target prevalent neoantigens that are shared across subsets of patients or tumor types.

**Overview of Neon's Neoantigen Platform, Treatment Approaches and Treatment Modalities**


***Neoantigen Selection: Neon's RECON Bioinformatics Engine***

At the core of our neoantigen platform is our RECON bioinformatics engine, which is designed to predict the most therapeutically-relevant neoantigen targets associated with each patient's tumor. Effective prediction is critical because, although many mutations within a patient's tumor will lead to the production of a mutated protein, not all mutated proteins lead to suitable therapeutic neoantigen targets.

RECON uses a number of inputs from each patient, including DNA sequences from samples of tumor and normal tissue, RNA sequences from tumor samples, and the patient's specific MHC allele profile. RECON processes data from these inputs using a proprietary combination of algorithms in order to produce a prioritized list of neoantigen-targeting peptides that we then manufacture for use in our product candidates. These algorithms seek to:

- **Identify** the mutations present within a patient's tumor;
- **Predict** which mutations will lead to neoantigens that will be presented by a patient's specific MHC allele profile; and
- **Select** the most therapeutically-relevant neoantigen-targeting peptides for use in our therapies based on a set of additional biological and pharmacological factors.

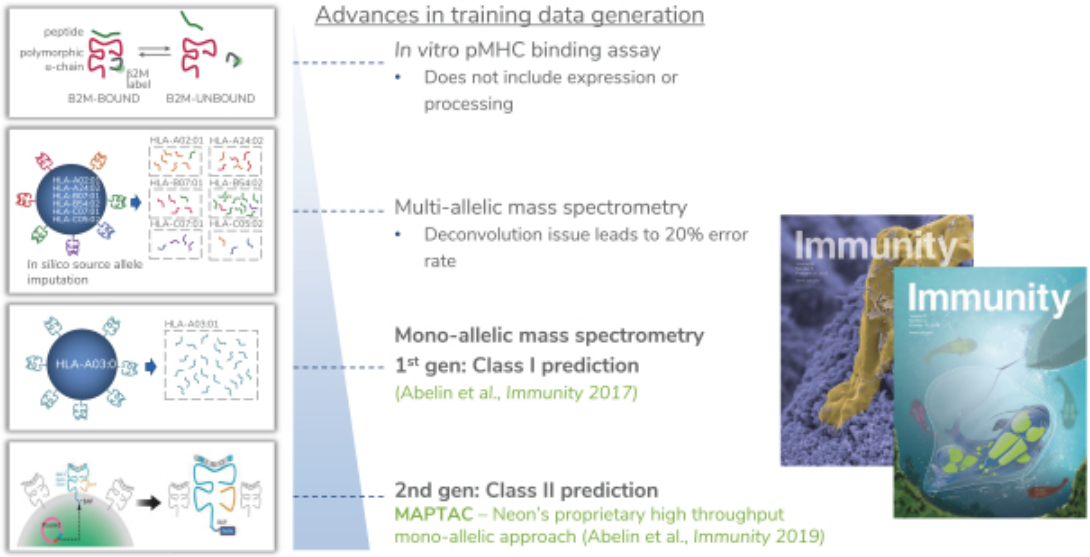
We believe we have built RECON as a leading neoantigen bioinformatics engine. By further leveraging the combination of leading-edge proteomics and machine learning expertise, we intend to strengthen our leadership position in identifying neoantigens. Importantly, refining predictions of therapeutic relevance of neoantigens will incorporate immunogenicity data generated from our ongoing and future clinical trials for each RECON predicted neoantigen. As a result, both proteomic and clinical data will continue to refine RECON's neoantigen prediction algorithms in an iterative manner.

RECON predictions of neoantigens, which uses somatic mutations that are accurately and robustly characterized as the starting point, recapitulates the key events in this pathway, including protein cleavage, antigen-HLA binding and T cell reactivity. Factors such as quantification of RNA expression of antigens are used in multiple steps in immunogen identification and design.

***Identification of Mutations*:** We believe that achieving a combination of high sensitivity and specificity is critical in identifying genetic mutations upon which to base neoantigen predictions. We use a proprietary combination of mutation detection algorithms, known as a mutation calling ensemble, to identify candidate mutations present within a patient's tumor by comparing the patient's normal DNA and tumor DNA sequences. Using this proprietary approach, we have demonstrated a consistently lower rate of false positive errors while maintaining sensitivity when compared to the use of a single mutation detection algorithm.

***Prediction of Neoantigen-MHC Presentation*:** We use a novel approach to predict which mutations lead to neoantigens that will bind to and be presented by MHC on the surface of a patient's cancer cells. Conventionally, neoantigen prediction is conducted using publicly available algorithms that are trained using limited datasets derived predominantly from *in vitro* binding assays. The utility of these assays to develop binding predictors is limited due to low throughput and does not incorporate critical insights into how peptides are processed. Later generations of algorithms use mass spectrometry techniques to isolate and sequence peptides from multiple MHC alleles. While these approaches have made advances in predicting neoantigen-MHC binding over *in vitro* binding assays, the utility of this multi-allelic mass spectrometry approach is limited because these algorithms are unable to discern which peptides are presented by each MHC allele. Further, requiring the use of a predictive algorithm to assign each peptide to an allele is a process that can result in a significant error rate. While these approaches have some utility, we believe, they lack adequate precision and depth across a wide enough range of alleles to have adequate clinical utility. It is our belief that superior data inputs will yield superior predictions and we have, therefore, made significant investments to generate a high-quality dataset to build the predictive abilities of our RECON bioinformatics engine.

**Overview of Data Sources for Neoantigen-MHC Presentation Prediction**

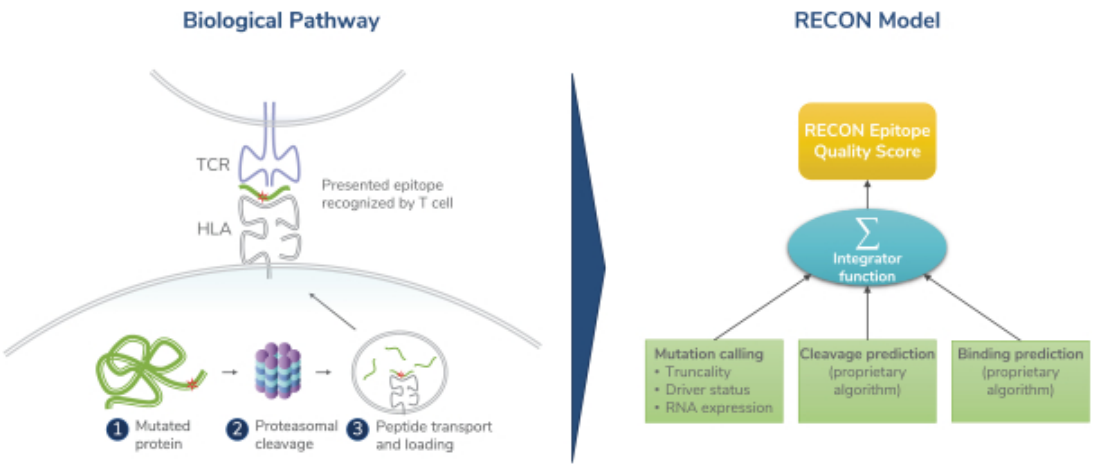



As shown in the graphic above, we use a proprietary allele-specific approach that leverages our mono-allelic MHC proteomic datasets that is differentiated from earlier techniques. Overall, this approach allows us to accurately predict neoantigens that are presented by specific MHC alleles relevant for each patient. We generated our mono-allelic datasets using a novel mass spectrometry-based method for profiling MHC-bound peptides that are presented by a single Class I or Class II MHC allele. The foundation for our approach to generating mono-allelic Class I MHC ligand datasets was published in *Immunity* in February 2017. This work was extended by our innovative higher-throughput mono-allelic approach, which we call MAPTAC (Mono-Allelic Purification with Tagged Allele Constructs), that was published in *Immunity* in October 2019. In particular, MAPTAC has enabled us to rapidly extend our data for Class I MHC alleles and also generate data for many Class II MHC alleles, many of which have no publicly available data. As of March 2019, our MAPTAC dataset included 101 Class I alleles, covering greater than 95% of allelic diversity for A, B, and C alleles, and 45 Class II alleles, covering 95.0%, 78.9%, and 42.7% of allelic diversity for DR, DP and DQ, respectively. Using our MAPTAC approach, we continue to expand our dataset for Class I and Class II alleles.

Using our datasets, we have developed unique MHC allele-specific algorithms that provide far greater predictive accuracy and lower false discovery rates than standard approaches. We have used this methodology to systematically investigate Class I and II MHC alleles, enabling broad coverage of alleles across geographic populations and ethnic groups. We have already achieved greater than ninety-nine percent population coverage in the United States through our coverage of one or more Class I (HLA-A, B and C) and Class II HLA (HLA DR, DP, and DQ) alleles for each patient. We believe these enhancements will enable us to develop more effective neoantigen-targeted therapies. Using this approach and with our growing proteomic database of greater than 1.2 million unique HLA bound peptides, we have generated high quality datasets that have resulted in positive predictive values greater than 50%. The performance of RECON to predict antigen-HLA binding exceeds that of standard approaches, such as netMHCPan, by up to greater than ten times for Class I HLAs and by up to greater than sixty times for Class II HLAs when using a recall-based measurement of performance. Our next-generation algorithms using mono-allelic data for Class I MHC alleles have now been deployed in our ongoing clinical trials and we plan to deploy our Class II MHC prediction capabilities in upcoming trials.

The figure below provides an overview of the neoantigen presentation pathway on the left and how RECON models this biology on the right.

**Overview of Neon's RECON Bioinformatics Engine**




In addition to mono-allelic mass spectrometry-based HLA-antigen presentation predictions, RECON predictions of neoantigens recapitulates other key events in this pathway. For example, we have also developed a proprietary algorithm designed to predict how proteins are processed into peptides and how this process influences which peptides can be presented by MHC. Factors such as quantification of RNA expression and truncality scores (which is a measure of the percent of cells that harbor the mutation) of antigens are used in multiple steps in immunogen identification and design. In addition, we have also observed that intra-tumoral MHC Class II presentation is dominated by professional antigen presenting cells, or APCs, rather than tumor cells. Therefore, tracking which tumor epitopes are most readily phagocytosed (or ingested by a cell) and presented by APCs further enhances the ability to pinpoint therapeutically relevant epitopes. These findings can be used to further enhance RECON's predictive power.

***Selection of the Most Therapeutically-Relevant Neoantigens*:** In our effort to select the most therapeutically-relevant neoantigens, in addition to the factors described above, we incorporate a number of additional filters and algorithms applied to RECON-identified neoantigens that account for several biological and pharmacological factors, as well as manufacturing considerations. These include prioritizing based on predictions

of T cell reactivity. Also, features of each mutation, such as truncality, help identify the most preferred immunogenic HLA bound antigens to target.

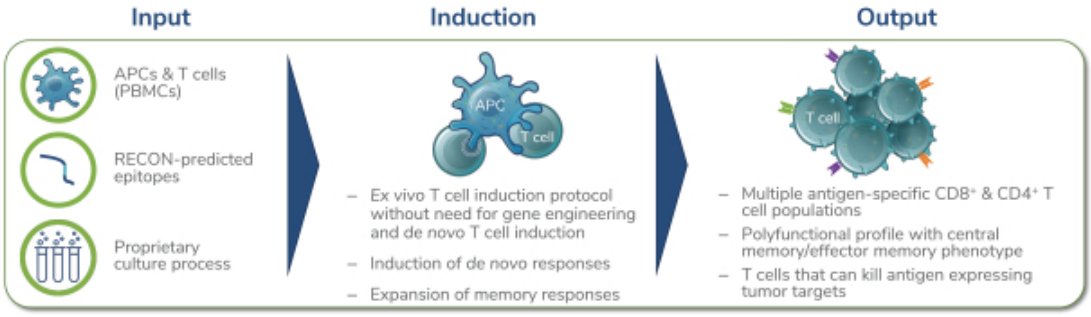
Our current version of RECON is trained using our mono-allelic mass spectrometry data for Class I MHC epitopes and is used in our ongoing clinical trials for NEO-PV-01. We plan to incorporate Class II MHC epitope prediction into the version of RECON used for future clinical trials, including for our planned clinical trial of NEO-PTC-01. Through intensive immune monitoring of epitope immunogenicity in our clinical studies, we can improve the quality of RECON's predictions over time by understanding the immune response to each epitope.

***Neoantigen Immunogenicity: Inducing T cells with NEO-STIM and Evaluating Antigen-specific T Cell Responses***

Fundamental to our platform is our ability to elicit neoantigen-specific immune responses, both *in vivo* and *ex vivo*, and to evaluate these responses in patients. It is therefore vital for us to understand how T cell responses can be induced and expanded to target neoantigens and to monitor the immune system response in treated patients.

We have developed a proprietary method for *ex vivo* T cell stimulation, which we call NEO-STIM, that allows us to directly prime, activate and expand antigen-specific T cells.

**Overview of NEO-STIM Induction Protocol**




NEO-STIM has several important advantages compared to other tumor-targeting T cell induction and expansion protocols including:

- Starting with peripherally collected apheresis material and does not require harvesting tumor-infiltrating lymphocytes, or TILs;
- No cell engineering required to generate potent antigen-specific T cells;
- Ability to both induce *de novo* and expand memory antigen-specific immune responses in the laboratory; and
- Generating T cells with desired phenotype that can kill antigen expressing tumor targets and autologous tumor without use of IL-2, which is a potent cytokine signaling molecule for the immune system, during the T cell culture process.

Given these advantages of NEO-STIM, we apply this important platform technology both for research purposes and as a key inline manufacturing step to generate neoantigen-specific adoptive T cell therapies. Applications for NEO-STIM include:

- ***Inline manufacturing for neoantigen-specific adoptive T cell therapies:*** We can generate therapeutic-scale T cell populations under current Good Manufacturing Practice, or cGMP, conditions that are

specific to a patient's neoantigen targets. NEO-STIM can be used in this way for programs targeting personal neoantigens specific to a patient's tumor, as in the case for NEO-PTC-01, or shared neoantigens such as RAS, as in the case for NEO-STC-01.

- ***Validating the immunogenicity of neoantigen targets:*** NEO-STIM's ability to induce de novo neoantigen-specific T cell responses allows us to confirm the immunological relevance of specific predicted neoantigens and is an important validation step for our shared neoantigen pipeline.
- ***Isolating neoantigen-specific T cell receptors:*** We generate tumor antigen-specific T cells and isolate TCRs specific to each tumor antigen that have the potential to be used in developing multiple TCR-based T cell therapies.
- ***Learning the rules for which epitopes are immunogenic:*** By testing many epitopes and T cell responses, we can learn the rules of immunogenicity that indicate which epitopes may successfully lead to immune responses. This information can then be used to improve RECON's prediction algorithms.

We have also developed extensive in-house immune-monitoring capabilities that allow us to interrogate the immune state of a patient before, during and after each therapeutic intervention. We evaluate multiple components of the immune system, including different types of immune cells and important classes of cytokines, in both the periphery and the tumor. To evaluate immune responses, we use a range of cutting-edge techniques, including rapid UV-exchange MHC multimers developed by one of our founders, Ton Schumacher, which allow us to analyze neoantigen-specific CD8+T cells, TCR sequencing to determine the distribution of neoantigen-specific T cells, single cell sequencing and multi-channel flow cytometry. We complement the use of these monitoring techniques with the use of other more common immune-monitoring techniques such as ELISpot assays and immunohistochemistry. Together, these techniques allow us to generate comprehensive immunological data from our clinical trials and to correlate them with our analysis of the tumor both before and after treatment. We expect to use these data to make ongoing improvements to RECON's neoantigen selection and prioritization algorithms, identify biomarkers that can help predict which patients will be responsive to therapy, further enhance clinical development strategies and inform generational improvements to our product candidate portfolio.

**Neon's Approaches and Product Candidates**

***Personal Neoantigen Approach***

For our personal medicine approach to neoantigen-targeted therapy, we are developing therapies that are tailored to each patient's specific set of tumor neoantigens. We are currently developing a personal neoantigen adoptive T cell therapy called NEO-PTC-01. We believe our personal approach has potential to be an effective new treatment across solid tumors that are unresponsive to checkpoint inhibitor therapy.

***Personal Neoantigen Adoptive T Cell Therapy Program: NEO-PTC-01***

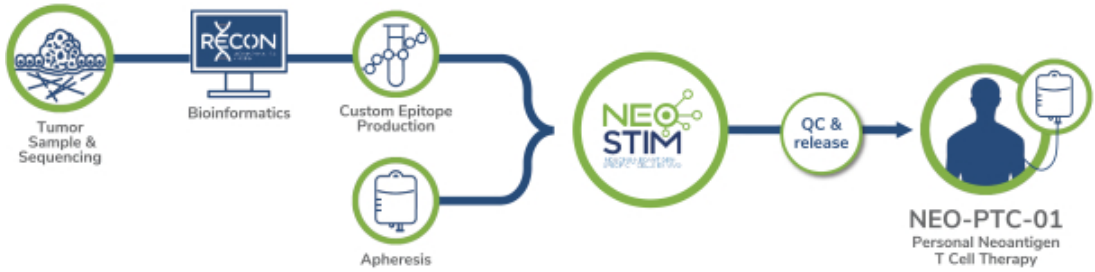
*Overview*

NEO-PTC-01, is a personal neoantigen T cell therapy consisting of multiple T cell populations targeting what we believe to be the most therapeutically-relevant neoantigens from each patient's tumor. NEO-PTC-01 is currently in preclinical development. In December 2019, we filed a CTA with the Dutch Health Authority to evaluate NEO-PTC-01 in the solid tumor setting in patients that are refractory to checkpoint inhibitors. We plan to initiate a Phase 1 dose escalation clinical trial in patients with metastatic melanoma who are refractory to checkpoint inhibitors in collaboration with the Netherlands Cancer Institute in the third quarter of 2020. The second planned indication for NEO-PTC-01 is metastatic ovarian cancer, with the potential to both expand to other solid tumor types and pursue clinical development in the United States.

NEO-PTC-01 leverages our neoantigen platform, including RECON and NEO-STIM. Using RECON, we select high ranking neoantigens personalized to each patient. This set of neoantigen-targeting peptides is then manufactured for each patient on an individual basis. We next leverage these custom-manufactured peptides in our proprietary *ex vivo* co-culture process, NEO-STIM, to prime, activate and expand autologous neoantigen-

specific T cells specific for each patient's personal set of neoantigens. We believe that this approach will allow us to specifically target each patient's individual tumor with T cells that can drive a robust and persistent anti-tumor response. The graphic below outlines the process that we will employ for NEO-PTC-01:

**NEO-PTC-01 Product Process**




*Product Development Rationale*

We believe that NEO-PTC-01 has the potential to unlock the potency of cell-based therapies in solid tumors. This stands in contrast to approved T cell therapies that have been limited to hematological cancers to date.

Adoptive T cell therapies, particularly chimeric antigen receptor T cells, or CAR-Ts, have demonstrated potent efficacy in the treatment of certain hematological cancers. These therapies use genetically-engineered constructs inserted into T cells that allows for the recognition and killing of cancer cells expressing certain cell surface targets, such as the B-lymphocyte antigens CD19 and BCMA. However, CAR-T approaches are currently restricted to single targets and treatment with CAR-T therapies has been observed to come with a significant toxicity profile.

Steven Rosenberg and his colleagues at the National Cancer Institute have demonstrated the potential of neoantigen-specific T cell therapies in the case studies of two patients enrolled in an ongoing Phase 2 clinical trial that characterized tumor infiltrating lymphocytes. A case study published in *Science* in May 2014 discusses the results of treatment of one female patient with metastatic cholangiocarcinoma with expanded autologous tumor T cells specific towards a mutation in the gene Erbb2IP. In this case, a cell therapy was prepared containing a 95% pure population of CD4+ T cells targeting this specific Erbb2IP mutation. Treatment with this therapy was associated with tumor regression two months later, with a maximum tumor size reduction of 30% observed at seven months post-treatment and disease stabilization for 13 months. A case study published in *The New England Journal of Medicine* in December 2016 discusses the results of treatment of one female patient with colorectal cancer with CD8+ T cells targeting the G12D point mutation in the KRAS oncogene. Treatment with this T cell population was associated with tumor regression 40 days later and disease control for nine months. In the case of this patient, the T cell therapy had no reported adverse effects and the patient was discharged from the hospital two weeks following therapy.

We believe that NEO-PTC-01's T cell therapy approach has several key advantages that overcome the challenges of other cell therapy approaches, including:

- *T cell induction and amplification outside of the body:* Using NEO-STIM, we can directly prime, activate and expand neoantigen-targeting T cells *ex vivo*. We believe that by performing these processes outside the body, we can avoid potential immunosuppression or inhibitory mechanisms in patients and optimize the phenotype and functionality of the neoantigen-targeting T cells.
- *Generating multiple memory and de novo neoantigen responses:* We aim to both expand existing memory T cell responses and prime *de novo* T cell responses from the naïve compartment that have not previously been observed in the patient. By expanding memory responses, we aim to increase the magnitude of pre-existing immune responses against neoantigens. By priming *de novo* responses, we

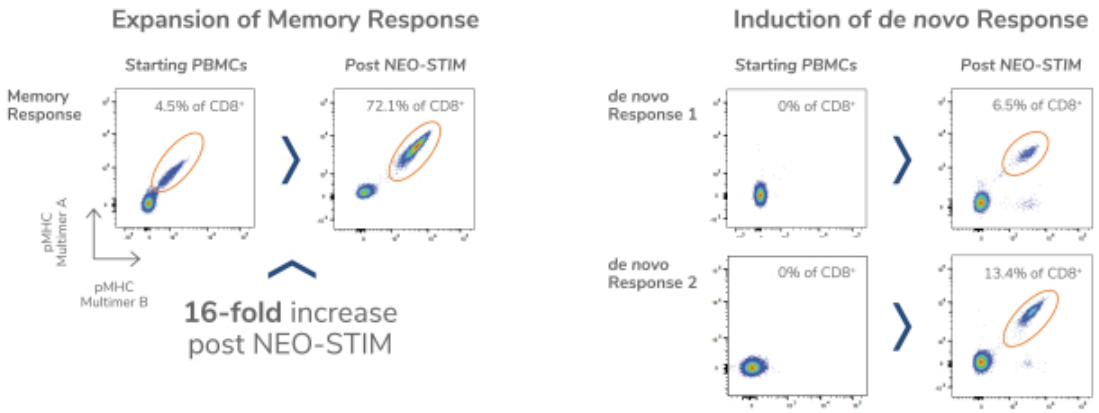
believe we can educate the immune system to recognize a broader set of neoantigen targets, thereby strengthening the immune response.

- *Broad utility across tumor types, including solid tumors:* Neoantigens are present across both solid and hematological tumor types. As a result, we believe that neoantigen targets will provide the tumor specificity required to develop safe, effective and durable T cell therapies for the treatment of solid tumors.
- *Potential impact in tumors with lower mutational burden:* In tumors with lower mutational burden where checkpoint inhibitors are less likely to be efficacious, we believe it may be possible to treat these patients through expanded populations of functional T cells specific for the most therapeutically-relevant neoantigens.

*Preclinical Development*

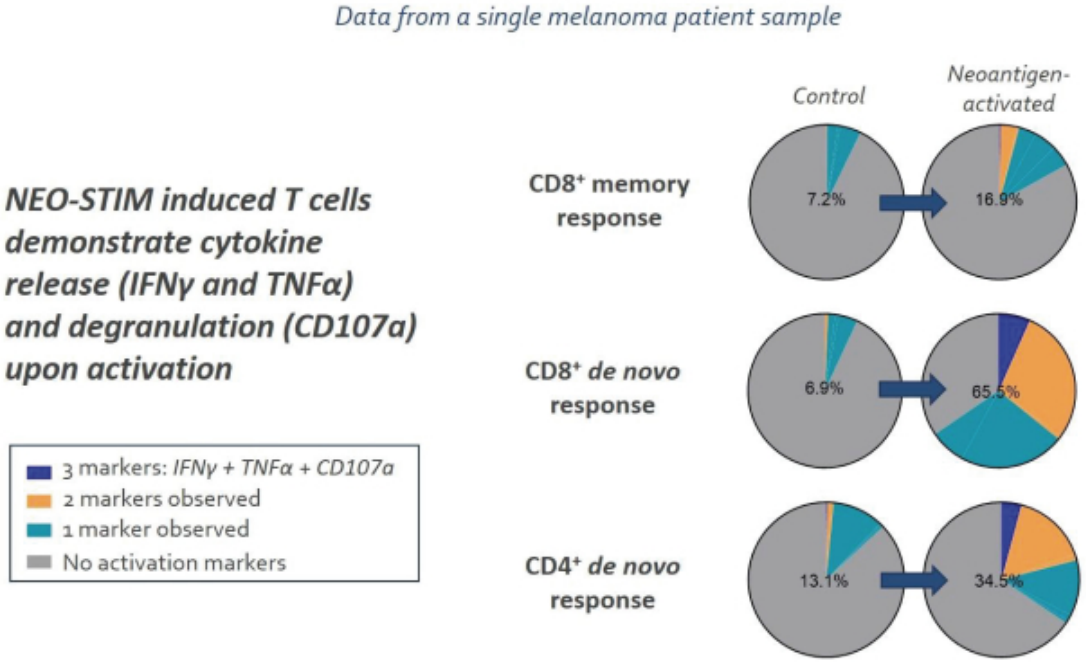
We are developing NEO-PTC-01 in collaboration with the Netherlands Cancer Institute, which is an academic research and treatment center with leading expertise in T cell biology and treatments. We presented preclinical data relating to NEO-PTC-01 at the Society of Immunotherapy of Cancer 2019 meeting, highlighting the proof of feasibility of our NEO-STIM induction protocol. Through these data, we demonstrated, reproducibly across multiple patient samples, the ability to generate multiple CD8+ and CD4+ T cell populations in each patient sample from the memory and naïve compartment. These T cells were highly functional and were specific for mutant neoantigens. In addition, these data showed that these cells were capable of *in vitro* cell killing and NEO-PTC-01-induced T cell cultures directly recognize autologous tumor sample material. We can now reproducibly generate these cell populations from patient material at a therapeutic manufacturing scale.

Our NEO-STIM induction protocol generates a polyclonal population of T cells. Once generated, we deeply characterize this cell product to understand the specificity and functionality of the induced cells. Data analyzed from a melanoma patient shows that NEO-STIM can induce CD8+ T cell responses towards patient-specific neoantigens in autologous patient peripheral blood mononuclear cells, or PBMCs. Specifically, in this patient, as the charts below and to the left illustrate, a pre-existing memory response was expanded 16-fold, from 4.5% of CD8+ T cells to 72.1% of CD8+ T cells being specific for the selected neoantigen. Additionally, as the charts below and to the right illustrate, we induced two CD8+ T cell responses from the naïve compartment, generating 6.5% and 13.4% of CD8+ T cells, respectively. Finally, in this patient, we induced three neoantigen specific CD4+ T cell responses as well.

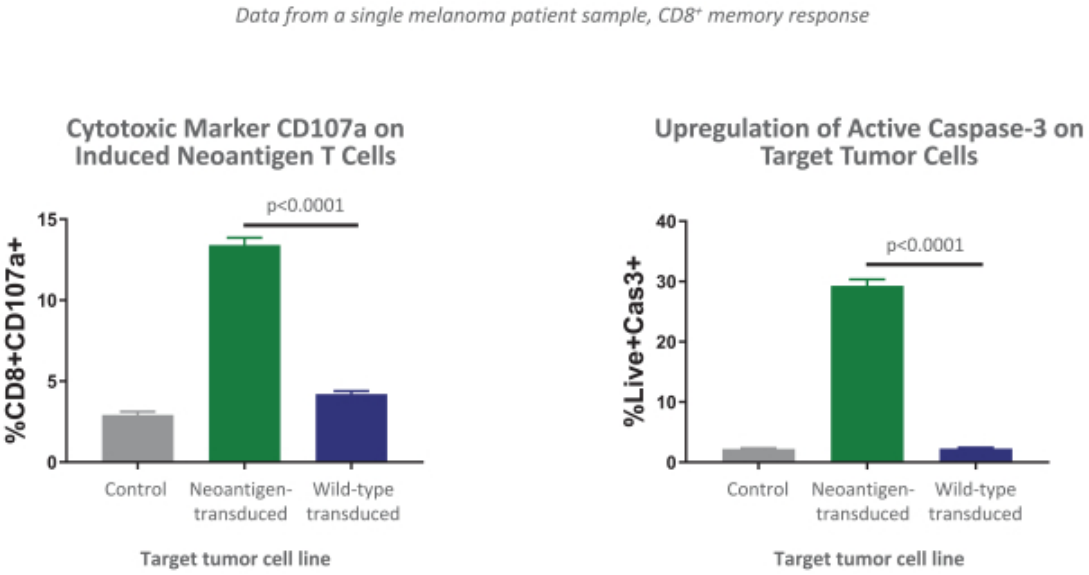



Since the infusion of polyfunctional T cells has been associated with better efficacy *in vivo* and long-term persistence (Appay *et al.*, *Nature Medicine*, 2008), we characterized the induced CD8+ and CD4+ T cells in more detail

for their functionality. As demonstrated in the charts below, upon re-challenge with mutant peptide loaded dendritic cells, neoantigen-specific T cells exhibited one, two and/or three of the following functions: IFNg, TNFα or CD107a.

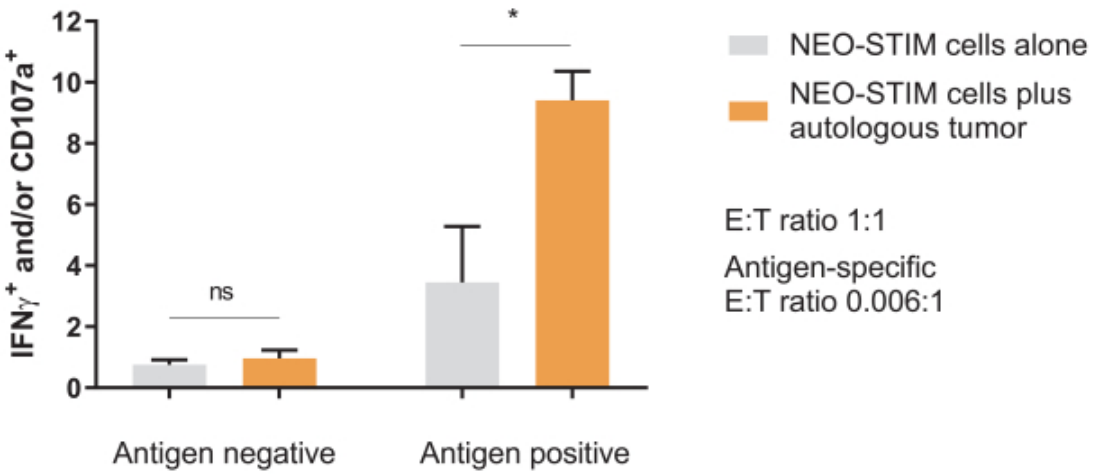



Finally, we set out to study the ability of the induced CD8+ T cells to kill tumor targets that process and present the neoantigen of interest. A375 tumor cell lines were stably transduced with the HLA restriction element, as well as the neoantigen of interest. Subsequently, and as demonstrated in the charts below, we performed a 6-hour co-culture with the induced T cells. We determined that the neoantigen specific CD8+ T cells upregulated CD107a and the tumor targets expressed active caspase 3 (an early apoptotic marker) upon co-culture.



Additionally, we found that NEO-PTC-01-induced T cells can directly recognize autologous tumors as shown in the figure below.

**Induced CD8+ T cells Recognize Autologous Tumors as Reflected by Induction of IFN*γ* and/or CD107a+**




In summary, our development activities confirm that the patient-specific neoantigens that were predicted through our RECON bioinformatics engine are immunogenic based on the induction of multiple neoantigen-specific CD8+ and CD4+ T cell responses. Further, the presence at the end of the NEO-STIM process of multiple enriched neoantigen-specific T cell populations (both memory and *de novo*) demonstrates our potential to generate new T cell responses and, as a result, cancer immunotherapies that may be effective to treat cancer patients.

*Clinical Development Plan*

We are focusing the initial clinical development of NEO-PTC-01 in solid tumors where we believe we can generate *de novo* neoantigen T cell populations *ex vivo*. We filed a CTA with the Dutch Health Authority in December 2019 to evaluate NEO-PTC-01 in a first-in-human clinical trial in patients that are refractory to checkpoint inhibitors. We plan to initiate a Phase 1 dose escalation clinical trial in patients with metastatic melanoma who are refractory to checkpoint inhibitors in collaboration with the Netherlands Cancer Institute in the third quarter of 2020. The primary objectives of this trial will be to evaluate the safety and feasibility of administering NEO-PTC-01 to patients. Additional objectives will be to evaluate immunogenicity and clinical efficacy. The second planned indication for NEO-PTC-01 is metastatic ovarian cancer.

Based on the data from the first exploratory trial, we will decide how to best proceed with further clinical development of NEO-PTC-01, including expanding to other tumor types and potential development in the United States.

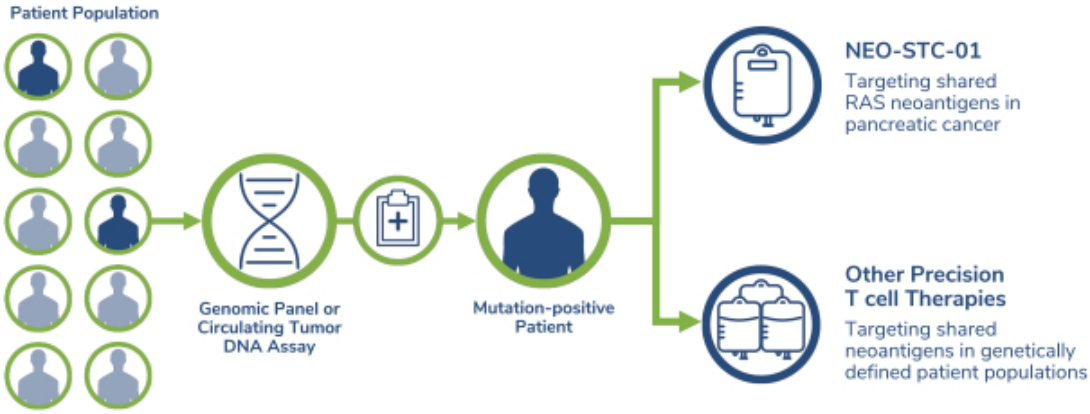
***Shared Neoantigen Approach***

*Overview*

Our precision medicine approach to neoantigen-targeted therapy targets neoantigens shared across subsets of patients. While most neoantigen targets are specific to an individual patient's tumor, there are prevalent neoantigens that are shared across subsets of patients or tumor types, and these are known as shared neoantigens.

We intend to develop multiple therapies directed towards these shared neoantigen targets using T cell therapies. We believe that our shared neoantigen approach could be complementary to our personal neoantigen therapies by providing readily available therapies that can be used in patients identified as having the relevant shared genetic mutation.

**Shared Neoantigen Approach**




Our shared neoantigen targets were identified using our bioinformatics capabilities, including RECON, to interrogate large genomic databases to discover a set of proprietary shared neoantigen targets across certain patient populations within major tumor types. This discovery work began under the direction of our founder, Nir Hacohen, at the Broad Institute, Inc., or the Broad, and continues today at Neon.

We are currently completing a comprehensive validation of our prevalent shared neoantigen targets using the following assessments:

- **Biochemical measurements** leveraging mass spectrometry approaches enable us to rapidly evaluate whether shared mutations are processed and presented on common HLAs as targetable shared neoantigens. These approaches allow us to de-risk targets early in the validation process.
- **Immunological experiments** evaluate whether our shared neoantigen targets are immunogenic. We use our proprietary NEO-STIM induction process to generate neoantigen-specific T cells from which we can also isolate and sequence neoantigen-specific TCRs specific to these shared neoantigens.
- **Functional biological assays** demonstrate the ability of these neoantigen-specific T cells or neoantigen-specific TCRs to recognize and kill cancer cells expressing the relevant shared neoantigens.

We have completed the validation of our first targets and plan to develop multiple adoptive T cell product candidates targeting different shared neoantigens. In addition, we continue to make significant progress with respect to TCR discovery and have assembled libraries of high-quality TCRs against various shared neoantigens across common HLAs. We plan to explore the potential development of our neoantigen-specific TCRs into multiple TCR-based T cell therapies, potentially in collaboration with external partners who would provide complementary technical capabilities.

*NEO-STC-01: Adoptive T cell Therapy for RAS-mediated Cancers*

NEO-STC-01 is a shared neoantigen adoptive T cell therapy that targets RAS mutations prevalent across many solid tumors. It is an autologous, non-engineered T cell product that leverages a premanufactured “target

warehouse" for RAS driver mutations, to generate multiple CD8+ and CD4+ target-specific T cell populations for potent anti-tumor effect.

**NEO-STC-01 Product Process**


NEO-STC-01 uses a precision approach to treat a genetically defined patient population with poor prognosis, for whom there are currently no effective therapies. NEO-STC-01 will be able to address multiple HLA alleles, greatly increasing the addressable patient population. In contrast, engineered TCR T cell therapies are limited to a single HLA allele per TCR, therefore requiring multiple products to address RAS mutations in the general population. For example, based on RECON predictions, NEO-STC-01 can potentially address up to two thirds of all RAS-mutant PDAC patients versus <10% of patients when using a TCR-T cell therapy for a single HLA allele.

Our NEO-STIM technology is also used here as an inline manufacturing step, similar to NEO-PTC-01. NEO-STIM uses PBMCs as a starting material which are more accessible than TILs, which are used by other adoptive T cell therapies. Further, use of PBMCs as a starting material has been shown to produce an optimal T cell phenotype with the potential to drive persistence and tumor cell killing. NEO-STIM also generates T cell populations from both the memory and naïve T cell compartments, broadening the patient's anti-tumor immune repertoire against the target RAS neoantigens. Additionally, since NEO-STC-01 targets known, common RAS neoantigens, we can pre-manufacture the peptides that feed into the manufacturing process for NEO-STC-01, which in turn helps to shorten the overall manufacturing time and allows patients to receive their treatments quicker.

NEO-STC-01 is currently in preclinical development and we have generated data that support mechanism of action and provide a strong rationale for further development. RAS mutant neo-epitopes in our RAS target warehouse have been extensively validated and T cell populations against them can be reproducibly induced in healthy donors. The induced T cells are cytotoxic and can kill patient-derived tumor cells at endogenous antigen levels. Process optimization will be ongoing in 2020 and learnings from NEO-PTC-01, Neon's personal T cell therapy, are expected to help accelerate preclinical development of NEO-STC-01.

**Manufacturing**

We have invested in manufacturing capabilities to supply cGMP product for our clinical programs. Currently, we outsource our manufacturing to third parties. We own and control proprietary methods and intellectual property regarding peptide and cell manufacturing. As our development programs expand and we build new process efficiencies, we expect to continually evaluate this strategy with the objective of satisfying

demand for registration trials and, if approved, the manufacture, sale and distribution of commercial products. We will be focusing on more efficient and scalable manufacturing, which we believe will lead to a commercially attractive cost of goods when operating at commercial scale.

We receive material from our contract manufacturing organizations, or CMOs, for preclinical testing. We receive clinical supply material manufactured in compliance with cGMP, and we conduct audits before and during the trial, in cooperation with a CMO, to ensure compliance with the mutually agreed process descriptions and cGMP regulations.

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. As a result, we continually evaluate our supplier relationships.

**Competition**

The biotechnology and pharmaceutical industries, and the immunotherapy subsector in particular, are characterized by rapid evolution of technologies, fierce competition and strong defense of intellectual property. While we believe that our product candidates, discovery programs, technology, knowledge, experience and scientific resources provide us with competitive advantages, we face competition from major pharmaceutical and biotechnology companies, academic institutions, governmental agencies and public and private research institutions, among others.

Any product candidates that we successfully develop and commercialize will compete with currently approved therapies and new therapies that may become available in the future. Key product features that would affect our ability to effectively compete with other therapeutics include the efficacy, safety and convenience of our products.

Many of the companies against which we may compete have significantly greater financial resources and expertise than we do in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products. In addition to fully-integrated biopharmaceutical companies and immunotherapy-focused oncology companies, we directly compete with a number of neoantigen T cell companies, including Achilles Therapeutics Limited, Adaptimmune Therapeutics plc, Adicet Bio, Inc., AgenTus Therapeutics, Inc., BioNTech SE, bluebird bio, Inc., Celgene Corporation, Genocea Biosciences, Inc., Gilead Sciences, Inc., Gritstone Oncology, Inc., Immatics Biotechnologies GmbH, IMV Inc., Iovance Biotherapeutics, Inc., Lion TCR Pte. Ltd., Marker Therapeutics, Inc., Medigene AG, Neogene Therapeutics, Inc., Nouscom AG, PACT Pharma, Inc., Regeneron Pharmaceuticals, Inc., Zelluna Immunotherapy AS and ZIOPHARM Oncology, Inc. Smaller or early-stage companies, including immunotherapy-focused and neoantigen-focused therapeutics companies, may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. 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.

The availability of reimbursement from government and other third-party payors will also significantly affect the pricing and competitiveness of our products. Our competitors also may obtain U.S. Food and Drug Administration, or 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.

**Intellectual Property**

Our success depends in part upon our ability to protect our core technology and intellectual property. To protect our intellectual property rights, we rely on patents, trademarks, copyrights and trade secret laws,

confidentiality procedures, and employee disclosure and invention assignment agreements. Our intellectual property is critical to our business and we strive to protect it through a variety of approaches, including by obtaining and maintaining patent protection in the United States and internationally for our product candidates, novel biological discoveries, new targets and applications, and other inventions that are important to our business. For our product candidates, we generally intend to pursue patent protection covering compositions of matter, methods of making and methods of use, including formulations and combination therapies.

As we continue the development of our product candidates, we intend to identify additional means of obtaining patent protection that would potentially enhance commercial success, including through claims covering additional methods of use and biomarkers and complementary diagnostic and/or companion diagnostic related claims.

The patent positions of biotechnology companies like ours are generally uncertain and involve complex legal, scientific and factual questions. In addition, the coverage claimed in a patent application can be significantly reduced before the patent is issued and its scope can be reinterpreted after issuance. Consequently, we may not obtain or maintain adequate patent protection for any of our product candidates. As of December 31, 2019, our patent portfolio included at least two issued U.S. patents with claims directed to methods of preparing therapeutic compositions and methods of treating cancer, at least 41 pending U.S. provisional or non-provisional patent applications, at least 19 foreign patents with claims directed to methods of preparing therapeutic compositions and compositions of matter, and at least 159 pending foreign patent applications, which patents and patent applications we owned or exclusively licensed. The claims of these owned or in-licensed patents and patent applications are directed toward various aspects of our product candidates and research programs, including claims related to compositions of matter, methods of use, drug product formulations, combination therapies, methods of manufacture, manufacturing precursors and methods of identifying active compounds. These owned patent applications, if issued, are expected to expire between 2037 and 2040, and these in-licensed patents and patent applications, if issued, are expected to expire on various dates from 2031 through 2039, in each case without taking into account any possible patent term adjustments or extensions.

Within our patent portfolio, as of December 31, 2019, we had an exclusive license from the Dana-Farber Cancer Institute, or DFCI, the Broad, and The General Hospital Corporation d/b/a Massachusetts General Hospital, or MGH, pursuant to our amended license agreement with the Broad, or the Broad Agreement, to at least two issued U.S. patents, at least seven pending U.S. provisional or non-provisional patent applications, at least 13 foreign patents, and at least 77 pending foreign patent applications that include claims directed to NEO-PV-01, such as compositions of matter, combination therapies, formulations, manufacturing processes, manufacturing precursors or uses thereof. These in-licensed patents and patent applications, if issued, are expected to expire on various dates from 2031 through 2037, without taking into account any possible patent term adjustment or extensions.

Within our patent portfolio, as of December 31, 2019, we had exclusive licenses pursuant to the Broad Agreement and others to at least four pending U.S. provisional or U.S. non-provisional patent applications, at least 10 foreign patents, and at least five pending foreign patent applications that include claims directed to NEO-PTC-01, such as compositions of matter, formulations, manufacturing processes, manufacturing precursors or uses thereof. These in-licensed patents and patent applications, if issued, are expected to expire on various dates from 2031 through 2040, in each case without taking into account any possible patent term adjustment or extensions.

Within our patent portfolio, as of December 31, 2019, we owned at least 10 pending U.S. provisional or U.S. non-provisional patent applications and at least 42 pending foreign patent applications, and had an exclusive license pursuant to the Broad Agreement, to at least one pending U.S. non-provisional patent application and at least 29 pending foreign patent applications that include claims directed to NEON / SELECT (including our NEO-SV-01 product candidate), such as compositions of matter, formulations, manufacturing processes, manufacturing precursors or uses thereof. These owned patent applications, if issued, are expected to expire

between 2037 and 2039, and these in-licensed patent applications, if issued, are expected to expire in 2036, in each case without taking into account any possible patent term adjustment or extensions.

We also have agreements with Stichting Sanquin Bloedvoorziening, the Netherlands Cancer Institute, Oncovir and other third parties under which we have rights to certain intellectual property, such as patents or patent applications.

We cannot predict whether the patent applications we pursue will issue as patents in any particular jurisdiction or whether the claims of any issued patents will provide any proprietary protection from competitors. Even if our pending patent applications are granted as issued patents, those patents, as well as any patents we license from third parties now or in the future, may be challenged, circumvented or invalidated by third parties.

The term of individual patents depends upon the legal term of the patents in the countries in which they are obtained. In most countries in which we file, the patent term is 20 years from the earliest date of filing of a non-provisional patent application. In the United States, the patent term of a patent that covers an FDA-approved drug or biologic may also be eligible for patent term extension, which permits patent term restoration as compensation for the patent term lost during FDA regulatory review process. The Hatch-Waxman Act permits a patent term extension of up to five years beyond the expiration of the patent. The length of the patent term extension is related to the length of time the drug or biologic is under regulatory review. Patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval and only one patent applicable to an approved drug or biologic may be extended. Similar provisions are available in Europe and other foreign jurisdictions to extend the term of a patent that covers an approved drug or biologic. In the future, if our products receive FDA approval, we expect to apply for patent term extensions on patents covering those products. We plan to seek patent term extensions to any of our issued patents in any jurisdiction where these are available, however there is no guarantee that the applicable authorities, including FDA in the United States, will agree with our assessment of whether these extensions should be granted, and if granted, the length of these extensions.

In addition to our reliance on patent protection for our inventions, product candidates and research programs, we also rely on trade secret protection for our confidential and proprietary information. For example, significant elements of our products, including aspects of sample preparation, methods of manufacturing, cell culturing conditions, computational-biological algorithms and related processes and software, are based on unpatented trade secrets that are not publicly disclosed. Although we take steps to protect our proprietary information and trade secrets, including through contractual means with our employees and consultants, third parties may independently develop substantially equivalent proprietary information and techniques or otherwise gain access to our trade secrets or disclose our technology. As a result, we may not be able to meaningfully protect our trade secrets. It is our policy to require our employees, consultants, outside scientific collaborators, sponsored researchers and other advisors to execute confidentiality agreements upon the commencement of employment or consulting relationships with us. These agreements provide that all confidential information concerning our business or financial affairs developed or made known to the individual or entity during the course of the party's relationship with us is to be kept confidential and not disclosed to third parties except in specific circumstances. In the case of employees, the agreements provide that all inventions conceived of by the individual that are related to our current or planned business or research and development or are made during normal working hours on our premises or using our equipment or proprietary information are our exclusive property. In addition, we take other appropriate precautions, such as physical and technological security measures, to guard against misappropriation of our proprietary technology by third parties. We have also adopted policies and conduct training that provides guidance on our expectations and our advice for best practices in protecting our trade secrets.

**License Agreement with the Broad Institute, Inc.**

On November 13, 2015, we entered into the Broad Agreement with the Broad and, in January and November 2018, we entered into amendments to the Broad Agreement. Under the Broad Agreement, we have been granted an exclusive worldwide license to certain intellectual property rights owned or controlled by the

Broad, DFCI and MGH to develop and commercialize any diagnostic, prognostic, preventative or therapeutic product for humans, including any neoantigen vaccine product. In particular, as of December 31, 2019, we have both exclusive and non-exclusive licenses to a patent portfolio comprised of 10 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, we have also been granted (i) a non-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. We are also entitled to sublicense the rights granted to us under the Broad Agreement. In connection with the Broad Agreement, we have also entered into a non-exclusive software license with the Broad under which we license 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, we paid the Broad a non-refundable license fee of $75,000. As additional consideration for the license, we must pay the Broad immaterial annual license maintenance fees and up to $12.6 million in developmental milestone payments and could be obligated to make up to $97.5 million in payments upon the achievement of specified sales milestones. We are also required to pay tiered royalties of low to mid single-digit percentages on net sales of products covered by the license, as well as between 10% to 30% of any consideration received by us from a sublicensee in consideration for a sublicense, which percentage is based on certain events set forth in the Broad Agreement. As partial consideration for the license, we reimbursed the Broad for $0.6 million of past patent expenses and issued 60,000 shares of our restricted common stock to each of the Broad, DFCI and MGH. We also agreed to reimburse the Broad for future patent expenses related to the in-licensed patents and patent applications. No development or commercial milestones have been achieved to date under the Broad Agreement. The royalty term will terminate on the later of (i) the expiration date of the last valid claim within the licensed patent rights and (ii) the 10th anniversary date of the first commercial sale of a product incorporating the licensed patent rights.

Either we, or the institutions party thereto, may terminate the Broad Agreement if the other party commits a material breach of the agreement and fails to cure that breach within 105 days (or 45 days in the case of our failure to make any payment or in the case of our breach of our diligence obligations) after written notice is provided, or, in the case of the Broad, upon our bankruptcy, insolvency, dissolution or winding up, or upon us bringing patent challenges relating to any patent families. In addition, we may terminate the Broad Agreement for convenience as it relates to certain patent families upon up to 120 days' prior written notice to the Broad. Upon expiration of the Broad Agreement, we will have a worldwide, perpetual, irrevocable, sublicensable license to the intellectual property previously covered by the Broad Agreement.

**Government Regulation**

Government authorities in the United States at the federal, state and local level and in other countries regulate, among other things, the research, development, testing, manufacture, quality control, approval, labeling, packaging, storage, record-keeping, promotion, advertising, distribution, post-approval monitoring and reporting, marketing and export and import of drug and biological products. Generally, before a new drug or biologic can be marketed, considerable data demonstrating its quality, safety and efficacy must be obtained, organized into a format specific for each regulatory authority, submitted for review and approved by the regulatory authority.

***U.S. Biological Product Development***

In the United States, the FDA regulates drugs under the Federal Food, Drug, and Cosmetic Act, or FDCA, and its implementing regulations and biologics under the FDCA, the Public Health Service Act, or PHSA, and their implementing regulations. Both drugs and biologics are also subject to other federal, state and local statutes and regulations. The process of obtaining regulatory approvals and the subsequent compliance with appropriate

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 post-market may subject an applicant to administrative or judicial sanctions. These sanctions could include, among other actions, the FDA's refusal to approve pending applications, withdrawal of an approval or license revocation, a clinical hold, untitled or warning letters, product recalls or 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.

Our product candidates must be approved by the FDA through a Biologics License Application, or BLA, process before they may be legally marketed in the United States. The process generally involves the following:

- Completion of extensive preclinical studies in accordance with applicable regulations, including studies conducted in accordance with good laboratory practice, or GLP, requirements;
- Submission to the FDA of an investigational new drug, or IND, application, which must become effective before human clinical trials may begin;
- Approval by an institutional review board, or IRB, or independent ethics committee at each clinical trial site before each trial may be initiated;
- Performance of adequate and well-controlled human clinical trials in accordance with applicable IND regulations, good clinical practice, or GCP, requirements and other clinical trial-related regulations to establish the safety and efficacy of the investigational product for each proposed indication;
- Submission to the FDA of a BLA;
- A determination by the FDA within 60 days of its receipt of a BLA to accept the filing for review;
- Satisfactory completion of an FDA pre-approval inspection of the manufacturing facility or facilities where the biologic will be produced to assess compliance with cGMP requirements to assure that the facilities, methods and controls are adequate to preserve the biologic's identity, strength, quality and purity;
- Potential FDA audit of the clinical trial sites that generated the data in support of the BLA; and
- FDA review and approval of the BLA, including consideration of the views of any FDA advisory committee, prior to any commercial marketing or sale of the biologic in the United States.

The preclinical and clinical testing and approval process requires substantial time, effort and financial resources, and we cannot be certain that any approvals for any of our product candidates will be granted on a timely basis, or at all.

***Preclinical Studies and IND***

Preclinical studies include laboratory evaluation of product chemistry and formulation, as well as *in vitro* and animal studies to assess the potential for adverse events and in some cases, to establish a rationale for therapeutic use. The conduct of preclinical studies is subject to federal regulations and requirements, including GLP regulations for safety/toxicology studies.

An IND sponsor must submit the results of the preclinical tests, together with manufacturing information, analytical data, any available clinical data or literature and plans for clinical studies, among other things, to the FDA as part of an IND. An IND is a request for authorization from the FDA to administer an investigational product to humans, and must become effective before human clinical trials may begin. Some long-term preclinical testing may continue after the IND is submitted. An IND automatically becomes effective 30 days after receipt by the FDA unless, before that time, the FDA raises concerns or questions related to one or more

proposed clinical trials and places the trial on clinical hold. In that case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. As a result, submission of an IND may not result in the FDA allowing clinical trials to commence.

***Clinical Trials***

The clinical stage of development involves the administration of the investigational product to healthy volunteers or patients under the supervision of qualified 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 in any clinical trial. Clinical trials are conducted under protocols detailing, among other things, the objectives of the clinical trial, dosing procedures, subject selection and exclusion criteria and the parameters to be used to monitor subject safety and assess efficacy. Each protocol, and any subsequent amendments to the protocol, must be submitted to the FDA as part of the IND. Furthermore, each clinical trial must be reviewed and approved by an IRB for each institution at which the clinical trial will be conducted to ensure that the risks to individuals participating in the clinical trials are minimized and are reasonable in relation to anticipated benefits. The IRB also approves the informed consent form that must be provided to each clinical trial subject or his or her legal representative, and must monitor the clinical trial until completed. There also are requirements governing the reporting of ongoing clinical trials and completed clinical trial results to public registries.

A sponsor who wishes to conduct a clinical trial outside of 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 a BLA. The FDA will accept a well-designed and well-conducted foreign clinical study not conducted under an IND if the study was conducted in accordance with GCP requirements, and the FDA is able to validate the data through an onsite inspection if deemed necessary.

Clinical trials generally are conducted in three sequential phases, known as Phase 1, Phase 2 and Phase 3, which may overlap.

- Phase 1 clinical trials generally involve a small number of healthy volunteers or disease-affected patients who are initially exposed to a single dose and then multiple doses of the product candidate. The primary purpose of these clinical trials is to assess the metabolism, pharmacologic action, side effect tolerability and safety of the product candidate.
- Phase 2 clinical trials involve studies in disease-affected patients to determine the dose required to produce the desired benefits. During Phase 2 clinical trials, safety and further pharmacokinetic and pharmacodynamic information is collected, possible adverse effects and safety risks are identified and a preliminary evaluation of efficacy is conducted.
- Phase 3 clinical trials generally involve a large number of patients at multiple sites and are designed to provide the data necessary to demonstrate the effectiveness of the product for its intended use, its safety in use and to establish the overall benefit/risk relationship of the product and provide an adequate basis for product labeling.

Post-approval trials, sometimes referred to as Phase 4 clinical trials, may be conducted after initial marketing approval. These trials are used to gain additional experience from the treatment of patients in the intended therapeutic indication. In certain instances, the FDA may mandate the performance of Phase 4 clinical trials as a condition of approval of a BLA.

Progress reports detailing the results of the clinical trials, among other information, must be submitted at least annually to the FDA and written IND safety reports must be submitted to the FDA and the investigators for serious and unexpected suspected adverse events, findings from other studies or animal or *in vitro* testing that suggest a significant risk for human subjects and any clinically important increase in the rate of a serious suspected adverse reaction over that listed in the protocol or investigator brochure.

Phase 1, Phase 2 and Phase 3 clinical trials may not be completed successfully within any specified period, if at all. The FDA or the sponsor may suspend or terminate 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 drug or biologic has been associated with unexpected serious harm to patients. 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. This group provides authorization for whether a trial may move forward at designated check points based on access to certain data from the trial. Concurrent with clinical trials, companies usually complete additional animal studies and also must develop additional information about the chemistry and physical characteristics of the drug or biologic, as well as finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the product and, among other things, companies must develop methods for testing the identity, strength, quality and purity of the final product. Additionally, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the product candidates do not undergo unacceptable deterioration over their shelf life.

***FDA Review Process***

Following completion of the clinical trials, data are analyzed to assess whether the investigational product is safe and effective for the proposed indicated use or uses. The results of preclinical studies and clinical trials are then submitted to the FDA as part of a BLA, along with proposed labeling, chemistry and manufacturing information to ensure product quality and other relevant data. The BLA is a request for approval to market the biologic for one or more specified indications and must contain proof of safety, purity and potency for the biologic. The application may include both negative and ambiguous results of preclinical studies and clinical trials, as well as positive findings. Data may come from company-sponsored clinical trials intended to test the safety and efficacy of a product's use or from a number of alternative sources, including studies initiated by investigators. To support marketing approval, the data submitted must be sufficient in quality and quantity to establish the safety and efficacy of the investigational product to the satisfaction of the FDA. FDA approval of a BLA must be obtained before a biologic may be marketed in the United States.

Under the Prescription Drug User Fee Act, or PDUFA, as amended, each BLA must be accompanied by a user fee. The FDA adjusts the 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 BLAs for products designated as orphan drugs, unless the product also includes a non-orphan indication.

The FDA reviews all submitted BLAs before it accepts them for filing, and may request additional information rather than accept a BLA for filing. The FDA must make a decision on accepting a BLA for filing within 60 days of receipt. Once the submission is accepted for filing, the FDA begins an in-depth review of the BLA. Under the goals and policies agreed to by the FDA under PDUFA, the FDA has 10 months from the filing date to complete its initial review of an original BLA and respond to the applicant, and six months from the filing date of an original BLA designated for priority review. The FDA does not always meet its PDUFA goal dates for standard and priority BLAs, and the review process is often extended by FDA requests for additional information or clarification.

Before approving a BLA, the FDA will conduct a pre-approval inspection of the manufacturing facilities for the new product to determine whether they comply with cGMP requirements. The FDA will not approve the product unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. The FDA also may audit data from clinical trials to ensure compliance with GCP requirements. Additionally, the FDA may refer applications for novel products or products that present difficult questions of safety or efficacy to

an advisory committee, typically a panel that includes clinicians and other experts, for review, evaluation and a recommendation as to whether the application should be approved and under what conditions, if any. The FDA is not bound by recommendations of an advisory committee, but it considers those recommendations when making decisions on approval. The FDA likely will reanalyze the clinical trial data, which could result in extensive discussions between the FDA and the applicant during the review process. After the FDA evaluates a BLA, it will issue an approval letter or a Complete Response Letter. An approval letter authorizes commercial marketing of the biologic with specific prescribing information for specific indications. A Complete Response Letter indicates that the review cycle of the application is complete and the application will not be approved in its present form. A Complete Response Letter usually describes all of the specific deficiencies in the BLA identified by the FDA. The Complete Response Letter may require additional clinical data, additional pivotal Phase 3 clinical trial(s) and/or other significant and time-consuming requirements related to clinical trials, preclinical studies or manufacturing. If a Complete Response Letter is issued, the applicant may either resubmit the BLA, addressing all of the deficiencies identified in the letter, or withdraw the application. Even if an applicant submits the requested data and information, the FDA may decide that the BLA does not satisfy the criteria for approval. Data obtained from clinical trials are not always conclusive and the FDA may interpret data differently than an applicant does.

***Orphan Drug Designation***

Under the Orphan Drug Act, the FDA may grant orphan designation to a drug or biological product intended to treat a rare disease or condition, which is generally a disease or condition that affects fewer than 200,000 individuals in the United States, or more than 200,000 individuals in the United States and for which there is no reasonable expectation that the cost of developing and making the product available in the United States for this type of disease or condition will be recovered from sales of the product.

Orphan drug designation must be requested before submitting a BLA. After the FDA grants orphan drug designation, the identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. Orphan drug designation does not convey any advantage in or shorten the duration of the regulatory review and approval process.

If a product that has orphan designation subsequently receives the first FDA approval for the disease or condition 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 to market the same drug for the same indication for seven years from the date of such approval, except in limited circumstances, such as a showing of clinical superiority to the product with orphan exclusivity by means of greater effectiveness, greater safety or providing a major contribution to patient care or in instances of drug supply issues. Competitors, however, may receive approval of either a different product for the same indication or the same product for a different indication but that could be used off-label in the orphan indication. Orphan drug exclusivity also could block the approval of one of our products for seven years if a competitor obtains approval before we do for the same product, as defined by the FDA, for the same indication we are seeking approval, or if our product is determined to be contained within the scope of the competitor's product for the same indication or disease. If one of our products designated as an orphan drug receives marketing approval for an indication broader than that which is designated, it may not be entitled to orphan drug exclusivity. Orphan drug status in the European Union has similar, but not identical, requirements and benefits.

***Expedited Development and Review Programs***

The FDA has a fast track program that is intended to expedite or facilitate the process for reviewing new drugs and biologics that meet certain criteria. Specifically, new drugs and biologics are eligible for fast track designation if they are intended to treat a serious or life-threatening condition and preclinical or clinical data demonstrate the potential to address unmet medical needs for the condition. Fast track designation applies to both the product and the specific indication for which it is being studied. The sponsor can request the FDA to

designate the product for fast track status any time before receiving BLA approval, but ideally no later than the pre-BLA meeting. In addition to other benefits, such as the ability to engage in more frequent interactions with the FDA, the FDA may initiate review of sections of a fast track drug's BLA before the application is complete. This rolling review is available if the applicant provides, and the FDA approves, a schedule for the submission of each portion of the BLA and the applicant pays the applicable user fee. However, the FDA's time period goal for reviewing an application does not begin until the last section of the BLA is submitted. Additionally, the 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.

Any product submitted to the FDA for marketing, including under a fast track program, may be eligible for other types of FDA programs intended to expedite development and review, such as priority review and accelerated approval. Any product is eligible for priority review if it treats a serious or life-threatening condition and, if approved, would provide a significant improvement in safety and effectiveness compared to available therapies. The FDA will attempt to direct additional resources to the evaluation of an application for a new drug or biologic designated for priority review in an effort to facilitate the review.

A product may also be eligible for accelerated approval, if it treats a serious or life-threatening condition and generally provides a meaningful advantage over available therapies. In addition, it must demonstrate an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, or IMM, that is reasonably likely to predict an effect on IMM or other clinical benefit. As a condition of approval, the FDA may require that a sponsor of a drug or biologic receiving accelerated approval perform adequate and well-controlled post-marketing clinical trials. If the FDA concludes that a drug or biologic shown to be effective can be safely used only if distribution or use is restricted, it will require those post-marketing restrictions that it deems necessary to assure safe use of the product.

Additionally, a drug or biologic may be eligible for designation as a breakthrough therapy if the product is intended, alone or in combination with one or more other drugs or biologics, to treat a serious or life-threatening condition and preliminary clinical evidence indicates that the product may demonstrate substantial improvement over currently approved therapies on one or more clinically significant endpoints. The benefits of breakthrough therapy designation include the same benefits as fast track designation, plus intensive guidance from the FDA to ensure an efficient drug development program.

Fast track designation, priority review, accelerated approval and breakthrough therapy designation do not change the standards for approval, but may expedite the development or approval process.

***Pediatric Information***

Under the Pediatric Research Equity Act, or PREA, as amended, a BLA or supplement to a BLA must contain data to assess the safety and efficacy of the drug 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. The FDA may grant deferrals for submission of pediatric data or full or partial waivers. A sponsor who is planning to submit a marketing application for a drug that includes a new active ingredient, new indication, new dosage form, new dosing regimen or new route of administration must submit an initial Pediatric Study Plan, or PSP, within 60 days of an end-of-Phase 2 meeting or, if there is no such meeting, as early as practicable before the initiation of the Phase 3 or Phase 2/3 study. The initial PSP must include an outline of the pediatric study or studies that the sponsor plans to conduct, including study objectives and design, age groups, relevant endpoints and statistical approach, or a justification for not including such detailed information, and any request for a deferral of pediatric assessments or a full or partial waiver of the requirement to provide data from pediatric studies along with supporting information. The FDA and the sponsor must reach an agreement on the PSP. A sponsor can submit amendments to an agreed-upon initial PSP at any time if changes to the pediatric plan need to be considered based on data collected from preclinical studies, early phase clinical trials and/or other clinical development programs.

***Post-marketing Requirements***

Following approval of a new product, the manufacturer and the approved product are subject to continuing regulation by the FDA, including, among other things, monitoring and record-keeping activities, reporting of adverse experiences, complying with promotion and advertising requirements, which include restrictions on promoting products for unapproved uses or patient populations (known as "off-label use") and limitations on industry-sponsored scientific and educational activities. Although physicians may prescribe legally available products for off-label uses, manufacturers may not market or promote off-label uses. Prescription biologic promotional materials must be submitted to the FDA in conjunction with their first use. Further, if there are any modifications to the biologic, including changes in indications, labeling or manufacturing processes or facilities, the applicant may be required to submit and obtain FDA approval of a new BLA or BLA supplement, which may require the development of additional data or preclinical studies and clinical trials.

The FDA may also place other conditions on approvals including the requirement for a Risk Evaluation and Mitigation Strategy, or REMS, to assure the safe use of the product. If the FDA concludes a REMS is needed, the sponsor of the BLA must submit a proposed REMS and the FDA will not approve the BLA without an approved REMS. A REMS could include medication guides, physician communication plans or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. Any of these limitations on approval or marketing could restrict the commercial promotion, distribution, prescription or dispensing of products. Product approvals may be withdrawn for non-compliance with regulatory standards or if problems occur following initial marketing. Newly discovered or developed safety or effectiveness data may require changes to a product's approved labeling, including the addition of new warnings and contraindications, and also may require the implementation of other risk management measures, including a REMS, or the conduct of post-marketing studies to assess a newly discovered safety issue.

FDA regulations require that products be manufactured in specific approved facilities and in accordance with cGMP regulations. We rely, and expect to continue to rely, on third parties for the production of clinical and commercial quantities of our products in accordance with cGMP regulations. These manufacturers must comply with cGMP regulations that require, among other things, quality control and quality assurance, the maintenance of records and documentation and the obligation to investigate and correct any deviations from cGMP. Manufacturers and other entities involved in the manufacture and distribution of approved biologics 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 cGMP requirements and other laws. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain cGMP compliance. The discovery of violative conditions, including failure to conform to cGMP regulations, could result in enforcement actions, and the discovery of problems with a product after approval may result in restrictions on a product, manufacturer or holder of an approved BLA, including recall.

***Other Regulatory Matters***

Manufacturing, sales, promotion and other activities following product approval are also subject to regulation by numerous regulatory authorities in the United States in addition to the FDA, including the Centers for Medicare & Medicaid Services, or CMS, other divisions of the Department of Health and Human Services, the Department of Justice, the Drug Enforcement Administration, the Consumer Product Safety Commission, the Federal Trade Commission, the Occupational Safety & Health Administration, the Environmental Protection Agency and state and local governments and governmental agencies.

***Other Healthcare Laws***

Healthcare providers, physicians, and third-party payors will play a primary role in the recommendation and prescription of any products for which we obtain marketing approval. Our future arrangements with third-party payors, healthcare providers and physicians may expose us to broadly applicable fraud and abuse and other

healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell and distribute any drugs for which we obtain marketing approval. In the United States, these laws include, without limitation, state and federal anti-kickback, false claims, physician transparency, and patient data privacy and security laws and regulations, including but not limited to those described below.

- The Anti-Kickback Statute, or AKS, makes it illegal for any person, including a prescription drug manufacturer (or a party acting on its behalf), to knowingly and willfully solicit, receive, offer or pay any remuneration, directly or indirectly, overtly or covertly, in cash or in kind, that is intended to induce or reward referrals, including the purchase, recommendation, order or prescription of a particular drug, for which payment may be made under a federal healthcare program, such as Medicare or Medicaid. Violations of this law are punishable by imprisonment, criminal fines, administrative civil money penalties and exclusion from participation in federal healthcare programs. In addition, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it.
- The federal False Claims Act imposes civil penalties, including through civil whistleblower or qui tam actions, against individuals or entities (including manufacturers) for, among other things, knowingly presenting, or causing to be presented false or fraudulent claims for payment by a federal healthcare program or making a false statement or record material to payment of a false claim or avoiding, decreasing or concealing an obligation to pay money to the federal government. The government may deem manufacturers to have "caused" the submission of false or fraudulent claims by, for example, providing inaccurate billing or coding information to customers or promoting a product off-label. Claims that include items or services resulting from a violation of the federal Anti-Kickback Statute are false or fraudulent claims for purposes of the False Claims Act. Our future marketing and activities relating to the reporting of wholesaler or estimated retail prices for our products, the reporting of prices used to calculate Medicaid rebate information and other information affecting federal, state and third-party reimbursement for our products, and the sale and marketing of our product and any future product candidates, are subject to scrutiny under this law.
- The federal anti-inducement law, which prohibits, among other things, the offering or giving of remuneration, which includes, without limitation, any transfer of items or services for free or for less than fair market value (with limited exceptions), to a Medicare or Medicaid beneficiary that the person knows or should know is likely to influence the beneficiary's selection of a particular supplier of items or services reimbursable by a federal or state governmental program.
- The Health Insurance Portability and Accountability Act of 1996, or HIPAA, imposes criminal and civil liability for knowingly and willfully executing a scheme, or attempting to execute a scheme, to defraud any healthcare benefit program, including private payors, or falsifying, concealing or covering up a material fact or making any materially false statements in connection with the delivery of or payment for healthcare benefits, items or services. Similar to the U.S. federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the healthcare fraud statute implemented under HIPAA or 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 of 2009, or HITECH, and their respective implementing regulations, imposes, among other things, specified requirements on covered entities and their business associates relating to the privacy and security of individually identifiable health information including mandatory contractual terms and required implementation of technical safeguards of such information. HITECH also created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions.
- The Physician Payments Sunshine Act, enacted as part of the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively, the

ACA, imposed new annual reporting requirements for certain manufacturers of drugs, devices, biologics, and medical supplies for which payment is available under Medicare, Medicaid, or the Children's Health Insurance Program, for certain payments and "transfers of value" provided to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members. Effective January 1, 2022, these reporting obligations will extend to include transfers of value made to certain non-physician providers such as physician assistants and nurse practitioners.

- Analogous state and foreign fraud and abuse laws and regulations, such as state anti-kickback and false claims laws, which may be broader in scope and apply regardless of payor. These laws are enforced by various state agencies and through private actions. Some state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant federal government compliance guidance, require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers, and restrict marketing practices or require disclosure of marketing expenditures.

State and foreign laws also govern the privacy and security of health information in some circumstances. These data privacy and security laws may differ from each other in significant ways and often are not pre-empted by HIPAA, which may complicate compliance efforts. California recently enacted the California Consumer Privacy Act, or CCPA, which creates new individual privacy rights for California consumers (as defined in the law) and places increased privacy and security obligations on entities handling personal data of consumers or households. The CCPA will require covered companies to provide certain disclosures to consumers about its data collection, use and sharing practices, and to provide affected California residents with ways to opt-out of certain sales or transfers of personal information. The CCPA went into effect on January 1, 2020, and the California Attorney General will commence enforcement actions against violators beginning July 1, 2020. While there is currently an exception for protected health information that is subject to HIPAA and clinical trial regulations, as currently written, the CCPA may impact our business activities. The California Attorney General has proposed draft regulations, which have not been finalized to date, that may further impact our business activities if they are adopted. The uncertainty surrounding the implementation of CCPA exemplifies the vulnerability of our business to the evolving regulatory environment related to personal data and protected health information.

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. It is possible that governmental authorities will conclude that our business practices do not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other related governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, imprisonment, disgorgement, exclusion of drugs from government funded healthcare programs, such as Medicare and Medicaid, reputational harm, additional oversight and reporting obligations if we become subject to a corporate integrity agreement or similar settlement to resolve allegations of non-compliance with these laws and the curtailment or restructuring of 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 its 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 product candidates, restrict or regulate post-approval activities, and affect our ability to profitably sell any product candidates for which we obtain marketing approval. We expect that current laws, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and 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, address a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected, increase the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program and extends the rebate program to individuals enrolled in Medicaid managed care organizations, establish annual fees and taxes on manufacturers of certain branded prescription drugs, and create a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 70% (increased pursuant to the Bipartisan Budget Act of 2018, effective as of 2019) point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D.

Since its enactment, there have been numerous judicial, administrative, executive, and legislative challenges to certain aspects of the ACA, and we expect there will be additional challenges and amendments to the ACA in the future. For example, various portions of the ACA are currently undergoing legal and constitutional challenges in the Fifth Circuit Court and the United States Supreme Court, and the Trump Administration has issued various Executive Orders which eliminated cost sharing subsidies and various provisions 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. Additionally, Congress has introduced several pieces of legislation aimed at significantly revising or repealing the ACA. It is unclear whether the ACA will be overturned, repealed, replaced, or further amended. We cannot predict what affect further changes to the ACA would have on our business.

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, due to subsequent legislative amendments to the statute, including the BBA, will remain in effect through 2029, 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 and

enacted 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 United States 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 United States government has passed legislation requiring pharmaceutical manufacturers to provide rebates and discounts to certain entities and governmental payors to participate in federal healthcare programs. Further, Congress and the current administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs, and the current administration recently released a "Blueprint", or plan, to reduce the cost of drugs. The current administrations' Blueprint contains certain measures that the U.S. Department of Health and Human Services, or HHS, is already working to implement. In May 2019, CMS issued a final rule to allow Medicare Advantage Plans the option of using step therapy, a type of prior authorization, for Part B drugs beginning January 1, 2020. This final rule codified CMS's policy change that was effective January 1, 2019. Although a number of these, and other proposed measures will require authorization through additional legislation to become effective, Congress and the Trump administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs. For example, on September 25, 2019, the Senate Finance Committee introduced the Prescription Drug Pricing Reduction Action of 2019, a bill intended to reduce Medicare and Medicaid prescription drug prices. The proposed legislation would restructure the Part D benefit, modify payment methodologies for certain drugs, and impose an inflation cap on drug price increases. An even more restrictive bill, the Lower Drug Costs Now Act of 2019, was introduced in the House of Representatives on September 19, 2019, and would require the HHS to directly negotiate drug prices with manufacturers. The Lower Drugs Costs Now Act of 2019 has passed out of the House and was delivered to the Senate on December 16, 2019. However, it is unclear whether either of these bills will make it through both chambers and be signed into law, and if either is enacted, what effect it would have on our business. Individual states in the United States have also increasingly passed legislation and implemented regulations designed to control pharmaceutical 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. Individual states in the United States have also been 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.

***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 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. However, we do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us.

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.

***U.S. Patent-Term Restoration and Marketing Exclusivity***

Depending upon the timing, duration and specifics of FDA approval of any of our product candidates, some of our U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, commonly referred to as the Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit restoration of the patent term of up to five years as compensation for patent term lost during product development and FDA regulatory review process. Patent-term restoration, however, cannot extend the remaining term of a patent beyond a total of 14 years from the product's approval date. The patent-term restoration period is generally one-half the time between the effective date of an IND and the submission date of a BLA plus the time between the submission date of a BLA and the approval of that application, except that the review period is reduced by any time during which the applicant failed to exercise due diligence. Only one patent applicable to an approved drug is eligible for the extension and the application for the extension must be submitted prior to the expiration of the patent. The U.S. PTO, in consultation with the FDA, reviews and approves the application for any patent term extension or restoration. In the future, we may apply for restoration of patent term for our currently owned or licensed patents to add patent life beyond its current expiration date, depending on the expected length of the clinical trials and other factors involved in the filing of the relevant BLA.

An abbreviated approval pathway for biological products shown to be similar to, or interchangeable with, an FDA-licensed reference biological product was created by the Biologics Price Competition and Innovation Act of 2009, or BPCI Act. This amendment to the PHSA, in part, attempts to minimize duplicative testing. Biosimilarity, which requires that the biological product be highly similar to the reference product notwithstanding minor

differences in clinically inactive components and that there be no clinically meaningful differences between the product and the reference product in terms of safety, purity and potency, can be shown through analytical studies, animal studies and a clinical trial or trials. Interchangeability requires that a biological product be biosimilar to the reference product and that the product can be expected to produce the same clinical results as the reference product in any given patient and, for products administered multiple times to an individual, that the product and the reference product 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 biological product without such alternation or switch.

A reference biological product is granted 12 years of data exclusivity from the time of first licensure of the product, and the FDA will not accept an application for a biosimilar or interchangeable product based on the reference biological product until four years after the date of first licensure of the reference product. “First licensure” typically means the initial date the particular product at issue was licensed in the United States. Date of first licensure does not include the date of licensure of (and a new period of exclusivity is not available for) a biological product if the licensure is for a supplement for the biological product or for a subsequent application by the same sponsor or manufacturer of the biological product (or licensor, predecessor in interest, or other related entity) for a change (not including a modification to the structure of the biological product) that results in a new indication, route of administration, dosing schedule, dosage form, delivery system, delivery device or strength, or for a modification to the structure of the biological product that does not result in a change in safety, purity, or potency.

Pediatric exclusivity is another type of regulatory market exclusivity in the United States. Pediatric exclusivity, if granted, adds six months to existing regulatory exclusivity periods. This six-month exclusivity may be granted based on the voluntary completion of a pediatric trial in accordance with an FDA-issued “Written Request” for such a trial.

***European Union Drug Development***

In the European Union, or EU, our future products also may be subject to extensive regulatory requirements. As in the United States, medicinal products can be marketed only if a marketing authorization from the competent regulatory agencies has been obtained.

Similar to the United States, the various phases of preclinical and clinical research in the European Union are subject to significant regulatory controls. Although the EU Clinical Trials Directive 2001/20/EC has sought to harmonize the EU clinical trials regulatory framework, setting out common rules for the control and authorization of clinical trials in the EU, the EU Member States have transposed and applied the provisions of the Directive differently. This has led to significant variations in the member state regimes. Under the current regime, before a clinical trial can be initiated it must be approved in each of the EU countries where the trial is to be conducted by two distinct bodies: the National Competent Authority, or NCA, and one or more Ethics Committees, or ECs. Under the current regime all suspected unexpected serious adverse reactions to the investigated drug that occur during the clinical trial must be reported to the NCA and ECs of the Member State where they occurred.

The EU clinical trials legislation currently is undergoing a transition process mainly aimed at harmonizing and streamlining clinical trial authorization, simplifying adverse event reporting procedures, improving the supervision of clinical trials and increasing their transparency. Recently enacted Clinical Trials Regulation EU No 536/2014 ensures that the rules for conducting clinical trials in the EU will be identical.

***European Union Drug Marketing***

Much like the Anti-Kickback Statue prohibition in the United States, 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 also prohibited in the EU. The provision of benefits or advantages to physicians is 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 EU Member States must be publicly disclosed. Moreover, agreements with physicians often must be the subject of prior notification and approval by the physician's employer, his or her competent professional organization and/or the regulatory authorities of the individual EU Member States. These requirements are provided in the national laws, industry codes or professional codes of conduct, applicable in the EU Member States. Failure to comply with these requirements could result in reputational risk, public reprimands, administrative penalties, fines or imprisonment.

***European Union Drug Review and Approval***

In the European Economic Area, or EEA, which is comprised of the 28 Member States of the EU (and Norway), Iceland and Liechtenstein, medicinal products can only be commercialized after obtaining a Marketing Authorization, or MA. There are two types of marketing authorizations.

- The Community MA is issued by the European Commission through the Centralized Procedure, based on the opinion of the Committee for Medicinal Products for Human Use, or CHMP, of the European Medicines Agency, or EMA, and is valid throughout the entire territory of the EEA. The Centralized Procedure is mandatory for certain types of products, such as biotechnology medicinal products, orphan medicinal products, advanced-therapy medicines such as gene-therapy, somatic cell-therapy or tissue-engineered medicines and medicinal products containing a new active substance indicated for the treatment of HIV, AIDS, cancer, neurodegenerative disorders, diabetes, auto-immune and other immune dysfunctions and viral diseases. The Centralized Procedure is optional for products containing a new active substance not yet authorized in the EEA, or for products that constitute a significant therapeutic, scientific or technical innovation or that are in the interest of public health in the EU.
- National MAs, which are issued by the competent authorities of the Member States of the EEA and only cover their respective territory, are available for products not falling within the mandatory scope of the Centralized Procedure. Where a product has already been authorized for marketing in a Member State of the EEA, this National MA can be recognized in another Member States through the Mutual Recognition Procedure. If the product has not received a National MA in any Member State at the time of application, it can be approved simultaneously in various Member States through the Decentralized Procedure. Under the Decentralized Procedure, an identical dossier is submitted to the competent authorities of each of the Member States in which the MA is sought, one of which is selected by the applicant as the Reference Member State, or RMS. The competent authority of the RMS prepares a draft assessment report, a draft summary of the product characteristics, or SPC, and a draft of the labeling and package leaflet, which are sent to the other Member States (referred to as the Member States Concerned) for their approval. If the Member States Concerned raise no objections, based on a potential serious risk to public health, to the assessment, SPC, labeling, or packaging proposed by the RMS, the product is subsequently granted a national MA in all the Member States (i.e., in the RMS and the Member States Concerned).

Under these procedures, before granting the MA, the EMA or the competent authorities of the Member States of the EEA make an assessment of the risk-benefit balance of the product on the basis of scientific criteria concerning its quality, safety and efficacy.

***European Union New Chemical Entity Exclusivity***

In the EU, new chemical entities, sometimes referred to as new active substances, qualify for eight years of data exclusivity upon marketing authorization and an additional two years of market exclusivity. The data exclusivity, if granted, prevents regulatory authorities in the EU from referencing the innovator's data to assess a

generic application for eight years, after which generic marketing authorization can be submitted, and the innovator's data may be referenced, but not approved for two years. The overall 10-year period will be extended to a maximum of 11 years if, during the first eight years of those 10 years, the marketing authorization holder obtains an authorization for one or more new therapeutic indications that, during the scientific evaluation prior to their authorization, are determined to bring a significant clinical benefit in comparison with currently approved therapies.

***European Union Orphan Designation and Exclusivity***

In the EU, the EMA's Committee for Orphan Medicinal Products grants orphan drug designation to promote the development of products that are intended for the diagnosis, prevention or treatment of life-threatening or chronically debilitating conditions affecting not more than five in 10,000 persons in the EU community (or where it is unlikely that the development of the medicine would generate sufficient return to justify the investment) and for which no satisfactory method of diagnosis, prevention or treatment has been authorized (or, if a method exists, the product would be a significant benefit to those affected).

In the EU, orphan drug designation entitles a party to financial incentives such as reduction of fees or fee waivers and 10 years of market exclusivity is granted following medicinal product approval. This period may be reduced to six years if the orphan drug designation criteria are no longer met, including where it is shown that the product is sufficiently profitable not to justify maintenance of market exclusivity. Orphan drug designation must be requested before submitting an application for marketing approval. Orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process.

***European Data Collection***

The collection and use of personal health data in the European Union are governed by the provisions of the Data Protection Directive, and, as of May 2018, the General Data Protection Regulation, or GDPR. This directive imposes several requirements relating to the consent of the individuals to whom the personal data relates, the information provided to the individuals, notification of data processing obligations to the competent national data protection authorities and the security and confidentiality of the personal data. The Data Protection Directive and GDPR also impose strict rules on the transfer of personal data out of the EU to the United States. Failure to comply with the requirements of the Data Protection Directive, the GDPR, and the related national data protection laws of the EU Member States may result in fines and other administrative penalties. The GDPR introduces new data protection requirements in the EU and substantial fines for breaches of the data protection rules. The GDPR regulations may impose additional responsibility and liability in relation to personal data that we process, including in respect of clinical trials, and we may be required 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.

***Rest of the World Regulation***

For other countries outside of the EU and the United States, such as countries in Eastern Europe, Latin America or Asia, the requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary from country to country. Additionally, the clinical trials must be conducted in accordance with GCP requirements and the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki.

If we fail to comply with applicable foreign regulatory requirements, we may be subject to, among other things, fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution.

***Additional Laws and Regulations Governing International Operations***

If we further expand our operations outside of the United States, we must dedicate additional resources to comply with numerous laws and regulations in each jurisdiction in which we plan to operate. The Foreign Corrupt Practices Act, or FCPA, prohibits any U.S. individual or business from offering, paying, promising to pay, or authorizing payment of money or anything of value, to any person, while knowing that all or a portion of such money or thing of value will be offered, given or promised, directly or indirectly, to any foreign official, political party or candidate to influence the foreign official in his or her official capacity, induce the foreign official to do or omit to do an act in violation of his or her lawful duty, or to secure any improper advantage in order to assist the individual or business in obtaining or retaining business. The FCPA also obligates companies whose securities are listed in the United States to comply with certain accounting provisions requiring the company to maintain books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries, and to devise and maintain an adequate system of internal accounting controls.

Compliance with the FCPA is expensive and difficult, particularly in countries in which corruption is a recognized problem. In addition, the FCPA presents particular challenges in the pharmaceutical industry, because, in many countries, hospitals are owned and operated by the government, and doctors and other hospital employees are considered foreign officials for the purposes of the statute. Certain payments made in connection with clinical trials and other work have been deemed to be improper payments to government officials and have led to FCPA enforcement actions.

Various laws, regulations and executive orders also restrict the use and dissemination outside of the United States, or the sharing with certain non-U.S. nationals, of information classified for national security purposes, as well as certain products and technical data relating to those products. If we expand our presence outside of the United States, we will need to dedicate additional resources to complying with these laws, and these laws may preclude us from developing, manufacturing, or selling certain products and product candidates outside of the United States, which could limit our growth potential and increase our development costs.

The failure to comply with laws governing international business practices may result in substantial civil and criminal penalties and suspension or debarment from government contracting. The U.S. Securities and Exchange Commission, or SEC, also may suspend or bar issuers from trading securities on U.S. exchanges for violations of the FCPA's accounting provisions.

***Reimbursement***

Sales of our products will depend, in part, on the extent to which our products, if approved, will be covered by third-party payors, such as government health programs, commercial insurers and managed healthcare organizations, as well as the level of reimbursement such that those third-party payors provide for our products. Patients and providers are unlikely to use our products unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of our products in which our products are used. In the United States, no uniform policy of coverage and reimbursement for drugs or biological products exists, and one payor's determination to provide coverage and adequate reimbursement for a product does not assure that other payors will make a similar determination. Accordingly, decisions regarding the extent of coverage and amount of reimbursement to be provided for any of our products candidates, if approved, will be made on a payor-by-payor basis. As a result, the coverage determination process may be a time-consuming and costly process that will require us to provide scientific and clinical support for the use of our products to each payor separately, with no assurance that coverage and adequate reimbursement will be obtained.

The Medicaid Drug Rebate Program requires pharmaceutical manufacturers to enter into and have in effect a national rebate agreement with the Secretary of HHS as a condition for states to receive federal matching funds for the manufacturer's outpatient drugs furnished to Medicaid patients. The ACA made several changes to the

Medicaid Drug Rebate Program, including increasing pharmaceutical manufacturers' rebate liability by raising the minimum basic Medicaid rebate on most branded prescription drugs and adding a new rebate calculation for "line extensions" (i.e., new formulations, such as extended release formulations) of solid oral dosage forms of branded products, creating a new method by which rebates owed by are calculated for drugs that are inhaled, infused, instilled, implanted or injected, as well as potentially impacting their rebate liability by modifying the statutory definition of AMP. The ACA also expanded the universe of Medicaid utilization subject to drug rebates by requiring pharmaceutical manufacturers to pay rebates on Medicaid managed care utilization and by enlarging the population potentially eligible for Medicaid drug benefits. Pricing and rebate programs must also comply with the Medicaid rebate requirements of the U.S. Omnibus Budget Reconciliation Act of 1990.

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003, or the MMA, established the Medicare Part D program to provide a voluntary prescription drug benefit to Medicare beneficiaries. Under Part D, Medicare beneficiaries may enroll in prescription drug plans offered by private entities that provide coverage of outpatient prescription drugs. Unlike Medicare Part A and B, Part D coverage is not standardized. While all Medicare drug plans must give at least a standard level of coverage set by Medicare, Part D prescription drug plan sponsors are not required to pay for all covered Part D drugs, and each drug plan can develop its own drug formulary that identifies which drugs it will cover and at what tier or level. However, Part D prescription drug formularies must include drugs within each therapeutic category and class of covered Part D drugs, though not necessarily all the drugs in each category or class. Any formulary used by a Part D prescription drug plan must be developed and reviewed by a pharmacy and therapeutic committee. Government payment for some of the costs of prescription drugs may increase demand for products for which we receive marketing approval. However, any negotiated prices for our products covered by a Part D prescription drug plan likely will be lower than the prices we might otherwise obtain. Moreover, while the MMA applies only to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in setting their own payment rates. Any reduction in payment that results from the MMA may result in a similar reduction in payments from non-governmental payors.

For a drug product to receive federal reimbursement under the Medicaid or Medicare Part B programs or to be sold directly to U.S. government agencies, the manufacturer must extend discounts to entities eligible to participate in the 340B drug pricing program. The required 340B discount on a given product is calculated based on the AMP and Medicaid rebate amounts reported by the manufacturer. As of 2010, the ACA expanded the types of entities eligible to receive discounted 340B pricing, although, under the current state of the law, with the exception of children's hospitals, these newly eligible entities will not be eligible to receive discounted 340B pricing on orphan drugs. In addition, as 340B drug pricing is determined based on AMP and Medicaid rebate data, the revisions to the Medicaid rebate formula and AMP definition described above could cause the required 340B discount to increase. The 340B program imposes ceilings on prices that drug manufacturers can charge for medications sold to certain health care facilities. It is unclear how this decision could affect covered hospitals who might purchase our products in the future, and affect the rates we may charge such facilities for our approved products. In addition, legislation may be introduced that, if passed, would further expand the 340B program to additional covered entities or would require participating manufacturers to agree to provide 340B discounted pricing on drugs used in an inpatient setting.

As noted above, the marketability of any products for which we receive regulatory approval for commercial sale may suffer if the government and other third-party payors fail to provide adequate coverage and reimbursement. An increasing emphasis on cost containment measures in the United States has increased and we expect will continue to increase the pressure on pharmaceutical pricing. 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.

These laws, and future state and federal healthcare reform measures may be adopted in the future, any of which may result in additional reductions in Medicare and other healthcare funding and otherwise affect the

prices we may obtain for any of our product candidates for which we may obtain regulatory approval or the frequency with which any such product candidate is prescribed or used.

In addition, in most foreign countries, 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 EU 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 EU 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 study 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 EU do not follow price structures of the United States and, generally, prices tend to be significantly lower. 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.

**Employees**

As of December 31, 2019, we had 71 full-time employees, 27 of whom have Ph.D. or M.D. degrees and 55 of whom are engaged in research and development activities. As of December 31, 2019, we had no part-time employees. None of our employees is represented by a labor union or covered by a collective bargaining agreement. We consider our relationship with our employees to be good.

During the year ended December 31, 2019, we announced that, as part of a new strategic focus, we were reducing our workforce by approximately 24% of our then current headcount. See “Notes to Consolidated Financial Statements” located elsewhere in this proxy statement/prospectus.

**Corporate History and Trademarks**

We were incorporated under the laws of the State of Delaware in October 2013 under our previous name, Onco3, Inc. Our executive offices are located at 40 Erie Street, Suite 110, Cambridge, MA 02139, and our telephone number is (617) 337-4701. Our website address is www.neontherapeutics.com. We do not incorporate the information on or accessible through our website into this report, and you should not consider any information on, or that can be accessed through, our website as part of this report.

We view our operations and measure our business as one reportable segment. All of the Company’s tangible assets are held in the United States. See “Notes to Consolidated Financial Statements” located elsewhere in this proxy statement/prospectus.

We are the owner of trademark rights in the NEON THERAPEUTICS, RECON, NEO-STIM, Precision NEO-STIM and MAPTAC trademarks, as well as certain other trademarks, including design versions of some of these trademarks. The symbols ™ and ® are not used in connection with the presentation of these trademarks in this report and their absence does not indicate a lack of trademark rights. Certain other trademarks used in this report are the property of third-party trademark owners and may be presented with or without trademark references.

**Available Information**

Our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and any amendments to these reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act

of 1934, are available free of charge on our website located at www.neontherapeutics.com as soon as reasonably practicable after they are filed with or furnished to the SEC. These reports are also available at the SEC's Internet website at www.sec.gov.

A copy of our Corporate Governance Guidelines, Code of Conduct and Business Ethics and the charters of the Audit Committee, Compensation Committee and Nominating and Corporate Governance Committee are posted on our website, www.neontherapeutics.com, under the heading "Investors."

**Description of Property**

Our headquarters are located at 40 Erie Street in Cambridge, Massachusetts, where we occupy approximately 26,806 square feet of office and laboratory space. This lease expires in September 2024 and we have an option to extend the term of the lease for an additional five years. We believe that our facilities are suitable and sufficient to meet our current needs.

**Legal Proceedings**

From time to time, we may be subject to legal proceedings and claims in the ordinary course of business. We are not currently aware of any such proceedings or claims that we believe will have, individually or in the aggregate, a material adverse effect on our business, financial condition or results of operations.

**Changes in and Disagreements with Accountants on Accounting and Financial Disclosure**

None.

**Quantitative and Qualitative Disclosures about Market Risk**

As of December 31, 2019, we had cash and cash equivalents of $29.4 million. Our cash and cash equivalents consist primarily of money market funds that are invested in U.S. government-backed securities. Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of U.S. interest rates. Due to the short-term nature of our cash equivalents, a sudden change in interest rates would not be expected to have material effect on our business, financial condition or results of operations. Because of the short-term nature of the investments in our portfolio, an immediate change by 100 basis points in market interest rates would not have a material impact on the fair market value of our investment portfolio or on our financial position or results of operations.

We are not currently exposed to significant market risk related to changes in foreign currency exchange rates. However, we have contracted with, and may continue to contract with, vendors that are located in Europe. We may be subject to fluctuations in foreign currency rates in connection with certain of these agreements. Transactions denominated in currencies other than the United States dollar are recorded based on exchange rates at the time such transactions arise. While we have not engaged in the hedging of our foreign currency transactions to date, we are evaluating the costs and benefits of initiating such a program and may in the future hedge selected significant transactions denominated in currencies other than the U.S. dollar as we expand our international operation and our risk grows.

Inflation generally affects us by increasing our cost of labor and clinical trial costs. We do not believe that inflation had a material effect on our business, financial condition or results of operations during the year-ended December 31, 2019.

**Financial Statements and Supplementary Data**

For our consolidated financial statements, together with the independent registered public accounting firm report thereon, see “Notes to Consolidated Financial Statements” located elsewhere in this proxy statement/prospectus.

**Changes in and Disagreements with Accountants on Accounting and Financial Disclosure**

None.

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

We are 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. Genetic mutations, which are a hallmark of cancer, can result in specific immune targets called neoantigens. The presence of neoantigens in cancer cells and their absence in normal cells makes them compelling, untapped targets for cancer therapy. By directing the immune system towards these targets, we believe our neoantigen-targeted therapies will offer a new level of patient and tumor specificity in the field of cancer immunotherapy that will drive a strong risk-benefit profile to dramatically improve patient outcomes.

We have deep expertise in the development of neoantigen therapies, with both T cell and vaccine modalities. We are leveraging over a decade of insights from our founders to develop neoantigen-targeted therapies that use two distinct approaches: the first approach utilizes fully personal therapies that target neoantigens specific to each individual, and the second approach utilizes therapies that target neoantigens that are shared across subsets of patients or tumor types. Both the personal neoantigen approach and the shared neoantigen approach focus on targeting a prioritized set of what we believe are the most therapeutically-relevant neoantigens.

Our most advanced T cell program is NEO-PTC-01, our personal neoantigen adoptive T cell therapy, which consists of multiple T cell populations that are generated to target each individual patient's unique set of neoantigens. We are focusing the initial clinical development of NEO-PTC-01 in solid tumors for patients who are refractory to checkpoint inhibitors. In December 2019, we announced that we filed a CTA with the Dutch Health Authority to evaluate NEO-PTC-01 in a first-in-human clinical trial. We plan to initiate a Phase 1 dose escalation clinical trial in metastatic melanoma in collaboration with the Netherlands Cancer Institute in the third quarter of 2020. The second planned indication for NEO-PTC-01 is metastatic ovarian cancer, with the potential to both expand to other solid tumor types and pursue clinical development in the United States.

We are also advancing a T cell therapy program targeting shared neoantigens in genetically defined patient populations to direct the immune system towards prevalent mutations that are shared across patients in specific tumor types. We intend to develop product candidates targeting shared neoantigens using both non-engineered and engineered T cell modalities. Our first product candidate using the shared neoantigen approach, NEO-STC-01, is a non-engineered adoptive T cell therapy that targets RAS mutations prevalent across many solid tumors. We are focusing our initial efforts with NEO-STC-01 on the treatment of pancreatic ductal adenocarcinoma, or PDAC, as over 84% of PDAC tumors have a RAS mutation and there is a significant unmet medical need for PDAC therapies. We have also assembled libraries of high-quality T cell receptors, or TCRs, against various shared neoantigens across common human leukocyte antigens, or HLAs which are suitable for an engineered TCR-T cell therapy approach.

We also have two neoantigen vaccines in our portfolio, NEO-PV-01, a fully personal neoantigen cancer vaccine, custom-designed and manufactured for each individual patient's tumor mutations, and NEO-SV-01, a neoantigen vaccine for the treatment of a subset of hormone receptor-positive breast cancer. NEO-PV-01 is in Phase 1b clinical development in metastatic disease settings, with three ongoing trials. In November 2019, we reported top line results from the first trial, NT-001, at the Society of Immunotherapy for Cancer 2019 meeting.

On November 20, 2019, we announced that, as part of a new strategic focus, we were reducing our workforce by approximately 24% of our then current headcount. This corporate restructuring was substantially completed during the fourth quarter of 2019. We also announced the cessation of additional spending commitments related to our cancer vaccine programs, NEO-PV-01 and NEO-SV-01. We will continue to conduct follow-up from our ongoing 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 initial clinical data from this trial in the second half of 2020. We have also ceased additional enrollment in our NT-003 trial in metastatic melanoma.

After a comprehensive review of strategic alternatives, on January 15, 2020, we entered into the Merger Agreement with BioNTech, pursuant to which, if all of the conditions to closing are satisfied or waived, we will become a wholly-owned subsidiary of BioNTech. The Merger Agreement was unanimously approved by the members of our Board and the Board resolved to recommend approval of the Merger Agreement to our shareholders. The closing of the Merger is subject to approval of our shareholders and the satisfaction of customary closing conditions. Certain of our stockholders who collectively own approximately 36% of the outstanding shares of our common stock have entered into voting agreements, pursuant to which they have agreed, among other things, and subject to the terms and conditions of the agreements, to vote in favor of the Merger.

Subject to the terms of the Merger Agreement, at Effective Time each share of our common stock issued and outstanding immediately prior to the Effective Time shall automatically be canceled and converted (without interest but subject to any withholding required under applicable law) into the right to receive 0.063 of an American Depositary Share of BioNTech, or Parent ADS, with each Parent ADS representing one ordinary share of BioNTech. The transaction is expected to close in the second quarter of 2020. See “Notes to Consolidated Financial Statements” located elsewhere in this proxy statement/prospectus.

To date, we have devoted substantially all of our resources to organizing and staffing our company, business planning, raising capital, acquiring and discovering product candidates, securing related intellectual property rights and conducting research and development activities related to our product candidates.

On June 29, 2018, we completed our IPO in which we issued and sold 6,250,000 shares of our common stock at a public offering price of $16.00 per share in exchange for net proceeds of $89.9 million after deducting underwriting discounts, commissions and other offering costs. Upon the completion of the IPO, all shares of redeemable convertible preferred stock then outstanding converted into an aggregate of 18,644,462 shares of common stock.

From inception through December 31, 2019, we have funded our operations primarily through an aggregate of $89.9 million of net proceeds from our IPO, as well as an aggregate of $161.1 million of net proceeds from sales of our preferred stock and convertible debt. To date, we have not generated any revenue from product sales and do not expect to do so for several years, if at all. Due to our significant research and development expenditures, we have generated substantial operating losses in each period since inception, including net losses of $79.8 million and $76.9 million in the years ended December 31, 2019 and 2018, respectively. As of December 31, 2019, we had an accumulated deficit of $253.5 million. We expect to incur substantial additional losses in the foreseeable future as we expand our research and development activities.

We expect to continue to incur substantial expenses in connection with our ongoing activities if, and as, we:

- initiate or continue clinical trials of our product candidates;
- advance our development programs into and through preclinical and clinical development;
- seek regulatory approvals for any product candidates that successfully complete clinical trials;
- hire additional clinical, quality assurance and scientific personnel;
- expand our operational, financial and management systems and increase personnel, including personnel to support our clinical development, manufacturing and commercialization efforts and our operations as a public company;
- maintain, expand and protect our intellectual property portfolio;
- establish a sales, marketing, medical affairs and distribution infrastructure to commercialize any products for which we may obtain marketing approval and intend to commercialize on our own or jointly with third parties; and
- acquire or in-license other product candidates and technologies.

As a result, we will need substantial additional funding to support our continuing operations and pursue our growth strategy. Until such time as we can generate significant revenue from product sales, if ever, we expect to finance our operations through the pursuit of a strategic transaction, sale of equity, debt financings or other capital sources, including collaborations with other companies. We may be unable to raise additional funds or enter into such other agreements or arrangements, including a strategic transaction, when needed on favorable terms, or at all. If we fail to raise capital or enter into such agreements as, and when, needed, we may have to significantly delay, scale back or discontinue the development and commercialization of one or more of our product candidates or delay our pursuit of potential in-licenses or acquisitions.

Because of the numerous risks and uncertainties associated with product development, we are unable to predict the timing or amount of expenses or the timing of when or if we will be able to achieve or maintain profitability. Even if we are able to generate product sales, 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 be forced to reduce or terminate our operations.

As of December 31, 2019, we had cash and cash equivalents of $29.4 million. We believe that, based on our current operating plan, our existing cash and cash equivalents will enable us to fund our operating expenses and capital expenditure requirements into the third quarter of 2020. We have based this estimate on assumptions that may prove to be wrong and we could exhaust our available capital resources sooner than we expect. See "—Liquidity and Capital Resources." To finance our operations beyond that point we will need to raise additional capital, which cannot be assured. We have concluded that this circumstance raises substantial doubt about our ability to continue as a going concern. See "Notes to Consolidated Financial Statements" located elsewhere in this proxy statement/prospectus.

**Components of Results of Operations**

***Revenue***

We have not generated any revenue from product sales and do not expect to generate any revenue from the sale of products for several years, if at all. If our development efforts for our current or future product candidates are successful and result in marketing approval or collaboration or license agreements with third parties, we may generate revenue in the future from a combination of product sales or payments from collaboration or license agreements that we may enter into with third parties.

***Operating Expenses***

*Research and Development Expenses*

Research and development expenses represent costs incurred by us for the discovery, development and manufacture of our product candidates and include:

- expenses incurred under agreements with third parties, including CROs, CMOs and suppliers;
- license fees to acquire and maintain in-process technology and data;
- costs related to the development of our platforms, including costs related to RECON and NEO-STIM;
- personnel-related costs, including salaries, benefits and non-cash stock-based compensation expense, for personnel engaged in research and development functions;
- costs of outside consultants, including their fees, related travel expenses and stock-based compensation expense;
- the costs of laboratory supplies and acquiring, developing and manufacturing preclinical study and clinical trial materials;
- costs related to compliance with regulatory requirements; and

- facility-related expenses, which include direct depreciation costs and allocated expenses for rent and maintenance of facilities and general support services.

We expense research and development costs as incurred. We recognize costs for certain development activities, such as clinical trials and manufacturing costs, based on an evaluation of the progress to completion of specific tasks using data such as patient enrollment or other information provided to us by our vendors. Payments for these activities are based on the terms of the individual agreements, which may differ from the pattern of costs incurred, and are reflected in our financial statements as prepaid or accrued external research and development expenses. Nonrefundable advance payments for goods or services to be received in the future for use in research and development activities are recorded as prepaid expenses. These amounts are recognized as an expense as the goods are delivered or the related services are performed, or until it is no longer expected that the goods will be delivered or the services rendered.

We use our employee and infrastructure resources across our multiple research and development programs directed toward developing our personal and shared approaches, as well as identifying and developing product candidates. We track outsourced development and manufacturing costs, including external clinical and regulatory costs, by development product candidates, but we do not allocate costs such as personnel costs or other internal costs to specific development of product candidates. These external and unallocated research and development expenses are summarized in the table below:

| | Year Ended December 31, | |
|---|---|---|
| | 2019 | 2018 |
| | (in thousands) | |
| NEO-PV-01 | $ 17,333 | $ 26,934 |
| NEO-PTC-01 | 4,257 | 2,452 |
| Other early-stage development expenses | 7,078 | 3,027 |
| Unallocated expenses | 31,050 | 28,012 |
| Total research and development expense | $ 59,718 | $ 60,425 |

At this time, we cannot reasonably estimate or know the nature, timing, and estimated costs of the efforts that will be necessary to complete the development of our product candidates. We are also unable to predict when, if ever, material net cash inflows will commence from sales of our products, if approved. This is due to the numerous risks and uncertainties associated with developing our product candidates, including the uncertainty related to:

- the addition and retention of key research and development personnel;
- successful and timely enrollment in and completion of our current or future clinical trials;
- costs associated with the preclinical development and clinical trials for our early discovery product candidates;
- maintaining agreements with third-party manufacturers for clinical supply for our clinical trials and commercial manufacturing, if our product candidates are approved;
- receipt of marketing approvals from applicable regulatory authorities;
- commercializing products, if and when approved, whether alone or in collaboration with others;
- the terms and timing of any collaboration, license or other arrangement, including the terms and timing of any milestone payments thereunder;
- obtaining and maintaining patent and trade secret protection and regulatory exclusivity for our products if and when approved; and
- continued acceptable safety profiles of our products following approval.

A change in the outcome of any of these variables with respect to the development of any of our product candidates would significantly change the costs, timing and viability associated with the development of that product candidate.

Research and development activities account for a significant portion of our operating expenses. We expect to maintain our research and development expenses over the next several years as we continue to implement our business strategy, which includes advancing clinical development of NEO-PTC-01 and progressing NEO-STC-01 into clinical development, expanding our research and development efforts, seeking regulatory approvals for any product candidates that successfully complete clinical trials, accessing and developing additional product candidates and maintaining personnel to support our research and development efforts. In addition, product candidates in later stages of clinical development generally incur higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials. As a result, we expect our research and development expenses to increase as our product candidates advance into later stages of clinical development.

*General and Administrative Expenses*

General and administrative expenses consist of personnel-related costs, including salaries, benefits and non-cash stock-based compensation expense, for our personnel in executive, legal, finance and accounting, human resources, business operations and other administrative functions, legal fees related to patent, intellectual property and corporate matters, fees paid for accounting, regulatory and tax services, insurance costs, consulting fees and facility-related costs not otherwise included in research and development expenses.

We expect to maintain our general and administrative expenses at similar levels in future periods to support our continued research and development activities, as well as the costs of operating as a public company.

***Other Income, Net***

Other income, net consists primarily of interest income related to our investments in cash equivalents and marketable securities.

**Results of Operations**

***Comparison of the Years Ended December 31, 2019 and 2018***

The following table summarizes our results of operations for the years ended December 31, 2019 and 2018, along with the changes in those items in dollars:

| | Year Ended December 31, | | |
|---|---|---|---|
| | 2019 | 2018 | Change |
| | (in thousands) | | |
| Operating expenses: | | | |
| Research and development | $ 59,718 | $ 60,425 | $ (707) |
| General and administrative | 21,420 | 18,276 | 3,144 |
| Total operating expenses | 81,138 | 78,701 | 2,437 |
| Loss from operations | (81,138) | (78,701) | (2,437) |
| Other income (expense), net | 1,362 | 1,767 | (405) |
| Net loss | $ (79,776) | $ (76,934) | $ (2,842) |

*Research and Development*

Research and development expenses decreased by $0.7 million from $60.4 million for the year ended December 31, 2018 to $59.7 million for the year ended December 31, 2019 due primarily to the following decreases:

- $7.1 million for external manufacturing costs to support NEO-PV-01 and NEO-PTC-01;
- the non-recurrence of a $0.6 million expense incurred during the year ended December 31, 2018 related to a one-time milestone payable under one of our collaboration agreements as a result of the closing of our IPO;
- $0.5 million for external costs related to advancing our preclinical development candidates; and
- $0.3 million for decreased stock-based compensation expense.

These decreases were partially offset by the following increases:

- $4.5 million for NEO-SV-01 costs, including expenses related to manufacturing, stability studies and the submission of an IND to the FDA;
- $1.3 million for personnel-related restructuring charges, including one-time employee termination costs, severance and other benefits in connection with our November 2019 workforce reduction;
- $1.3 million for personnel-related costs due to increased headcount, all of which were incurred prior to the November 2019 workforce reduction;
- $0.5 million for facility-related costs, including occupancy costs, as well as depreciation and other maintenance costs; and
- $0.2 million for external development costs to support our ongoing NEO-PV-01 clinical trials.

*General and Administrative*

General and administrative expenses increased by $3.1 million from $18.3 million for the year ended December 31, 2018 to $21.4 million for the year ended December 31, 2019 due primarily to the following increases:

- $2.2 million for personnel-related costs due to increased headcount, including $1.4 million of increased stock-based compensation expense;
- $0.9 million for other general and administrative costs primarily due to the increased costs of being a public company, as well as additional insurance and tax related expenditures; and
- $0.5 million for professional fee expenses, primarily associated with the Company’s pursuit of strategic alternatives.

These increases were partially offset by $0.5 million for decreased expenses related to the timing of expenditures associated with protecting the Company’s owned and in-licensed intellectual property.

*Other Income (Expense), Net*

Other income decreased by $0.4 million from $1.8 million for the year ended December 31, 2018 to $1.4 million for the year ended December 31, 2019 primarily as a result of decreased interest income on our cash, cash equivalents and marketable securities.

## Liquidity and Capital Resources

### *Sources of Liquidity*

Since our inception, we have incurred significant losses in each period and on an aggregate basis. We have not yet commercialized any of our product candidates, which are in various phases of preclinical and clinical development, and we do not expect to generate revenue from sales of any products for several years, if at all. We have funded our operations through December 31, 2019 primarily with aggregate net proceeds of $89.9 million from our IPO, as well as an aggregate of $161.1 million of net proceeds from sales of our preferred stock and convertible debt. As of December 31, 2019, we had cash and cash equivalents of $29.4 million.

On July 1, 2019, we 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, our common stock, convertible securities or other equity securities in one or more offerings. We also simultaneously entered into a Controlled Equity Offering Sales Agreement, or the Sales Agreement, with Cantor Fitzgerald & Co., or the Sales Agent, to provide for the offering, issuance and sale of up to an aggregate amount of $50.0 million of our common stock from time to time in "at-the-market" offerings under the Shelf Registration Statement and subject to the limitations thereof. As of December 31, 2019, we have sold $0.4 million of our common stock in "at the market offerings" under the Shelf Registration Statement, prior to applicable commissions under the Sales Agreement. We pay to the Sales Agent cash commissions of 3.0% of the aggregate gross proceeds of sales of common stock under the Sales Agreement. Sales of common stock, convertible securities or other equity securities by us under the Shelf Registration Statement may represent a significant percentage of our common stock currently outstanding.

### *Historical Cash Flows*

The following table provides information regarding our cash flows for each of the periods presented (in thousands):

| | Year Ended December 31, | |
|---|---|---|
| | 2019 | 2018 |
| | (in thousands) | |
| Net cash provided by (used in): | | |
| Operating activities | $ (73,412) | $ (63,428) |
| Investing activities | 49,597 | (32,611) |
| Financing activities | 510 | 90,338 |
| Net decrease in cash, cash equivalents and restricted cash | $ (23,305) | $ (5,701) |

*Cash Used in Operating Activities*

The cash used in operating activities resulted primarily from our net losses adjusted for non-cash charges and changes in components of working capital, which are primarily the result of increased expenses and timing of vendor payments.

During the year ended December 31, 2019, operating activities used $73.4 million of cash, primarily resulting from our net loss of $79.8 million and net cash used by changes in our operating assets and liabilities of $3.9 million, partially offset by net non-cash charges of $10.2 million. Net cash used by changes in our operating assets and liabilities for the year ended December 31, 2019 consisted primarily of a $2.3 million decrease in accounts payable, a $0.7 million decrease in accrued expenses and other liabilities and a $1.1 million decrease in operating lease liabilities, partially offset by a $0.3 million decrease in prepaid expenses and other current assets.

During the year ended December 31, 2018, operating activities used $63.4 million of cash, primarily resulting from our net loss of $76.9 million, partially offset by net non-cash charges of $7.7 million and changes in our operating assets and liabilities of $5.8 million. Net cash provided by changes in our operating assets and liabilities for the year ended December 31, 2018 consisted primarily of a $4.1 million increase in accrued expenses and other liabilities and a $2.0 million increase in accounts payable, partially offset by a $0.3 million increase in prepaid expenses and other current assets.

*Cash Provided by (Used in) Investing Activities*

During the year ended December 31, 2019, net cash provided by investing activities was $49.6 million, consisting of proceeds from the sales and maturities of marketable securities of $50.7 million, partially offset by purchases of property and equipment of $1.1 million.

During the year ended December 31, 2018, net cash used in investing activities was $32.6 million, consisting of purchases of marketable securities of $72.9 million and purchases of property and equipment of $3.2 million, partially offset by proceeds from the sales and maturities of marketable securities of $43.6 million.

*Cash Provided by Financing Activities*

During the year ended December 31, 2019, net cash provided by financing activities was $0.5 million, primarily consisting of $0.3 million of net proceeds from the issuance of shares of common stock pursuant to our ATM facility and $0.2 million in proceeds from the exercise of stock options and the issuance of shares under our employee stock purchase plan.

During the year ended December 31, 2018, net cash provided by financing activities was $90.3 million, primarily consisting of $93.0 million of net proceeds from our IPO, after deducting underwriting discounts and commissions, and $0.4 million in proceeds from the exercise of stock options, partially offset by payments of IPO costs of $3.1 million.

***Funding Requirements***

We expect to continue to incur substantial expenses in connection with our ongoing research and development activities, particularly as we advance the preclinical activities and clinical trials of our product candidates. As a result, we expect to incur substantial operating losses and negative operating cash flows for the foreseeable future.

Based on our current operating plan, we expect that our existing cash and cash equivalents will enable us to fund our operating expenses and capital expenditure requirements into the third quarter of 2020. However, we have based this estimate on assumptions that may prove to be wrong and we could exhaust our capital resources sooner than we expect.

Because of the numerous risks and uncertainties associated with the development of our product candidates or programs and because the extent to which we may enter into collaborations with third parties for development of our product candidates is unknown, we may incorrectly estimate the timing and amounts of increased capital outlays and operating expenses associated with completing the research and development of our product candidates. Our funding requirements, both near and long-term, as well as the timing and amount of our operating expenditures, will depend largely on:

- the initiation, progress, scope, timing, costs and results of preclinical or nonclinical testing and studies and clinical trials for our product candidates;
- the clinical development plans we establish for these product candidates;
- the number and characteristics of product candidates that we develop or may in-license;

- the terms of any collaboration agreements we may choose to execute;
- the outcome, timing and cost of meeting regulatory requirements established by the FDA, EMA and other comparable foreign regulatory authorities;
- the cost of filing, prosecuting, defending and enforcing our patent claims and other intellectual property rights;
- the cost of defending intellectual property disputes, including any patent infringement actions that may be brought by third parties in the future against us or our product candidates;
- the effect of competing technological and market developments;
- the cost and timing of formulation development and manufacturing, including the completion of commercial-scale outsourced manufacturing activities; and
- the cost of establishing sales, marketing and distribution capabilities for any product candidates for which we may receive regulatory approval in regions where we choose to commercialize our products on our own.

A change in the outcome of any of these or other variables with respect to the development of any of our product candidates could significantly change the costs and timing associated with the development of that product candidate. Furthermore, our operating plans may change in the future and we may need additional funds to meet operational needs and capital requirements associated with these changed operating plans.

In addition to the variables described above, if and when any of our product candidates successfully complete development, we will incur substantial additional costs associated with regulatory filings, marketing approval, post-marketing requirements, maintaining our intellectual property rights and regulatory protection, in addition to other commercial costs. We cannot reasonably estimate these costs at this time.

Until such time, if ever, as we can generate substantial product revenue, we expect to finance our cash needs through the pursuit of a strategic transaction, or a combination of equity or debt financings and collaboration arrangements. We currently have no credit facility or committed sources of capital. To the extent that we raise additional capital through a future strategic transaction or the future sale of equity or debt, the ownership interests of our stockholders will be diluted and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our existing common stockholders. If we raise additional funds through the issuance of debt securities, these securities could contain covenants that would restrict our operations. We may require additional capital beyond our currently anticipated amounts and additional capital may not be available on reasonable terms, or at all. If we raise additional funds through collaboration arrangements or other strategic transactions in the future, we may have to relinquish valuable rights to our technologies, future revenue streams or product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate development or future commercialization efforts.

We have concluded that the above circumstance raises substantial doubt about our ability to continue as a going concern. See “Notes to Consolidated Financial Statements” located elsewhere in this proxy statement/prospectus.

**Off-Balance Sheet Arrangements**

During the periods presented we did not have, and we do not currently have, any off-balance sheet arrangements, as defined under applicable SEC rules.

**Contractual Obligations**

The following table summarizes our contractual obligations as of December 31, 2019 and the effects that these obligations are expected to have on our liquidity and cash flows in future periods:

| | Payments Due by Period | | | | |
|---|---|---|---|---|---|
| | Total | Less Than 1 Year | 1 to 3 Years | 3 to 5 Years | More Than 5 Years |
| | (in thousands) | | | | |
| Operating lease commitments(1) | $9,780 | $ 1,948 | $4,072 | $3,760 | $ — |
| Total | $9,780 | $ 1,948 | $4,072 | $3,760 | $ — |

(1) Primarily represents minimum payments due for our lease of office and laboratory space in Cambridge, Massachusetts under an operating lease agreement that expires in 2024.

We enter into contracts in the normal course of business with CROs, CMOs and other third parties for clinical trials, preclinical research studies and testing and manufacturing services. These contracts are generally cancelable by us upon up to 120 days prior written notice. Payments due upon cancellation consist only of payments for services provided or expenses incurred, including noncancelable obligations of our service providers up to and through the date of cancellation. These payments are not included in the preceding table as the amount and timing of these payments are not known. In December 2019, we provided notice to an independent third party who performs manufacturing, analytical testing and quality assurance services related to the manufacture of drug product and/or peptides for use in our preclinical and clinical activities that we were terminating our manufacturing agreement for convenience. We accrued the costs associated with terminating this agreement during the year ended December 31, 2019. No payments are included in the preceding table, as we do not expect to incur a material amount of future costs associated with the termination of the agreement.

In the normal course of business, we have also entered into license and collaboration agreements with third parties. We have not included future payments under these agreements in the table of contractual obligations above since obligations under these agreements are contingent upon future events such as our achievement of specified development, regulatory or commercial milestones, or are tied to royalties on net product sales. As of December 31, 2019 and 2018, the aggregate maximum amount of milestone payments we could be required to make under our then-existing license and collaboration agreements was approximately $116.9 million. As of December 31, 2019 and 2018, we were unable to estimate the timing or likelihood of achieving these milestones or generating future product sales. During the year ended December 31, 2018 and as a result of the closing of our IPO, we recorded approximately $0.6 million of incremental research and development expense related to a milestone payable under one of our collaboration agreements.

**Critical Accounting Policies and Significant Judgments and Estimates**

Our management's discussion and analysis of our financial condition and results of operations is based on our consolidated financial statements, which have been prepared in accordance with generally accepted accounting principles in the United States. The preparation of these consolidated financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the consolidated financial statements, as well as the reported expenses incurred during the reporting periods. Our estimates are based on our historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions. In addition, we believe that the accounting policies discussed below are critical to understanding our historical and future performance, as these policies relate to the more significant areas involving management's judgments and estimates.

***Leases***

Effective January 1, 2019, we adopted Accounting Standards Codification Topic 842, or ASC 842, with no restatement of prior periods or cumulative adjustment to retained earnings. Comparative periods in our financial statements will be presented in accordance with the existing guidance under ASC 840.

Upon adoption, we took advantage of the transition package of practical expedients permitted within ASU 2016-02, which allowed us to not 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, we also have made an accounting policy election to exclude leases with an initial term of twelve months or less from its balance sheet.

Under ASC 842, we determine 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, we include options to extend or terminate the lease when it is reasonably certain that it will exercise that option. We use the implicit rate when readily determinable and use our 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.

We recognize lease costs on a straight-line basis over the lease term, and include amounts related to short-term leases.

Adoption of the new standard resulted in the recognition of operating lease right-of-use assets and operating lease liabilities of approximately $8.7 million and $8.9 million, respectively, as of January 1, 2019. The adoption of the new standard did not materially impact our condensed consolidated statement of operations. See “Notes to Consolidated Financial Statements” located elsewhere in this proxy statement/prospectus.

***Research and Development Expenses and Related Accruals***

Research and development expenses include costs directly attributable to the conduct 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; costs related to the development of our platforms, unless such costs meet the criteria to be capitalized as internal-use software, 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.

We enter into various research and development contracts with research institutions and other companies and record accruals for estimated ongoing research costs. When evaluating the adequacy of the accrued liabilities, we analyze progress of the studies or trials, including the phase or completion of events, invoices received and contracted costs. This process involves reviewing open contracts and purchase orders, communicating with personnel to identify services that have been performed and estimating the level of service performed and the associated costs incurred for the services for which we have not yet been invoiced. The financial terms of these agreements are subject to negotiation, vary from contract to contract and may result in uneven payment flows. There may be instances in which payments made to our vendors will exceed the level of services provided and result in a prepayment of the expense. If the actual timing of the performance of services or the level of effort varies from our estimate, we adjust the accrual or amount of prepaid expense accordingly. Significant judgments and estimates are made in determining the accrued balances at the end of any reporting

period. Although we do not expect our estimates to be materially different from amounts actually incurred, our understanding of the status and timing of services performed relative to the actual status and timing of services performed may vary and may result in us reporting amounts that are too high or too low in any particular period. To date, we have not made any material adjustments to our prior estimates of accrued research and development expenses.

***Stock-Based Compensation***

We measure stock-based compensation expense related to restricted common stock, restricted stock units and stock options granted to our employees and directors based on the fair value on the date of grant. We recognize compensation expense for these awards over the requisite service period, which is generally the vesting period of the respective award. Generally, we issue awards with only service-based vesting conditions and record the expense for these awards using the straight-line method. We have also granted certain stock-based awards with performance-based vesting conditions. We recognize compensation expense for awards with performance-based vesting conditions over the remaining service period when management determines that achievement of the performance condition is probable.

We estimate the fair value of the stock options granted using the Black-Scholes option-pricing model, which uses as inputs the fair value of our common stock and subjective assumptions we make, including the expected stock price volatility, the expected term of the award, the risk-free interest rate and expected dividends. Because there had been no public market for our common stock prior to our IPO, there is a lack of Company-specific historical and implied volatility data. Accordingly, we base our estimates of expected volatility on the historical volatility of 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. We use the simplified method to calculate the expected term for options granted to employees and directors. We utilize this method as we do not have sufficient historical exercise data to provide a reasonable basis upon which to estimate the expected term. For options granted to nonemployees, we utilize the contractual term of the arrangement as the basis for the expected term assumption. The expected dividend yield is assumed to be zero as we have never paid dividends and do not have current plans to pay any dividends on common stock. We determine the fair value of restricted common stock awards and restricted stock units based on the fair value of our common stock, less any applicable purchase price. We determine compensation expense for discounted purchases under our employee stock purchase plan using the Black-Scholes model to compute the fair value of the look-back provision plus the purchase discount, and recognize this compensation expense over the offering period.

The Company accounts for stock-based compensation expense related forfeitures as the forfeiture occurs.

Effective January 1, 2019, equity-classified share-based payment awards issued to nonemployees will be measured at grant date fair value similarly to those of employees. See “Notes to Consolidated Financial Statements” located elsewhere in this proxy statement/prospectus.

*Determination of Fair Value of Common Stock on Grant Dates prior to our IPO*

Due to the absence of an active market for our common stock prior to the commencement of trading of our common stock on the Nasdaq Global Select Market on June 27, 2018 in connection with our IPO, the estimated fair values of our common stock as of the grant dates prior to our IPO were determined using contemporaneous valuations performed in accordance with the guidance outlined in the American Institute of Certified Public Accountants Practice Aid, *Valuation of Privately-Held Company Equity Securities Issued as Compensation*, also known as the Practice Aid. Following our IPO, it is no longer necessary for us to estimate the fair value of our common stock in connection with our accounting for stock options or other equity awards, as the fair value of our common stock can be determined by reference to its closing price on The Nasdaq Global Select Market on the applicable grant date.

Valuations of our common stock were performed by third parties at various dates, which resulted in valuations of our common stock of $1.30 per share as of December 31, 2015, $2.00 per share as of April 30, 2016, $2.65 per share as of September 20, 2016, $5.80 per share as of December 31, 2016, $9.65 per share as of December 1, 2017, $10.20 per share as of January 24, 2018 and $11.90 per share as of April 16, 2018. In addition to considering the results of these third-party valuations, our board of directors considered various objective and subjective factors to determine the fair value of our common stock as of each grant date, which may be a date later than the most recent third-party valuation date, including:

- the prices at which we sold shares of preferred stock and the superior rights and preferences of the preferred stock relative to our common stock at the time of each grant;
- the progress of our research and development programs, including the status of preclinical studies and current and planned clinical trials for our product candidates;
- our stage of development and commercialization and our business strategy;
- external market conditions affecting the biotechnology industry, and trends within the biotechnology industry;
- our financial position, including cash on hand, and our historical and forecasted performance and operating results;
- the lack of an active public market for our common stock and our preferred stock;
- the likelihood and potential timing of achieving a liquidity event, such as an IPO or a sale of our company in light of prevailing market conditions; and
- the analysis of IPOs and the market performance of similar companies in the biopharmaceutical industry.

The assumptions underlying these valuations represented management's best estimates, which involved inherent uncertainties and the application of management judgment. Significant changes to the key assumptions used in the valuations could have resulted in different fair values of our common stock at each valuation date.

**Recently Issued Accounting Pronouncements**

For a discussion of new accounting pronouncements see "Notes to Consolidated Financial Statements" located elsewhere in this proxy statement/prospectus.

**Emerging Growth Company Status**

The Jumpstart Our Business Startups Act of 2012, or the JOBS Act, permits an "emerging growth company" such as us to take advantage of an extended transition period to comply with new or revised accounting standards applicable to public companies until those standards would otherwise apply to private companies. We have irrevocably elected to "opt out" of this provision and, as a result, we will comply with new or revised accounting standards when they are required to be adopted by public companies that are not emerging growth companies.

## NEON SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT

The following table sets forth information, to the extent known by Neon or ascertainable from public filings, with respect to the beneficial ownership of Neon common stock as of March 23, 2020 by:

- each of Neon directors;
- each of Neon named executive officers;
- all of Neon directors and executive officers as a group; and
- each person, or group of affiliated persons, who is known by Neon to be the beneficial owner of greater-than-5.0% of Neon common stock.

The column entitled "Percentage Beneficially Owned" is based on a total of shares of Neon common stock outstanding as of March 23, 2020.

Beneficial ownership is determined in accordance with the rules and regulations of the SEC and includes voting or investment power with respect to Neon common stock. Shares of Neon common stock subject to options that are currently exercisable or exercisable within 60 days of March 23, 2020 are considered outstanding and beneficially owned by the person holding the options for the purpose of calculating the percentage ownership of that person but not for the purpose of calculating the percentage ownership of any other person. Except as otherwise noted, the persons and entities in this table have sole voting and investing power with respect to all of the shares of Neon common stock beneficially owned by them, subject to community property laws, where applicable. Except as otherwise indicated in the table below, addresses of named beneficial owners are in care of Neon Therapeutics, Inc., 40 Erie Street, Suite 110, Cambridge, Massachusetts 02139.

| Name of Beneficial Owner | Number of Shares Beneficially Owned | Percentage Beneficially Owned |
|---|---|---|
| **5% Stockholders:** | | |
| Third Rock Venture III, L.P.(1) | 9,741,636 | 33.67% |
| Entities affiliated with Access Industries Holdings LLC(2) | 3,004,524 | 10.38% |
| Entities affiliated with Fidelity(3) | 1,528,496 | 5.28% |
| Entities affiliated with JFL Capital Management LLC(4) | 1,519,819 | 5.25% |
| **Executive Officers and Directors:** | | |
| Hugh O'Dowd(5) | 924,655 | 3.15% |
| Yasir B. Al-Wakeel, B.M.B.Ch.(6) | 233,011 | * |
| Richard Gaynor(7) | 241,864 | * |
| Robert Bazemore(8) | 13,930 | * |
| Robert Kamen, Ph.D.(9) | 14,000 | * |
| Eric S. Lander, Ph.D.(10) | 148,000 | * |
| Cary G. Pfeffer, M.D.(11) | 14,000 | * |
| Stephen A. Sherwin, M.D.(12) | 64,000 | * |
| Robert Tepper, M.D.(13) | 9,755,636 | 33.70% |
| Meryl Zausner(14) | 44,000 | * |
| **All current executive officers and directors as a group (11 persons)(15)** | **11,541,167** | **38.51%** |

* Represents beneficial ownership of less than one percent of outstanding Neon common stock.

(1) Information herein is based solely upon a Schedule 13G filed with the SEC on February 13, 2019. Consists of: 9,741,636 shares of Neon common stock held by Third Rock Ventures III, L.P., or TRV III LP. Each of Third Rock Ventures III GP, LP, or TRV III GP, the general partner of TRV III LP, Third Rock Ventures GP III, LLC, or TRV III LLC, the general partner of TRV III GP, and Mark Levin, Kevin Starr and Dr. Tepper, the managers of TRV II LLC, may be deemed to share voting and investment power over the shares held of record by TRV III LP. Each of Third Rock Ventures III GP, LP, or TRV III GP, the general

partner of TRV III LP, and Third Rock Ventures GP III, LLC, TRV III LLC, the general partner of TRV III GP, and Mark Levin, Kevin Starr and Dr. Tepper, the managers of TRV III LLC, may be deemed to share voting and investment power over the shares held of record by TRV III LP. The address for each of TRV II LP and TRV III LP is 29 Newbury Street, Suite 401, Boston, MA 02116.

(2) Information contained herein is based on a Form 4 filing filed by Access Industries Holdings LLC ("Access") on March 23, 2020. Consists of: (i) 2,013,576 shares of Neon Common Stock held by Access and (ii) 990,948 shares of Neon common stock held by Clal Biotechnology Industries Ltd., or CBI. CBI is a public company traded on Tel Aviv stock exchange. CBI's direct controlling shareholder is Clal Industries Ltd., or CI. CI is a private company which is ultimately controlled by Mr. Len Blavatnik through Access. Each of CI and Access may be deemed to share voting and investment power over the shares held of record by CBI. Each of CI and Access disclaim beneficial ownership of all shares held by CBI, except to the extent of their pecuniary interest therein. The address for Access is c/o Access Industries, Inc., 40 W. 57th Street, 28th Floor, New York, NY 10019 and the address for CBI is 3 Azrieli Center Triangle Tower, 45th Floor, 132 Menachem Begin Road, Tel Aviv 6702301, Israel.

(3) Information herein is based solely upon a Schedule 13G/A filed with the SEC on February 7, 2020. FMR LLC and Abigail P. Johnson report sole voting power of 485,712 shares of Neon common stock and sole power to dispose or direct the disposition of 1,528,496 shares of Neon common stock. Edward C. Johnson 3d is a Director and the Chairman of FMR LLC and Abigail P. Johnson is a Director, the Vice Chairman and the President of FMR LLC. Members of the family of Edward C. Johnson 3d, including Abigail P. Johnson, are the predominant owners, directly or through trusts, of Series B voting common shares of FMR LLC, representing 49% of the voting power of FMR LLC. The Johnson family group and all other Series B shareholders have entered into a shareholders' voting agreement under which all Series B voting common shares will be voted in accordance with the majority vote of Series B voting common shares. Accordingly, through their ownership of voting common shares and the execution of the shareholders' voting agreement, members of the Johnson family may be deemed, under the Investment Company Act of 1940, to form a controlling group with respect to FMR LLC. Neither FMR LLC nor Edward C. Johnson 3d nor Abigail P. Johnson has the sole power to vote or direct the voting of the shares owned directly by the various investment companies registered under the Investment Company Act, or Fidelity Funds, advised by Fidelity Management & Research Company, or FMR Co, a wholly owned subsidiary of FMR LLC, which power resides with the Fidelity Funds' Boards of Trustees. Fidelity Management & Research Company carries out the voting of the shares under written guidelines established by the Fidelity Funds' Boards of Trustees. The address for Fidelity Select Portfolios is Brown Brothers Harriman & Co., 525 Washington Blvd., Jersey City, NJ 07310, Attn: Michael Lerman, 15th Floor, Corporate Actions, the address for Fidelity Advisor Series VII is State Street Bank & Trust, PO Box 5756, Boston, Massachusetts 02206, Attn: Bangle & Co fbo Fidelity Advisor Series VII: Fidelity Advisor Biotechnology Fund, and the address for Fidelity Securities Fund is The Northern Trust Company, Attn: Trade Securities Processing, C-1N, 801 South Canal Street, Chicago, IL 60607, Fidelity Securities Fund: Fidelity OTC Portfolio, Reference account #26-68304.

(4) Information herein is based solely upon a Schedule 13G filed with the SEC on March 23, 2020. JFL Capital Management LLC ("JFL") reports shared voting and dispositive power of 1,519,819 shares of Neon common stock and sole voting and dispositive power of 607,929 shares of Neon common stock. The address for JFL Capital Management LLC is 2110 Ranch Road 620 S, #341732, Lakeway, Texas 78734.

(5) Consists of: (i) 469,418 shares of Neon common stock and (ii) 455,237 shares of Neon common stock underlying options exercisable within 60 days of March 23, 2020.

(6) Consists of: (i) 42,381 shares of Neon common stock and (ii) 190,630 shares of Neon common stock underlying options exercisable within 60 days of March 23, 2020.

(7) Consists of: (i) 50,826 shares of Neon common stock and (ii) 191,038 shares of Neon common stock underlying options exercisable within 60 days of March 23, 2020.

(8) Consists of 13,930 shares of Neon common stock underlying options exercisable within 60 days of March 23, 2020.

(9) Consists of 14,000 shares of Neon common stock underlying options exercisable within 60 days of March 23, 2020.

(10) Consists of: (i) 134,000 shares of Neon common stock and (ii) 14,000 shares of Neon common stock underlying options exercisable within 60 days of March 23, 2020.
(11) Consists of 14,000 shares of Neon common stock underlying options exercisable within 60 days of March 23, 2020.
(12) Consists of: (i) 45,000 shares of Neon common stock and (ii) 19,000 shares of Neon common stock underlying options exercisable within 60 days of March 23, 2020.
(13) Consists of: (i) 9,741,636 shares of Neon common stock held by TRV III LP and (ii) 14,000 shares of common stock underlying options exercisable within 60 days of March 23, 2020. Dr. Tepper is affiliated with TRV III LP. Each of TRV III GP, the general partner of TRV III LP, and TRV III LLC, the general partner of TRV III GP, and Mark Levin, Kevin Starr and Dr. Tepper, the managers of TRV III LLC, may be deemed to have voting and investment power over the shares held of record by TRV III LP.
(14) Consists of 44,000 shares of Neon common stock underlying options exercisable within 60 days of March 23, 2020.
(15) See notes (5) through (14) above; also includes Jolie M. Siegel, who is an executive officer, but not a named executive officer.

## CERTAIN MATERIAL U.S. FEDERAL INCOME TAX CONSIDERATIONS

The following is a summary of certain material U.S. federal income tax considerations with respect to the Merger applicable to U.S. holders (as defined below) of shares of Neon common stock. This summary is based on the Internal Revenue Code of 1986, as amended, or the Code, its legislative history, existing and proposed regulations, and published rulings and court decisions, all as currently in effect. These laws are subject to change, possibly with retroactive effect. We have not and will not seek any rulings from the Internal Revenue Service, or the IRS, regarding the matters discussed below. There can be no assurance that the IRS will not take positions concerning the tax consequences of the Merger that are different from those discussed below, or that a court will not sustain such a position if so challenged.

This discussion applies to you only if you exchange your shares of Neon common stock for BionNTech ADSs in the Merger and you hold your shares of Neon common stock and BioNTech ADSs as capital assets for tax purposes. This section does not address all aspects of U.S. federal income taxaction that may be applicable to U.S. holders in light of their particular circumstances or status, including, for example:

- a holder who acquired shares of Neon common stock pursuant to the exercise of employee stock options or otherwise as compensation;
- a financial institution;
- a corporation that accumulates earnings to avoid U.S. federal income tax;
- a pension plan;
- a dealer or broker in stocks, securities, or currencies;
- a trader in securities that elects to use a mark-to-market method of accounting for securities holdings;
- a tax-exempt organization;
- an S corporation, partnership, or other pass-through entity (or an investor in an S corporation, partnership or other pass-through entity);
- an insurance company;
- a mutual fund, a regulated investment company, or a real estate investment trust;
- an individual retirement or other tax-deferred account;
- a person who holds shares of Neon common stock as part of a straddle, hedging, conversion, constructive sale, or other integrated transaction;
- a U.S. holder (as defined below) whose functional currency is not the U.S. dollar;
- a holder of shares of Neon common stock that holds any BioNTech ADSs or BioNTech Shares immediately prior to the Merger; or
- a U.S. expatriate or former long-term resident of the United States.

This discussion does not address the tax consequences to any Neon stockholder that is or will become a five-percent transferee shareholder of BioNTech within the meaning of the applicable Treasury Regulations under Section 367 of the Code. In general, a five-percent transferee shareholder of BioNTech is a Neon stockholder that will own directly, indirectly or constructively through attribution rules, at least five percent of either the total voting power or total value of BioNTech immediately after the Merger. If you believe you are or could become a five-percent transferee shareholder of BioNTech, you should promptly consult your tax advisor about the U.S. federal income tax consequences to you of the Merger, as certain special rules and time-sensitive tax procedures may apply to you.

In addition, this discussion does not address any consequences arising under the laws of any state, local or foreign jurisdiction, or taxes other than income taxes, including any tax consequences arising under the alternative minimum tax, the Medicare tax on net investment income or the rules regarding "qualified small business stock" or "Section 1244 Stock". Determining the actual tax consequences of the Merger to you may be complex. They will depend on your specific situation and on factors that are not within the control of Neon or BioNTech. You should consult with your own tax advisor as to the tax consequences of the Merger in your particular circumstances.

If a partnership or entity treated as a partnership for U.S. federal income tax purposes holds shares of Neon common stock, the tax treatment of a partner generally will depend on the status of the partners and the tax treatment of the partnership. If you are a partner of a partnership holding shares of Neon common stock, you should consult your tax advisors.

For purposes of this discussion, the term "U.S. holder" means a holder of shares of Neon common stock that exchanges such stock for BioNTech ADSs in the Merger and is:

- an individual citizen or resident of the United States,
- a corporation (or other entity treated as a corporation for U.S. federal income tax purposes) created or organized in or under the laws of the United States, any U.S. state or the District of Columbia,
- an estate the income of which is subject to U.S. federal income taxation regardless of its source, or
- a trust that either (1) is subject to the primary supervision of a court within the United States and the control of one or more U.S. persons or (2) has a valid election in effect under applicable U.S. Treasury regulations to be treated as a U.S. person.

The tax consequences to Neon stockholders who are not "U.S. holders" as defined above could differ significantly from the consequences discussed below. Neon stockholders who are not U.S. holders should consult their tax advisors concerning the tax consequences to them of exchanging shares of Neon common stock in the Merger.

For a summary of material U.S. federal income tax considerations relating to the ownership and disposition of BioNTech ADSs, U.S. holders of shares of Neon common stock should review the discussion set forth in BioNTech's registration statement on Form F-1 filed with the SEC on September 9, 2019 in "Taxation—Material U.S. Federal Income Tax Considerations."

*General Tax Consequences of the Merger*

The Merger is intended to qualify as a nonrecognition transaction for U.S. federal income tax purposes. The Merger is conditioned upon the delivery of legal opinions from Goodwin Procter LLP and Covington & Burling LLP to Neon and BioNTech, respectively, substantially to the effect that the Merger (i) will constitute a reorganization within the meaning of Section 368(a) of the Code, and (ii) will not result in the recognition of gain under Section 367(a)(1) of the Code by any holder of shares of Neon common stock (other than any holder of shares of Neon common stock that is a five-percent transferee shareholder of BioNTech within the meaning of Treasury Regulations Section 1.367(a)-3(c)(5)(ii) immediately following the Merger or that held BioNTech Shares or BioNTech ADSs immediately prior to the Merger).

The opinions of Goodwin Procter LLP and Covington & Burling LLP will be based on assumptions, representations, warranties and covenants, including those contained in the Merger Agreement and in representation letters to be provided by Neon, BioNTech and Merger Sub to be delivered at the time of closing. The accuracy of such assumptions, representations and warranties, and compliance with such covenants, could affect the conclusions set forth in such opinions. The opinions will not be binding on the IRS or the courts. No IRS ruling has been or will be requested regarding the U.S. federal income tax consequences of the Merger.

Based on representations contained in the representation letters provided by Neon, BioNTech and Merger Sub and on certain factual assumptions, all of which must continue to be true and accurate in all material respects as of the time the Merger is completed, and subject to the qualifications and limitations set forth above and in the legal opinions and representation letters, it is the opinion of Goodwin Procter LLP and Covington & Burling LLP that (i) the Merger will constitute a reorganization within the meaning of Section 368(a) of the Code, and (ii) the Merger will not result in the recognition of gain under Section 367(a)(1) of the Code by any holder of shares of Neon common stock (other than any holder of shares of Neon common stock that is a five-percent transferee shareholder of BioNTech within the meaning of Treasury Regulations Section 1.367(a)-3(c)(5)(ii) immediately following the Merger or that held BioNTech Shares or BioNTech ADSs immediately prior to the Merger).

Based upon the foregoing, the material U.S. federal income tax consequences of the Merger will be as follows:

- when you exchange all of your shares of Neon common stock solely for BioNTech ADSs, you will not recognize any gain or loss except in respect of cash received in lieu of a fractional BioNTech ADS, as discussed below under the heading "—Cash Received In Lieu of a Fractional New BioNTech ADS;"
- the aggregate adjusted tax basis of the BioNTech ADSs you actually receive will be equal to the aggregate adjusted tax basis of your shares of Neon common stock surrendered for the BioNTech ADSs, reduced by the adjusted tax basis allocable to any fractional BioNTech ADS deemed received as described below; and
- the holding period of BioNTech ADSs will include the period during which you held the shares of Neon common stock prior to the Merger.

*Cash Received In Lieu of a Fractional New BioNTech ADS.*

If you receive cash in lieu of a fractional BioNTech ADS, you generally will be treated as having received the BioNTech ADS pursuant to the Merger and then as having sold that fractional BioNTech ADS for the cash received in lieu of the fractional BioNTech ADS. You generally will recognize gain or loss based on the difference between the amount of cash you receive in lieu of a fractional BioNTech ADS and the portion of your aggregate adjusted tax basis of the shares of Neon common stock you surrendered that is allocable to the fractional BioNTech ADS. The gain or loss generally will be long-term capital gain or loss if the holding period for your shares of Neon common stock is more than one year at the Effective Time. Under current law, long-term capital gains generally are taxed at a reduced U.S. federal income tax rate for non-corporate taxpayers. Any gain or loss recognized by you with respect to such shares of Neon common stock will be short-term capital gain if such shares of Neon common stock has been held for one year or less as of the Effective Time. Short-term capital gains are taxed at ordinary income rates.

*Tax Consequences if the Merger Does Not Qualify as a Non-Recognition Transaction*

If the Merger fails to qualify as a nonrecognition transaction as the parties intend and you have a gain in your shares of Neon common stock, the Merger will be a fully taxable transaction to you. You generally will recognize capital gain equal to the difference between (i) the fair market value of the BioNTech ADSs you receive in the Merger plus the amount of cash received in lieu of a fractional BioNTech ADS and (ii) your adjusted tax basis in your shares of Neon common stock exchanged therefor. If you have a loss in your shares of Neon common stock, in certain circumstances, you may not be able to recognize your loss even if the Merger generally fails to qualify as a nonrecognition transaction. You are urged to consult your own tax advisor regarding the consequences of the Merger to you if the Merger is treated as a taxable transaction.

*Backup Withholding and Information Reporting on the Merger*

Payments of cash made to you in connection with the Merger may be subject to information reporting and "backup withholding" unless you:

- provide a correct taxpayer identification number and any other required information to the exchange agent, or
- are otherwise exempt from backup withholding.

You generally may establish your exempt status by providing the required certification on IRS Form W-9. You should consult your tax advisor regarding the application of the U.S. information reporting and backup withholding rules.

Backup withholding is not an additional tax. Amounts withheld as backup withholding may be credited against your U.S. federal income tax liability, and you may request a refund of any excess amounts withheld under the backup withholding rules by timely filing the appropriate claim for refund with the IRS and timely furnishing any required information.

You will be required to retain records pertaining to the Merger. Each U.S. holder who is required to file a U.S. federal income tax return and who is a "significant holder" that receives BioNTech ADSs in the Merger will be required to file a statement with the holder's U.S. federal income tax return setting forth such holder's tax basis in the shares of Neon common stock surrendered and the fair market value of the BioNTech ADSs and cash, if any, received in the Merger. A "significant holder" is a holder of Neon capital stock who, immediately before the Merger, owned at least 5% (by vote or value) of the total outstanding stock of Neon prior to the Merger or had an aggregate tax basis in securities of Neon of $1,000,000 or more.

## MATERIAL GERMAN TAX CONSIDERATIONS

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.

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 proxy statement/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 proxy statement/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, and given that the ADSs represent a beneficial ownership interest in the underlying BioNTech Shares the ADSs should 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 BioNTech Shares (*i.e.*, the financial institution on behalf of which the BioNTech 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 other tax-exempt investors.

This discussion does not address the treatment of ADSs that are (i) held in connection with a permanent establishment or fixed base through which a U.S. treaty beneficiary carries on business or performs personal services in Germany or (ii) part of business assets for which a permanent representative in Germany has been appointed.

***General Rules for the Taxation of Holders Not Tax Resident in Germany***

Non-German resident holders of ADSs are subject to German taxation with respect to German source income (*beschränkte Steuerpflicht*). According to the ADR Tax Circular, income from the shares should be attributed to the holder of the ADSs for German tax purposes. As a consequence, income from the ADSs should be treated as German source income.

***German Withholding Taxation of Dividends of the U.S. Treaty Beneficiaries of the ADSs***

Generally, the full amount of a dividend distributed by BioNTech to a non-German resident holder which does not maintain a permanent establishment or other taxable presence in Germany is subject to (final) German withholding tax at an aggregate rate of 26.375%. 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 a non-German resident holder which does not maintain a permanent establishment or other taxable presence in Germany would be treated as German source income and be subject to German tax if the ADSs qualify as a 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 C 1-S2252/08/10004 :017, as most recently amended by circular dated September 16, 2019, reference number IV C 1-S2252/08/10004 :027, provides that taxes need not be withheld when the holder of the custody account is not a resident of Germany for tax purposes and the income is not subject to German taxation. The circular further states that there is no obligation to withhold such tax even if the non-resident holder owns 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 which qualifies as a non-German company 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.

## DESCRIPTION OF BIONTECH SHARE CAPITAL AND ARTICLES OF ASSOCIATION (*SATZUNG*)

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 proxy statement/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, including an amount of €5,524,506 relating to 5,524,506 ordinary shares held in treasury. 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 BioNTech 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, under certain conditions, 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 represented at the time such resolution is adopted to exclude preemptive rights both where the general meeting itself resolves that the new securities shall be issued under exclusion of preemptive rights 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 under exclusion of preemptive rights; 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 (or on any other stock exchange or on 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 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 BioNTech 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 BioNTech Shares may, subject to certain formal prerequisites, request that a shareholders' meeting be convened. Shareholders representing in the aggregate at least five percent of BioNTech 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 generally 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*) may be resolved upon request of a shareholder holding 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.

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| Board System | A European stock corporation (*Societas Europaea*) may choose to have a two-tier board structure composed of the Management Board (*Vorstand*) and the Supervisory Board (*Aufsichtsrat*). We have chosen this structure.<br><br>The Management Board is responsible for running the company's affairs and representing the company in dealings with third parties.<br><br>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.<br><br>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.<br><br>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 | 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. |

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| | the fulfilment of co-determination requirements. The articles of association of the company must specify if the Supervisory Board has more than three members.<br><br>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.<br><br>Under European law, a member of the Supervisory Board of a company may be elected for a term of up to six years. The articles of association may provide for a shorter term. Our Supervisory Board members are, if the general meeting does not resolve on a shorter term, elected for a | 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. |

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| | 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.<br><br>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 least 5% of the company's share capital are entitled to request that an extraordinary shareholders' meeting be convened. In the | 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. |

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| | 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.<br><br>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.<br><br>With respect to Management Board meetings, a Management Board member may transmit its (written or verbal) vote via another Management Board member.<br><br>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 | Under Delaware law, stockholders have no preemptive rights to subscribe to |

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| | law, existing shareholders have a statutory subscription right for any additional issue of shares or any security convertible into shares pro rata to the nominal value of their respective holdings in the company, unless (i) shareholders representing three-quarters of the registered share capital present at the shareholders' meeting have resolved upon the whole or partial exclusion of the subscription right and (ii) there exists good and objective cause for such exclusion. No separate resolution on the exclusion of subscription rights is required if all shareholders waive their statutory subscription rights. | additional issues of stock or to any security convertible into such stock unless, and except to the extent that, such rights are expressly provided for in the certificate of incorporation. |
| Authority to Allot | Under applicable European and German law, the Management Board may not allot shares, grant rights to subscribe for or to convert any security into shares unless a shareholder resolution to that effect has been passed at the company's shareholders' meeting granting the Management Board with such authority—subject to the approval of the Supervisory Board—in each case in accordance with the provisions of the German Stock Corporation Act. | Under Delaware law, if the corporation's certificate of incorporation so provides, the board of directors has the power to authorize the issuance of stock. It may authorize capital stock to be issued for consideration consisting of cash, any tangible or intangible property or any benefit to the corporation or any combination thereof. It may determine the amount of such consideration by approving a formula. In the absence of actual fraud in the transaction, the judgment of the directors as to the value of such consideration is conclusive. |
| Liability of Directors and Officers | Under German law, any provision, whether contained in the company's articles of association or any contract or otherwise, that purports to exempt a Management or Supervisory Board member from any liability that would otherwise attach to such board member in connection with any negligence, default, breach of duty or breach of trust in relation to the company is void.<br><br>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 when it is unable to fulfill its third party obligations, certain tortious conduct or | 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:<br>• any breach of the director's duty of loyalty to the corporation or its stockholders;<br>• acts or omissions not in good faith or that involve intentional misconduct or a knowing violation of law;<br>• intentional or negligent payment of unlawful dividends or stock purchases or redemptions; or |

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| | special circumstances, only the company has the right to claim damages from members of either board. The company may waive claims for damages against a negligent Management or Supervisory Board member only after the expiry of three years. | • any 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:<br>• the approval of the board of directors; and<br>• 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 | 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 |

| European Union/Federal Republic of German | Delaware |
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| duties of Management and Supervisory Board members is generally determined by European and German legislation and by the courts.<br><br>Statutory and fiduciary duties of members of the Management Board to the company include, among others:<br>• to act in accordance with the law, the company's articles of association and the rules of procedure for the Management Board, if any;<br>• to report to the Supervisory Board on a regular basis as well as on certain important occasions;<br>• to exercise reasonable care, skill and diligence;<br>• to maintain a proper accounting system;<br>• to not compete, directly or indirectly, with the company without permission by the supervisory board; and<br>• to secure that no further transactions are made in case of insolvency.<br><br>Statutory and fiduciary duties of members of the Supervisory Board to the company include, among others:<br>• to effectively supervise the Management Board's handling of the company's affairs;<br>• to evaluate and issue a resolution on certain transactions which can only be conducted by the Management Board after approval of the Supervisory Board;<br>• to approve the company's financial statements;<br>• to appoint the Management Board members and to represent the company in transactions | 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.<br><br>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.<br><br>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.<br><br>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. |

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| | between the company and members of the Management Board; and<br>• to approve service contracts between individual members of the Supervisory Board and the company. | |
| 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 generally 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.<br><br>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.<br><br>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.<br><br>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.<br><br>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 | 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:<br>• 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<br>• either (i) allege with particularity the efforts made by the plaintiff to obtain the action the plaintiffdesires 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.<br><br>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. |

| European Union/Federal Republic of German | Delaware |
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| 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. | |

**Stock Exchange Listing**

ADSs representing BioNTech Shares are listed on Nasdaq under the symbol "BNTX."

## DESCRIPTION OF THE BIONTECH ADSs

### 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 proxy statement/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 "Certain Material U.S. Federal Income Tax Considerations" and "Material German Tax Considerations" included elsewhere in this proxy statement/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 receive no value for them.** The depositary will exercise or distribute rights only if we ask it to and provide satisfactory assurances to the depositary that it is legal to do so. If the depositary will exercise rights, it will purchase the securities to which the rights relate and distribute those securities or, in the case of shares, new ADSs representing the new shares, to subscribing ADS holders, but only if ADS holders have paid the exercise price to the depositary. U.S. securities laws may restrict the ability of the depositary to distribute rights or ADSs or other securities issued on exercise of rights to all or certain ADS holders, and the securities distributed may be subject to restrictions on transfer.

*Other Distributions.* The depositary will send to ADS holders anything else we distribute on deposited securities by any means it thinks is legal, fair and practical. If it cannot make the distribution in that way, the depositary has a choice. It may decide to sell what we distributed and distribute the net proceeds, in the same way as it does with cash. Or, it may decide to hold what we distributed, in which case ADSs will also represent the newly distributed property. However, the depositary is not required to distribute any securities (other than ADSs) to ADS holders unless it receives satisfactory evidence from us that it is legal to make that distribution. The depositary may sell a portion of the distributed securities or property sufficient to pay its fees and expenses in connection with that distribution. U.S. securities laws may restrict the ability of the depositary to distribute securities to all or certain ADS holders, and the securities distributed may be subject to restrictions on transfer.

The depositary is not responsible if it decides that it is unlawful or impractical to make a distribution available to any ADS holders. We have no obligation to register ADSs, shares, rights or other securities under the Securities Act. We also have no obligation to take any other action to permit the distribution of ADSs, shares, rights or anything else to ADS holders. **This means that you may not receive the distributions we make on our shares or any value for them if it is illegal or impractical for us to make them available to you**.

**Deposit, Withdrawal and Cancellation**

***How are ADSs issued?***

The depositary will deliver ADSs if you or your broker deposits shares or evidence of rights to receive shares with the custodian. Upon payment of its fees and expenses and of any taxes or charges, such as stamp taxes or stock transfer taxes or fees, the depositary will register the appropriate number of ADSs in the names you request and will deliver the ADSs to or upon the order of the person or persons that made the deposit.

***How can ADS holders withdraw the deposited securities?***

You may surrender your ADSs to the depositary for the purpose of withdrawal. Upon payment of its fees and expenses and of any taxes or charges, such as stamp taxes or stock transfer taxes or fees, the depositary will

deliver the shares and any other deposited securities underlying the ADSs to the ADS holder or a person the ADS holder designates at the office of the custodian. Or, at your request, risk and expense, the depositary will deliver the deposited securities at its office, if feasible. However, the depositary is not required to accept surrender of ADSs to the extent it would require delivery of a fraction of a deposited share or other security. The depositary may charge you a fee and its expenses for instructing the custodian regarding delivery of deposited securities.

***How do ADS holders interchange between certificated ADSs and uncertificated ADSs?***

You may surrender your ADR to the depositary for the purpose of exchanging your ADR for uncertificated ADSs. The depositary will cancel that ADR and will send to the ADS holder a statement confirming that the ADS holder is the registered holder of uncertificated ADSs. Upon receipt by the depositary of a proper instruction from a registered holder of uncertificated ADSs requesting the exchange of uncertificated ADSs for certificated ADSs, the depositary will execute and deliver to the ADS holder an ADR evidencing those ADSs.

**Voting Rights**

***How do ADS holders vote?***

ADS holders may instruct the depositary how to vote the number of deposited shares their ADSs represent. If we request the depositary to solicit your voting instructions (and we are not required to do so), the depositary will notify you of a shareholders' meeting and send or make voting materials available to you. Those materials will describe the matters to be voted on and explain how ADS holders may instruct the depositary how to vote. For instructions to be valid, they must reach the depositary by a date set by the depositary. The depositary will try, as far as practical, subject to the laws of the State of New York and the provisions of our articles of association or similar documents, to vote or to have its agents vote the shares or other deposited securities as instructed by ADS holders. If we do not request the depositary to solicit your voting instructions, you can still send voting instructions, and, in that case, the depositary may try to vote as you instruct, but it is not required to do so.

**Except by instructing the depositary as described above, you won't be able to exercise voting rights unless you surrender your ADSs and withdraw the shares. However, you may not know about the meeting enough in advance to withdraw the shares.** In any event, the depositary will not exercise any discretion in voting deposited securities and it will only vote or attempt to vote as instructed or as described in the following sentence. If (i) we asked the depositary to solicit your instructions at least 30 days before the meeting date, (ii) the depositary does not receive voting instructions from you by the specified date and (iii) we confirm to the depositary that:

- we wish the depositary to vote uninstructed shares;
- we reasonably do not know of any substantial shareholder opposition to a particular question; and
- the particular question is not materially adverse to the interests of shareholders,

the depositary will consider you to have authorized and directed it to vote the number of deposited securities represented by your ADSs in favor of any resolution that we proposed in the invitation to the shareholders' meeting.

We cannot assure you that you will receive the voting materials in time to ensure that you can instruct the depositary to vote your shares. In addition, the depositary and its agents are not responsible for failing to carry out voting instructions or for the manner of carrying out voting instructions. **This means that you may not be able to exercise voting rights and there may be nothing you can do if your shares are not voted as you requested.**

In order to give you a reasonable opportunity to instruct the depositary as to the exercise of voting rights relating to deposited securities, if we request the depositary to act, we agree to give the depositary notice of any such meeting and details concerning the matters to be voted upon at least 30 days in advance of the meeting date.

**Fees and Expenses**

| *Persons depositing or withdrawing shares or ADS holders must pay:* | *For:* |
|---|---|
| $5.00 (or less) per 100 ADSs (or portion of 100 ADSs) | Issuance of ADSs, including issuances resulting from a distribution of shares or rights or other property |
| | Cancellation of ADSs for the purpose of withdrawal, including if the deposit agreement terminates |
| $.05 (or less) per ADS | Any cash distribution to ADS holders |
| A fee equivalent to the fee that would be payable if securities distributed to you had been shares and the shares had been deposited for issuance of ADSs | Distribution of securities distributed to holders of deposited securities (including rights) that are distributed by the depositary to ADS holders |
| $.05 (or less) per ADS per calendar year | Depositary services |
| Registration or transfer fees | Transfer and registration of shares on our share register to or from the name of the depositary or its agent when you deposit or withdraw shares |
| Expenses of the depositary | Cable and facsimile transmissions (when expressly provided in the deposit agreement) |
| | Converting foreign currency to U.S. dollars |
| Taxes and other governmental charges the depositary or the custodian has to pay on any ADSs or shares underlying ADSs, such as stock transfer taxes, stamp duty or withholding taxes | |
| Any charges incurred by the depositary or its agents for servicing the deposited securities | |

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 BioNTech Shares from an exchange outside the United States on which they were listed and do not list the shares on another exchange outside the United States;
- the depositary has reason to believe the ADSs have become, or will become, ineligible for registration on Form F-6 under the Act;
- we appear to be insolvent or enter insolvency proceedings;
- all or substantially all the value of the deposited securities has been distributed either in cash or in the form of securities;
- there are no deposited securities underlying the ADSs or the underlying deposited securities have become apparently worthless; or
- there has been a replacement of deposited securities.

If the deposit agreement will terminate, the depositary will notify ADS holders at least 90 days before the termination date. At any time after the termination date, the depositary may sell the deposited securities. After that, the depositary will hold the money it received on the sale, as well as any other cash it is holding under the deposit agreement, unsegregated and without liability for interest, for the pro rata benefit of the ADS holders that have not surrendered their ADSs. Normally, the depositary will sell as soon as practicable after the termination date.

After the termination date and before the depositary sells, ADS holders can still surrender their ADSs and receive delivery of deposited securities, except that the depositary may refuse to accept a surrender for the purpose of withdrawing deposited securities or reverse previously accepted surrenders of that kind that have not settled if it would interfere with the selling process. The depositary may refuse to accept a surrender for the purpose of withdrawing sale proceeds until all the deposited securities have been sold. The depositary will continue to collect distributions on deposited securities, but, after the termination date, the depositary is not required to register any transfer of ADSs or distribute any dividends or other distributions on deposited securities to the ADSs holder (until they surrender their ADSs) or give any notices or perform any other duties under the deposit agreement except as described in this paragraph.

**Limitations on Obligations and Liability**

***Limits on our Obligations and the Obligations of the Depositary; Limits on Liability to Holders of ADSs***

The deposit agreement expressly limits our obligations and the obligations of the depositary. It also limits our liability and the liability of the depositary. We and the depositary:

- are only obligated to take the actions specifically set forth in the deposit agreement without negligence or bad faith, and the depositary will not be a fiduciary or have any fiduciary duty to holders of ADSs;

- are not liable if we are or it is prevented or delayed by law or by events or circumstances beyond our or its ability to prevent or counteract with reasonable care or effort from performing our or its obligations under the deposit agreement;
- are not liable if we or it exercises discretion permitted under the deposit agreement;
- are not liable for the inability of any holder of ADSs to benefit from any distribution on deposited securities that is not made available to holders of ADSs under the terms of the deposit agreement, or for any special, consequential or punitive damages for any breach of the terms of the deposit agreement;
- have no obligation to become involved in a lawsuit or other proceeding related to the ADSs or the deposit agreement on your behalf or on behalf of any other person;
- may rely upon any documents we believe or it believes in good faith to be genuine and to have been signed or presented by the proper person;
- are not liable for the acts or omissions of any securities depository, clearing agency or settlement system; and
- the depositary has no duty to make any determination or provide any information as to our tax status, or any liability for any tax consequences that may be incurred by ADS holders as a result of owning or holding ADSs or be liable for the inability or failure of an ADS holder to obtain the benefit of a foreign tax credit, reduced rate of withholding or refund of amounts withheld in respect of tax or any other tax benefit.

In the deposit agreement, we and the depositary agree to indemnify each other under certain circumstances.

**Requirements for Depositary Actions**

Before the depositary will deliver or register a transfer of ADSs, make a distribution on ADSs, or permit withdrawal of shares, the depositary may require:

- payment of stock transfer or other taxes or other governmental charges and transfer or registration fees charged by third parties for the transfer of any shares or other deposited securities;
- satisfactory proof of the identity and genuineness of any signature or other information it deems necessary; and
- compliance with regulations it may establish, from time to time, consistent with the deposit agreement, including presentation of transfer documents.

The depositary may refuse to deliver ADSs or register transfers of ADSs when the transfer books of the depositary or our transfer books are closed or at any time if the depositary or we think it advisable to do so.

**Your Right to Receive the Shares Underlying your ADSs**

ADS holders have the right to cancel their ADSs and withdraw the underlying shares at any time except:

- when temporary delays arise because (i) the 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.

## COMPARISON OF SHAREHOLDER RIGHTS

The rights of BioNTech shareholders are currently governed by the laws of the European Union, the Federal Republic of Germany and BioNTech's Articles of Association (*Satzung*). The rights of Neon stockholders are currently governed by Delaware law and Neon's certificate of incorporation and bylaws. As a result of the Merger, Neon stockholders will be entitled to receive a portion of the Merger Consideration in BioNTech ADSs. Each BioNTech ADS represents one BioNTech Share. Following completion of the Merger, the rights of Neon stockholders who become holders of BioNTech ADSs in the Merger will be governed by the deposit agreement and influenced by the laws of the European Union, the Federal Republic of German and BioNTech's Articles of Association (*Satzung*).

The following discussion summarizes the material differences between the current rights of BioNTech shareholders and the current rights of Neon stockholders. These differences arise from differences between Delaware law and the laws of the Federal Republic of Germany and the European Union, the governing instruments of the two companies, and the securities laws and regulations governing the two companies.

Although it is impracticable to compare all of the aspects in which Delaware law and the laws of the Federal Republic of Germany and the European Union, and BioNTech's and Neon's governing instruments, differ with respect to equityholder rights, the following discussion summarizes certain material differences between them. This summary is not intended to be complete, and it is qualified in its entirety by reference to Delaware law, the laws of the Federal Republic of Germany and of the European Union, BioNTech's Articles of Association (*Satzung*) and Neon's certificate of incorporation and bylaws. In addition, the identification of some of the differences in the rights of equityholders as material is not intended to indicate that other differences that are equally important do not exist. BioNTech and Neon urge you to carefully read this entire proxy statement/prospectus, the relevant provisions of Delaware law and the laws of the Federal Republic of Germany and the European Union and the other documents to which BioNTech and Neon refer in this proxy statement/prospectus for a more complete understanding of the differences between the rights of a BioNTech shareholder and the rights of a Neon stockholder. For a description of the rights of holders of BioNTech ADSs, see "Description of the BioNTech ADSs." For information on how to obtain the governing instruments of BioNTech and Neon, see "Where You Can Find More Information." Neon stockholders are encouraged to obtain and read these documents.

| | **BioNTech Shareholder Rights** | **Neon Stockholder Rights** |
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| ***Share Capital:*** | As of the date of this proxy statement/prospectus, the issued and outstanding share capital of BioNTech as registered with the commercial register is EUR 226,779,744, divided into 226,779,744 registered shares (*Namensaktien*). All shares are shares with no par-value (*Stückaktien ohne Nennbetrag*) with a notional amount attributable to each ordinary share of EUR 1.00. | As of the record date, Neon had 28,931,978 shares of common stock issued and outstanding. |
| ***Authorized Capital:*** | Under § 4(5) of BioNTech's Articles of Association (*Satzung*), the Management Board is authorized to increase the share capital, on one or more occasions, by a total of up to €105,818,002 by issuing, on one or | The aggregate number of shares that Neon is authorized to issue is 160,000,000, consisting of (i) 150,000,000 shares of Neon common stock, par value $0.001 per share, and (ii) 10,000,000 shares of |

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| | 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. | undesignated preferred stock, par value $0.001 per share. |
| ***Conditional Capital:*** | Pursuant to § 4(6) of BioNTech's Articles of Association (*Satzung*), its share capital is conditionally increased by €21,874,806 through issuance of 21,874,806 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 BioNTech's ESOP to members of its Management Board and to certain of its employees.<br><br>Pursuant to § 4(7) of BioNTech's Articles of Association (*Satzung*), its share capital is conditionally increased by €87,499,260 through issuance of 87,499,260 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 BioNTech 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. | N/A |
| ***Preferred Stock:*** | As of the effective date of this proxy statement/prospectus, BioNTech has | The Neon Board, without further action by Neon stockholders, has the |

| | BioNTech Shareholder Rights | Neon Stockholder Rights |
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| | not issued any preferred stock (*Vorzugsaktien*). | authority to issue up to 10,000,000 shares of preferred stock in one or more series. The Neon Board has the authority to determine the terms of each series of preferred stock, within the limits of the Neon charter, the Neon bylaws and the laws of the state of Delaware, and the Neon Board could take that action without stockholder approval. These terms include the number of shares in a series, voting rights, if any, preferences and the relative, participating, optional or other special rights of the shares of each series and any qualifications, limitations and restrictions thereof. The issuance of Neon preferred stock could delay, defer or prevent a change in control of Neon.<br><br>As of the record date, Neon does not have any preferred stock issued and outstanding. |
| ***Dividend Rights:*** | Distributions of dividends on shares in BioNTech for a given fiscal year are generally determined by a process in which the Management Board and Supervisory Board submit a proposal to BioNTech's annual general shareholders' meeting held in the subsequent fiscal year and such annual general shareholders' meeting resolves that dividends be distributed.<br><br>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 | Holders of shares of Neon common stock are entitled to receive dividends when and if declared by the Neon Board out of funds legally available therefor, subject to any statutory or contractual restrictions on the payment of dividends. |

| | BioNTech Shareholder Rights | Neon Stockholder Rights |
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| | deducted when calculating the profit available for distribution. Further, instead of appropriating net profits to the shareholders as dividends, the general meeting may also resolve to carry profits forward to the subsequent year or transfer them to BioNTech's reserves.<br><br>BioNTech's 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. | |
| ***Purchase and Redemption Rights:*** | BioNTech'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 BioNTech's share capital at the time of the relevant resolution or at the time the authorization is exercised. These shares held by BioNtech (including shares attributable to it pursuant to the German Stock Corporation Act (*Aktiengesetz*, 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 of BioNTech's shareholders, (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.<br><br>Under the abovementioned authorization, BioNTech may not | Shares of Neon common stock do not have preemptive, subscription, or conversion rights or redemption or sinking fund provisions. |

| | BioNTech Shareholder Rights | Neon Stockholder Rights |
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| | acquire treasury shares for trading purposes. Further, the treasury shares so acquired may only be used as specified in the authorization.<br><br>In addition to the abovementioned authorization by the shareholders' meeting, the German Stock Corporation Act (*Aktiengesetz*, AktG) allows for the purchase of treasury shares in other, very limited circumstances, such as to avert serious harm from BioNTech, to offer such treasury shares to employees of BioNTech or is affiliates or by way of universal succession.<br><br>BioNTech may redeem shares only under very limited circumstances. For example, BioNTech may —subject to certain limitations—redeem treasury shares. A compulsory redemption of shares however is—also subject to further limitations—only possible if the Articles of Association (*Satzung*) in the version in effect prior to the issuance of the relevant shares had provided so. The Articles of Association of BioNTech as in effect as of the date of effective date of this proxy statement/prospectus does not allow for a compulsory redemption of shares. | |
| ***Preemptive Rights:*** | When BioNTech issues new shares, convertible bonds, bonds with warrants, profit participation rights or participating bonds, its shareholders generally have preemptive rights. 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*).<br><br>Further, it is possible for a shareholder resolution approved by | Shares of Neon common stock do not have preemptive rights. |

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| | three-quarters of the share capital represented at the time such resolution is adopted to exclude preemptive rights both where the general meeting itself resolves that the new securities shall be issued under exclusion of preemptive rights and in relation to the authorized capital, i.e., an authorization to the Management Board to, with the consent of the Supervisory Board, as the case may be, resolve on the issuance of new securities under exclusion of preemptive rights; 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.<br><br>Under BioNTech's 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 certain circumstances. See "Description of Share Capital and Articles of Association (*Satzung*)—Future Changes to Share Capital—Preemptive Rights." | |
| ***Inspection Rights:*** | Pursuant to German law the shareholders of BioNTech do not have inspection rights. However, in the general meeting a shareholder may request any information | Under Section 220 of the DGCL, a stockholder or his agent has a right to inspect the corporation's stock ledger, a list of all of its stockholders and its other books and records |

| | BioNTech Shareholder Rights | Neon Stockholder Rights |
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| | pertaining to "matters of the company" (*Angelegenheiten der Gesellschaft*) that is reasonably required to evaluate a subject matter on the meeting agenda, subject to certain exceptions specified in the German Stock Corporation Act (*Aktiengesetz*, AktG). | during the usual hours of business upon written demand stating his purpose (which must be reasonably related to such person's interest as a stockholder). If the corporation refuses to permit such inspection or refuses to reply to the request within five business days of the demand, the stockholder may apply to the Delaware Court of Chancery for an order to compel such inspection. |
| ***Appraisal Rights:*** | Appraisal rights persist in the event of a merger, certain forms of a de-merger and a change of the organizational form of BioNTech, in each case subject to certain prerequisites and exceptions, as well as where BioNTech enters into a domination agreement or a profit transfer agreement as the controlled entity. Where such rights apply, the relevant shareholder is entitled to dispose of its shares at a compensation equal to their fair value. The compensation is to be set in the transaction documentation. Where it falls short of the value the shareholder can make a request to the court to increase the compensation accordingly. | Under Section 262 of the DGCL a stockholder of a Delaware corporation generally has appraisal rights in connection with certain mergers or consolidations in which the corporation is participating, subject to specified procedural requirements. The DGCL does not confer appraisal rights, however, if the corporation's stock is either (1) listed on a national securities exchange, or (2) held of record by more than 2,000 holders.<br><br>Even if a corporation's stock meets these requirements, the DGCL still provides appraisal rights if shareholders of the corporation are required to accept for their stock in certain mergers or consolidations anything other than:<br>• shares of stock of the corporation surviving or resulting from such merger or consolidation, or depository receipts in respect thereof;<br>• shares of stock of any other corporation, or depository receipts in respect thereof, which shares of stock (or depository receipts in respect thereof) or depository receipts at the effective date of the merger or consolidation will be either listed on a national securities exchange or held of record by more than 2,000 holders; |

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| | | • cash in lieu of fractional shares or fractional depository receipts described in the foregoing; or<br>• any combination of the foregoing.<br>In accordance with Section 262 of the DGCL, no appraisal rights are available to holders of shares of Neon common stock in connection with the Merger. |
| ***Voting Rights:*** | Each ordinary share of BioNTech carries one vote at a shareholders' meeting. | Each share of Neon common stock entitles the holder to one vote on each matter properly submitted to a vote of stockholders. |
| ***Votes on Certain Transactions:*** | Resolutions of the general meeting are, in accordance with BioNTech's 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. A majority of at least two thirds of the votes cast is required for amendments to the Articles of Association unless at least half of the stated capital is represented at the meeting, subject to the requirement of a greater majority in certain circumstances. 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 BioNTech's shares could potentially control the outcome of resolutions. | Except as otherwise required by law, holders of Neon common stock shall not be entitled to vote on any amendment to the Neon charter (including any amendment to a certificate of designations filed with respect to any series of preferred stock) that alters or changes the powers, preferences, rights or other terms of one or more outstanding series of preferred stock if the holders of such affected series are entitled to vote, either separately or together with the holders of one or more other such series, on such amendment pursuant to the Neon charter (including any certificate of designation filed with respect to any series of preferred stock) or pursuant to the DGCL. The vote of the holders of a majority of the voting power of the stock represented at a meeting at which a quorum is present is generally required to take stockholder action, unless a different vote is required by law or specifically required by the Neon charter or Neon bylaws, Delaware law, or Nasdaq. The holders of Neon preferred stock will have such voting rights (if any) as the Neon Board establishes, or as provided in the Neon charter or as determined by state law. |

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| | | The Neon charter does not provide for cumulative voting rights. |
| ***Amendment of Corporate Governance Documents:*** | BioNTech's corporate governance documents are the Articles of Association (*Satzung*) and the rules of procedure for the Management Board and for the Supervisory Board as well as by charters or rules of procedure for Supervisory Board Committees.<br><br>The Articles of Association may only be amended by a shareholders' resolution adopted with a majority of the votes cast unless less than half of the stated capital is represented at the meeting, in which case a majority of at least two thirds of the votes cast is required. Requirements of a greater majorities apply in certain circumstances. The Supervisory Board is competent to amend the rules of procedure for both itself and for the Management Board as well as the charters or rules of procedure for its committees. | Under Section 242 of the DGCL, the Neon charter may be amended upon a resolution by the Neon Board and approved by:<br>• the holders of a majority of the outstanding shares entitled to vote, and<br>• a majority of the outstanding shares of each class entitled to a class vote, if any.<br>The Neon charter provides that, for amendments to Article V, Section 1, Article VI, Section 3 and Article VII of the Neon charter, any amendment must be approved by the affirmative vote of not less than two thirds (2/3) of the outstanding shares of each class entitled to vote thereon as a class.<br><br>The Neon bylaws may be amended, or repealed by the approval of a majority of the directors of the Neon Board then in office. The Neon bylaws may also be amended or repealed at any annual meeting of stockholders, or special meeting of stockholders called for such purpose, by the affirmative vote of not less than two thirds (2/3) of the outstanding shares of capital stock entitled to vote on such amendment or repeal, voting together as a single class. |
| ***Shareholder Action by Written Consent:*** | In the case of a European stock corporation governed by German law such as BioNTech, shareholder action cannot be taken by written consent. | The Neon charter prohibits stockholder action by written consent for any action required or permitted to be taken by Neon stockholders at any annual or special meeting of stockholders.<br><br>The Neon bylaws may be amended, or repealed by the approval of a majority of the directors of the Neon Board then in office. The Neon bylaws may also be amended or |

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| | | repealed at any annual meeting of stockholders, or special meeting of stockholders called for such purpose, by the affirmative vote of not less than two thirds (2/3) of the outstanding shares of capital stock entitled to vote on such amendment or repeal, voting together as a single class. |
| ***Shareholders' Meetings:*** | 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.<br><br>Pursuant to BioNTech's Articles of Association (*Satzung*), shareholders' meetings may be held at its seat or in any municipality in Germany with more than 500,000 inhabitants. Generally, shareholders' meetings are convened by BioNTech's Management Board, or its Supervisory Board. Shareholders representing in the aggregate at least five percent of BioNTech Shares may, subject to certain formal prerequisites, request that a shareholders' meeting be convened. Shareholders representing in the aggregate at least five percent of BioNTech 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 or by registered mail.<br><br>Shareholders may participate in and vote in the shareholders' meeting if they are registered as a shareholder with BioNTech's share register. A shareholder who wishes to attend the shareholders' meeting—either in person or by proxy, which may also | The Neon bylaws provide that the annual meeting of stockholders shall be held at the hour, date and place within or without the United States which is fixed by the Neon Board, which time, date and place may subsequently be changed at any time by vote of the Neon Board. If no annual meeting of stockholders has been held for a period of thirteen (13) months after Neon's last annual meeting of stockholders, a special meeting in lieu thereof may be held, and such special meeting shall have all the force and effect of an annual meeting of stockholders. |

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| | be appointed by BioNTech (*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 BioNTech's Management Board). | |
| ***Shareholder Quorum:*** | In general, no quorum is required for the general meeting to adopt resolutions. However, where not at least half of the stated capital is represented at the meeting, resolutions to amend the articles require the majority of at least two thirds of the votes cast (subject to the requirement of a greater majority in certain circumstances). Specific quorums are required for the exercise of certain minority rights such as the right to require the Management Board that it convene a general meeting. | The Neon bylaws provide that a majority of the outstanding shares entitled to vote, present in person or represented by proxy, shall constitute a quorum at any meeting of stockholders. If less than a quorum is present at a meeting, the holders of voting stock representing a majority of the voting power present at the meeting or the presiding officer may adjourn the meeting from time to time, and the meeting may be held as adjourned without further notice. At such adjourned meeting at which a quorum is present, any business may be transacted which might have been transacted at the original meeting. The stockholders present at a duly constituted meeting may continue to transact business until adjournment, notwithstanding the withdrawal of enough stockholders to leave less than a quorum. |
| ***Shareholder Proposals and Shareholder Nominations of Directors:*** | The members of the Management Board of BioNTech are appointed by the Supervisory Board, with no say of the shareholders. However, the shareholders' meeting may pass a vote of no-confidence (*Vertrauensentzug durch die Hauptversammlung*), in which case the Supervisory Board may remove the relevant member of the Management Board from office.<br><br>The shareholders can make proposals as to whom the general meeting should elect as a Supervisory Board member. BioNTech's Articles of Association (*Satzung*) does not provide for nomination rights of individual shareholders. | The Neon bylaws provide that stockholders seeking to nominate candidates for election as directors or to bring business before an annual meeting of stockholders must provide timely notice of their proposal in writing to Neon's corporate secretary. As specified in the Neon bylaws, director nominations and the proposal of business to be considered by stockholders may be made only pursuant to a notice of meeting, brought specifically by or at the direction of the Neon Board or by a stockholder of record at the time of giving the stockholder's notice who is entitled to vote at the meeting and who has complied with the notice |

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| | | procedures that are provided in the Neon bylaws.<br><br>Generally, to be timely, a stockholder's notice must be received by Neon's corporate secretary at the principal executive offices of Neon not less than 90 days nor more than 120 days prior to the first anniversary of the preceding year's annual meeting. If the date of the annual meeting is more than 30 days before or more than 60 days after that anniversary date, however, notice by the stockholder must be delivered not later than the close of business on the 90th day prior to that annual meeting or the 10th day following the day on which Neon first publicly announces the date of that annual meeting. |
| ***Appointment and Number of Directors:*** | Pursuant to BioNTech's Articles of Association (*Satzung*), BioNTech must have at least two members on its Management Board. The Supervisory Board may determine that the Management Board is to consist of a higher number of members. The members of the Management Board of BioNTech are appointed by the Supervisory Board.<br><br>Pursuant to BioNTech's Articles of Association and applicable statutory law, the Supervisory Board of BioNTech must consist of at least four, but no more than twenty-one members. The members of BioNTech's Supervisory Board are elected by the shareholders' meeting. | The Neon charter provides that the number of directors will be fixed from time to time by resolution of the Neon Board. The Neon Board currently consists of eight directors. |
| ***Classification of the Board:*** | A European stock corporation may choose to have a two-tier board structure composed of the Management Board (*Vorstand*) and the Supervisory Board (*Aufsichtsrat*). BioNTech has chosen this structure.<br><br>The Management Board is responsible for running the | The Neon Board is classified into three classes. Each director is appointed for a three-year term. |

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| | company's affairs and representing the company in dealings with third parties.<br><br>The Supervisory Board has a control and supervisory function. The Supervisory Board does not actively manage BioNTech; however, certain Management Board actions require the approval of the Supervisory Board. | |
| ***Board Meetings:*** | If not otherwise required by mandatory law, the Management Board has a quorum if all members of the Management Board have been invited and at least half of its members participate in the adoption of the resolution. Members of the Management Board may cast their vote in writing, by telephone, by telefax, or by means of electronic media.<br><br>Unless mandatory law requires otherwise, the resolutions of the Management Board are passed by a majority of the votes cast, with abstentions not to be taken into account. In the event of a tie the chairperson—currently Prof Ugur Sahin—has the casting vote.<br><br>The Supervisory Board must convene twice every calendar half year, with the goal to convene every quarter. The Supervisory Board meeting has a quorum if at least three members participate in the adoption of the resolution, with members also participating if they abstain from voting. Resolutions of the Supervisory Board are in principle passed at meetings with personal attendance of the members. However, absent members may submit their written vote through another member of the Supervisory Board. Also, it is generally permissible for members to participate and cast their vote by | The Neon bylaws provide that the regular annual meeting of the Neon Board shall be held on the same date and at the same place as the Neon annual meeting following the close of such meeting of stockholders. Other regular meetings of the Neon Board may be held at such hour, date and place as the Neon Board may by resolution from time to time determine and publicize by means of reasonable notice given to any director who is not present at the meeting at which such resolution is adopted. Special meetings of the Neon Board may be called, orally or in writing, by or at the request of a majority of the directors, the Chairman of the Neon Board, if one is elected, or the President. The person calling any such special meeting of the Neon Board may fix the hour, date and place thereof.<br><br>At any meeting of the Neon, a majority of the total number of directors shall constitute a quorum for the transaction of business, but if less than a quorum is present at a meeting, a majority of the directors present may adjourn the meeting from time to time, and the meeting may be held as adjourned without further notice. Any business which might have been transacted at the meeting as originally noticed may be transacted at such adjourned meeting at which a quorum is present. The total number of directors includes |

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| | telephone. Further, the Supervisory Board may pass resolutions in writing, by telephone, fax, video conference or email, or in a combined form.<br><br>A resolution of the Supervisory Board requires a majority of the votes cast, with abstentions not being taken into account. In the event of a tie, the vote of the chairperson of the Supervisory Board, currently Helmut Jeggle, shall have the casting vote. | any unfilled vacancies on the Neon Board.<br><br>At any meeting of the Neon Board at which a quorum is present, the vote of a majority of the directors present shall constitute action by the Neon Board, unless otherwise required by law, by the Neon charter or Neon bylaws. |
| ***Board Committees:*** | The Supervisory Board may form sub-committees. Currently, the Supervisory Board has an Audit Committee, a Remuneration, Nominating and Corporate Governance Committee and a Capital Markets Committee. | Currently, the Neon Board has an Audit Committee, a Compensation Committee and a Nominating and Corporate Governance Committee. |
| ***Removal of Directors:*** | Pursuant to BioNTech's Articles of Association (*Satzung*) the members of BioNTech's Management Board are appointed by the Supervisory Board for a maximum period of five years with an opportunity to be reelected. 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 by the shareholders' meeting (*Vertrauensentzug durch die Hauptversammlung*). The shareholders themselves are not entitled to appoint or dismiss the members of the Management Board.<br><br>BioNTech's 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 | The Neon charter provides that, subject to the rights granted to any series of preferred stock, directors may only be removed for cause and only upon the affirmative vote of holders of at least two thirds (2/3) of the voting power of all then outstanding shares of stock then entitled to vote generally in the election of directors. |

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| | year after the election, i.e. for a period of approx. five years. 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, passed with the simple majority of the votes cast. | |
| ***Board Vacancies:*** | 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, also see *Board Meetings*. In case of emergencies, a vacant position on the Management Board may be filled by an individual appointed by the court.<br><br>Vacant positions on the Supervisory Board are filled in accordance with the general rules of appointment. Only under very limited circumstances may a vacant position on the Supervisory Board be filled by an individual appointed by the court. | The Neon bylaws provide that, subject to the rights granted to any series of preferred stock, any vacancies or newly created directorships on the Neon Board will be filled only by the affirmative vote of a majority of the directors then in office, even though less than a quorum, and not by the stockholders. |
| ***Limitation of Director Liability:*** | Under statutory law the members of the Management Board and of the Supervisory Board are liable towards the Company in case of a breach of their duties. Insofar as these duties derive from mandatory law, any contractual limitation of their liability is invalid. Enforcement of such claims in court is limited after five years.<br><br>Only under very limited circumstances are members of the Management Board or of the Supervisory Board liable vis-à-vis the Company's shareholders or vis-à-vis third parties. | The Neon charter provides that Neon directors shall not be personally liable to Neon or its stockholders for monetary damages for breach of his or her fiduciary duty as a director, except for liability (a) for any breach of the director's duty of loyalty to Neon or its stockholders, (b) for acts or omissions not in good faith or which involve intentional misconduct or a knowing violation of law, (c) under Section 174 of the DGCL or (d) for any transaction from which the director derived an improper personal benefit. |
| ***Directors and Officers Indemnity:*** | Pursuant to statutory law a German stock corporation is required to indemnify its Management Board members and Supervisory Board | The Neon charter provides that a director is not personally liable to Neon or its stockholders for monetary damages for breach of his |

| BioNTech Shareholder Rights | Neon Stockholder Rights |
| --- | --- |
| members where the relevant claim or loss does not result from a breach of duty. Otherwise the company must not do so, with agreements to the contrary being invalid.<br><br>Accordingly, none of the members of BioNTech's Management Board or Supervisory Board have entered into agreements that contain indemnification clauses with the Company or with third parties such as shareholders. | or her fiduciary duty as a director, except for liability (a) for any breach of the director's duty of loyalty to the Corporation or its stockholders, (b) for acts or omissions not in good faith or which involve intentional misconduct or a knowing violation of law, (c) under Section 174 of the DGCL or (d) for any transaction from which the director derived an improper personal benefit.<br><br>If the DGCL is amended after the effective date of the charter to authorize corporate action further eliminating or limiting the personal liability of directors, then the liability of a director of the Corporation shall be eliminated or limited to the fullest extent permitted by the DGCL, as so amended. Under Delaware law, Neon is also authorized to carry directors' and officers' insurance to protect Neon, its directors, officers and certain employees from some liabilities. The Neon bylaws further provide that Neon will pay the expenses incurred by a director in connection with any proceeding in which such director is involved by reason of fact that such indemnitee is or was a director of Neon, but only upon receipt of an undertaking by the director to repay all amounts so advanced if it should be ultimately determined by final judicial decision that the indemnitee is not entitled to indemnification for such expenses. The Neon bylaws provide that Neon may pay the expenses incurred by an executive officer in connection with any proceeding in which such executive officer is involved by reason of fact that such indemnitee is or was an executive officer of Neon, but only upon receipt of an undertaking by the officer to repay all amounts so advanced if it should be ultimately determined by final judicial decision that the indemnitee |

| | BioNTech Shareholder Rights | Neon Stockholder Rights |
|---|---|---|
| | | is not entitled to indemnification for such expenses.<br><br>Although Neon's charter provides directors with protection from awards for monetary damages for breaches of their duty of care, it does not eliminate such duty. In particular, Neon's charter has no effect on the availability of equitable remedies such as an injunction or rescission based on a director's breach of his or her duty of care. |
| ***Insurance:*** | BioNTech provides directors' and officers' liability insurance for the members of its Management and Supervisory Boards against civil liabilities, which they may incur in connection with their activities on behalf of BioNTech. | Under Delaware law, Neon is also authorized to carry directors' and officers' insurance to protect Neon, its directors, officers and certain employees from some liabilities. |
| ***Claims and 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 generally 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.<br><br>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 | Under the DGCL, any Neon stockholder may bring an action in Neon's name to procure a judgment in Neon's favor, also known as a derivative action, provided that the stockholder bringing the action is a holder of shares of Neon common stock at the time of the transaction to which the action relates or such stockholder's stock thereafter devolved by operation of law. |

| | BioNTech Shareholder Rights | Neon Stockholder Rights |
|---|---|---|
| | 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.<br><br>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 or the Supervisory Board for certain wrongdoings.<br><br>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. | |
| ***Conflicts of Interest Transactions:*** | BioNTech has adopted a Conflicts of Interest Policy which is applicable to, among others, the members of the Supervisory Board, the members of the Management Board and to employees. According to said policy | Neon has adopted a related party transactions policy. Pursuant to this policy, the audit committee of Neon has the primary responsibility for reviewing and approving or disapproving "related party |

| | BioNTech Shareholder Rights | Neon Stockholder Rights |
|---|---|---|
| | any actual, potential or perceived conflict of interest must be disclosed. If the conflict is transactional in nature and involves a member of the Management Board or the Supervisory Board, the Management Board or Supervisory Board, as the case may be, with the abstention of the conflicted member, shall decide whether to approve the transaction. | transactions," which are transactions between Neon and related persons in which the aggregate amount involved exceeds or may be expected to exceed $120,000 and in which a related person has or will have a direct or indirect material interest. For purposes of this policy, a related person is defined as a director, executive officer, nominee for director, or greater than 5% beneficial owner of Neon common stock, in each case since the beginning of the most recently completed year, and their immediate family members. |
| ***Certain Business Combinations:*** | Business combinations, irrespective of their volume and importance do not require shareholders' approval *per se*. Shareholders' approval will be necessary, however, where the combination involves corporate action that can be taken only on the basis of a shareholders' resolution such as an amendment to the Articles of Association (*Satzung*), the issuance of shares (where same needs to be resolved by the general meeting) or a merger where BioNTech itself is the transferring or the surviving entity. | Under Delaware law, only a majority of Neon outstanding voting power is required to approve mergers and other business combinations between Neon and third parties. Neon's charter does not require that a higher percentage of outstanding voting power approve such transactions.<br><br>Neon has not opted out of Section 203 of the DGCL, which provides that, if a person acquires 15% or more of the outstanding voting stock of a Delaware corporation, thereby becoming an "interested stockholder", that person may not engage in certain "business combinations" with the corporation, including mergers, purchases and sales of 10% or more of the assets of the corporation, stock purchases and other transactions pursuant to which the percentage of the corporation's stock owned by the interested stockholder increases (other than on a pro rata basis) or pursuant to which the interested stockholder receives a financial benefit from the corporation, for a period of three years after becoming an interested stockholder unless one of the following exceptions applies: (i) the Neon Board approved the acquisition of stock pursuant to which the person |

| BioNTech Shareholder Rights | Neon Stockholder Rights |
| --- | --- |
| | became an interested stockholder or the transaction that resulted in the person becoming an interested stockholder prior to the time that the person became an interested stockholder; (ii) upon consummation of the transaction that resulted in the person becoming an interested stockholder such person owned at least 85% of the outstanding voting stock of the corporation, excluding, for purposes of determining the voting stock outstanding, voting stock owned by directors who are also officers and certain employee stock plans; or (iii) the transaction is approved by the Neon Board and by the affirmative vote of two-thirds of the outstanding voting stock of Neon which is not owned by the interested stockholder. An "interested stockholder" also includes the affiliates and associates of a 15% or more owner and any affiliate or associate of the corporation who was the owner of 15% or more of the outstanding voting stock within the three-year period prior to determine whether a person is an interested stockholder. |

## EXCHANGE CONTROLS

There are currently no legal restrictions in the Federal Republic of Germany on international capital movements and foreign exchange transactions, except in limited embargo circumstances (*Teilembargo*) relating to certain areas, entities or persons as a result of applicable resolutions adopted by the United Nations and the European Union. Restrictions currently exist with respect to, among others, Belarus, 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.

## SUBMISSION OF STOCKHOLDER PROPOSALS

Only such business will be conducted at the Neon Special Meeting as will have been brought by the Neon Board before the Neon Special Meeting pursuant to the attached "Notice of Special Meeting of Neon Stockholders."

If the Merger is completed prior to the Neon 2020 annual meeting, Neon will not hold an annual meeting of its stockholders in 2020. If the Merger is consummated prior to the BioNTech 2020 annual meeting, Neon stockholders will be entitled to participate provided that they are registered with BioNTech's share register and have given notice of their attendance no later than seven days prior to the date of the stockholder's meeting. As noted with respect to the BioNTech procedures above, requesting the addition of one or several items to the agenda of any stockholders' meeting is possible for stockholders then representing in the aggregate at least five percent of ordinary shares in BioNTech or owning shares with an aggregate nominal value of at least €500,000 and, in both cases, being registered with BioNTech's share register no later than 25 days prior to the date of the stockholder's meeting. If the Merger is consummated after the BioNTech 2020 annual meeting, Neon stockholders will be entitled to participate, as shareholders of BioNTech, in the BioNTech 2021 annual meeting.

If the Merger Proposal is not approved by the requisite vote of the Neon stockholders or if the transactions contemplated by the Merger Agreement are not completed for any other reason, Neon will hold an annual meeting of its stockholders. In such case, and as previously stated in the Neon proxy statement filed with the SEC on April 26, 2019, any Neon stockholder who intends to present a proposal at such annual meeting of stockholders must ensure that the proposal is received by Neon's Corporate Secretary or sent to Neon's principal executive offices at Neon Therapeutics, Inc., 40 Erie Street, Suite 110, Cambridge, Massachusetts 02139, Attention: Corporate Secretary:

- on or before December 27, 2019, if the proposal is submitted for inclusion in Neon's proxy materials for that meeting pursuant to Rule 14a-8 under the Exchange Act; or
- on or after the close of business on February 19, 2020, and on or before the close of business on March 20, 2020, for directors to be nominated or other proposals to be properly presented at the 2020 annual meeting that are not to be included in Neon's proxy statement for the Neon 2020 annual meeting (or, if the date Neon holds its 2020 annual meeting of stockholders is advanced by more than 30 days, or delayed by more than 60 days, from June 18, 2020, notice must be received by Neon's Corporate Secretary at Neon Therapeutics, Inc., 40 Erie Street, Suite 110, Cambridge, Massachusetts 02139, Attention: Corporate Secretary, no earlier than the close of business on the 120th day prior to, and no later than the close of business on the 90th day prior to, the 2020 annual meeting of stockholders or the 10th day following the day on which public announcement of the date of the Neon annual meeting of stockholders is first made), in which case the notice of the proposal must meet certain requirements set forth in Neon's bylaws and Neon will not be required to include the proposal in Neon's proxy materials. All stockholder proposals must comply with Neon's bylaws and SEC regulations, including Rule 14a-8.

## OTHER BUSINESS AT THE NEON SPECIAL MEETING

Neon knows of no other matters that will be presented for consideration at the Neon Special Meeting.

## LEGAL MATTERS

The validity of the BioNTech Shares underlying the BioNTech ADSs to be issued in the Merger will be passed upon for BioNTech by Freshfields Bruckhaus Deringer LLP, Hamburg, Germany. Covington & Burling LLP, New York, New York, represented BioNTech in connection with the Merger and in the preparation of this proxy statement/prospectus. Members of Freshfields Bruckhaus Deringer LLP are the beneficial owners of less than 1% of our ordinary shares.

## EXPERTS

The consolidated financial statements of BioNTech as of December 31, 2019 and 2018 and for each of the years in the three-year period ended December 31, 2019 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 as of December 31, 2019 and 2018 and for each of the two years in the period ended December 31, 2019 included in the registration statement have been so included in reliance on the report (which contains an explanatory paragraph relating to Neon'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 JUDGMENTS

BioNTech is incorporated and currently existing under European laws and the laws of the Federal Republic of Germany. In addition, all of BioNTech's directors and officers reside outside of the United States and BioNTech's assets and those of its 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 BioNTech or those persons in the United States or to enforce in the United States judgments obtained in U.S. courts against BioNTech 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 its supervisory Board and Management Board, its 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 BioNTech, certain members of its Management and Supervisory Boards and senior management and the experts named in this proxy statement/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 BioNTech, the members of its Management Board, Supervisory Board, senior management or the experts named in this proxy statement/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

BioNTech has filed a registration statement on Form F-4, including the exhibits and annexes thereto, with the SEC under the Act, to register the BioNTech Shares that Neon stockholders will receive in connection with the Merger. This proxy statement/prospectus, which is part of the registration statement as well as a proxy statement with respect to the Neon Special Meeting, does not contain all of the information set forth in the registration statement and the exhibits to the registration statement, and some parts have been omitted in accordance with the rules and regulations of the SEC. BioNTech may also file amendments to the registration statement. For further information, you are referred to the registration statement and the exhibits and schedules filed as part of the registration statement. If a document has been filed as an exhibit to the registration statement, you are referred to the copy of the document that has been filed. Each statement in this proxy statement/prospectus relating to a document filed as an exhibit is qualified in all respects by the filed exhibit.

Neon files annual, quarterly, and current reports, proxy statements and other information with the SEC. The SEC maintains a website that contains reports, proxy and information statements, and other information regarding issuers, including Neon, who file electronically with the SEC. The address of that website is www.sec.gov. Investors may also consult Neon's and BioNTech's websites for more information about Neon and BioNTech, respectively. Neon's website is www.neontherapeutics.com. BioNTech's website is www.biontech.de. Information included on these websites is not incorporated by reference into and does not constitute a part of this proxy statement/prospectus.

Neon has supplied all information contained in this proxy statement/prospectus relating to Neon, and BioNTech has supplied all information contained in this proxy statement/prospectus relating to BioNTech.

Any person, including any beneficial owner, to whom this proxy statement/prospectus is delivered may request copies of this proxy statement/prospectus and any of the annexes incorporated by reference in this document or other information concerning Neon, without charge, by requesting them in writing or by telephone from Neon at the following address and telephone number:

Neon Therapeutics, Inc.
Attention: Corporate Secretary
40 Erie Street, Suite 110
Cambridge, Massachusetts 02139
Telephone number: (617) 337-4701

**THIS PROXY STATEMENT/PROSPECTUS DOES NOT CONSTITUTE THE SOLICITATION OF A PROXY IN ANY JURISDICTION TO OR FROM ANY PERSON TO WHOM OR FROM WHOM IT IS UNLAWFUL TO MAKE SUCH PROXY SOLICITATION IN THAT JURISDICTION. YOU SHOULD RELY ONLY ON THE INFORMATION CONTAINED OR INCORPORATED BY REFERENCE IN THIS PROXY STATEMENT/PROSPECTUS TO VOTE YOUR SHARES AT THE NEON SPECIAL MEETING. THE PARTIES HAVE NOT AUTHORIZED ANYONE TO PROVIDE YOU WITH INFORMATION THAT IS DIFFERENT FROM WHAT IS CONTAINED IN THIS PROXY STATEMENT/PROSPECTUS.**

**THIS PROXY STATEMENT/PROSPECTUS IS DATED APRIL 2, 2020. YOU SHOULD NOT ASSUME THAT THE INFORMATION CONTAINED IN THIS PROXY STATEMENT/PROSPECTUS IS ACCURATE AS OF ANY DATE OTHER THAN THAT DATE, AND THE MAILING OF THIS PROXY STATEMENT/PROSPECTUS TO STOCKHOLDERS DOES NOT CREATE ANY IMPLICATION TO THE CONTRARY.**

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## Report of Independent Registered Public Accounting Firm

To the Management and the Supervisory Board of BioNTech SE

### Opinion on the Financial Statements

We have audited the accompanying consolidated statements of financial position of BioNTech SE (the Company) as of December 31, 2019 and 2018, the related consolidated statements of operations, comprehensive loss, changes in equity and cash flows for each of the three years in the period ended December 31, 2019, 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, 2019 and 2018, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2019, 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/ Andreas Weigel
Wirtschaftsprüfer
(German Public Auditor)

Ernst & Young GmbH Wirtschaftsprüfungsgesellschaft

We have served as the Company's auditor since 2018.

Cologne, Germany
March 31, 2020

## Consolidated Statements of Financial Position

| *(in thousands)* Assets | Note | As of December 31, 2019 | As of December 31, 2018 |
|---|---|---|---|
| **Non-current assets** | | | |
| Intangible assets | 11 | € 89,434 | € 88,042 |
| Property, plant and equipment | 10 | 93,044 | 66,200 |
| Right-of-use assets | 19 | 55,018 | 49,766 |
| Other financial assets | 12 | — | 18 |
| **Total non-current assets** | | **€ 237,496** | **€ 204,025** |
| **Current assets** | | | |
| Inventories | 13 | 11,722 | 5,789 |
| Trade receivables | 14 | 11,913 | 18,938 |
| Other financial assets | 12 | 1,680 | 336 |
| Other assets | 15 | 9,069 | 9,164 |
| Income tax assets | | 756 | 891 |
| Deferred expense | | 5,862 | 2,348 |
| Cash and cash equivalents | 12 | 519,149 | 411,495 |
| **Total current assets** | | **€ 560,151** | **€ 448,961** |
| **Total assets** | | **€ 797,647** | **€ 652,986** |
| **Equity and liabilities** | | | |
| **Equity** | | | |
| Share capital* | 16 | 232,304 | 193,296 |
| Capital reserve* | 16 | 686,714 | 344,115 |
| Treasury shares* | 16 | (5,525) | — |
| Accumulated losses | | (424,827) | (245,771) |
| Other reserves | 17 | 4,826 | (25,487) |
| **Equity attributable to equity holders of the parent** | | **€ 493,492** | **€ 266,153** |
| Non-controlling interest | | — | 847 |
| **Total equity** | | **€ 493,492** | **€ 267,000** |
| **Non-current liabilities** | | | |
| Financial liabilities | 12 | 68,904 | 54,218 |
| Contract liabilities | 4 | 97,109 | 205,647 |
| **Total non-current liabilities** | | **€ 166,013** | **€ 259,865** |
| **Current liabilities** | | | |
| Tax provisions | | 150 | 297 |
| Provisions | | 762 | 710 |
| Financial liabilities | | 1,823 | — |
| Trade payables | 12 | 20,498 | 41,721 |
| Contract liabilities | 4 | 93,583 | 66,027 |
| Other financial liabilities | 12 | 13,836 | 8,266 |
| Other liabilities | 18 | 7,490 | 9,100 |
| **Total current liabilities** | | **€ 138,142** | **€ 126,121** |
| **Total liabilities** | | **€ 304,155** | **€ 385,986** |
| **Total equity and liabilities** | | **€ 797,647** | **€ 652,986** |

* Numbers have been adjusted to reflect capital increase due to 1:18 share split which occurred on September 18, 2019.

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

## Consolidated Statements of Operations

| *(in thousands, except per share data)* | Note | Years ended December 31, 2019 | 2018 | 2017 |
|---|---|---|---|---|
| Revenues from contracts with customers | 4 | € 108,589 | € 127,575 | € 61,598 |
| Cost of sales | 7.1 | (17,361) | (13,690) | (9,318) |
| **Gross profit** | | **€ 91,228** | **€ 113,885** | **€ 52,280** |
| Research and development expenses | 7.2 | (226,466) | (143,040) | (85,496) |
| Sales and marketing expenses | 7.3 | (2,718) | (3,041) | (6,603) |
| General and administrative expenses | 7.4 | (45,547) | (26,334) | (23,520) |
| Other operating income | 7.5 | 2,724 | 5,396 | 2,349 |
| Other operating expenses | | (739) | (720) | (288) |
| **Operating loss** | | **€(181,518)** | **€ (53,854)** | **€(61,277)** |
| Finance income | 7.6 | 4,122 | 8,046 | 2,133 |
| Finance expenses | 7.7 | (326) | (48) | (26,007) |
| Interest expense related to lease liability | 19 | (1,718) | (1,721) | (676) |
| Share of loss of equity method investees | | — | (84) | (78) |
| **Loss before tax** | | **€(179,440)** | **€ (47,662)** | **€(85,905)** |
| Income taxes | 8 | 268 | (600) | (45) |
| **Loss for the period** | | **€(179,172)** | **€ (48,262)** | **€(85,950)** |
| Attributable to: | | | | |
| Equity holders of the parent | | (179,056) | (48,019) | (85,653) |
| Non-controlling interests | | (116) | (243) | (297) |
| | | **€(179,172)** | **€ (48,262)** | **€(85,950)** |
| **Earnings per share** | | | | |
| *in EUR* | | | | |
| Basic & diluted, loss per share for the year attributable to ordinary equity holders of the parent | 9 | € (0.85) | € (0.25) | € (0.51) |

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

## Consolidated Statements of Comprehensive Loss

| *(in thousands)* | Note | Years ended December 31, 2019 | 2018 | 2017 |
|---|---|---|---|---|
| **Loss for the period** | | **€(179,172)** | **€(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 | | 77 | 10 | (23) |
| **Net other comprehensive income that may be reclassified to profit or loss in subsequent periods** | | **77** | **10** | **(23)** |
| **Other comprehensive income for the period, net of tax** | | **77** | **10** | **(23)** |
| **Comprehensive loss for the period, net of tax** | | **€(179,095)** | **€(48,252)** | **€(85,973)** |
| Attributable to: | | | | |
| Equity holders of the parent | | (178,979) | (48,009) | (85,677) |
| Non- controlling interests | | (116) | (243) | (297) |
| **Comprehensive loss for the period, net of tax** | | **€(179,095)** | **€(48,252)** | **€(85,973)** |

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

## Consolidated Statements of Changes in Stockholders' Equity

| | | Year ended December 31, 2019 | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | Equity attributable to equity holders of the parent | | | | | | | | |
| *(in thousands)* | Note | Share capital* | Capital reserve* | Treasury shares* | Accumulated losses | Other reserves | Foreign currency translation reserve | Total | Non-controlling interest | Total equity |
| **As of January 1, 2019** | | **€193,296** | **344,115** | **—** | **(245,771)** | **(25,474)** | **(13)** | **266,153** | **847** | **267,000** |
| Loss for the period | | — | — | — | (179,056) | — | — | **(179,056)** | (116) | **(179,172)** |
| Other comprehensive income | | — | — | — | — | — | 77 | **77** | — | **77** |
| **Total comprehensive income** | | **—** | **—** | **—** | **(179,056)** | **—** | **77** | **(178,979)** | **(116)** | **(179,095)** |
| Issuance of share capital | 16 | 8,126 | 41,748 | — | — | — | — | **49,874** | — | **49,874** |
| Capital increase Series B | 16 | 17,990 | 186,390 | (5,525) | — | — | — | **198,855** | — | **198,855** |
| Capital increase initial public offering (referred to as IPO) | 16 | 10,517 | 132,743 | — | — | — | — | **143,260** | — | **143,260** |
| Acquisition of non-controlling interest | 16 | 2,375 | (1,644) | — | — | — | — | **731** | (731) | **—** |
| Transaction costs | 16 | — | (16,638) | — | — | — | — | **(16,638)** | — | **(16,638)** |
| Share-based payments | 17 | — | — | — | — | 30,236 | — | **30,236** | — | **30,236** |
| **As of December 31, 2019** | | **€232,304** | **686,714** | **(5,525)** | **(424,827)** | **4,762** | **64** | **493,492** | **—** | **493,492** |

* Numbers have been adjusted to reflect capital increase due to 1:18 share split which occurred on September 18, 2019.

| | | Year ended December 31, 2018 | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | Equity attributable to equity holders of the parent | | | | | | | | |
| *(in thousands)* | Note | Share capital* | Capital reserve* | Treasury shares* | Accumulated losses | Other reserves | Foreign currency translation reserve | Total | Non-controlling interest | Total equity |
| **As of January 1, 2018** | | **€166,764** | **8,922** | **—** | **(197,753)** | **(27,206)** | **(23)** | **(49,296)** | **1,090** | **(48,206)** |
| Loss for the period | | — | — | — | (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 | 16 | 25,949 | 329,867 | — | — | — | — | **355,816** | — | **355,816** |
| Share based payments | 17 | — | — | — | — | 7,641 | — | **7,641** | — | **7,641** |
| Settlement of share-based payment plan | | 583 | 5,326 | — | — | (5,909) | — | **—** | — | **—** |
| **As of December 31, 2018** | | **€193,296** | **344,115** | **—** | **(245,771)** | **(25,474)** | **(13)** | **266,153** | **847** | **267,000** |

* Numbers have been adjusted to reflect capital increase due to 1:18 share split which occurred on September 18, 2019.

| *(in thousands)* | Note | Year ended December 31, 2017<br>Equity attributable to equity holders of the parent<br>Share capital* | Capital reserve* | Treasury shares* | Accumulated losses | Other reserves | Foreign currency translation reserve | Total | Non-controlling interest | Total equity |
|---|---|---|---|---|---|---|---|---|---|---|
| **As of January 1, 2017** | | **€ 3,270** | **172,416** | **—** | **(112,100)** | **(33,115)** | **—** | **30,471** | **1,387** | **31,858** |
| Loss for the period | | — | — | — | (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 | 16 | 163,494 | (163,494) | — | — | — | — | **—** | — | **—** |
| Share based payments | 17 | — | — | — | — | 5,909 | — | **5,909** | — | **5,909** |
| **As of December 31, 2017** | | **€166,764** | **8,922** | **—** | **(197,753)** | **(27,206)** | **(23)** | **(49,296)** | **1,090** | **(48,206)** |

* Numbers have been adjusted to reflect capital increase due to 1:18 share split which occurred on September 18, 2019.

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

## Consolidated Statements of Cash Flows

| *(in thousands)* | Years ended December 31, 2019 | 2018 | 2017 |
|---|---|---|---|
| **Operating activities** | | | |
| Loss for the period | €(179,172) | € (48,262) | € (85,950) |
| Income taxes | (268) | 600 | 45 |
| Loss before tax | **€(179,440)** | **€ (47,662)** | **€ (85,905)** |
| Adjustments to reconcile loss before tax to net cash flows: | | | |
| Depreciation and amortization of property, plant, equipment and intangible assets | 33,896 | 21,984 | 10,529 |
| Share-based payment expense | 30,235 | 7,641 | 5,909 |
| Net foreign exchange differences | 70 | 459 | 24,820 |
| (Gain)/Loss on disposal of property, plant and equipment | 542 | (14) | 15 |
| Finance income | (1,782) | (1,996) | (2,133) |
| Interest on lease liability | 1,718 | 1,721 | 676 |
| Finance expense | 326 | 48 | 53 |
| Share of loss of an associate and a joint venture | — | 84 | 78 |
| Working capital adjustments: | | | |
| Decrease/(Increase) in trade receivable and contract assets | 2,939 | (18,732) | (2,816) |
| Decrease/(Increase) in inventories | (5,798) | (1,253) | (574) |
| (Decrease)/Increase in trade and other payables, contract liabilities and provisions | (80,577) | (21,080) | (4,574) |
| Interest received | 1,256 | 1,996 | 2,133 |
| Interest paid | (2,044) | (1,769) | (729) |
| Income tax received (paid), net | 122 | (304) | (45) |
| **Net cash flows used in operating activities** | **€(198,537)** | **€ (58,877)** | **€ (52,562)** |
| **Investing activities** | | | |
| Purchase of property, plant and equipment | (38,592) | (29,901) | (24,320) |
| Proceeds from sale of property, plant and equipment | 21 | 705 | 5,193 |
| Purchase of intangibles assets | (32,488) | (37,256) | (33,422) |
| Acquisition of subsidiaries and businesses, net of cash acquired | (6,056) | — | — |
| **Net cash flows used in investing activities** | **€ (77,115)** | **€ (66,452)** | **€ (52,549)** |
| **Financing activities** | | | |
| Proceeds from issuance of share capital, net of costs | 375,351 | 361,725 | — |
| Proceeds from loans and borrowings | 11,000 | 5,600 | — |
| Payment of finance lease liabilities | (3,061) | (2,148) | (1,643) |
| **Net cash flows from/(used in) financing activities** | **€ 383,290** | **€365,177** | **€ (1,643)** |
| Net increase/(decrease) in cash and cash equivalents | 107,638 | 239,848 | (106,753) |
| Change in cash resulting from exchange rate differences | 16 | (459) | (24,820) |
| Cash and cash equivalents at January 1 | 411,495 | 172,106 | 303,680 |
| **Cash and cash equivalents at December 31** | **€ 519,149** | **€411,495** | **€ 172,106** |

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

## Notes to the Consolidated Financial Statements

### 1 Corporate Information

BioNTech SE is a limited company incorporated and domiciled in Germany. American Depository Shares (ADS) representing BioNTech's 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 International Financial Reporting Standards (IFRS) consolidated financial statements present the financial position and the results of operation of BioNTech SE and its subsidiaries, hereinafter also referred to as "BioNTech" 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.

During the year ended December 31, 2019 the following changes to the Group structure occurred:

- Two entities were founded in the United States: BioNTech USA Holding, LLC and BioNTech Research & Development, Inc. Both are wholly owned subsidiaries of BioNTech SE.
- reBOOST Management GmbH, was acquired through a share purchase which represents a related party transaction.

All entities listed above are included in the Group's consolidated financial statements.

Information on the Group's structure is provided in Note 5.

The consolidated financial statements of the Group for the year ended year ended December 31, 2019 were authorized for issue in accordance with a resolution of the directors on March 31, 2020.

### 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 prepares and publishes its consolidated financial statements in Euros. Unless otherwise stated, the numbers are rounded to thousands of Euros. Accordingly, numerical figures shown as totals in some tables may not be exact arithmetic aggregations of the figures that preceded them.

#### 2.2 Basis of Consolidation

The consolidated financial statements comprise the financial statements of the Company and its controlled investees (subsidiaries).

The Group controls an investee if, and only if, the Group has

- power over the investee (*i.e.*, existing rights that give it the current ability to direct the relevant activities of the investee);
- exposure, or rights, to variable returns from its involvement with the investee; and
- the ability to use its power over the investee to affect its returns.

Generally, there is a presumption that a majority of voting rights results in control.

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.

The statement of operations 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 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 operations. Any investment retained is recognized at fair value.

### 2.3 Summary of Significant Accounting Policies

#### 2.3.1 Business combinations and Goodwill

Business combinations are accounted for using the acquisition method. The cost of an acquisition is measured as the aggregate of the consideration transferred, which is measured at acquisition date fair value, and the amount of any non-controlling interests in the acquiree.

Goodwill is initially measured at cost as the excess of the aggregate of the consideration transferred and the amount recognized for non-controlling interests and any previous interest held over the net identifiable assets acquired and liabilities assumed.

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 or non-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 as non-current assets and liabilities, respectively.

#### 2.3.3 Fair Value Measurement

Fair value is a market-based measurement. For some assets and liabilities, observable market transactions or market information is available. For other assets and liabilities, observable market transactions or market information might not be available. When a price for an identical asset or liability is not observable, another valuation technique is used. To increase consistency and comparability in fair value measurements, there are three levels of the fair value hierarchy:

- Level 1 contains the use of quoted prices in active markets for identical assets or liabilities.

- Level 2 inputs are inputs other than quoted prices included within Level 1 that are observable for the asset or liability either directly or indirectly.
- Level 3 inputs are unobservable.

Within this hierarchy, estimated values are made by management based on reasonable assumptions, including other fair value methods.

For assets and liabilities that are recognized in the financial statements at fair value on a recurring basis, 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

**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.

**Recognition of Taxes**

Current and deferred tax items are recognized similar to the underlying transaction either in profit or loss, other comprehensive income or directly in equity.

The Group offsets current tax assets and current tax liabilities if, and only if, it has a legally enforceable right to set off the recognized amounts and intends either to settle on a net basis, or to realize the asset and settle the liability simultaneously. Deferred tax assets and deferred tax liabilities are only offset when the Group 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 operations 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 operations 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 early 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 incremental borrowing 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 subsequently measured at amortized cost using the effective interest method. It is remeasured when there is a change in future lease payments arising from a change in an index or rate, if there is a change in the 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 operations if the carrying amount of the right-of-use asset has been reduced to zero.

The Group presents right-of-use assets separately 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 | 2-25 |
| 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 operations on a straight-line basis over the lease term.

### 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 operations in the expense category that is consistent with the function of the intangible assets.

A summary of the useful lives applied to the Group's intangible assets is as follows:

| Intangible assets | Useful life (Years) |
|---|---|
| Intellectual property rights | 10-20 |
| Licenses | 3-20 |

Intangible assets with indefinite useful lives are not amortized, but are tested for impairment at least annually, or when there is an indication for impairment, either individually or at the level of a cash-generating unit (see Note 2.3.13 for further details). The assessment of indefinite life is reviewed annually to determine whether the indefinite life continues to be supportable. If not, the change in useful life from indefinite to finite is made on a prospective basis.

The Group has classified advanced payments on intangible assets as intangible assets which are not yet ready for use. Advanced payments on intangible assets are tested for impairment on an annual basis.

An intangible asset is derecognized upon disposal (*i.e.*, at the date the recipient obtains control) or when no future economic benefits are expected from its use or disposal. Any gain or loss arising upon derecognition of the asset (calculated as the difference between the net disposal proceeds and the carrying amount of the asset) is included in the statement of operations.

***Research and Development Costs***

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

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

Owing to the high risks up to the time that pharmaceutical products are approved, these criteria are not met in the Biotech business sector until regulatory approval has been provided. Therefore, the Group has not yet capitalized any development expenditures. The related expenditure is reflected in the statement of operations 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.

**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 rate (EIR) method, and are subject to impairment. Gains and losses are recognized in the statement of operations 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 have been transferred in terms of fulfilling the derecognition criteria.

**Impairment of Financial Assets**

An allowance for expected credit losses (ECLs) is 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 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.

**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 operations 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 operations.

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 operations.

### 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 finished goods: 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 a pre-tax discount rate that reflects current market assessments of the time value of money and the risks specific to the asset. In determining fair value less costs of disposal, recent market transactions 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 operations 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 operations 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

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 operations 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, 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 17.

These costs are recognized in cost of sales, research and development expenses, sales and marketing expenses or general and administrative expenses, together with a corresponding increase in equity (other reserves), 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 Standards applied for the First Time

In 2019 several new and amended standards and interpretations became effective. These were applied for the first time, but did not have an impact on the consolidated financial statements of the Group.

| Standards/Interpretations | 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 improvement cycle to IFRS 2015-2017 | January 1, 2019 |

## 2.5 Standard issued but not yet effective

The new and amended standards and interpretations that are issued, but not yet effective, up to the date of issuance of the Group's financial statements and that might have an impact on the Group's financial statements are disclosed below. The Group has not early adopted any standards and intends to adopt these new and amended standards and interpretations, if applicable, when they become effective.

| Standards/Interpretations | Date of application |
|---|---|
| Amendments to IFRS 3 Business Combinations | January 1, 2020 |
| Amendments to IFRS 9, IAS 39 and IFRS 7 Interest Rate Benchmark Reform | January 1, 2020 |
| Amendments to IAS 1 and IAS 8 Definition of Material | January 1, 2020 |
| Amendments to References to the Conceptual Framework in IFRS Standards | January 1, 2020 |
| Amendments to IAS 1 Presentation of Financial Statements: Classification of Liabilities as Current or Non-current | January 1, 2022 |

The Group does not expect a significant impact of the application of any of these amendments.

## 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 or non-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.

For the carrying amounts of the revenue recognition-related contract balances, see Note 4.

**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.

**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 when calculating the fair value of the share option.

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. For awards which were granted prior to the initial public offering, at a time where no quoted market prices existed, the valuation model assumptions included the option's underlying share price. For awards which were granted post the initial public offering, the grant date's share prices on the Nasdaq Global Select Market were included in the valuation.

For further disclosures relating to share-based payments, see Note 17.

**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 19.

**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.

For further disclosures relating to deferred taxes, see Note 8.

## 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:

| | Years ended December 31, | | |
|---|---|---|---|
| *(in thousands)* | **2019** | **2018** | **2017** |
| Revenues resulting from collaboration and license agreements | € 84,428 | €101,837 | €42,333 |
| *Genentech Inc.* | *64,026* | *49,536* | *27,829* |
| *Pfizer Inc.* | *14,348* | *7,174* | *—* |
| *Sanofi S.A.* | *4,233* | *41,712* | *5,665* |
| *Genmab A/S* | *—* | *2,740* | *6,765* |
| *Eli Lilly and Company* | *1,821* | *676* | *2,074* |
| Revenues from other sales transactions | 24,161 | 25,738 | 19,265 |
| **Total** | **€108,589** | **€127,575** | **€61,598** |

Through December 31, 2019, 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€64,026 was recognized as revenue in the year ended December 31, 2019 (k€49,536 in 2018; k€27,829 in 2017). As of December 31, 2019, k€131,556 upfront fees is recognized as deferred revenue within contract liabilities in the statement of financial position (as of December 31, 2018: k€195,582).

Through December 31, 2019, 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 the Company performs under the agreement and measured based on the costs incurred under the respective research programs. Of these upfront fees, k€4,233 was recognized as revenue in the year ended December 31, 2019 (k€8,535 in 2018; k€5,665 in 2017). As of December 31, 2019, k€34,483 upfront fees is recognized as deferred revenue within contract liabilities in the statement of financial position (as of December 31, 2018: k€38,716). 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.

Through December 31, 2019, BioNTech received k€43,044 in upfront fees from Pfizer under the Pfizer Collaboration Agreement. Such amounts are initially deferred and subsequently recognized as revenue as BioNTech performs under the agreement and measured based on the time elapsed under the respective research programs. Of these upfront fees, k€14,348 was recognized as revenue in the year ended December 31, 2019 (k€7,174 in 2018). As of December 31, 2019, k€21,522 upfront fees is recognized as deferred revenue within contract liabilities in the statement of financial position (as of December 31, 2018: k€35,870).

The transactions resulting from product sales that are included within the revenue from other sales transactions are as follows:

| | Years ended December 31, | | |
|---|---|---|---|
| *(in thousands)* | **2019** | **2018** | **2017** |
| Product sales of JPT Peptide Technologies GmbH | €12,111 | €10,748 | €10,652 |

During the year ended December 31, 2019, BioNTech recognized revenue of k€1,059 under a bill-and-hold transaction for which the customer already had obtained control. The bill-and-hold arrangement is substantive since the request to retain the product in BioNTech's facilities until January 2020 was initiated by the customer.

### 4.2 Contract Balances

| *(in thousands)* | December 31, 2019 | December 31, 2018 |
|---|---|---|
| Trade receivables | € 11,913 | € 18,938 |
| Contract liabilities | 190,692 | 271,674 |

Trade receivables are non-interest bearing and are generally settled within 20 to 30 days.

Contract assets are recognized for revenue earned from sales and services based on individual customer contracts of BioNTech Innovative Manufacturing Services GmbH. However, the customers' advance payments exceeded BioNTech's transferred goods and services for which a conditional right to consideration exists. Therefore, only contract liabilities net of contract assets are presented as per December 31, 2019 and December 31, 2018, respectively.

Contract liabilities include mainly upfront fees received from BioNTech's major collaboration and license agreements. The outstanding balances of these accounts decreased during the year ended December 31, 2019 as revenues resulting from these agreements exceeded further payments received from the collaborators due to the achievement of milestones. During the year ended December 31, 2019, BioNTech did not receive upfront fees or an unconditional right of consideration from the collaboration and license agreements (year ended December 31, 2018: k€41,120) and recognized revenues resulting from collaboration and license agreements of k€82,607 (during the year ended December 31, 2018: k€65,068), which reduced the contract liabilities. In addition, during the year ended December 31, 2019, a milestone payment of k€1,821 was received from the Eli Lilly and Company collaboration agreement and recorded as revenue.

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

| | Years ended December 31, | | |
|---|---|---|---|
| *(in thousands)* | 2019 | 2018 | 2017 |
| Amounts included in contract liabilities at the beginning of the year | €82,607 | €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. In case the contractual activities progress, the achievement of development milestones will be used to measure the progress toward complete satisfaction.

The deferred revenue allocated to the remaining performance obligations (unsatisfied or partially unsatisfied) as at year-end are as follows:

| *(in thousands)* | December 31, 2019 | December 31, 2018 |
|---|---|---|
| Within one year | € 90,453 | € 64,522 |
| More than one year | 97,109 | 205,647 |
| **Total** | **€ 187,562** | **€ 270,169** |

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 at an amount of k€3,130 (December 31, 2018: k€1,505).

## 5 Group information

### Information about Subsidiaries

The consolidated financial statements of the Group include the following subsidiaries:

| Name | Country of incorporation | Registered office | % equity interest December 31, 2019 | % equity interest December 31, 2018 |
|---|---|---|---|---|
| BioNTech RNA Pharmaceuticals GmbH | Germany | Mainz | 100% | 100% |
| BioNTech Delivery Technologies GmbH (previously BioNTech Protein Therapeutics GmbH) | Germany | Halle (previously Mainz) | 100% | 100% |
| BioNTech Diagnostics GmbH | Germany | Mainz | 100% | 100% |
| BioNTech Small Molecules GmbH | Germany | Mainz | 100% | 100% |
| BioNTech IVAC GmbH (previously BioNTech Business Services GmbH) | Germany | Mainz | 100% | 100% |
| BioNTech Austria Beteiligungen GmbH | Austria | Vienna | 100% | 100% |
| BioNTech Innovative Manufacturing Services GmbH | Germany | Idar - Oberstein | 100% | 100% |
| reBOOST Management GmbH | Germany | Mainz | 100% | n/a |
| JPT Peptide Technologies GmbH | Germany | Berlin | 100% | 100% |
| JPT Inc. (previously TheraCode JPT Inc.) | United States | Acton | 100% | 100% |
| BioNTech USA Holding LLC | United States | New York | 100% | n/a |
| BioNTech Research and Development Inc. | United States | New York | 100% | n/a |
| BioNTech Cell & Gene Therapies GmbH | Germany | Mainz | 100% | 94.50% |
| BioNTech Real Estate Holding GmbH (previously Apta IT GmbH) | Germany | Holzkirchen | 100% | 100% |
| BioNTech Real Estate Verwaltungs GmbH | Germany | Holzkirchen | 100% | 100% |
| BioNTech Real Estate GmbH & Co. KG | Germany | Holzkirchen | 100% | 100% |

During the year ended December 31, 2019, two entities were founded in the United States: BioNTech USA Holding, LLC and BioNTech Research & Development, Inc. Both are wholly owned subsidiaries of BioNTech SE. Additionally, reBOOST Management GmbH, was acquired through a share purchase which represents a related party transaction.

During the year ended December 31, 2018, BioNTech Real Estate Verwaltungs GmbH and BioNTech Real Estate GmbH & Co. KG were established.

**Parent Company**

ATHOS KG, Holzkirchen, Germany owns 100% of shares in AT Impf GmbH, Munich, Germany and is the beneficiary owner of BioNTech. AT Impf GmbH, Munich, Germany is the parent company of the Group and owned the following percentage of ordinary shares in BioNTech at the following dates as indicated:

| Name | Country of incorporation | Registered office | Ownership of ordinary shares in BioNTech (in %) December 31, 2019 | December 31, 2018 |
|---|---|---|---|---|
| AT Impf GmbH | Germany | Munich | 50.33% | 54.16% |

**Entity with significant Influence over the Group**

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

| Name | Country of incorporation | Registered office | Ownership of ordinary shares in BioNTech (in %) December 31, 2019 | December 31, 2018 |
|---|---|---|---|---|
| Medine GmbH | Germany | Mainz | 18.38% | 21.57% |

## 6 Business Combinations

**MAB Discovery GmbH**

In January 2019, BioNTech entered into an 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:

| *(in thousands)* | Fair value recognized on acquisition MAB Discovery GmbH |
|---|---|
| **Assets** | |
| Goodwill | € 2,205 |
| Other intangible assets | 2,711 |
| Property, plant and equipment | 999 |
| Inventories | 135 |
| **Total identifiable net assets at fair value** | **€ 6,050** |

| *(in thousands)* | Cash flow on acquisition MAB Discovery GmbH |
|---|---|
| Net cash acquired | — |
| Cash paid | € 6,050 |
| **Net cash flow on acquisition** | **€ (6,050)** |

The consolidated financial statements include the results of MAB Discovery since the acquisition date. From the date of acquisition, MAB Discovery contributed k€4,299 to loss before tax in the Technology Platform business segment from continuing operations of the Group. If the transaction would have occurred at the beginning of the reporting period, an estimated amount of k€5,232 would have contributed to loss before tax in the Technology Platform business segment. From the date of acquisition, MAB Discovery did not generate any revenue and no revenue would have been generated if the transaction would have occurred at the beginning of the reporting period. 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 of k€91 relating to the acquisition have been expensed and are included in the general and administrative expenses within the 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 (hereinafter also referred to as “reBOOST”) from Medine GmbH, which is wholly owned by BioNTech’s Chief Executive Officer, Ugur Sahin. The k€279 purchase price consists of k€31 cash consideration and assumption of liabilities of up to k€248. The related party acquisition closed on September 2, 2019.

The consolidated financial statements include the results of reBOOST since the acquisition date. From the date of acquisition, reBOOST contributed k€213 to loss before tax in the Technology Platform business segment from continuing operations of the Group. If the transaction would have occurred at the beginning of the reporting period, an estimated amount of k€237 would have contributed to loss before tax in the Technology Platform business segment. From the date of acquisition, reBOOST did not generate any revenue and no revenue would have been generated if the transaction would have occurred at the beginning of the reporting period. The Group acquired reBOOST because it expects to lift synergies and other benefits arising from the ongoing collaborations of reBOOST with different co-operations.

## 7 Income and Expenses

### 7.1 Costs of Sales

| *(in thousands)* | Years ended December 31, 2019 | 2018 | 2017 |
|---|---|---|---|
| Wages, benefits and social security expense | € 7,206 | € 6,726 | €6,105 |
| Laboratory supplies | 3,845 | 1,368 | 2,849 |
| Purchased services | 1,986 | 2,514 | — |
| Depreciation and amortization | 1,467 | 1,367 | — |
| Other | 2,857 | 1,715 | 364 |
| **Total** | **€17,361** | **€13,690** | **€9,318** |

### 7.2 Research and Development Expenses

| *(in thousands)* | Years ended December 31, 2019 | 2018 | 2017 |
|---|---|---|---|
| Wages, benefits and social security expense | € 83,213 | € 45,668 | €31,970 |
| Purchased services | 65,552 | 42,079 | 22,686 |
| Laboratory supplies | 37,218 | 22,921 | 15,762 |
| Depreciation and amortization | 27,533 | 18,312 | 9,859 |
| Lease and lease related cost | 2,527 | 2,404 | 3,475 |
| IT costs | 3,800 | 1,572 | 366 |
| Travel costs | 1,546 | 1,281 | 776 |
| Transport costs | 1,081 | 668 | 396 |
| Job advertisement expenses | 1,040 | 352 | — |
| Other | 2,956 | 7,783 | 206 |
| **Total** | **€226,466** | **€143,040** | **€85,496** |

### 7.3 Sales and Marketing Expenses

| *(in thousands)* | Years ended December 31, 2019 | 2018 | 2017 |
|---|---|---|---|
| Wages, benefits and social security expense | €1,938 | €1,728 | €1,631 |
| Purchased services | 247 | 794 | 2,771 |
| Travel costs | 88 | 267 | 260 |
| Other | 445 | 252 | 1,940 |
| **Total** | **€2,718** | **€3,041** | **€6,603** |

### 7.4 General and Administrative Expenses

| *(in thousands)* | Years ended December 31, 2019 | 2018 | 2017 |
|---|---|---|---|
| Wages, benefits and social security expense | €19,122 | € 8,582 | € 9,861 |
| Purchased services | 6,419 | 5,177 | 3,544 |
| IT and office equipment | 4,573 | 3,774 | 2,706 |
| Depreciation and amortization | 4,855 | 2,284 | 630 |
| Lease and lease related cost | 1,715 | 1,012 | 1,611 |
| Travel costs | 1,391 | 1,043 | 247 |
| Insurance premiums | 1,061 | 145 | 99 |
| Laboratory supplies | 785 | 456 | 63 |
| Job advertisement expenses | 548 | 861 | 719 |
| Other | 5,078 | 3,000 | 4,039 |
| **Total** | **€45,547** | **€26,334** | **€23,520** |

### 7.5 Other Operating Income

| (in thousands) | Years ended December 31, 2019 | 2018 | 2017 |
|---|---|---|---|
| Government grants | €1,547 | €4,228 | €2,266 |
| Other | 1,177 | 1,168 | 83 |
| **Total** | **€2,724** | **€5,396** | **€2,349** |

### 7.6 Finance Income

| (in thousands) | Years ended December 31, 2019 | 2018 | 2017 |
|---|---|---|---|
| Interest income | €1,781 | €1,996 | €2,133 |
| Foreign exchange gains (net) | 2,341 | 6,050 | — |
| **Total** | **€4,122** | **€8,046** | **€2,133** |

Finance income results from BioNTech's interests on short-term deposits. In the years ended December 31, 2019 and December 31, 2018 results from BioNTech's unhedged USD cash accounts were recorded as foreign exchange gains.

### 7.7 Finance Expense

| (in thousands) | Years ended December 31, 2019 | 2018 | 2017 |
|---|---|---|---|
| Financial instruments measured at amortized cost | €326 | € 48 | € 53 |
| Foreign exchange loss (net) | — | — | 25,955 |
| **Total** | **€326** | **€ 48** | **€26,007** |

In the year ended December 31, 2017, foreign exchange losses as a result from BioNTech's unhedged USD cash accounts were recorded as finance expenses.

## 8 Income Tax

Tax expense for the years ended December 31, 2019, December 31, 2018 and December 31, 2017 are comprised of current income taxes and other taxes.

The following table illustrates the reconciliation of tax expense to the estimated tax rate for the periods indicated. The reconciliation for the year ended December 31, 2019 excludes an amount of k€28 for property tax expenses.

| *(in thousands)* | Years ended December 31, 2019 | 2018 | 2017 |
|---|---|---|---|
| Loss before tax | **€(179,440)** | **€(47,662)** | **€(85,905)** |
| Expected tax benefit (based on BioNTech`s statutory tax rate of 30.78%, 2018: 30.99%, 2017: 30.86%) | 55,240 | 14,776 | 26,517 |
| *Effects* | | | |
| Government grants exempted from taxes | 48 | 28 | 17 |
| Non-deductible expenses | (58) | (18) | (22) |
| Add-back for trade tax purposes | (110) | (96) | (70) |
| Non-recognition of tax effect on share-based payment expenses | (9,308) | — | — |
| Tax-effective equity transaction costs | 5,121 | — | — |
| Utilization of tax losses | — | 1,165 | — |
| Non-recognition of deferred taxes on tax losses and temporary differences | (51,197) | (13,634) | (26,015) |
| Deviation valuation allowance prior year due to change tax rate | 192 | — | — |
| Effect from lower foreign income tax rate | (102) | — | — |
| Adjustment prior year tax | 316 | — | — |
| Other effects | 154 | (2,821) | (472) |
| **Income tax expense** | **€ 296** | **€ (600)** | **€ (45)** |

**Deferred Taxes**

Deferred taxes for the periods indicated relate to the following:

**Year ended December 31, 2019**

| *(in thousands)* | January 1, 2019 | Recognized in P&L | December 31, 2019 |
|---|---|---|---|
| Fixed assets | € (90) | € (565) | € (655) |
| Inventories | — | 596 | 596 |
| Leases | 306 | 206 | 512 |
| Contract liabilities (prior year revenues) | 28,441 | (4,898) | 23,543 |
| Provisions | 134 | 53 | 187 |
| Other (incl. deferred expenses) | 161 | 1,926 | 2,087 |
| **Deferred Tax Assets Net (before valuation)** | **€ 28,951** | **€ (2,681)** | **€ 26,270** |
| Valuation Adjustment | **(28,951)** | **2,681** | **(26,270)** |
| **Deferred Tax Assets Net (after valuation)** | **—** | **—** | **—** |

**Year ended December 31, 2018**

| *(in thousands)* | January 1, 2018 | Recognized in P&L | December 31, 2018 |
|---|---|---|---|
| Fixed assets | € (877) | € 787 | € (90) |
| Inventories | 83 | (83) | — |
| Leases | 83 | 223 | 306 |
| Contract liabilities (prior year revenues) | 16,631 | 11,810 | 28,441 |
| Provisions | 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)** | **—** | **—** | **—** |

Accumulated tax losses of the Group for the periods indicated amount to the following:

| *(in thousands)* | Years ended December 31, 2019 | 2018 | 2017 |
|---|---|---|---|
| Corporate Tax | €356,044 | €179,264 | €178,491 |
| Trade Tax | 352,341 | 176,425 | 176,024 |

Deferred tax assets on tax losses have not been capitalized as there is not 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 as at December 31, 2019 relate to Germany and the United States (as at December 31, 2018: Germany). There is no expiration date for any of the accumulated tax losses under German or US tax law.

## 9 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.

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 including the EPS information below give retroactive effect to the share split for all periods presented.

The following table reflects the income and share data used in the basic and diluted EPS calculations:

| *(in thousands)* | Years ended December 31, 2019 | 2018 | 2017 |
|---|---|---|---|
| **Loss attributable to ordinary equity holders of the parent for basic earnings** | **€(179,056)** | **€ (48,019)** | **€ (85,653)** |
| **Weighted average number of ordinary shares for basic EPS** | **211,499** | **190,710** | **166,764** |
| Effects of dilution from share options | — | — | — |
| **Weighted average number of ordinary shares adjusted for the effect of dilution** | **211,499** | **190,710** | **166,764** |

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.

## 10 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, 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** |
| As of January 1, 2019 | **€22,147** | **€ 73,613** | **€ 7,091** | **€102,853** |
| Additions | 7,269 | 8,700 | 22,623 | 38,592 |
| Disposals | — | (105) | (10) | (115) |
| Reclassifications | 53 | — | (53) | — |
| Currency differences | — | (1) | 1 | — |
| Acquisition of subsidiaries and businesses, net of cash acquired | — | 999 | — | 999 |
| **As of December 31, 2019** | **€29,469** | **€ 83,206** | **€ 29,652** | **€142,329** |

| *(in thousands)* | Land and buildings | Equipment, tools and installations | Construction in progress and advance payments | Total |
|---|---|---|---|---|
| **Cumulative depreciation and impairment charges** | | | | |
| As of January 1, 2018 | **€ 5,690** | **€ 22,013** | — | **€ 27,703** |
| Depreciation | 782 | 8,349 | — | 9,131 |
| Disposals | — | (182) | — | (182) |
| **As of December 31, 2018** | **€ 6,472** | **€ 30,180** | — | **€ 36,652** |
| As of January 1, 2019 | **€ 6,472** | **€ 30,180** | — | **€ 36,652** |
| Depreciation | 1,854 | 10,861 | — | 12,715 |
| Disposals | — | (79) | — | (79) |
| Currency differences | — | (3) | — | (3) |
| **As of December 31, 2019** | **€ 8,326** | **€ 40,959** | — | **€ 49,285** |

| *(in thousands)* | Land and buildings | Equipment, tools and installations | Construction in progress and advance payments | Total |
|---|---|---|---|---|
| **Carrying amount** | | | | |
| As of January 1, 2018 | **€ 7,387** | **€ 36,067** | **€ 6,153** | **€ 49,606** |
| As of December 31, 2018 | **€15,675** | **€ 43,433** | **€ 7,091** | **€ 66,200** |
| **As of December 31, 2019** | **€21,143** | **€ 42,247** | **€ 29,652** | **€ 93,044** |

## 11 Intangible Assets

| *(in thousands)* | Goodwill | Concessions, licenses and similar rights | Advance payments | Total |
|---|---|---|---|---|
| **Acquisition costs** | | | | |
| 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 of December 31, 2018** | **€ 534** | **€ 101,853** | **€ 1,497** | **€103,883** |
| As of January 1, 2019 | **€ 534** | **€ 101,853** | **€ 1,497** | **€103,883** |
| Additions | — | 11,744 | 1,529 | 13,273 |
| Disposals | — | (133) | (477) | (610) |
| Reclassifications | — | 146 | (146) | — |
| Currency differences | — | (23) | — | (23) |
| Acquisition of subsidiaries and businesses, net of cash acquired | 2,444 | 2,726 | — | 5,170 |
| **As of December 31, 2019** | **€ 2,978** | **€ 116,313** | **€ 2,403** | **€121,693** |

| *(in thousands)* | Goodwill | Concessions, licenses and similar rights | Advance payments | Total |
|---|---|---|---|---|
| **Cumulative depreciation and impairment charges** | | | | |
| As of January 1, 2018 | — | **€ 5,833** | — | **€ 5,833** |
| Depreciation | — | 10,009 | — | 10,009 |
| **As of December 31, 2018** | **—** | **€ 15,842** | **—** | **€ 15,842** |
| As of January 1, 2019 | **—** | **€ 15,842** | **—** | **€ 15,842** |
| Depreciation | — | 16,502 | — | 16,502 |
| Disposals | — | (81) | — | (81) |
| Currency differences | — | (3) | — | (3) |
| **As of December 31, 2019** | **—** | **€ 32,260** | **—** | **€ 32,260** |

| *(in thousands)* | Goodwill | Concessions, licenses and similar rights | Advance payments | Total |
|---|---|---|---|---|
| **Carrying amount** | | | | |
| As of January 1, 2018 | **€ 534** | **€ 79,438** | **€ 3,565** | **€ 83,537** |
| As of December 31, 2018 | **€ 534** | **€ 86,011** | **€ 1,497** | **€ 88,042** |
| **As of December 31, 2019** | **€ 2,978** | **€ 84,053** | **€ 2,403** | **€ 89,434** |

### Contractual Commitments

Contractual commitments for the acquisition of intangible assets amounts to Nil as of December 31, 2019 (as of December 31, 2018: k€19,482).

### 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 (CGU).

The goodwill acquired in the respective business combinations for the dates indicated is presented in the following table:

| | MAB Discovery | | JPT Peptide Technologies | | reBOOST | | Total | |
|---|---|---|---|---|---|---|---|---|
| *(in thousands)* | As of December 31, 2019 | As of December 31, 2018 | As of December 31, 2019 | As of December 31, 2018 | As of December 31, 2019 | As of December 31, 2018 | As of December 31, 2019 | As of December 31, 2018 |
| Goodwill | € 2,205 | — | € 534 | € 534 | € 239 | — | € 2,978 | € 534 |

The Group performs its annual goodwill impairment test for the respective year as per October 1.

The recoverable amount was determined on a value in use calculation using cash flow projections from budgets approved by senior management covering at least 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 December 31, 2019 is 9.0% (for the year ended December 31, 2018: 12.2%) and cash flows beyond the five-year period are extrapolated using a 1.8% growth rate (for the year ended December 31, 2018: 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**

Intangible assets not yet available for use did not exist in the years ended December 31, 2019 and December 31, 2018.

## 12 Financial Assets and Financial Liabilities

### 12.1 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.

| *(in thousands)* | December 31, 2019 | December 31, 2018 |
|---|---|---|
| Cash and cash equivalents at banks and on hand | € 519,149 | € 411,495 |
| **Total** | **€ 519,149** | **€ 411,495** |

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, 2019 and December 31, 2018.

### 12.2 Categories of Financial Instruments

**Financial assets at amortized cost**

| *(in thousands)* | December 31, 2019 | December 31, 2018 |
|---|---|---|
| Trade receivables | € 11,913 | € 18,938 |
| Other financial assets and receivables | 1,680 | 354 |
| **Total** | **€ 13,593** | **€ 19,292** |
| Total current | 13,593 | 19,273 |
| Total non-current | — | 18 |

**Financial liabilities: Financial liabilities at amortized cost (including interest-bearing loans and borrowings)**

| *(in thousands)* | Maturity | December 31, 2019 | December 31, 2018 |
|---|---|---|---|
| Trade payables | | € 19,909 | € 41,721 |
| Lease liabilities | | 56,683 | 50,752 |
| 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 | 7,600 | 1,600 |
| Other financial liabilities | | 11,551 | 6,132 |
| **Total** | | **€ 104,743** | **€ 104,205** |
| Total current | | 35,699 | 49,987 |
| Total non-current | | 69,044 | 54,218 |

**2.15% Secured Loan**

The loan is secured by a lien over land and buildings with a carrying value of k€10,000 as at December 31, 2019 (December 31, 2018: k€10,000). 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, 2019, the undrawn available amount is k€1,000.

**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 as at December 31, 2019 (December 31, 2018: k€9,450). The loan is repayable by quarterly instalments of k€286.4 commencing on September 30, 2020. As at December 31, 2019, the available undrawn amount of k€1,850 will be drawn on a predetermined date.

### 12.3 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, 2019 and December 31, 2018, the carrying value approximates their fair values as there have been no significant changes in relevant interest rates since inception of the respective loans.

### 12.4 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.

### 12.5 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 as well as other price risk are not considered as risks for the Group.

The sensitivity analysis in the following sections relate to the position as at December 31, 2019 and December 31, 2018.

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.

#### 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 dates indicated are as follows:

| *(in thousands)* | December 31, 2019 | December 31, 2018 |
|---|---|---|
| USD Bank accounts | € 213,913 | € 176,376 |
| **Total** | **€ 213,913** | **€ 176,376** |

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.

| Currency | Country | 1 € = Closing rate 2019 | Closing rate 2018 | Average rate 2019 | Average rate 2018 |
|---|---|---|---|---|---|
| USD | United States | 1.1234 | 1.1450 | 1.1195 | 1.1810 |

| *(in thousands)* | Change in USD rate | Effect on loss before tax | Effect on pre-tax equity |
|---|---|---|---|
| 2019 | +5 % | € (10,186) | € (10,186) |
| 2019 | -5% | € 11,259 | € 11,259 |
| 2018 | +5 % | € (8,399) | € (8,399) |
| 2018 | -5% | € 9,283 | € 9,283 |

## 12.6 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. An analysis of the aging of receivables and the creditworthiness of customers is used to evaluate this risk 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 12.2. The Group does not hold collateral as security.

### 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, 2019 and December 31, 2018 are the carrying amounts as illustrated in Note 12.1.

## 12.7 Liquidity Risk

Generally, 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, 2019**

| *(in thousands)* | Less than 1 year | 1 to 5 years | More than 5 years | Total |
|---|---|---|---|---|
| Interest bearing loans and borrowings | € 2,220 | € 10,693 | € 8,355 | **€ 21,268** |
| Trade and other payables | € 20,498 | — | — | **€ 20,498** |
| Lease liabilities | € 5,176 | € 17,882 | € 55,852 | **€ 78,910** |
| Other financial liabilities | € 10,351 | — | — | **€ 10,351** |
| **Total** | **€ 38,245** | **€ 28,575** | **€ 64,207** | **€131,027** |

**Year ended December 31, 2018**

| *(in thousands)* | Less than 1 year | 1 to 5 years | More than 5 years | Total |
|---|---|---|---|---|
| Interest bearing loans and borrowings | — | € 5,600 | — | **€ 5,600** |
| Trade and other payables | 41,721 | — | — | **41,721** |
| Lease liabilities | 3,822 | 13,346 | 56,524 | **73,692** |
| Other financial liabilities | 6,132 | — | — | **6,132** |
| **Total** | **€ 51,675** | **€ 18,946** | **€ 56,524** | **€127,145** |

### 12.8 Changes in Liabilities arising from Financing Activities

**Year ended December 31, 2019**

| *(in thousands)* | January 1, 2019 | Cash flows | New leases and disposals | Reclassification | December 31, 2019 |
|---|---|---|---|---|---|
| Current obligations under lease contracts | € 2,134 | € (3,061) | € 1,484 | € 2,928 | **€ 3,485** |
| Non-current obligations under lease contracts | 48,618 | — | 8,437 | (2,928) | **54,127** |
| Interest-bearing loans and borrowings | 5,600 | 11,000 | — | — | **16,600** |
| **Total** | **€ 56,352** | **€ 7,939** | **€ 9,921** | **—** | **€ 74,212** |

**Year ended December 31, 2018**

| *(in thousands)* | January 1, 2018 | Cash flows | New leases and disposals | 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** |

### 13 Inventories

| *(in thousands)* | December 31, 2019 | December 31, 2018 |
|---|---|---|
| Raw materials and supplies | € 8,201 | € 4,475 |
| Unfinished goods | 2,888 | 80 |
| Finished goods | 633 | 1,234 |
| **Total** | **€ 11,722** | **€ 5,789** |

During the year ended December 31, 2019, inventories of k€2,182 (during the year ended December 31, 2018: k€1,789) were recognized as an expense and recognized in cost of sales.

BioNTech has not pledged any inventories as securities for liabilities.

### 14 Trade Receivables

| *(in thousands)* | December 31, 2019 | December 31, 2018 |
|---|---|---|
| Trade receivables | € 11,913 | € 18,938 |
| **Total** | **€ 11,913** | **€ 18,938** |

Trade receivables are non-interest bearing and are generally due on terms of 20 to 30 days. As described in Note 12.6, expected credit loss for trade receivables is immaterial.

### 15 Other Assets

| *(in thousands)* | December 31, 2019 | December 31, 2018 |
|---|---|---|
| Sales tax receivable | € 7,536 | € 8,611 |
| Prepayments on inventories | 351 | 155 |
| Other | 1,182 | 398 |
| **Total** | **€ 9,069** | **€ 9,164** |

As at December 31, 2019, other assets mainly comprised interest income of k€529 and receivables from withholding taxes of k€310 (as at December 31, 2018, other assets were mainly comprised of interest income of k€270).

## 16 Issued Capital and Reserves

### Year ended December 31, 2019

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.

The financing transactions that occurred during the year ended December 31, 2019 were as follows:

### Issuance of Share Capital

In January 2019, BioNTech issued 5,088,204 shares and increased its share capital by k€5,088. The cash investment of k€80,006 was received in 2018 (k€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 with nominal amount of k€ 3,039 of BioNTech for a total of k€49,864 (k$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 k€198,548 (k$225,622). These share issuances led to an increase of share capital of k€ 17,990 and capital reserve of k€ 186,390 and recognition of a treasury share balance of k€ 5,525.

### Initial Public Offering (IPO)

On October 10, 2019, BioNTech increased its share capital by k€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 $15.00. On November 6, 2019, BioNTech increased its share capital by k€517 upon the execution of the underwriter´s option. American Depositary Shares which represent ordinary shares were issued at a price of $15.00 (under both issuances). The gross proceeds were k€143,260 (k$157,761) including k€10,517 increase in share capital and k€132,743 increase in capital reserve.

### Acquisition of Non-Controlling Interest

As of March 14, 2019, BioNTech acquired the remaining 5.5% of non-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 €1.00 each. This acquisition was recognized within equity

and resulted in the derecognition of the non-controlling interest of k€731 as well as an increase to the share capital of k€2,375. The net effect of the transaction of k€1,644 was recognized as a decrease in the capital reserve.

**Year ended December 31, 2018**

During the year ended December 31, 2018, the issued capital increased by k€26,532. The increase was mainly related to k€22,588 issued during the Series A financing round, k€3,361 issued as share capital and k€583 issued in the course of settling the share-based payment plan. As a result of the financing transactions the capital reserve increased during the year ended December 31, 2018, by k€335,193.

**Year ended December 31, 2017**

During the year ended December 31, 2017, a capital increase from company funds increased the issued capital and decreased the capital reserve by k€163,494.

## 17 Share-Based Payments

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 including share-based payment information below give retroactive effect to the share split for all periods presented.

During the years ended December 31, 2019, December 31, 2018 and December 31, 2017, the Group had the following share-based arrangements.

### 17.1 Chief Executive Officer Grant (Equity-Settled)

**Description of Share-Based Payments**

In September 2019, BioNTech agreed to grant Prof. Ugur Sahin, M.D. an option to purchase 4,374,963 ordinary shares, subject to Prof. Sahin's continuous employment with BioNTech. The options' per share exercise price is the Euro translation of the public offering price from BioNTech's initial public offering, €13.60 ($15.00). The option will vest annually in equal installments after four years commencing on the first anniversary of the initial public offering and will be exercisable four years after the initial public offering. The option will be subject to the terms, conditions, definitions and provisions of the Employee Stock Ownership Plan (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 BioNTech), and (b) for each twelve-month period starting on the fifth or subsequent anniversary of the Allocation Date, 107% of the target share price applicable for the prior twelve-month period); and (iii) the closing price for the fifth trading day prior to the start of the relevant exercise window is higher than the exercise price by at least the same percentage by which the Nasdaq Biotechnology Index or a comparable successor index as of such time is higher than such index was as of the last trading day before the Allocation Date. The Option Rights can be exercised at the latest ten years after the Allocation Date. If they have not been exercised by that date, they will lapse without compensation.

**Measurement of Fair Values**

A Monte-Carlo simulation model has been used to measure the fair value at grant date of the Chief Executive Officer Grant. This model incorporates the impact of the performance criteria regarding share price and index development described above in the calculation of the award's fair value at grant date. The inputs used in the measurement of the fair value at grant date of the Chief Executive Officer Grant were as follows:

| | Grant date October 10, 2019 |
|---|---|
| Weighted average fair value | € 5.63 |
| Weighted average share price | € 13.60 |
| Exercise price | € 13.60 |
| Expected volatility (%) | 41.4% |
| Expected life (years) | 5.37 |
| Risk-free interest rate (%) | 1.52% |

The options' per share exercise price is the Euro translation of the public offering price from BioNTech's 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.

**Reconciliation of Outstanding Share-Options**

The number and weighted-average exercise price of share options under the Chief Executive Officer Grant during the year ended December 31, 2019 were as follows:

| | Share options outstanding | Number of Ordinary Shares underlying options | Weighted-average exercise price (€) |
|---|---|---|---|
| As of January 1, 2019 | — | — | — |
| Granted | 4,374,963 | 4,374,963 | 13.60 |
| **As of December 31, 2019** | **4,374,963** | **4,374,963** | **13.60** |

The options outstanding at December 31, 2019 have a weighted-average expected life of 5.12 years.

**Expense recognized in the Statement of Operations**

The expense recognized for employee services received during the year ended December 31, 2019 is shown in the following table:

| *(in thousands)* | Year ended December 31, 2019 |
|---|---|
| Research and development expenses | € 3,208 |
| **Total** | **€ 3,208** |

There were no cancellations or modifications to the awards in the year ended December 31, 2019.

**17.2 Employee Stock Ownership Plan (Equity-Settled)**

**Description of 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). 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.

**Measurement of Fair Values**

The fair value of the ESOP has been measured using a binomial model. Service conditions attached to the arrangement were not taken into account in measuring the fair value.

The share options can only be exercised by the grantee if the price of the share is equal or greater to the Threshold Amount as defined in the arrangement. Moreover, the option rights can only be exercised if the IPO has occurred. Both conditions have been incorporated into the fair value at grant date.

The inputs used in the measurement of the fair values at grant date of the ESOP was as follows:

| | Grant date 15 November 2018 | Grant dates between February 21 - April 3, 2019 | Grant dates between April 29 - May 31, 2019 | Grant date December 1, 2019 |
|---|---|---|---|---|
| Weighted average fair value | € 7.41 | € 6.93 | € 7.04 | € 9.49 |
| Weighted average share price | € 14.40 | € 15.72 | € 16.03 | € 19.84 |
| Exercise price | € 10.14 | € 15.03 | € 15.39 | € 15.82 |
| Expected volatility (%) | 46.0% | 46.0% | 46.0% | 46.0% |
| Expected life (years) | 5.84 | 6.00 | 6.00 | 5.50 |
| Risk-free interest rate (%) | 0.05% | 0.05% | 0.05% | 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.

**Reconciliation of Outstanding Share-Options**

The number and weighted-average exercise prices of share options under the ESOP during the years ended December 31, 2019 and December 31, 2018 were as follows:

| | Share options outstanding | Number of Ordinary Shares underlying options | Weighted-average exercise price (€) |
|---|---|---|---|
| As of January 1, 2018 | — | — | — |
| Granted | 658,109 | 11,845,962 | 10.14 |
| **As of December 31, 2018** | **658,109** | **11,845,962** | **10.14** |
| As of January 1, 2019 | 658,109 | 11,845,962 | 10.14 |
| Granted | 14,511 | 261,198 | 15.17 |
| Forfeited | (17,237) | (310,266) | 10.85 |
| **As of December 31, 2019** | **655,383** | **11,796,894** | **10.23** |

The options outstanding at December 31, 2019 have a weighted-average expected life of 4.73 years.

**Expense recognized in the Statement of Operations**

The expense recognized for employee services received during the years ended December 31, 2019 and December 31, 2018 is shown in the following table:

| *(in thousands)* | Years ended December 31, 2019 | 2018 |
|---|---|---|
| Cost of sales | € 896 | € 114 |
| Research and development expenses | 20,016 | 6,786 |
| Sales and marketing expenses | 108 | 13 |
| General and administrative expenses | 6,008 | 728 |
| **Total** | **€27,028** | **€7,641** |

There were no cancellations or modifications to the awards in the years ended December 31, 2019 and December 31, 2018.

## 17.3 Share appreciation rights (Equity-Settled)

**Description of Share-Based Payments**

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 during the years ended December 31, 2019 and December 31, 2018.

**Measurement of Fair Values**

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€ |
| Exercise price | 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.

**Expense recognized in the Statement of Operations**

The expense recognized for employee services received during the year ended December 31, 2017 is shown in the following table:

| *(in thousands)* | Year ended December 31, 2017 |
|---|---|
| Cost of sales | — |
| Research and development expenses | 3,620 |
| Sales and marketing expenses | 14 |
| General and administrative expenses | 2,275 |
| **Total** | **€ 5,909** |

## 17.3 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 the year ended December 31, 2018.

## 18 Other Liabilities

| *(in thousands)* | December 31, 2019 | December 31, 2018 |
|---|---|---|
| Liabilities employees | € 6,710 | € 5,236 |
| Other | 780 | 3,864 |
| **Total** | **€ 7,490** | **€ 9,100** |

Other liabilities comprise accruals for outstanding invoices in the amount of k€715 as at December 31, 2019 (as at December 31, 2018: k€3,739) and several other non-material positions.

## 19 Leases

### 19.1 Amounts Recognized in the Statement of Financial Positions

**Right-of-Use Assets**

The following amounts are presented as right-of-use assets within the statement of financial positions as of the dates indicated:

| | December 31, 2019 | December 31, 2018 |
|---|---|---|
| Buildings | € 54,956 | € 49,718 |
| Equipment, tools and installations | 7 | 21 |
| Automobiles | 55 | 27 |
| **Total** | **€ 55,018** | **€ 49,766** |

Additions to the right-of-use assets during the year ended December 31, 2019 were k€10,040 (during the year ended December 31, 2018: k€723).

**Lease Liability**

The following amounts are included in other financial liabilities as of the dates indicated:

| *(in thousands)* | December 31, 2019 | December 31, 2018 |
|---|---|---|
| Current | € 3,485 | € 2,134 |
| Non-current | 54,127 | 48,618 |
| **Total** | **€ 57,612** | **€ 50,752** |

## 19.2 Amounts Recognized in the Statement of Operations

**Depreciation Charge of Right-of-Use Assets**

| *(in thousands)* | Years ended December 31, 2019 | 2018 | 2017 |
|---|---|---|---|
| Buildings | €4,614 | €2,751 | €1,759 |
| Equipment, tools and installations | 25 | 60 | 111 |
| Automobiles | 40 | 35 | 39 |
| **Total depreciation charge** | **€4,679** | **€2,846** | **€1,909** |
| Interest on lease liabilities | €1,718 | €1,721 | € 676 |
| Expense related to short-term leases (included in other expenses) | 442 | 431 | 442 |
| Expense relating to leases of low-value assets that are not short-term leases (included in other expenses) | 90 | 90 | 95 |
| **Total amounts recognized in profit or loss** | **€6,929** | **€5,088** | **€3,122** |

## 19.3 Amounts recognized in the Statements of Cash Flows

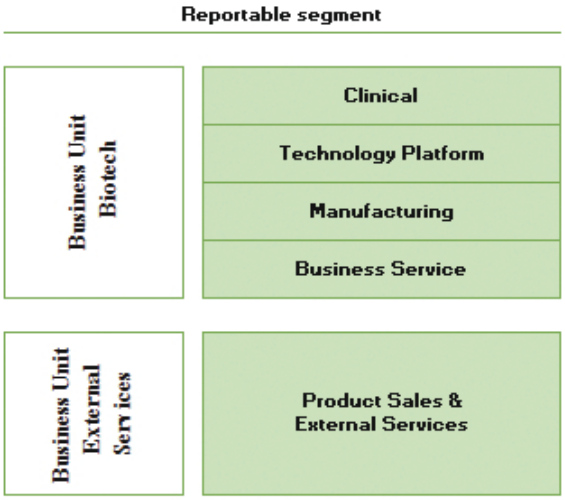
During the year ended December 31, 2019, the total cash outflow for leases amounted to k€4,779 (during the year ended December 31, 2018: k€3,847 during the year ended December 31, 2017: k€2,319).

## 20 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:




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 for the periods indicated:

| | Business Unit BioNTech | | | | External Services Business Unit | | | |
|---|---|---|---|---|---|---|---|---|
| *(in thousands)* | Clinical | Technology Platform | Manufacturing | Business Service | Product Sales & External Services | Total | Adjustments | Group |
| **Year ended December 31, 2019** | | | | | | | | |
| **Revenues** | | | | | | | | |
| Collaboration Revenues | € 33,493 | € 2,147 | € 48,788 | — | — | € 84,428 | | € 84,428 |
| Revenues from other sales transactions | — | 692 | 2 | — | 23,467 | 24,161 | | 24,161 |
| Cost of sales | — | — | — | — | (16,923) | (16,923) | (438) | (17,361) |
| **Gross profit** | **€ 33,493** | **€ 2,839** | **€ 48,790** | **—** | **€ 6,544** | **€ 91,666** | **€ (438)** | **€ 91,228** |
| **Income / Expenses** | | | | | | | | |
| Research and development expenses | (91,516) | (79,119) | (50,478) | (5,192) | (600) | (226,905) | 439 | (226,466) |
| Sales and marketing expenses | — | — | — | (1,302) | (1,415) | (2,717) | (1) | (2,718) |
| General and administrative expenses | — | — | (3,821) | (38,756) | (2,970) | (45,547) | — | (45,547) |
| Other result | 1,125 | 307 | 59 | 23 | 468 | 1,982 | 3 | 1,985 |
| **Segment operating income / (loss)** | **€(56,898)** | **€ (75,973)** | **€ (5,450)** | **€(45,227)** | **€ 2,027** | **€(181,521)** | **€ 3** | **€(181,518)** |

| | Business Unit BioNTech | | | | External Services Business Unit | | | |
|---|---|---|---|---|---|---|---|---|
| *(in thousands)* | Clinical | Technology Platform | Manufacturing | Business Service | Product Sales & External Services | Total | Adjustments | Group |
| **Year ended December 31, 2018** | | | | | | | | |
| **Revenues** | | | | | | | | |
| Collaboration Revenues | € 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** |
| **Income / Expenses** | | | | | | | | |
| 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 income / (loss)** | **€ (8,119)** | **€ (13,908)** | **€ (8,401)** | **€(25,231)** | **€ 1,753** | **€ (53,906)** | **€ 52** | **€ (53,854)** |

| *(in thousands)* | Business Unit BioNTech | | | | External Services Business Unit | | | |
|---|---|---|---|---|---|---|---|---|
| | Clinical | Technology Platform | Manufacturing | Business Service | Product Sales & External Services | Total | Adjustments | Group |
| **Year ended December 31, 2017** | | | | | | | | |
| **Revenues** | | | | | | | | |
| Collaboration Revenues | € 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** | **—** | **€ 9,623** | **€ 52,280** | **—** | **€ 52,280** |
| Income / Expenses | | | | | | | | |
| 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 income / (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 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 for the year ended December 31, 2019, the presentation of k439 of research and development cost was adjusted (for the year ended December 31, 2018: k292).

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. During the year ended December 31, 2019, the revenue generated from the Genentech and Pfizer collaboration agreements represent each more than 10% of BioNTech's overall revenue resulting from collaboration and license agreements. The revenues were partly recorded in the Clinical as well as Manufacturing segment. During the year ended December 31, 2018, the revenue generated from the Genentech and Sanofi collaboration agreements represent each more than 10% of BioNTech's overall revenue resulting from collaboration and license agreements. The revenues were partly recorded in the Clinical, Technology Platform as well as Manufacturing segment. During the year ended December 31, 2017, the revenue generated from the Genentech, Genmab and Sanofi collaboration agreements represent each more than 10% of BioNTech's overall revenue resulting from collaboration and license agreements. The revenues were partly recorded in the Clinical, Technology Platform as well as Manufacturing

segment. The total amounts of revenues generated with these customers in the periods presented are disclosed in Note 4.

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.

## 21 Related Party Disclosures

### 21.1 Parent and Ultimate Controlling Party

ATHOS KG, Holzkirchen, Germany owns 100% of shares in AT Impf GmbH, Munich Germany and is the beneficial owner of the shares of BioNTech. AT Impf GmbH, Munich, Germany, is the parent company of the Group.

### 21.2 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 of the Group**

| *(in thousands)* | December 31, 2019 | December 31, 2018 | December 31, 2017 |
|---|---|---|---|
| Short-term employee benefits | € 1,847 | € 1,161 | € 880 |
| Share-based payment transactions | 18,151 | 6,163 | 1,855 |
| **Total compensation paid to key management personnel** | **€ 19,998** | **€ 7,324** | **€ 2,735** |

In September 2019, BioNTech agreed to grant Prof. Ugur Sahin, M.D., BioNTech's co-founder and Chief Executive Officer, an option to purchase 4,374,963 ordinary shares (see Note 17).

Executive officers also participate in the Group's ESOP and SAR program (see Note 17).

**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 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. Prof. Ugur Sahin, M.D., our co-founder and Chief Executive Officer, owns a significant amount of shares in TRON.

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

| *(in thousands)* | December 31, 2019 | December 31, 2018 | 0 |
|---|---|---|---|
| Consulting services / patent assignment | € 56 | € 25 | € 25 |
| Purchases of various goods and services from TRON | 9,968 | 11,160 | 6,553 |
| **Total** | **€ 10,024** | **€ 11,185** | **€6,578** |

The outstanding balances of transactions related to key management personnel were as follows as at the periods indicated:

| *(in thousands)* | December 31, 2019 | December 31, 2018 |
|---|---|---|
| TRON | € 1,843 | € 2,160 |
| **Total** | **€ 1,843** | **€ 2,160** |

### 21.3 Other Related Party Transactions

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

| *(in thousands)* | December 31, 2019 | December 31, 2018 | December 31, 2017 |
|---|---|---|---|
| Purchases of various goods and services from entities controlled by ATHOS KG | € 2,071 | € 2,431 | € 1,240 |
| Purchases of property and other assets from entities controlled by ATHOS KG | — | 4,748 | — |
| **Total** | **€ 2,071** | **€ 7,179** | **€ 1,240** |

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

| *(in thousands)* | December 31, 2019 | December 31, 2018 |
|---|---|---|
| ATHOS KG | € 51 | € 587 |
| **Total** | **€ 51** | **€ 587** |

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

## 22 Events After the Reporting Period

22.1 In December 2019, BioNTech Delivery Technologies GmbH (previously BioNTech Protein Therapeutics GmbH; also referred to as “BioNTech Delivery Technologies”), a wholly owned subsidiary of BioNTech SE, entered into an agreement to acquire all assets, employees and proprietary know-how of Lipocalyx GmbH and its related parties (also referred to as “Lipocalyx”) in exchange for a total consideration of cash at an amount of k€6,516 and additional contingent consideration provisionally estimated at an amount of €572. Current assets and non-current assets before purchase price allocation accounted for in accordance with German GAAP at an amount of k€139 and k€77 (unaudited amounts) were acquired. No liabilities were assumed as part of this asset deal. The operational drug delivery business of Lipocalyx is based in Halle (Saale), Germany. The employees of Lipocalyx were transferred automatically to BioNTech Delivery Technologies with effect as of the closing date. The acquisition closed on January 6, 2020.

22.2 On January 12, 2020, BioNTech's Supervisory Board appointed Ryan Richardson to the Management Board as Chief Strategy Officer (CSO) and Managing Director. In his new role he will support and contribute to the creation and implementation of the Company's long-term growth strategy in collaboration with the management team. Ryan has previously served as Senior Vice President, Corporate Development & Strategy after joining the Company in 2018.

22.3 On January 16, 2020, BioNTech and Neon Therapeutics, Inc. (listed on the Nasdaq) have entered into a definitive merger agreement, under which BioNTech will acquire Neon in an all-stock transaction initially valued at approximately $67.0 million, based on the closing price of BioNTech's ADSs of $34.55 on Wednesday, January 15, 2020 (also referred to as "Merger"). At closing, BioNTech will issue, and Neon shareholders will receive, 0.063 of BioNTech's American Depositary Shares, or ADSs, in exchange for each of their shares of Neon. 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. 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. The Merger is conditioned upon, among other things, the approval of the Merger Agreement by the shareholders of Neon and other customary closing conditions.

22.4 On March 16, 2020 BioNTech announced further details on the Company's R&D effort, "Project Lightspeed", to develop a potential vaccine to induce immunity and prevent COVID-19 infection in response to the growing global health threat posed by the disease. BioNTech's product candidate, BNT162, is a potential first-in-class mRNA vaccine in the worldwide effort against COVID-19. BioNTech intends to initiate clinical testing for BNT162 in late April 2020, subject to regulatory approval, as part of a global clinical development program in Europe (commencing in Germany), the United States and China. The Company has been in close contact with regulatory and scientific authorities around the world and is in ongoing discussions with research organizations to make a vaccine available to the public as quickly as possible worldwide.

As part of its global development program, BioNTech announced a strategic alliance with Shanghai Fosun Pharmaceutical (Group) Co., Ltd ("Fosun Pharma"; Stock Symbol: 600196.SH, 02196.HK) to jointly develop its COVID-19 vaccine in China. Under the agreement, both companies will collaborate to conduct clinical trials in China, leveraging Fosun Pharma's clinical development, regulatory, and commercial capabilities in the country. Upon regulatory approval, Fosun Pharma will commercialize the vaccine in China, while BioNTech retains the full rights to develop and commercialize the vaccine in the rest of the world. Fosun Pharma will pay BioNTech up to $135 million (€120 million) in upfront and potential future investment and milestone payments, including an equity investment of USD $50 million (€44 million) for 1,580,777 ordinary shares in BioNTech, subject to execution of share subscription documentation and approval from regulatory authorities in China. Future gross profits from the sale of the vaccine in China will be shared by the two companies.

On March 17, 2020 BioNTech and Pfizer Inc. (NYSE: PFE, "Pfizer") announced that the companies have agreed to a letter of intent regarding the co-development and distribution (excluding China) of a potential mRNA-based coronavirus vaccine aimed at preventing COVID-19 infection. The companies have executed a Material Transfer and Collaboration Agreement to enable the parties to immediately start working together.

## 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, 2019 and 2018, 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 the years then ended, 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, 2019 and 2018, and the results of its operations and its cash flows for the years then ended 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.

*Change in Accounting Principle*

As discussed in Note 2 to the consolidated financial statements, the Company changed the manner in which it accounts for leases in 2019.

**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. 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 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 2, 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, 2019 | December 31, 2018 |
|---|---|---|
| **Assets** | | |
| Current assets: | | |
| Cash and cash equivalents | $ 29,395 | $ 52,700 |
| Marketable securities | — | 50,611 |
| Prepaid expenses and other current assets | 1,848 | 2,116 |
| Total current assets | 31,243 | 105,427 |
| Operating lease, right-of-use assets | 7,542 | — |
| Property and equipment, net | 7,109 | 8,205 |
| Other long-term assets | 478 | 456 |
| Total assets | $ 46,372 | $ 114,088 |
| **Liabilities and Stockholders' Equity** | | |
| Current liabilities: | | |
| Accounts payable | $ 1,702 | $ 4,268 |
| Accrued expenses | 7,464 | 8,422 |
| Operating lease liabilities, current | 1,241 | — |
| Total current liabilities | 10,407 | 12,690 |
| Operating lease liabilities, net of current portion | 6,542 | — |
| Other liabilities | 6 | 149 |
| Total liabilities | 16,955 | 12,839 |
| Commitments and contingencies (Note 8) | | |
| Stockholders' equity: | | |
| Common stock, $0.001 par value; 150,000,000 shares authorized as of December 31, 2019 and 2018; 28,729,725 and 28,314,274 shares issued and outstanding as of December 31, 2019 and 2018, respectively | 29 | 28 |
| Additional paid-in capital | 282,926 | 275,058 |
| Accumulated other comprehensive loss | — | (75) |
| Accumulated deficit | (253,538) | (173,762) |
| Total stockholders' equity | 29,417 | 101,249 |
| Total liabilities and stockholders' equity | $ 46,372 | $ 114,088 |

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, | |
|---|---|---|
| | 2019 | 2018 |
| Operating expenses: | | |
| Research and development | $ 59,718 | $ 60,425 |
| General and administrative | 21,420 | 18,276 |
| Total operating expenses | 81,138 | 78,701 |
| Loss from operations | (81,138) | (78,701) |
| Other income (expense), net | | |
| Interest income | 1,401 | 1,792 |
| Other expense | (39) | (25) |
| Total other income (expense), net | 1,362 | 1,767 |
| Net loss | (79,776) | (76,934) |
| Accretion of redeemable convertible preferred stock to redemption value | — | (6,371) |
| Net loss attributable to common stockholders | $ (79,776) | $ (83,305) |
| Net loss per share attributable to common stockholders, basic and diluted | $ (2.86) | $ (5.54) |
| Weighted average common shares outstanding, basic and diluted | 27,878,701 | 15,036,397 |
| Comprehensive loss: | | |
| Net loss | $ (79,776) | $ (76,934) |
| Other comprehensive loss: | | |
| Unrealized gains (losses) on marketable securities | 75 | (62) |
| Total other comprehensive income (loss) | 75 | (62) |
| Comprehensive loss | $ (79,701) | $ (76,996) |

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, 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 |
| Stock-based compensation expense | — | — | — | — | — | 7,340 | — | — | 7,340 |
| Issuance of common stock, net of issuance costs of $1 | — | — | — | 327,602 | 1 | 333 | — | — | 334 |
| Exercise of stock options | — | — | — | 44,132 | — | 115 | — | — | 115 |
| Issuance of common stock; ESPP purchase | — | — | — | 62,927 | — | 63 | — | — | 63 |
| Issuance of restricted common stock | — | — | — | 25,000 | — | — | — | — | — |
| Cancellation of restricted common stock | — | — | — | (44,210) | — | — | — | — | — |
| Vesting of restricted common stock | — | — | — | — | — | 17 | — | — | 17 |
| Unrealized gains on marketable securities | — | — | — | — | — | — | 75 | — | 75 |
| Net loss | — | — | — | — | — | — | — | (79,776) | (79,776) |
| **Balance at December 31, 2019** | — | $ — | $ — | 28,729,725 | $ 29 | $ 282,926 | $ — | $ (253,538) | $ 29,417 |

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, 2019 | 2018 |
|---|---|---|
| **Cash flows from operating activities:** | | |
| Net loss | $ (79,776) | $ (76,934) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | |
| Depreciation and amortization expense | 1,644 | 1,458 |
| Non-cash lease expense | 1,186 | — |
| Net amortization of premiums and discounts on marketable securities | 5 | (4) |
| Stock-based compensation expense | 7,340 | 6,229 |
| Loss on disposal of property and equipment | 39 | 25 |
| Changes in operating assets and liabilities: | | |
| Prepaid expenses and other current assets | 268 | (340) |
| Other long-term assets | (22) | 125 |
| Accounts payable | (2,311) | 1,951 |
| Accrued expenses and other liabilities | (716) | 4,062 |
| Lease liabilities | (1,069) | — |
| Net cash used in operating activities | (73,412) | (63,428) |
| **Cash flows from investing activities:** | | |
| Purchases of marketable securities | — | (72,939) |
| Sales and maturities of marketable securities | 50,681 | 43,550 |
| Purchases of property and equipment | (1,084) | (3,222) |
| Net cash provided by (used in) investing activities | 49,597 | (32,611) |
| **Cash flows from financing activities:** | | |
| Proceeds from initial public offering of common stock, net of commissions and underwriting discounts | — | 93,000 |
| Proceeds from equity offerings, net of issuance costs | 334 | — |
| Proceeds from exercise of stock options | 115 | 404 |
| Proceeds from the issuance of common stock under ESPP | 63 | — |
| Repurchase of unvested restricted common stock | (2) | (1) |
| Payment of initial public offering costs | — | (3,065) |
| Net cash provided by financing activities | 510 | 90,338 |
| Net decrease in cash, cash equivalents and restricted cash | (23,305) | (5,701) |
| Cash, cash equivalents and restricted cash, beginning of period | 53,156 | 58,857 |
| Cash, cash equivalents and restricted cash, end of period | $29,851 | $ 53,156 |
| **Supplemental disclosure of non-cash items:** | | |
| Accretion of redeemable convertible preferred stock to redemption value | $ — | $ 6,371 |
| 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 |

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, 2019 | 2018 |
|---|---|---|
| Cash and cash equivalents | $29,395 | $52,700 |
| Restricted cash included in other long-term assets | 456 | 456 |
| Total cash, cash equivalents and restricted cash | $29,851 | $53,156 |

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

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 over a decade of insights from its founders to develop neoantigen-targeted therapies that use two distinct approaches: the first approach utilizes fully personal therapies that target neoantigens specific to each individual, and the second approach utilizes shared therapies that target neoantigens that are shared across subsets of patients or tumor types. Both the personal neoantigen approach and the shared neoantigen approach focus on targeting a prioritized set of what the Company believes are the most therapeutically-relevant neoantigens.

On November 20, 2019, the Company announced that, as part of a new strategic focus, it was reducing its workforce by approximately 24% of its then current headcount. This corporate restructuring was substantially completed during the fourth quarter of 2019. The Company also announced the cessation of 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 ongoing 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 initial clinical data from this trial in the second half of 2020. The Company has also ceased enrollment in its NT-003 trial in metastatic melanoma.

On January 15, 2020, the Company entered into an agreement with BioNTech SE ("BioNTech") pursuant to which, if all of the conditions to closing are satisfied or waived, the Company will become a wholly-owned subsidiary of BioNTech (the "Merger Agreement" and such transaction, the "Merger"). The Merger Agreement was unanimously approved by the members of the Company's board of directors (the "Board"), and the Board resolved to recommend approval of the Merger Agreement to the Company's shareholders. The closing of the Merger is subject to approval of the Company's shareholders and the satisfaction of customary closing conditions (see Note 18).

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 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, 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 December 31, 2019 and 2018, the Company had an accumulated deficit of $253.5 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 December 31, 2019, the Company had cash and cash equivalents of $29.4 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 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. 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 pursuit of a strategic transaction, sale of equity, debt financings or other capital sources, including collaborations with other companies. The Company may be unable to raise additional funds or enter into such other agreements or arrangements, including a strategic transaction, 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 consolidated financial statements. While the Company has plans in place to mitigate this risk, which primarily consist of pursuing a strategic transaction and reducing cash expenditures, there is no guarantee that the Company will be successful in these mitigation efforts.

## 2. Basis of Presentation and 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, 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.

**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, 2019 and 2018.

**Restricted Cash**

As of December 31, 2019 and 2018, the Company had restricted cash of $0.5 million, 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**

The Company regularly evaluates its long-lived assets for impairment whenever events or changes in business circumstances indicate that the carrying amount of the asset may not be fully recoverable. If indications of impairment exist, projected future undiscounted cash flows associated with the asset are compared to the carrying amount to determine whether the asset's value is recoverable. If the carrying value of the asset exceeds such projected undiscounted cash flows, the asset will be written down to its estimated fair value. There were no significant impairments of long-lived assets for the years ended December 31, 2019 or 2018.

**Deferred Offering Costs**

The Company capitalizes certain legal, professional accounting and other third-party fees that are directly associated with in-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.

No deferred offering costs were capitalized as of December 31, 2019 or 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; costs related to the development of our platforms, unless such costs meet the criteria to be capitalized as internal-use software; 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 the phase or completion of events, 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 accounts for its stock-based compensation awards to employees and directors in accordance with ASC 718, *Compensation—Stock Compensation* ("ASC 718"). ASC 718 requires all stock-based payments to employees, including grants of employee stock options, restricted stock awards ("RSAs") and restricted stock units ("RSUs"), to be recognized as expense in the consolidated statements of operations and comprehensive loss based on their grant date fair values.

The fair value of each stock option granted to employees and directors 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. Because

there had been no public market for the Company's common stock prior to the IPO, there is a lack of Company-specific historical and implied volatility data. Accordingly, the Company bases its estimates of expected volatility on the historical volatility of 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 nonemployee 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. The Company estimates the grant date fair value of each RSA and RSU using intrinsic value, which is based on the fair value of the Company's common stock, less any purchase price. Compensation expense for discounted purchases under the Company's employee stock purchase plan is measured using the Black-Scholes model to compute the fair value of the look-back provision plus the purchase discount, and is recognized as compensation expense over the offering period.

Compensation expense related to awards to employees and directors is recognized on a straight-line basis based on the grant date fair value over the associated service period of the award, which is generally the vesting term. 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.

Effective January 1, 2019, upon the adoption of ASU No. 2018-07, *Compensation—Stock Compensation (Topic 718):Improvements to Nonemployee Share-Based Payment Accounting* ("ASU 2018-07"), equity-classified share-based payment awards issued to nonemployees will be measured at grant date fair value similarly to those of employees (see Recently Adopted Accounting Pronouncements). Prior to the adoption of ASU 2018-07, and for the year ending December 31, 2018, compensation expense for share-based awards granted to nonemployees 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 no longer revalued as the equity instruments vest. ASU 2018-07 also 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 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.

**Restructuring Expenses**

The Company records costs and liabilities associated with exit and disposal activities in accordance with Accounting Standard Codification ("ASC") 420, *Exit or Disposal Cost Obligations*. Such costs are based on estimates of fair value in the period liabilities are incurred. The Company evaluates and adjusts these costs as appropriate for changes in circumstances as additional information becomes available.

**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. Other comprehensive loss for all periods presented consists solely of unrealized gains (losses) on marketable securities.

**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, unvested restricted stock units 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 ("U.S.").

**Recently Adopted Accounting Pronouncements**

*ASU No. 2016-02, Leases*

In February 2016, the Financial Accounting Standards Board ("FASB") issued ASU No. 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, 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 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 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 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 lease right-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 December 31, 2019, the Company did not have any finance leases. The adoption of the New Leasing Standards did not materially impact the Company's consolidated statement of operations.

Refer to Note 7, Leases, for further information on the application of ASU 2016-02 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 2018-07, which 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 ASU 2018-07, 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 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 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. 2018-13, *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.

In December 2019, the FASB issued ASU No. 2019-12, *Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes* ("ASU 2019-12"), which is intended to simplify various aspects related to the accounting for income taxes. ASU 2019-12 removes certain exceptions to the general principles in Topic 740 and also clarifies and amends existing guidance to improve consistent application. This guidance is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2020, with early adoption permitted. The Company is currently evaluating the potential impact that the adoption of ASU 2019-12 may have on 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, 2019 Using | | |
|---|---|---|---|---|
| | Total | Level 1 | Level 2 | Level 3 |
| Cash equivalents: | | | | |
| Money market funds | $29,075 | $29,075 | $ — | $ — |
| | $29,075 | $29,075 | $ — | $ — |

| | Total | Fair Value Measurements at December 31, 2018 Using 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 years ended December 31, 2019 or 2018. There were no liabilities measured at fair value on a recurring basis as of December 31, 2019 or 2018.

## 4. Marketable Securities

The Company did not hold any marketable securities at December 31, 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 |

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, 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 consolidated results of operations.

## 5. Property and Equipment, Net

Property and equipment, net consisted of the following (in thousands):

| | December 31, | |
|---|---|---|
| | 2019 | 2018 |
| Software | $ 1,180 | $ 1,180 |
| Laboratory equipment | 9,234 | 8,230 |
| Computer equipment | 102 | 102 |
| Furniture and fixtures | 316 | 371 |
| Leasehold improvements | 680 | 592 |
| Assets under construction | — | 511 |
| | 11,512 | 10,986 |
| Less: Accumulated depreciation and amortization | (4,403) | (2,781) |
| | $ 7,109 | $ 8,205 |

Depreciation and amortization expense for the years ended December 31, 2019 and 2018 was $1.6 million and $1.5 million, respectively.

## 6. Accrued Expenses

Accrued expenses consisted of the following (in thousands):

| | December 31, | |
|---|---|---|
| | 2019 | 2018 |
| Accrued compensation costs | $2,635 | $3,364 |
| Accrued retention payments | 795 | — |
| Accrued restructuring costs | 981 | — |
| Accrued professional service fees | 904 | 1,262 |
| Accrued external research and manufacturing costs | 1,717 | 3,001 |
| Accrued additions of property and equipment | — | 243 |
| Other accrued expenses | 432 | 552 |
| | $7,464 | $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.

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):

| | Year Ended December 31, 2019 |
|---|---|
| **Lease cost** | |
| Operating lease cost | $ 2,008 |
| Variable lease cost | 963 |
| Short-term lease cost | 435 |
| Total lease cost | $ 3,406 |
| Cash paid for amounts included in the measurement of lease liabilities | $ 1,890 |

Variable lease expense includes common area maintenance, utility charges and management fees, and was $1.0 million for the year ended December 31, 2019.

The weighted average remaining lease term and weighted average discount rate of our operating leases are as follows:

| | As of December 31, 2019 |
|---|---|
| Weighted average remaining lease term in years | 4.7 |
| Weighted average discount rate | 10% |

Amortization of the operating lease right-of-use asset for the lease was $1.2 million for the year ended December 31, 2019 and was included in operating expenses.

Future lease payments for the Company's operating leases as of December 31, 2019 were as follows (in thousands):

| Year Ending December 31, | |
|---|---|
| 2020 | $ 1,948 |
| 2021 | 2,006 |
| 2022 | 2,066 |
| 2023 | 2,128 |
| 2024 | 1,632 |
| Total future minimum lease payments | $ 9,780 |
| Less: interest | (1,997) |
| Present value of operating lease liabilities | $ 7,783 |

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 had a five-year term and was terminable 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. In December 2019, the Company provided notice to the Vendor that it was terminating the Manufacturing Agreement for convenience. The Company has accrued the costs associated with terminating this agreement during the year ended December 31, 2019. The Company does not expect to incur a material amount of future costs associated with the termination of the agreement.

*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 15) 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 U.S. and foreign jurisdictions.

Pursuant to the terms of the Broad Agreement, the Company has also been granted (i) a non-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 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 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 consolidated financial statements. During the year ended December 31, 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 years ended December 31, 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.

**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, 2019 or 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

**Series A Redeemable Convertible Preferred Stock**

At various closing dates during the years ended December 31, 2016 and 2015, the Company issued and sold an aggregate of 55,500,000 shares of Series A redeemable convertible preferred stock ("Series A preferred stock") at a price of $1.00 per share. The shares were issued in exchange for cash proceeds of $50.9 million, net of issuance costs of $0.1 million, and the conversion of then-outstanding convertible notes and accrued interest of $4.6 million.

**Series B Redeemable Convertible Preferred Stock**

In December 2016, the Company entered into a stock purchase agreement and issued and sold 24,911,030 shares of Series B redeemable convertible preferred stock ("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.

**Conversion of Redeemable Convertible Preferred Stock Upon IPO**

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.

Prior to the Company's IPO, the holders of the Company's Series A preferred stock and Series B preferred stock had certain voting rights, dividend rights, liquidation preferences, redemption rights and conversion privileges. 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. All rights, preferences and privileges associated with the outstanding redeemable convertible preferred stock were terminated upon this conversion.

The Company's amended and restated certificate of incorporation now authorizes the Company to issue up to 10,000,000 shares of undesignated preferred stock, $0.001 par value per share. As of December 31, 2019 and 2018, no shares of preferred stock were issued or outstanding.

## 10. Common Stock

As of December 31, 2019 and 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 years ended December 31, 2019 or 2018.

As of December 31, 2019 and 2018 the Company has reserved for future issuance the following number of shares of common stock:

| | As of December 31, | |
|---|---|---|
| | 2019 | 2018 |
| Shares reserved for exercise of outstanding stock options | 3,374,541 | 2,548,073 |
| Shares reserved for vesting of restricted stock units | 1,053,394 | — |
| 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 | 490,215 | 270,000 |
| | 4,918,150 | 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 Securities and Exchange Commission, which was declared effective on July 8, 2019 (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 OfferingSM 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. Under the Sales Agreement, the Company is required to pay to Cantor cash commissions of 3.0% of the aggregate gross proceeds of sales of common stock under the Sales Agreement. During the three months ended December 31, 2019, the Company sold an aggregate of 327,602 shares under the ATM and received approximately $0.3 million in net proceeds after deducting commissions and offering costs.

## 11. 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 December 31, 2019, 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 December 31, 2019 there were no 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 year ended December 31, 2019.

**Stock Options**

The following table summarizes changes in stock option activity during the year ended December 31, 2019:

| | Number of Shares | Weighted Average Exercise Price | Weighted Average Contractual Term | Aggregate Intrinsic Value |
|---|---|---|---|---|
| | | | *(in years)* | *(in thousands)* |
| Outstanding as of December 31, 2018 | 2,548,073 | $ 7.11 | 8.68 | $ 1,965 |
| Granted | 1,334,028 | 5.69 | | |
| Exercised | (44,132) | 2.62 | | |
| Forfeited | (463,428) | 7.63 | | |
| Outstanding as of December 31, 2019 | 3,374,541 | $ 6.53 | 7.59 | $ 270 |
| Options vested or expected to vest as of December 31, 2019 | 3,374,541 | $ 6.53 | 7.57 | $ 270 |
| Options exercisable as of December 31, 2019 | 1,540,865 | $ 6.52 | 6.84 | $ — |

The weighted average grant-date fair value per share of stock options granted during the years ended December 31, 2019 and 2018 was $4.39 and $8.81, respectively.

The aggregate intrinsic value of stock options exercised during the years ended December 31, 2019 and 2018 was $0.1 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:

| | Year Ended December 31, | |
|---|---|---|
| | 2019 | 2018 |
| Expected volatility | 93.72% | 101.10% |
| Risk-free interest rate | 2.31% | 2.69% |
| Expected dividend yield | 0.00% | 0.00% |
| Expected life (in years) | 6.01 | 6.00 |

There were no stock option awards granted to nonemployees during the years ended December 31, 2019 or 2018.

**Restricted Stock Units**

During the year ended December 31, 2019, under the 2018 Plan, the Company granted RSUs as part of the Company's employee equity compensation program. 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 year ended December 31, 2019:

| | Number of Shares | Weighted Average Grant-Date Fair Value per Share |
|---|---|---|
| Unvested as of December 31, 2018 | — | $ — |
| Granted | 1,172,339 | $ 3.47 |
| Vested | — | $ — |
| Cancelled | (118,945) | $ 5.15 |
| Unvested as of December 31, 2019 | 1,053,394 | $ 3.27 |

**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 years ended December 31, 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 year ended December 31, 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 |
| Canceled | (44,210) | $ 1.25 |
| Vested | (258,716) | $ 2.02 |
| Unvested restricted common stock as of December 31, 2019 | 106,038 | $ 2.78 |

The aggregate fair value of restricted common stock awards that vested during the years ended December 31, 2019 and 2018, based upon the fair values of the stock underlying the restricted stock awards on the day of vesting, was $1.0 million and $3.1 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 years ended December 31, 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. As of December 31, 2019, the repurchase option on all 120,000 of these shares had 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 |
|---|---|---|
| Unvested restricted common stock as of December 31, 2018 | 350,625 | $ 1.29 |
| Vested | (170,625) | $ 1.29 |
| Unvested restricted common stock as of December 31, 2019 | 180,000 | $ 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, 2019 and 2018, based upon the fair values of the stock underlying the restricted stock awards on the day of vesting, was $0.7 million and $2.3 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 consolidated statements of operations and comprehensive loss (in thousands):

| | Year Ended December 31, | |
|---|---|---|
| | 2019 | 2018 |
| Research and development expenses | $ 3,589 | $ 3,840 |
| General and administrative expenses | 3,751 | 2,389 |
| | $ 7,340 | $ 6,229 |

During the year ended December 31, 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 (see Note 8). During the year ended December 31, 2018 the second repurchase options expired due to the achievement of the respective specified criteria and the Company recognized $0.4 million of stock-based compensation expense (see Note 8).

As of December 31, 2019, the Company had an aggregate of $8.6 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 2.2 years. As of December 31, 2019, the Company also had an aggregate of $0.3 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 0.7 years. Additionally as of December 31, 2019, the Company had an aggregate of $2.7 million of unrecognized stock-based compensation expense related to unvested RSUs, which is expected to be recognized over a weighted-average period of approximately 1.5 years.

## 12. 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 $0.5 million and $0.1 million in contributions to the 401(k) Plan for the years ended December 31, 2019 and 2018, respectively.

## 13. Income Taxes

During the years ended December 31, 2019 and 2018 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, | |
|---|---|---|
| | 2019 | 2018 |
| Federal statutory income tax rate | 21.0% | 21.0% |
| State taxes, net of federal benefit | 5.9 | 5.9 |
| Federal and state research and development tax credits | 3.7 | 4.7 |
| Other | 0.1 | 0.3 |
| Nondeductible items | (1.0) | (1.3) |
| Change in valuation allowance | (29.7) | (30.6) |
| Effective income tax rate | — % | — % |

Net deferred taxes consisted of the following (in thousands):

| | December 31, | |
|---|---|---|
| | 2019 | 2018 |
| Deferred tax assets: | | |
| Net operating loss carryforwards | $ 42,122 | $ 32,096 |
| Capitalized research and development expenses | 18,206 | 8,611 |
| Research and development tax credit carryforwards | 9,619 | 6,414 |
| Operating lease liability | 2,126 | — |
| Stock-based compensation | 1,188 | 150 |
| Deferred rent | — | 230 |
| Accruals and reserves | 911 | 866 |
| Other | 6 | 4 |
| Total deferred tax assets | 74,178 | 48,371 |
| Valuation allowance | (71,214) | (47,536) |
| Deferred tax liabilities: | | |
| Right-of-use asset | (2,060) | — |
| Depreciation | (904) | (835) |
| Net deferred tax assets | $ — | $ — |

As of December 31, 2019, the Company had federal net operating loss carry forwards of approximately $153.9 million, which resulted in a deferred tax asset of $32.3 million, of which $79.1 million will begin to expire in 2034 and $74.8 million which can be carried forward indefinitely. As of December 31, 2019, the Company also had state net operating loss carry forwards of approximately $155.2 million, which resulted in deferred tax assets of $9.8 million, which begin to expire in 2034.

As of December 31, 2019, the Company had federal research and development tax credit carry forwards of approximately $7.6 million, which resulted in a deferred tax asset of $7.6 million, which begin to expire in 2034. As of December 31, 2019, the Company also had state research and development tax credit carry forwards of approximately $2.6 million, which resulted in a deferred tax asset of $2.0 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, 2019 and 2018. 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, 2019 and 2018 were primarily due to the increase in net operating loss carryforwards, and were as follows:

| | Year Ended December 31, | |
|---|---|---|
| | 2019 | 2018 |
| Valuation allowance as of beginning of year | $ 47,536 | $ 23,964 |
| Increases recorded to income tax provision | 26,041 | 23,765 |
| Decreases recorded as a benefit to income tax provision | (2,363) | (193) |
| Valuation allowance as of end of year | $ 71,214 | $ 47,536 |

The Company has not recorded any amounts for unrecognized tax benefits as of December 31, 2019 or 2018.

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, 2019 and 2018, 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, 2019 and 2018, 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.

## 14. 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, | |
|---|---|---|
| | 2019 | 2018 |
| Numerator: | | |
| Net loss | $ (79,776) | $ (76,934) |
| Accretion of redeemable convertible preferred stock to redemption value | — | (6,371) |
| Net loss attributable to common stockholders | $ (79,776) | $ (83,305) |
| Denominator: | | |
| Weighted average common shares outstanding, basic and diluted | 27,878,701 | 15,036,397 |
| Net loss per share attributable to common stockholders, basic and diluted | $ (2.86) | $ (5.54) |

The Company excluded 286,038 and 734,589 shares of restricted common stock for the years ended December 31, 2019 and 2018, respectively, 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:

| | Year Ended December 31, | |
|---|---|---|
| | 2019 | 2018 |
| Outstanding stock options | 3,374,541 | 2,548,073 |
| Unvested restricted stock units | 1,053,394 | — |
| Unvested restricted common stock | 286,038 | 734,589 |
| | 4,713,973 | 3,282,662 |

## 15. 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 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 $1.7 million and $2.0 million during the years ended December 31, 2019 and 2018, respectively. At December 31, 2019 and 2018, the Company had $0.3 million and $2.0 million in accounts payable and accrued expenses due to the Broad, respectively.

## 16. Corporate Restructuring

On November 20, 2019, the Company announced that, as part of a new strategic focus, it was reducing its workforce by approximately 24% of its then current headcount. This corporate restructuring was substantially completed during the fourth quarter of 2019.

During the three months ended December 31, 2019, the Company recorded approximately $1.3 million of restructuring-related costs including employee severance, benefits and related costs in accordance with ASC 420, *Exit or Disposal Activities*. These costs are reflected within research and development expenses in the consolidated statement of operations.

The following table summarizes the restructuring reserve for the periods indicated (in thousands):

| | Year Ended December 31, 2019 |
|---|---|
| Restructuring reserve beginning balance | $ — |
| Restructuring expenses incurred during the period | 1,289 |
| Amounts paid during the period | (308) |
| Restructuring reserve ending balance | $ 981 |

## 17. Selected Quarterly Financial Data (Unaudited)

The following table contains selected quarterly financial information for 2019 and 2018. 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.

| | 2019 | | | |
|---|---|---|---|---|
| | First Quarter | Second Quarter | Third Quarter | Fourth Quarter |
| | (in thousands, except per share data) | | | |
| Total operating expenses | $ 21,580 | $ 22,315 | $ 19,254 | $ 17,989 |
| Total other income (expense), net | 556 | 383 | 274 | 149 |
| Net loss attributable to common stockholders | $(21,024) | $(21,932) | $(18,980) | $(17,840) |
| Net loss per share attributable to common stockholders, basic and diluted | $ (0.76) | $ (0.79) | $ (0.68) | $ (0.63) |

| | 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) |

## 18. Subsequent Events

On January 15, 2020, the Company entered into 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, 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. The closing of the Merger is subject to approval of the Company’s shareholders and the satisfaction of customary closing conditions. Certain of the Company’s stockholders who collectively own approximately 36% of the outstanding shares of the Company’s common stock have entered into voting agreements, pursuant to which they have agreed, among other things, and subject to the terms and conditions of the agreements, to vote in favor of the Merger.

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 canceled 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 is expected to close during the second quarter of 2020.

**Annex A**

***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

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Company Disclosure Schedule
Parent Disclosure Schedule

# 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 no par-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 on Section 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 Rules 13a-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 in Section 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 Form F-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 the Form 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 the contribution-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 Form F-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 by Section 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 this Section 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

**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

[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.

**Endor Lights, Inc.**

By: /s/ Sean Marett
Name: Sean Marett
Title: Director

By: /s/ Dr. Sierk Poetting
Name: Dr. Sierk Poetting
Title: Director

[Signature Page to Agreement and Plan of Merger]

## 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.

**Annex B**

**FORM OF VOTING AGREEMENT**

**THIS VOTING AGREEMENT** ("Agreement"), dated as of January 15, 2020, is made by and between BioNTech SE, a *Societas Europaea* organized and existing under the laws of Germany ("Parent"), and each of the persons set forth on Schedule A hereto (each, a "Stockholder"). Capitalized terms used herein and not defined shall have the meanings ascribed to them in the Agreement and Plan of Merger, dated as of January 15, 2020, and entered into concurrently with the execution and delivery of this Agreement, by and among Neon Therapeutics, Inc., a Delaware corporation (the "Company"), Parent and Endor Lights, Inc., a Delaware corporation and a wholly-owned subsidiary of Parent ("Merger Sub") (as such agreement may be subsequently amended or modified, the "Merger Agreement").

**WHEREAS**, Parent, Merger Sub and the Company have entered into the Merger Agreement, providing for the merger of Merger Sub with and into the Company (the "Merger"), with the Company surviving the Merger as a wholly-owned subsidiary of Parent;

**WHEREAS**, as of the date hereof, each Stockholder is the record and/or beneficial owner (as defined in Rule 13d-3 under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), which meaning will apply for all purposes of this Agreement) of the number of shares of common stock, par value $0.001 per share of the Company (the "Company Common Stock"), indicated opposite such Stockholder's name on Schedule A attached hereto (together with any New Shares (as defined in Section 3 below), the "Shares");

**WHEREAS**, subject to the execution of the Merger Agreement by all parties thereto, the Board of Directors of the Company (the "Board") has approved, for purposes of any applicable anti-takeover laws and regulations, and any applicable provision of the Company's Amended and Restated Certificate of Incorporation, the transactions contemplated by this Agreement;

**WHEREAS**, as a condition and inducement to the willingness of Parent and Merger Sub to enter into the Merger Agreement, each Stockholder, severally and not jointly or jointly and severally, and on such Stockholder's own account with respect to such Stockholder's Shares, has agreed to enter into and perform this Agreement; and

**NOW, THEREFORE**, in consideration of, and as a condition to, Parent and Merger Sub entering into the Merger Agreement and proceeding with the Contemplated Transactions, the parties agree as follows:

1. Agreement to Vote Shares. Each Stockholder agrees that, prior to the Expiration Date (as defined in Section 2 below), at any meeting of the stockholders of the Company or any adjournment or postponement thereof, with respect to the Merger, the Merger Agreement or any Acquisition Proposal, each such Stockholder shall:

(a) appear at such meeting or otherwise cause all of such Stockholder's Shares to be counted as present thereat for purposes of calculating a quorum; and

(b) from and after the date hereof until the Expiration Date, vote (or cause to be voted) all of such Stockholder's Shares, in each case, to the fullest extent that such Shares are entitled to be voted at the time of any vote: (i) in favor of adoption of the Merger Agreement and the approval of the Contemplated Transactions as to which stockholders of the Company are called upon to vote or consent in favor of any matter necessary for consummation of the Contemplated Transactions, and in favor of any proposal to adjourn or postpone such meeting to a later date if there are not sufficient votes for adoption of the Merger Agreement on the date on which such meeting is held; (ii) against any action or agreement that would reasonably be expected to result in a breach in any material respect of any covenant, representation or warranty or any other obligation or agreement of the Company or any of its Subsidiaries or Affiliates under

the Merger Agreement or that would, to the knowledge of such Stockholder, result in any of the conditions to the Company's or any of its Subsidiaries' or Affiliates' obligations under the Merger Agreement not being fulfilled; and (iii) against any Acquisition Proposal or any acquisition agreement in furtherance of an Acquisition Proposal, or any agreement, transaction or other matter that is intended to, or would reasonably be expected to, impede, interfere with, delay, postpone, discourage or materially and adversely affect the consummation of the Contemplated Transactions. Each Stockholder shall not take or commit or agree to take any action inconsistent with the foregoing.

2. Expiration Date. As used in this Agreement, the term "Expiration Date" shall mean the earliest to occur of: (a) the Effective Time; (b) such date and time as the Merger Agreement shall be validly terminated pursuant to Article VIII thereof; (c) such date and time as (i) any amendment or change to the Merger Agreement is effected without the Stockholder's consent that decreases the Exchange Ratio or changes the form of consideration payable under the Merger Agreement to the Stockholder, or (ii) any amendment or change to the Merger Agreement that is not approved by the Board is effected without the Stockholder's consent that materially and adversely affects the Stockholder; and (d) upon mutual written agreement of the parties hereto to terminate this Agreement. Upon termination or expiration of this Agreement, no party hereto shall have any further obligations or liabilities under this Agreement; provided, however, that (A) such termination or expiration shall not relieve any party hereto from liability for any fraud or willful and intentional breach of this Agreement prior to termination hereof and (B) this Section 2 and Sections 11, 15, 16, 17, 18, 19, 20, 21, 22 and 23 shall survive any such termination or expiration. For clarity, this Agreement shall not terminate upon any Company Adverse Recommendation Change (pursuant to Section 5.4 of the Merger Agreement) unless the Merger Agreement is terminated in accordance with its terms.

3. Additional Purchases. Each Stockholder agrees that any shares of capital stock of the Company that such Stockholder purchases or with respect to which such Stockholder otherwise acquires beneficial ownership after the execution of this Agreement and prior to the Expiration Date, including, without limitation, by the exercise of a Company Option or the vesting or other settlement of a Company RSU or Company Restricted Stock ("New Shares"), shall be subject to the terms and conditions of this Agreement to the same extent as if they constituted Shares as of the date hereof and the representation and warranties in Section 5 below shall be true and correct as of the date that beneficial ownership of such New Shares is acquired. Each Stockholder agrees to promptly notify Parent in writing of the nature and amount of any New Shares acquired by such Stockholder.

4. Agreement to Retain Shares and Other Covenants.

(a) From and after the date hereof until the Expiration Date, each Stockholder shall not Transfer (as defined below) (or cause or permit the Transfer of) any of such Stockholder's Shares, or enter into any agreement relating thereto, except for (i) the use of already-owned Shares (or effecting a "net exercise" of a Company Option or a "net settlement" of a Company RSU) either to pay the exercise price upon the exercise of a Company Option or to satisfy such Stockholder's tax withholding obligation upon the exercise of a Company Option or settlement of a Company RSU, in each case as permitted pursuant to the terms of any of the Company Equity Plans or award agreement, (ii) the transfer of Shares by any Stockholder who is an individual to any immediate family members (i.e., spouse, lineal descendant or antecedent, brother or sister, adopted child or grandchild or the spouse of any child, adopted child, grandchild or adopted grandchild) of such Stockholder, a trust established for the direct or indirect benefit of such Stockholder and/or for the direct or indirect benefit of one or more members of such Stockholder's immediate family, a charitable trust or charitable organizations, including a donor-advised fund, or upon the death of such Stockholder, provided that, as a condition to such Transfer, the recipient agrees to be bound by this Agreement (including expressly agreeing to the irrevocable proxy set forth in Section 7 hereof), (iii) the transfer of Shares by any Stockholder who is an individual to any person or entity if and to the extent required by any non-consensual order, by divorce decree or by will, intestacy or other similar law, provided that, as a condition to such Transfer, the recipient agrees to be bound by this Agreement (including expressly agreeing to the irrevocable proxy set forth in Section 7 hereof), (iv) the transfer of Shares by any

Stockholder who is a legal entity to an Affiliate of such Stockholder, or to any stockholder, member or partner of any such Stockholder, provided that, as a condition to such Transfer, the recipient agrees to be bound by this Agreement (including expressly agreeing to the irrevocable proxy set forth in Section 7 hereof), or (v) with Parent's prior written consent and in Parent's sole discretion (such exceptions set forth in sections (i) through (v) referred to as "Permitted Transfers"). Any Transfer (other than a Permitted Transfer), or purported Transfer (other than a Permitted Transfer), of Shares in breach or violation of this Agreement shall be void and of no force or effect.

(b) For purposes of this Agreement, a Person shall be deemed to have effected a "Transfer" of a Share if such Person, directly or indirectly, (i) sells, pledges, encumbers, hypothecates, assigns, grants an option with respect to (or otherwise enters into a hedging arrangement with respect to), tenders or disposes (by merger, by testamentary disposition, by the creation of a Lien (as defined in Section 5(c) below), by operation of law or otherwise) of such Share or any interest in such Share, (ii) deposits any Shares into a voting trust or enters into a voting agreement or arrangement or grants any proxy or power of attorney with respect thereto that is inconsistent with this Agreement, (iii) permits any Liens to be created on any Shares, or (iv) agrees or commits (whether or not in writing) to take any of the actions referred to in the foregoing clause (i), (ii) or (iii).

(c) Each Stockholder shall use commercially reasonable efforts to take, or cause to be taken, all reasonable actions, and to do, or cause to be done, all things reasonably necessary to fulfill such Stockholder's obligations under this Agreement, including, without limitation, attending, if applicable, any meeting of the stockholders of the Company or any adjournment or postponement thereof (or executing valid and effective proxies to any other attending participant of any meeting of the stockholders of the Company or any adjournment or postponement thereof in lieu of attending such meeting of the stockholders of the Company or any adjournment or postponement thereof).

5. Representations and Warranties of Each Stockholder. Each Stockholder hereby represents and warrants to Parent as follows:

(a) such Stockholder has the full power and authority to execute and deliver this Agreement and to perform such Stockholder's obligations hereunder, subject to applicable federal securities laws and the terms of this Agreement; if such Stockholder is not an individual, it is duly organized, validly existing and in good standing under the laws of its jurisdiction of organization and has taken all action necessary, to execute, deliver and perform its obligations under this Agreement and to consummate the transactions contemplated hereby;

(b) this Agreement (assuming this Agreement constitutes a valid and binding agreement of Parent) has been duly executed and delivered by or on behalf of such Stockholder and constitutes a valid and binding agreement with respect to such Stockholder, enforceable against such Stockholder in accordance with its terms, except as enforcement may be limited by general principles of equity whether applied in a court of law or a court of equity and by bankruptcy, insolvency and similar laws affecting creditors' rights and remedies generally;

(c) such Stockholder is the record and/or beneficial owner of the number of Shares, Company Options, Company RSUs and Company Restricted Stock indicated opposite such Stockholder's name on Schedule A, in each case free and clear of any liens, claims, charges, proxies, powers of attorney, rights of first offer or rights of first refusal, voting agreement or voting trust or any other agreement, arrangement, or restriction with respect to the voting of such Shares, or other encumbrances or restrictions of any kind whatsoever ("Liens"), and has sole or shared, and otherwise unrestricted, voting power with respect to such Shares, except (a) for any such Lien that may be imposed as contemplated by this Agreement (including any Permitted Transfer) and (b) any applicable restrictions on transfer under the Securities Act of 1933, as amended (the "Securities Act") or any state securities laws. Except to the extent of any New Shares acquired after the date hereof (which shall become Shares subject to the terms of this Agreement upon that acquisition), the Shares, Company Options, Company RSUs and Company Restricted Stock set forth on

Schedule A opposite the name of such Stockholder are the only securities of the Company owned of record and/or beneficially by such Stockholder on the date hereof;

(d) the execution and delivery of this Agreement by such Stockholder does not, and the performance by such Stockholder of his or her obligations hereunder and the compliance by such Stockholder with any provisions hereof will not, (i) if such Stockholder is not an individual, conflict with or violate any provision of its articles of incorporation, bylaws or similar organizational documents or (ii) violate or conflict with, result in a material breach of or constitute a default (or an event that with notice or lapse of time or both would become a material default) under, or give to others any rights of termination, amendment, acceleration or cancellation of, or result in the creation of a Lien on any of such Stockholder's Shares pursuant to, any agreement, instrument, note, bond, mortgage, contract, lease, license, permit or other obligation or any order, arbitration award, judgment or decree to which such Stockholder is a party or by which such Stockholder is bound, or any law, statute, rule or regulation to which such Stockholder is subject;

(e) the execution and delivery of this Agreement by such Stockholder does not, and the performance of this Agreement by such Stockholder does not and will not, require any consent, approval, authorization or permit of, or filing with or notification to, any governmental or regulatory authority by such Stockholder except for applicable requirements, if any, of the Exchange Act or the Securities Act, and except where the failure to obtain such consents, approvals, authorizations or permits, or to make such filings or notifications, would not prevent or delay the performance by such Stockholder of its, his or her obligations under this Agreement in any material respect;

(f) no broker, investment banker, financial advisor, finder, agent or other Person is entitled to any broker's, finder's, financial adviser's or other similar fee or commission in connection with this Agreement based upon arrangements made by or on behalf of such Stockholder in its, his or her capacity as such; and

(g) such Stockholder understands and acknowledges that Parent and Merger Sub are entering into the Merger Agreement in reliance upon such Stockholder's execution and delivery of this Agreement.

6. Representations and Warranties of Parent and Merger Sub. Each of Parent and Merger Sub hereby represents and warrants to each Stockholder as follows:

(a) each of Parent and Merger Sub is duly organized, validly existing and in good standing under the laws of its jurisdiction of organization, and each of Parent and Merger Sub has all requisite power and authority to execute and deliver this Agreement and perform their respective obligations hereunder, subject to applicable federal securities laws and the terms of this Agreement and the execution, delivery and performance of this Agreement have been duly authorized by all necessary action on the part of Parent and Merger Sub;

(b) this Agreement (assuming this Agreement constitutes a valid and binding agreement of each Stockholder) has been duly executed and delivered by or on behalf of each of Parent and Merger Sub and constitutes a valid and binding agreement with respect to each of Parent and Merger Sub, enforceable against each of Parent and Merger Sub in accordance with its terms, except as enforcement may be limited by general principles of equity whether applied in a court of law or a court of equity and by bankruptcy, insolvency and similar laws affecting creditors' rights and remedies generally; and

(c) the execution and delivery of this Agreement by each of Parent and Merger Sub does not, and the performance of this Agreement by each of Parent and Merger Sub does not and will not, require any consent, approval, authorization or permit of, or filing with or notification to, any governmental or regulatory authority by Parent or Merger Sub except for applicable requirements, if any, of the Exchange Act or the Securities Act, and except where the failure to obtain such consents, approvals, authorizations or permits, or to make such filings or notifications, would not prevent or delay the performance by Parent or Merger Sub of their respective obligations under this Agreement in any material respect.

7. Irrevocable Proxy Coupled with an Interest. Subject to the last sentence of this Section 7, and, except as otherwise set forth herein, without in any way limiting such Stockholder's right to vote such Stockholder's Shares in its sole discretion on any other matters that may be submitted to a stockholder vote, consent or other approval, by execution of this Agreement, each Stockholder does hereby appoint Parent with full power of substitution and re-substitution, as such Stockholder's true and lawful attorney and irrevocable proxy, to the fullest extent of such Stockholder's rights with respect to such Stockholder's Shares, to vote each of such Shares solely with respect to the matters set forth in Section 1 hereof at any meeting of the stockholders of the Company or any adjournment or postponement thereof. EACH STOCKHOLDER INTENDS THIS PROXY TO BE IRREVOCABLE AND COUPLED WITH AN INTEREST HEREUNDER UNTIL THE EXPIRATION DATE, AND SUCH PROXY SHALL NOT BE TERMINATED BY OPERATION OF ANY LAW OR UPON THE OCCURRENCE OF ANY OTHER EVENT OTHER THAN THE TERMINATION OF THIS AGREEMENT OR OCCURRENCE OF THE EXPIRATION DATE, IN EACH CASE PURSUANT TO SECTION 2 ABOVE, AND SUCH STOCKHOLDER HEREBY REVOKES ANY PROXY PREVIOUSLY GRANTED BY SUCH STOCKHOLDER WITH RESPECT TO SUCH STOCKHOLDER'S SHARES, AND REPRESENTS THAT NONE OF SUCH PREVIOUSLY-GRANTED PROXIES ARE IRREVOCABLE. Notwithstanding anything contained herein to the contrary, this irrevocable proxy shall automatically terminate upon the Expiration Date.

8. No Solicitation. From and after the date hereof until the Expiration Date, each Stockholder shall not, and shall not permit his or her Representatives to, directly or indirectly, (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, or (c) enter into any letter of intent, agreement, contract, commitment or agreement in principle 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, in each case except as permitted pursuant to the terms of the Merger Agreement. It is understood that this Agreement limits the rights of each Stockholder only to the extent that such Stockholder is acting in such Stockholder's capacity as a stockholder of the Company, and nothing herein shall be construed as preventing such Stockholder or any of its Affiliates acting in its capacity as an officer or director of the Company, or as a trustee or fiduciary of any ERISA plan or trust, from fulfilling the obligations of such office (including, subject to the limitations contained in Section 5.3 and Section 5.4 of the Merger Agreement, the performance of obligations required by the fiduciary obligations of such Stockholder acting solely in its capacity as an officer, director, trustee or fiduciary) and no action taken solely in any such capacity as an officer or director of the Company, or a trustee or fiduciary of any ERISA plan or trust, shall be deemed to constitute a breach of this Agreement.

9. Specific Enforcement. The parties hereto agree that irreparable damage would occur in the event any provision of this Agreement was not performed in accordance with the terms hereof or was otherwise breached. It is accordingly agreed that the parties hereto shall be entitled to specific relief hereunder, including, without limitation, an injunction or injunctions to prevent and enjoin breaches of the provisions of this Agreement and to enforce specifically the terms and provisions hereof, in any state or federal court in any competent jurisdiction, in addition to any other remedy to which they may be entitled at law or in equity. Any requirements for the securing or posting of any bond with respect to any such remedy are hereby waived.

10. Further Assurances. Each Stockholder shall, from time to time, execute and deliver, or cause to be executed and delivered, such additional or further consents, documents and other instruments as Parent may reasonably request from such Stockholder for the purpose of effectively carrying out the transactions contemplated by this Agreement. If Stockholder is a married individual and any of the Shares constitutes community property or otherwise need spousal or other approval for this Agreement to be legal, valid and

binding, such Stockholder shall deliver to Parent, concurrently herewith, a duly executed consent of such Stockholder's spouse, in the form attached hereto as Exhibit I.

11. Notice. 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), to Parent or Merger Sub to the address or email address set forth in Section 9.9 of the Merger Agreement and to each Stockholder at its, his or her address or email address set forth opposite such Stockholder's name on Schedule A attached hereto (or at such other address or email address for a party hereto as shall be specified by like notice).

12. Certain Restrictions.

(a) Each Stockholder shall not, directly or indirectly, take any action that would make any representation or warranty of such Stockholder contained herein untrue or incorrect in any material respect. Each Stockholder shall notify Parent of any development occurring after the date hereof that causes, or that would reasonably be expected to cause, any breach of any of the representations and warranties of such Stockholder set forth in Section 5 above.

(b) Each Stockholder hereby waives and agrees not to exercise any rights (including under Section 262 of the Delaware General Corporation Law) to demand appraisal of any shares of Company Common Stock or rights to dissent from the Merger which may arise with respect to the Merger.

(c) Each Stockholder shall not, in such Stockholder's capacity as a stockholder of the Company, bring, commence, institute, maintain, prosecute or voluntarily aid any action, which (i) challenges the validity of or seeks to enjoin the operation of any provision of this Agreement or (ii) alleges that the execution and delivery of this Agreement by such Stockholder, or the approval of the Merger Agreement by the Board, breaches any fiduciary duty of the Board or any member thereof.

13. Disclosure. Each Stockholder shall permit the Company and Parent to disclose in all documents and schedules filed with the SEC that Parent or the Company determines to be necessary in connection with the Contemplated Transactions, such Stockholder's identity and ownership of such Stockholder's Shares and the nature of such Stockholder's commitments, arrangements and understandings under this Agreement, and each Stockholder agrees to promptly give to Parent (or the Company, if so directed by Parent) any information related to such Stockholder that Parent or the Company may reasonably require for the preparation of any such disclosures; provided that such Stockholder shall have a reasonable opportunity to review and approve such disclosure prior to any such filing, such approval not to be unreasonably withheld, conditioned or delayed. None of the information relating to any Stockholder provided by or on behalf of any Stockholder in writing for inclusion in such documents and schedules filed with the SEC will, at the respective times that such documents and schedules are filed with the SEC or are first mailed, contain any untrue statement of material fact or omit to state any material fact or omit to state any material fact required to be stated therein or necessary in order to make the statements therein, in light of the circumstances under which they were made, not misleading.

14. Stop Transfer Instructions. At all times commencing with the execution and delivery of this Agreement and continuing until the Expiration Date, in furtherance of this Agreement, each Stockholder hereby authorizes the Company or its counsel to notify the Company's transfer agent that there is a stop transfer order with respect to all of such Stockholder's Shares (and that this Agreement places limitations on the voting and transfer of such Shares).

15. Severability. If any term or other provision of this Agreement is determined to be 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 transactions contemplated hereby is not affected in any manner materially adverse to any party hereto. 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 hereto as closely as possible to the fullest extent permitted by applicable law in an acceptable manner to the end that the transactions contemplated hereby are fulfilled to the extent possible.

16. Binding Effect and Assignment. All of the covenants and agreements contained in this Agreement shall be binding upon, and inure to the benefit of, the respective parties hereto and their permitted successors, assigns, heirs, executors, administrators and other legal representatives, as the case may be. 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 Parent may assign any of its rights and obligations hereunder to one or more of its Affiliates at any time (including any Person who acquires control of Parent at any time following the date of this Agreement); provided, further, that such transfer or assignment shall not relieve Parent or Merger Sub of its obligations hereunder.

17. No Waivers. No waivers of any breach of this Agreement extended by Parent to any Stockholder shall be construed as a waiver of any rights or remedies of Parent with respect to any other Stockholder who has executed an agreement substantially in the form of this Agreement with respect to such Stockholder's Shares or with respect to any subsequent breach of such Stockholder or any such other Stockholder. 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.

18. Governing Law; Jurisdiction and Venue. 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 or the transactions contemplated hereby, on behalf of itself or its property, by the personal delivery of copies of such process to such party. Nothing in this Section 18 shall affect the right of any party hereto to serve legal process in any other manner permitted by law.

19. Waiver of Jury Trial. 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.

20. No Agreement Until Executed. Irrespective of negotiations among the parties hereto or the exchanging of drafts of this Agreement, this Agreement shall not constitute or be deemed to evidence a contract, agreement, arrangement or understanding between the parties hereto unless and until (a) the Merger Agreement is executed by all parties thereto, and (b) this Agreement is executed by all parties hereto.

21. Entire Agreement; Amendment. This Agreement constitutes the entire agreement and supersedes all prior agreements and understandings, both written and oral, among or between any of the parties with respect to the subject matter hereof. Any provision of this Agreement may be amended or waived prior to the Expiration Date 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.

22. Effect of Headings. The section headings herein are for convenience only and shall not affect the construction of interpretation of this Agreement.

23. Counterparts; Effectiveness. 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.

[Signature Page Follows Next]

IN WITNESS WHEREOF, each of the parties has caused this Agreement to be executed on its behalf by its duly authorized officers as of the day and year first above written.

**BIONTECH SE**

By: _____
Name: _____
Title: _____

[Signature Page to Voting Agreement]

**STOCKHOLDER**

Name:

[●]

By:
Name:
Title:

[Signature Page to Voting Agreement]

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## SCHEDULE A

| Stockholder Name, Address & Email Address | Shares | Company Options | Company RSUs | Company Restricted Stock |
|---|---|---|---|---|

**EXHIBIT I**

**SPOUSAL CONSENT**

The undersigned represents that the undersigned is the spouse of:

_____

Name of Stockholder

and that the undersigned is familiar with the terms of the Voting Agreement (the "Agreement"), entered into as of January 15, 2020, by and among, *inter alios*, BioNTech SE, a *Societas Europaea* organized and existing under the laws of Germany, and the undersigned's spouse. The undersigned hereby agrees that the interest of the undersigned's spouse in all property which is the subject of the Agreement shall be irrevocably bound by the terms of the Agreement and by any amendment, modification, waiver or termination signed by the undersigned's spouse. The undersigned further agrees that the undersigned's community property interest in all property which is the subject of the Agreement shall be irrevocably bound by the terms of the Agreement, and that the Agreement shall be binding on the executors, administrators, heirs and assigns of the undersigned. The undersigned further authorizes the undersigned's spouse to amend, modify or terminate the Agreement, or waive any rights thereunder, and that each such amendment, modification, waiver or termination signed by the undersigned's spouse shall be binding on the community property interest of undersigned in all property which is the subject of the Agreement and on the executors, administrators, heirs and assigns of the undersigned, each as fully as if the undersigned had signed such amendment, modification, waiver or termination.

Dated: , 2020

_____

Name:

**Annex C**

**Opinion of Duff & Phelps, LLC**

DUFF & PHELPS

January 15, 2020

Neon Therapeutics, Inc.
40 Erie Street
Suite 110
Cambridge, MA 02139

Ladies and Gentlemen:

Neon Therapeutics, Inc. (the "Company") has engaged Duff & Phelps, LLC ("Duff & Phelps") to serve as an independent financial advisor to the Board of Directors (the "Board of Directors") of the Company (solely in their capacity as members of the Board of Directors) to provide an opinion (the "Opinion") as of the date hereof as to the fairness, from a financial point of view, to the holders of shares of Company Common Stock (as defined hereinafter) of the Exchange Ratio (as defined hereinafter) provided for in the contemplated transaction described below (the "Proposed Transaction") (without giving effect to any impact of the Proposed Transaction on any particular stockholder other than in its capacity as a stockholder).

**Description of the Proposed Transaction**

It is Duff & Phelps understanding that the Company is considering entering 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"), pursuant to which, among other things, Merger Sub will merge with and into the Company (the "Merger") and each outstanding share of the common stock, par value $0.001 per share, of the Company ("Company Common Stock") will be converted into the right to receive .063 (the "Exchange Ratio") of an American Depositary Share of Parent ("Parent ADS"). The terms and conditions of the Merger are more fully set forth in the Merger Agreement.

**Scope of Analysis**

In connection with this Opinion, Duff & Phelps has made such reviews, analyses and inquiries as it has deemed necessary and appropriate under the circumstances. Duff & Phelps also took into account its assessment of general economic, market and financial conditions, as well as its experience in securities and business valuation, in general, and with respect to similar transactions, in particular. Duff & Phelps' procedures, investigations, and financial analysis with respect to the preparation of its Opinion included, but were not limited to, the items summarized below:

1. Reviewed the following documents:

    a. The Company's annual reports and audited financial statements on Form 10-K filed with the Securities and Exchange Commission ("SEC") for the year ended December 31, 2018 and the Company's unaudited interim financial statements for the nine months ended September 30, 2019 included in the Company's Form 10-Q filed with the SEC;

    b. Financial projections for the Company's neoantigen, T cell-focused programs NEO-PTC-01 and NEO-STC-01 and for the Company's vaccine programs NEO-PV-01 and NEO-SV-01 for the years

ending December 31, 2020 through 2050, prepared by Management, reflecting the probability of success specified by Management;

c. Presentation materials prepared by Management, including, but not limited to:

i. Board of Directors report, dated March 15, 2019
ii. Board of Directors report, dated July 18, 2019
iii. 2019 Strategic Planning, dated August 1, 2019
iv. 2019 Strategic Planning, dated August 27, 2019
v. Strategic Options Discussion, dated August 2019
vi. Board of Directors Meeting, dated September 17, 2019;
vii. Business Development Update dated October 2, 2019;
viii. Restructuring Discussion Update, dated 2019;
ix. Financing Update, dated 2019;
x. Neon Asset Models Shared with Board of Directors, dated 2019;
xi. Long Term Forecast Assumptions, dated 2019;

d. License agreement by and between The Broad Institute, Inc. and the Company, dated November 13, 2015;

e. Other internal documents relating to the history, current operations, and probable future outlook of the Company, provided to us by Management;

f. A letter dated January 14, 2020 from the management of the Company which made certain representations as to historical financial statements, financial projections and the underlying assumptions including, without limitation, the probability of success, and a pro forma schedule of assets and liabilities (including identified contingent liabilities) for the Company on a post-transaction basis; and

g. Documents related to the Proposed Transaction, including the letter of intent dated January 8, 2020 and the draft Merger Agreement dated January 15, 2020;

2. Discussed the information referred to above and the background and other elements of the Proposed Transaction with Management and representatives and their investment bank Ondra LLP;

3. Reviewed the historical trading price and trading volume of the Company Common Stock and Parent ADS and the publicly traded securities of certain other companies that Duff & Phelps deemed relevant;

4. Performed certain valuation and comparative analyses using generally accepted valuation and analytical techniques consisting of a discounted cash flow analysis; and

5. Conducted such other analyses and considered such other factors as Duff & Phelps deemed appropriate.

**Assumptions, Qualifications and Limiting Conditions**

In performing its analyses and rendering this Opinion with respect to the Proposed Transaction, Duff & Phelps, with the Company's consent:

1. Relied upon the accuracy, completeness, and fair presentation of all information, data, advice, opinions and representations obtained from public sources or provided to it from private sources, including Management, and did not independently verify such information;

2. Relied upon the fact that the Board of Directors and the Company have been advised by counsel as to all legal matters with respect to the Proposed Transaction, including whether all procedures required by law to be taken in connection with the Proposed Transaction have been duly, validly and timely taken;

3. Assumed that any estimates, evaluations, forecasts and projections furnished to Duff & Phelps were reasonably prepared and based upon the best currently available information and good faith judgment of the

person furnishing the same, and Duff & Phelps expresses no opinion with respect to such projections or the underlying assumptions;

4. Assumed that information supplied and representations made by Management are substantially accurate regarding the Company and the Proposed Transaction;

5. Assumed, at the direction of Management, that the Exchange Ratio is equal to .063 and will not be adjusted pursuant to the Merger Agreement;

6. Assumed, with Management's consent, that the trading price for the Parent ADS is a reliable reflection of its fair market value;

7. Assumed that the representations and warranties made in the Merger Agreement are substantially accurate;

8. Assumed that the final versions of all documents reviewed by Duff & Phelps in draft form conform in all material respects to the drafts reviewed;

9. Assumed that there has been no material change in the assets, liabilities, financial condition, results of operations, business, or prospects of the Company or the Parent since the date of the most recent financial statements and other information made available to Duff & Phelps, and that there is no information or facts that would make the information reviewed by Duff & Phelps incomplete or misleading;

10. Assumed that all of the conditions required to implement the Proposed Transaction will be satisfied and that the Proposed Transaction will be completed in accordance with the Merger Agreement without any amendments thereto or any waivers of any terms or conditions thereof; and

11. Assumed that all governmental, regulatory or other consents and approvals necessary for the consummation of the Proposed Transaction will be obtained without any adverse effect on the Company.

To the extent that any of the foregoing assumptions or any of the facts on which this Opinion is based prove to be untrue in any material respect, this Opinion cannot and should not be relied upon. Furthermore, in Duff & Phelps' analysis and in connection with the preparation of this Opinion, Duff & Phelps has made numerous assumptions with respect to industry performance, general business, market and economic conditions and other matters, many of which are beyond the control of any party involved in the Proposed Transaction.

Duff & Phelps has prepared this Opinion effective as of the date hereof. This Opinion is necessarily based upon market, economic, financial and other conditions as they exist and can be evaluated as of the date hereof, and Duff & Phelps disclaims any undertaking or obligation to advise any person of any change in any fact or matter affecting this Opinion which may come or be brought to the attention of Duff & Phelps after the date hereof.

Duff & Phelps did not evaluate the Company's or the Parent's solvency or conduct an independent appraisal or physical inspection of any specific assets or liabilities (contingent or otherwise). Duff & Phelps has not been requested to, and did not, (i) initiate any discussions with, or solicit any indications of interest from, third parties with respect to the Proposed Transaction, the assets, businesses or operations of the Company, or any alternatives to the Proposed Transaction, (ii) negotiate the terms of the Proposed Transaction, and therefore, Duff & Phelps has assumed that such terms are the most beneficial terms, from the Company's perspective, that could, under the circumstances, be negotiated among the parties to the Merger Agreement and the Transaction, or (iii) advise the Board of Directors or any other party with respect to alternatives to the Proposed Transaction.

Duff & Phelps is not expressing any opinion as to the market price or value of the Company's common stock or the Parent's common stock (or anything else) after the announcement or the consummation of the Proposed Transaction. This Opinion should not be construed as a valuation opinion, credit rating, solvency opinion, an analysis of the Company's credit worthiness, as tax advice, or as accounting advice. Duff & Phelps has not made, and assumes no responsibility to make, any representation, or render any opinion, as to any legal matter.

In rendering this Opinion, Duff & Phelps is not expressing any opinion with respect to the amount or nature of any compensation to any of the Company's officers, directors, or employees, or any class of such persons, relative to the Exchange Ratio provided for in the Proposed Transaction, or with respect to the fairness of any such compensation.

This Opinion is furnished for the use and benefit of the Board of Directors in connection with its consideration of the Proposed Transaction. This Opinion (i) does not address the merits of the underlying business decision to enter into the Proposed Transaction versus any alternative strategy or transaction; (ii) does not address any transaction related to the Proposed Transaction; (iii) is not a recommendation as to how the Board of Directors or any stockholder should vote or act with respect to any matters relating to the Proposed Transaction, or whether to proceed with the Proposed Transaction or any related transaction, and (iv) does not indicate that the Exchange Ratio in the Proposed Transaction is the best possibly attainable under any circumstances; instead, it merely states whether the Exchange Ratio is within a range suggested by certain financial analyses. The decision as to whether to proceed with the Proposed Transaction or any related transaction may depend on an assessment of factors unrelated to the financial analysis on which this Opinion is based. This letter should not be construed as creating any fiduciary duty on the part of Duff & Phelps to any party.

This Opinion is solely that of Duff & Phelps, and Duff & Phelps' liability in connection with this letter shall be limited in accordance with the terms set forth in the engagement letter between Duff & Phelps and the Company dated December 17, 2020 (the "Engagement Letter"). This letter is confidential, and its use and disclosure is strictly limited in accordance with the terms set forth in the Engagement Letter.

**Disclosure of Prior Relationships**

Duff & Phelps has acted as financial advisor to the Board of Directors and will receive a fee for its services. No portion of Duff & Phelps' fee is contingent upon either the conclusion expressed in this Opinion or whether or not the Proposed Transaction is successfully consummated. Pursuant to the terms of the Engagement Letter, a portion of Duff & Phelps' fee is payable upon Duff & Phelps' stating to the Board of Directors that it is prepared to deliver its Opinion. During the two years preceding the date of this Opinion, Duff & Phelps has provided valuation and other financial advisory services to the Parent. For these prior engagements, Duff & Phelps received fees, expense reimbursement, and indemnification.

**Conclusion**

Based upon and subject to the foregoing, Duff & Phelps is of the opinion that as of the date hereof, the Exchange Ratio provided for in the Proposed Transaction is fair, from a financial point of view, to the holders of shares of Company Common Stock (without giving effect to any impact of the Proposed Transaction on any particular stockholder other than in its capacity as a stockholder).

This Opinion has been approved by the Opinion Review Committee of Duff & Phelps.

Respectfully submitted,

/s/ Duff & Phelps, LLC

Duff & Phelps, LLC