

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

FORM 6-K

**REPORT OF FOREIGN PRIVATE ISSUER PURSUANT TO RULE 13a-16 OR 15d-16
UNDER THE SECURITIES EXCHANGE ACT OF 1934**

FOR THE MONTH OF AUGUST 2020

COMMISSION FILE NUMBER 001-39081

BioNTech SE

(Translation of registrant's name into English)

**An der Goldgrube 12
D-55131 Mainz
Germany
+49 6131-9084-0**

(Address of principal executive offices)

Indicate by check mark whether the registrant files or will file annual reports under cover Form 20-F or Form 40-F: Form 20-F Form 40-F

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1):

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7):

DOCUMENTS INCLUDED AS PART OF THIS FORM 6-K

On August 11, 2020, BioNTech SE (the “Company”) issued a press release providing a development update and reporting its financial results for the three and six months ended June 30, 2020. Attached hereto as Exhibit 99.1 are the press release, the interim condensed consolidated financial statements as well as the operating and financial review and prospects of the Company, for the three and six months ended June 30, 2020.

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

BioNTech SE

By: /s/ Dr. Sierk Poetting
Name: Dr. Sierk Poetting
Title: Chief Financial Officer

Date: August 11, 2020

EXHIBIT INDEX

<u>Exhibit</u>	<u>Description of Exhibit</u>
99.1	Second Quarter 2020 Financial Results Press Release dated August 11, 2020 and Quarterly Report for the Three and Six Months Ended June 30, 2020



BioNTech Announces Second Quarter 2020 Financial Results and Corporate Progress

- Pivotal Phase 2b/3 trial for BNT162 vaccine program against COVID-19 initiated with first clinical results expected as early as October 2020
- Initial commercial supply agreements for BNT162 signed with the United States, Japan, Canada and the United Kingdom for more than 250 million doses in 2020 and 2021
- Published data update for the lead FixVac product candidate BNT111 in *Nature* and announced a partnership with Regeneron to advance combination therapy with anti-PD-1 into Phase 2 trial in melanoma
- Presented data for BNT122 Phase 1 trial in multiple solid tumors at AACR Annual Meeting; on track to initiate randomized Phase 2 trials in adjuvant NSCLC and adjuvant CRC by the end of 2020
- Ended Q2 2020 with cash and cash equivalents of €573 million (\$642 million¹) and raised an additional €681 million (\$762 million¹) in gross proceeds from an equity private placement and follow-on underwritten offering leading to an expected pro-forma cash and cash equivalents balance of €1.25 billion (\$1.40 billion¹). In addition, up to €100 million (\$112 million¹) secured in loan financing from the European Investment Bank in June 2020. Financing transactions are subject to closing conditions which were not fulfilled before June 30, 2020

Conference call and webcast for analysts and investors scheduled for August 11, 2020 at 08:00 a.m. ET (2:00 p.m. CET)

MAINZ, Germany, August 11, 2020 (GLOBE NEWSWIRE) -- BioNTech SE (Nasdaq: BNTX, “BioNTech” or “the Company”), a clinical-stage biotechnology company focused on patient-specific immunotherapies for the treatment of cancer and infectious diseases, today provided an update on its corporate progress and reported financial results for the quarter ended June 30, 2020.

“We made significant progress in the second quarter toward our goal of advancing our oncology programs and toward bringing a COVID-19 vaccine to market as quickly as possible. I am incredibly proud of our team, who has worked tirelessly to initiate our BNT162 Phase 2b/3 trial in record time and put us in a position to seek regulatory review as early as October of this year, if our trials are successful,” said **Ugur Sahin, BioNTech’s CEO and Co-founder**. “In addition, we have significantly strengthened our balance sheet, providing financial resources to advance our broad pipeline of novel immunotherapies targeting oncology and infectious disease.”

Second Quarter 2020 and Subsequent Updates**Infectious disease****COVID-19 Vaccine Program – BNT162**

- Released data from the ongoing U.S. Phase 1/2 placebo-controlled, observer-blinded clinical trial, evaluating nucleoside-modified messenger RNA vaccine candidate (BNT162b1) in 45 subjects, and data from the ongoing Germany trial in 60 subjects.
- Received Fast Track designation for BNT162b1 and BNT162b2 from the U.S. Food and Drug Administration (FDA).
- Initiated a Phase 2b/3 study for BNT162b2 in up to 30,000 participants aged 18 to 85 years at approximately 120 sites globally; if successful, BioNTech and Pfizer plan to file for market authorization or regulatory approval as early as October 2020.
- Initiation of a Phase 1 study for BNT162b1 to evaluate safety and immunogenicity in Chinese participants to support potential regulatory approval in China.
- Announced initial commercial supply agreements totaling more than 250 million doses with the United Kingdom, the United States, Japan and Canada in 2020 and 2021, with an option to purchase up to an additional 500 million doses. All agreements are subject to clinical success and regulatory approval.

Oncology**FixVac**

- BNT111 – On July 30, BioNTech announced the publication of interim Phase 1 data for BNT111, the Company's lead mRNA-based FixVac cancer vaccine program, in *Nature*. The trial, designed to evaluate safety and tolerability of vaccinated patients with stage IIIB-C and stage IV melanoma, included 89 patients and highlighted a favorable tolerability profile of BNT111. An efficacy analysis conducted within a subset of 42 checkpoint-inhibitor (CPI)-experienced metastatic melanoma patients showed that BNT111 mediates durable responses both as a single agent and in combination with anti-PD-1 antibodies by establishing an association with activation and strong expansion of tumor-antigen-specific CD4+ and CD8+ T cells.
- BNT111 – On July 31, BioNTech and Regeneron Pharmaceuticals, Inc. announced a strategic collaboration to jointly conduct a randomized Phase 2 study for the treatment of melanoma that has progressed after prior PD-1 blockade, utilizing BNT111 FixVac and Regeneron's Libtayo® in combination.
- BNT111 – BioNTech expects to initiate this Phase 2 trial with registrational potential in the second half of 2020.
- BNT113 – Planned initiation of a potentially registrational Phase 2 trial in HPV16+ head and neck cancer expected in 2H 2020.

- BNT1142 – Planned data update from a Phase 1 trial in triple negative breast cancer (TNBC) is expected in 2H 2020. The exploratory Phase 1 study tests immunogenicity and safety of vaccination with individualized neoantigen immunotherapy and non-mutated tumor-associated antigens in TNBC.

Individualized neoantigen specific immunotherapy (iNeST)

- BNT122 – BioNTech and Genentech reported a data update for the Phase 1a and 1b trial in multiple solid tumors in June 2020 as part of the American Association for Cancer Research (AACR) Virtual Annual Meeting II. As a monotherapy and in combination with atezolizumab, RO7198457 (BNT122/RG6180) was observed to have a manageable safety profile and to induce significant levels of neoantigen-specific immune responses, even in late-stage, heavily pre-treated patients. RO7198457 (BNT122/RG6180) is partnered with Genentech.
- BNT122 – BioNTech expects to provide an enrollment update from the Phase 2 trial (IMCODE-001) in first line melanoma in 2H 2020 with an interim data update anticipated in 2H 2021.
- BNT122 – Two Phase 2 clinical trials are planned in the adjuvant setting. The first adjuvant Phase 2 study is currently recruiting for patients and first patient dosing is expected in 2H 2020. The trial is designed to evaluate the efficacy and safety of RO7198457 (BNT122/RG6180) plus atezolizumab compared with atezolizumab alone in patients with early and adjuvant stage non-small-cell lung cancer (NSCLC). The second Phase 2 study will be in colorectal cancer in adjuvant setting and is expected to initiate in 2H 2020. This trial will be a multi-site, open-label, Phase 2, randomized trial to compare the efficacy of RO7198457 (BNT122/ RG6180) versus watchful waiting in patients with circulating tumor DNA (ctDNA) positive, surgically resected Stage 2/3 rectal cancer, or Stage 2 (high risk)/Stage 3 colon cancer.

mRNA intratumoral immunotherapy

- BNT131 – BioNTech expects to provide a data update from the Phase 1 trial in solid tumors in 2H 2020. The trial is a first-in-human (FIH), multi-site, 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 a monotherapy and in combination with cemiplimab in patients with advanced solid tumors. The data to be presented will include safety, tolerability and pharmacodynamic biomarkers. SAR441000/BNT131 is partnered with Sanofi.

CAR-T cell immunotherapy

- BNT211 – Initiation of a Phase 1/2a open-label, multi-site dose escalation and dose expansion basket trial with or without a CLDN6 CARVac immunotherapy is expected in 2H 2020. While the preclinical focus has mainly been on ovarian cancer, patients with uterine, testicular, lung and gastric cancers may also be enrolled.

Neoantigen-Targeting T Cells

- BNT221 (NEO-PTC-01) – Initiation of a Phase 1 dose escalation trial of BNT221 is expected in 2H 2020 for the treatment of metastatic melanoma in patients who are refractory or unresponsive to checkpoint inhibitors. The primary objectives will be to evaluate the safety and feasibility of administering BNT221 to patients. Additional objectives include evaluation of immunogenicity and clinical efficacy.

Next-generation checkpoint immunomodulators

- BNT311 – BioNTech expects to provide a data update in 2H 2020, which will include dose-escalation data from the Phase 1/2 trial in multiple solid tumors for GEN1042/BNT311 (PD-L1x4-1BB). The program is partnered with Genmab.

Toll-Like receptor binding agonist

- BNT411 – On July 8, the first patient was dosed in a Phase 1/2a, first-in-human, open-label, dose-escalation trial with expansion cohorts to evaluate the safety, pharmacokinetics, pharmacodynamics and preliminary efficacy of BNT411 as a monotherapy in patients with solid tumors and in combination with atezolizumab, carboplatin and etoposide in patients with chemotherapy-naïve extensive-stage small cell lung cancer (ES-SCLC).

Corporate Development

During the second quarter, BioNTech completed the acquisition of Neon Therapeutics, Inc. BioNTech continues to integrate the new subsidiary, based in Cambridge, Massachusetts, which serves as BioNTech's U.S. headquarters.

Second Quarter 2020 Financial Results

Cash Position: Cash and cash equivalents as of June 30, 2020, were €573.0 million.

- On July 27, 2020, BioNTech announced the closing of an underwritten offering of 5,500,000 American Depository Shares ("ADSs"), each representing one of BioNTech's ordinary shares, at a public offering price of \$93.00 per ADS, for gross proceeds of €456.8 million (\$511.5 million¹). The underwritten offering had no accounting impact within the second quarter 2020.
- On July 22, 2020, BioNTech announced the terms of a rights offering of rights to subscribe for ordinary shares, including ordinary shares represented by ADSs, extended to holders of its ordinary shares and ADSs. Certain holders irrevocably agreed not to transfer or exercise their rights in the rights offering, and the shares underlying those rights were offered in the underwritten offering. The ADS rights exercise period expires at 12:01 a.m. (New York City time) on August 14, 2020 and the ordinary share rights exercise period expires one minute after 11:59 p.m. (Mainz, Germany time) on August 14, 2020. The rights offering had no accounting impact within the second quarter 2020.
- On June 29, 2020, BioNTech announced the signing of a private investment of €223.9 million (\$250.7 million¹) by Temasek and another accredited investor. The private placement includes an investment of approximately €123.9 million (\$138.7 million¹) in ordinary shares and a €100.0 million (\$112.0 million¹) investment in a 4-year mandatory convertible note. Upon closing, private placement investors will receive 2,595,996 ordinary shares in BioNTech, which will be subject to a 180-day lock-up agreement. The 4-year mandatory convertible note will come with a coupon of 4.5% per annum and a conversion premium of 20% above the reference price. The investment is subject to customary closing conditions, which were not fulfilled before June 30, 2020 and had no accounting impact within the second quarter 2020.

- On June 11, 2020, the European Investment Bank (EIB) and BioNTech entered into a €100.0 million (\$112.0 million¹) loan financing agreement to support the development of BNT162. The deal will also allow the Company to expand its manufacturing capacity in order to rapidly supply the vaccine, worldwide, in response to the pandemic. The EIB debt investment will be disbursed in two tranches of €50.0 million (\$56.0 million¹) each. The closing of the financing agreement, subject to achieving certain milestone events, was not fulfilled before June 30, 2020 and had no accounting impact within the second quarter 2020.
- In Q2 2020 BioNTech received an aggregate of €216.7 million (\$236.0 million) in non-refundable upfront payments from the BNT162 collaboration agreements and equity investments with Pfizer and Fosun Pharma.

Revenue: Total revenue, consisting primarily of revenue from collaboration agreements, was €41.8 million for the three months ended June 30, 2020, compared to €25.8 million for the three months ended June 30, 2019. For the period of six months ended June 30, 2020, total revenue was €69.4 million, compared to €51.9 million for the comparative prior year period. The revenue from collaboration agreements overall increased due to the recognition of revenue from our new collaboration agreements signed with Pfizer and Fosun Pharma as part of the Company's BNT162 vaccine program against COVID-19. The revenues from other sales transactions increased due to increased orders and include sales of diagnostic products, peptides, retroviral vectors for clinical supply and development and manufacturing services sold to third-party customers.

Research and Development Expenses: Research and development expenses were €95.2 million for the three months ended June 30, 2020, compared to €53.4 million for the three months ended June 30, 2019. For the period of six months ended June 30, 2020, total research and development expenses were €160.3 million, compared to €110.6 million for the comparative prior year period. The increase was mainly due to an increase in headcount leading to higher wages, benefits and social security expenses as well as an increase in expenses for purchased research and development services, especially with respect to our BNT162 program. In addition, from the date of acquisition, the new U.S.-based subsidiary, BioNTech US Inc., contributed to our research and development expenses.

General and Administrative Expenses: General and administrative expenses were €18.8 million for the three months ended June 30, 2020, compared to €14.6 million for the three months ended June 30, 2019. For the period of six months ended June 30, 2020, total general and administrative expenses were €34.6 million, compared to €23.9 million for the comparative prior year period. The increase was mainly influenced by higher expenses for purchased management consulting and legal services as well as an increase in headcount leading to higher wages, benefits and social security expenses. In addition, from the date of acquisition, our new U.S.-based subsidiary, BioNTech US Inc., contributed to our general and administrative expenses.

Net Loss: Net loss was €88.3 million for the three months ended June 30, 2020, compared to €50.1 million for the three months ended June 30, 2019. For the period of six months ended June 30, 2020, total net loss was €141.7 million, compared to €90.8 million for the comparative prior year period.

Shares Outstanding: Shares outstanding as of June 30, 2020 were 232,673,455.

Financial Guidance:

- As a result of increased spending related to BNT162, BioNTech now expects net cash used in operating activities and for purchases of property and equipment to be between €450 million and €600 million in the full year 2020.
- BioNTech anticipates that existing cash and cash equivalents, the net proceeds from the recent underwritten offering and the expected net proceeds from the private investment announced in June 2020 will enable the Company to fund operating expenses and capital requirements through at least the next 24 months.

Full financial statements can be found in the 6-K filing as published on the SEC website under <https://www.sec.gov/>.

Conference Call and Webcast Information

BioNTech SE will host a conference call and webcast today at 08:00 a.m. ET (2:00 p.m. CET) to report its financial results for the quarter ended June 30, 2020 and provide a corporate update.

To participate in the conference call, please dial the following numbers 15-20 minutes prior to the start of the call and provide the Conference ID: 1963889.

United States international: +1 646 741 3167
United States domestic (toll-free): +1 877 870 9135
Germany: +49 692 2222 625

Participants may also access the slides and the webcast of the conference call via the “Events & Presentations” page of the Investor Relations section of the Company’s website at <https://biontech.de/>. A replay of the webcast will be available shortly after the conclusion of the call and archived on the Company’s website for 30 days following the call.

Financial and Operational Results for the Second Quarter Ended June 30, 2020**Key Pipeline Updates**

Below is a summary of our clinical product candidates, organized by platform and indication.

Oncology

BioNTech has also continued to advance its broad oncology pipeline. With the initiation of a first-in-human (FIH) Phase 1 clinical trial for TLR7 agonist (BNT411), the oncology pipeline now includes 11 products in 12 ongoing trials across the mRNA-, antibody- and small molecule technologies. In Q2 and subsequent, BioNTech reported 2 interim data updates on clinical trials for 2 different oncology product candidates. Up to four further data updates are expected in 2H 2020. In 2H 2020, BioNTech intends to initiate three Phase 2 trials (BNT111, BNT 113, BNT122), two additional FIH trials (BNT211, BNT221) and is currently recruiting subjects for RO7198457 (BNT122/RG6180) for a Phase 2 clinical trial in adjuvant NSCLC.

FixVac

Our FixVac product candidates contain selected combinations of pharmacologically optimized uridine mRNA encoding known cancer-specific shared antigens. These candidates 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. FixVac is currently being evaluated in five clinical trials including:

- BNT111 in a Phase 1 trial in advanced melanoma.
 - A data update was recently published in *Nature*. The trial, designed to evaluate safety and tolerability of vaccinated patients with stage IIIB-C and stage IV melanoma, included 89 patients and highlighted a favorable tolerability profile of BNT111. An efficacy analysis conducted within a subset of 42 checkpoint-inhibitor (CPI)-experienced metastatic melanoma patients showed that BNT111 mediates durable responses both as a single agent and in combination with anti-PD-1 antibodies by establishing an association with activation and strong expansion of tumor-antigen-specific CD4+ and CD8+ T cells.
 - On July 31, BioNTech and Regeneron Pharmaceuticals, Inc. announced a strategic collaboration to jointly conduct a randomized Phase 2 study for the treatment of melanoma that has progressed after prior PD-1 blockade, utilizing BNT111 FixVac and Regeneron's Libtayo® in combination.
 - We expect to initiate this Phase 2 trial with registrational potential in the second half of 2020.
- BNT112 in a Phase 1/2 trial in prostate cancer ongoing.
- BNT113 in a Phase 1 trial in HPV16+ head and neck cancers. We are planning to initiate a Phase 2 trial with registrational potential for BNT113 in HPV+ head and neck cancers in the second half of 2020.

- BNT1142 in a Phase 1 trial in triple negative breast cancer (TNBC). A data update from the trial is expected in the second half of 2020. The exploratory Phase 1 study evaluates immunogenicity and safety of vaccination with individualized neoantigen immunotherapy and non-mutated tumor-associated antigens in TNBC.
- BNT115 in a Phase 1 trial in ovarian cancer ongoing.
- BNT116 is in preclinical development for non-small cell lung cancer.

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. RO7198457 (BNT122/ RG6180) is partnered with Genentech.

- We, in collaboration with Genentech, reported a data update for the Phase 1a and 1b trial in multiple solid tumors in June 2020 as part of the American Association for Cancer Research (AACR) Virtual Annual Meeting II. As a monotherapy and in combination with atezolizumab, RO7198457 (BNT122/RG6180) was observed to have a manageable safety profile and to induce significant levels of neoantigen-specific immune responses, even in late-stage, heavily pre-treated patients.
- We expect to provide an enrollment update from the Phase 2 trial (IMCODE-001) in first line melanoma in the second half of 2020 with an interim data update anticipated in the second half of 2021.
- We and Genentech plan to conduct two Phase 2 clinical trials in the adjuvant setting. The first adjuvant Phase 2 study is currently recruiting for patients, and first patient dosing is expected in the second half of 2020. The trial is designed to evaluate the efficacy and safety of RO7198457 (BNT122/RG6180) plus atezolizumab compared with atezolizumab alone in patients with early and adjuvant stage non-small cell lung cancer (NSCLC). The second Phase 2 study will be in colorectal cancer in adjuvant setting and is expected to initiate in the second half of 2020. This trial will be a multi-site, open-label, Phase 2, randomized trial to compare the efficacy of RO7198457 (BNT122/RG6180) versus watchful waiting in patients with circulating tumor DNA (ctDNA) positive, surgically resected Stage 2/3 rectal cancer or Stage 2 (high risk)/Stage 3 colon cancer.

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).

- We expect to report a data update in the second half of 2020 from the ongoing Phase 1 trial. The trial is a first-in-human, multi-center, open-label, dose escalation and expansion trial to evaluate the safety, pharmacokinetics, pharmacodynamics and anti-tumor activity of SAR441000 (BNT131) administered intratumorally as a monotherapy and in combination with cemiplimab in patients with advanced solid tumors. The data to be presented will include safety, tolerability and pharmacodynamic biomarkers.

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 sdiscovery 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 1/2a clinical trial for BNT211 in patients with advanced CLDN6+ solid tumors in the second half of 2020. While the preclinical focus has mainly been on ovarian cancer, patients with uterine, testicular, lung and gastric cancers may also be enrolled.

Neo-antigen targeting T cells

Through our recent Neon acquisition, we obtained a neoantigen-targeting T cell platform that can be utilized to develop product candidates across several neoantigen-targeting non-engineered and engineered T cell therapies. Our lead product candidate under this platform is our individualized neoantigen-targeting T cell therapy, BNT221.

- We expect to initiate a Phase 1 dose escalation trial of BNT221 in the second half of 2020 for the treatment of metastatic melanoma in patients who are refractory or unresponsive to checkpoint inhibitors. The primary objectives will be to evaluate the safety and feasibility of administering BNT221 to patients. Additional objectives include evaluation of immunogenicity and clinical efficacy.

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. BioNTech expects to provide a data update for the BNT311 trial, which will include dose-escalation data in the second half of 2020.

Targeted cancer antibodies

MVT-5873 (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.

Small molecule immunomodulators

BNT411 is our novel small molecule TLR7 agonist product candidate. BNT411 is engineered for high potency and high selectivity for the TLR7 receptor to activate both the adaptive and innate immune system.

- On July 8, 2020, the first patient was dosed in a Phase 1/2a, first-in-human, open-label, dose-escalation trial with expansion cohorts to evaluate the safety, pharmacokinetics, pharmacodynamics and preliminary efficacy of BNT411 as a monotherapy in patients with solid tumors, and in combination with atezolizumab, carboplatin and etoposide in patients with chemotherapy-naïve extensive-stage small cell lung cancer (ES-SCLC).

In addition, we have several other cancer immunotherapy programs in pre-clinical 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 clinical trials for our first two RiboMab product candidates, BNT141 and BNT142, both 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.

Infectious Disease Immunotherapies

COVID-19 Vaccine Program

In response to the coronavirus global pandemic, the company assembled a global consortium of partners including Pfizer (worldwide collaboration outside of China) and Fosun Pharma (China). BioNTech's vaccine program against COVID-19, BNT162, leverages our proprietary mRNA platform. Currently there are four vaccine candidates: two of the four vaccine candidates include a nucleoside modified mRNA (modRNA), one includes a uridine containing mRNA (uRNA), and the fourth vaccine candidate utilizes self-amplifying mRNA (saRNA). Each mRNA format is combined with a lipid nanoparticle (LNP) formulation. The larger spike sequence is included in two of the vaccine candidates, and the smaller optimized receptor binding domain (RBD) from the spike protein is included in the other two candidates.

Along with our partner, Pfizer:

- We released data from the ongoing U.S. Phase 1/2 placebo-controlled, observer-blinded clinical trial, evaluating nucleoside-modified mRNA vaccine candidate (BNT162b1) in 45 subjects, and data from an ongoing Germany trial in 60 subjects.
- We received Fast Track designation for BNT162b1 and BNT162b2 from the U.S. Food and Drug Administration (FDA).
- We initiated a Phase 2b/3 study for BNT162b2 in up to 30,000 participants aged 18 to 85 years at approximately 120 sites globally. If successful, BioNTech and Pfizer plan to file for market authorization or regulatory approval as early as October 2020.

- We completed initial commercial supply agreements totaling more than 250 million doses with the United Kingdom, the United States, Japan and Canada to be delivered in 2020 and 2021, with an option to purchase an additional 500 million doses. All agreements are subject to clinical success and regulatory approval.

Along with our partner, Fosun, we have initiated a Phase 1 study for BNT162b1 to evaluate safety and immunogenicity in Chinese participants to support a potential regulatory approval pathway in China.

Flu vaccine

We have a collaboration with Pfizer to develop mRNA-based immunotherapies for the prevention of influenza, product candidate BNT161. We expect to begin clinical testing in 2021.

Infectious diseases

We have a research collaboration with the University of Pennsylvania, under which we have the exclusive option to develop and commercialize mRNA immunotherapies for the treatment of up to 10 infectious disease indications. We expect the first clinical trial under this collaboration to start in the first half of 2021. We have also 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.

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 product to enter the clinic in the second half of 2021.

¹ All amounts translated using the exchange rate published by the German Central Bank (Deutsche Bundesbank) in effect as of June 30, 2020.

² IVAC_M_uID is also being investigated in arm 2 (N=15) of the 3 arm TNBC-MERIT trial, with BNT114 as an optional treatment; BNT114 is investigated in arm 1 (N=12) and arm 3 (N=15) of the TNBC-MERIT trial (total patients in study: N=42).

About BioNTech

Biopharmaceutical New Technologies is a next generation immunotherapy company pioneering novel therapies for cancer and other serious diseases. The Company exploits a wide array of computational discovery and therapeutic drug platforms for the rapid development of novel biopharmaceuticals. Its broad portfolio of oncology product candidates includes individualized and off-the-shelf mRNA-based therapies, innovative chimeric antigen receptor T cells, bi-specific checkpoint immuno-modulators, targeted cancer antibodies and small molecules. Based on its deep expertise in mRNA vaccine development and in-house manufacturing capabilities, BioNTech and its collaborators are developing multiple mRNA vaccine candidates for a range of infectious diseases alongside its diverse oncology pipeline. BioNTech has established a broad set of relationships with multiple global pharmaceutical collaborators, including Genmab, Sanofi, Bayer Animal Health, Genentech, a member of the Roche Group, Regeneron, Genevant, Fosun Pharma, and Pfizer.

For more information, please visit www.BioNTech.de

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, including, but not limited to, statements concerning: our expected cash usage for 2020 and beyond; our anticipated cash runway; the timing, completion and extent of subscription of the rights offering; the planned next steps in BioNTech's pipeline programs and specifically including, but not limited to, statements regarding plans to initiate clinical trials of BioNTech's product candidates; expectations for data announcements with respect to BioNTech's clinical trials; the timing for any potential emergency use authorizations or approvals for BNT162; and our ability to scale-up manufacturing capacity for BNT162 and supply the quantities of BNT162 to support clinical development and, if approved, market demand, including our production estimates for 2020 and 2021. In some cases, forward-looking statements can be identified by terminology such as "will," "may," "should," "expects," "intends," "plans," "aims," "anticipates," "believes," "estimates," "predicts," "potential," "continue," or the negative of these terms or other comparable terminology, although not all forward-looking statements contain these words. The forward-looking statements in this press release are neither promises nor guarantees, and you should not place undue reliance on these forward-looking statements because they involve known and unknown risks, uncertainties, and other factors, many of which are beyond BioNTech's control and which could cause actual results to differ materially from those expressed or implied by these forward-looking statements. You should review the risks and uncertainties described under the heading "Risk Factors" in BioNTech's Annual Report on Form 20-F filed with the U.S. Securities and Exchange Commission (SEC) on March 31, 2020 and in subsequent filings made by BioNTech with the SEC, which are available on the SEC's website at <https://www.sec.gov/>. Except as required by law, BioNTech disclaims any intention or responsibility for updating or revising any forward-looking statements contained in this press release in the event of new information, future developments or otherwise. These forward-looking statements are based on BioNTech's current expectations and speak only as of the date hereof.

Investor Relations

Sylke Maas, Ph.D.
VP Investor Relations & Business Strategy
Tel: +49 (0)6131 9084 1074
E-mail: Investors@biontech.de

Media Relations

Jasmina Alatovic
Senior Manager Global External Communications
Tel: +49 (0)6131 9084 1513 or +49 (0)151 1978 1385
E-mail: Media@biontech.de

BIONTECH



BioNTech SE

Quarterly Report for the Three and Six Months ended June 30, 2020

BioNTech SE

Quarterly Report for the Three and Six Months ended June 30, 2020

Index

[Interim Condensed Consolidated Financial Statements](#)

<u>Interim Condensed Consolidated Statements of Financial Position</u>	3
<u>Interim Condensed Consolidated Statements of Operations</u>	4
<u>Interim Condensed Consolidated Statements of Comprehensive Loss</u>	5
<u>Interim Condensed Consolidated Statements of Changes in Stockholder's Equity</u>	6
<u>Interim Condensed Consolidated Statements of Cash Flows</u>	7
<u>Selected Explanatory Notes to the Interim Condensed Consolidated Financial Statements</u>	8
1 <u>Corporate Information</u>	8
2 <u>Basis of Preparation, Significant Accounting Policies</u> and further Accounting Topics	8
3 <u>Segment Information</u>	10
4 <u>Revenue from Contracts with Customers</u>	12
5 <u>Business Combinations</u>	13
6 <u>Income Tax</u>	16
7 <u>Intangible Assets</u>	16
8 <u>Property, Plant and Equipment</u>	16
9 <u>Financial Assets and Financial Liabilities</u>	17
10 <u>Issued Capital and Reserves</u>	18
11 <u>Share-Based Payments</u>	19
12 <u>Related Party Disclosures</u>	23
13 <u>Events after the Reporting Period</u>	24

[Operating and Financial Review and Prospects](#)

<u>Operating Results</u>	26
<u>Liquidity and Capital Resources</u>	40
<u>Risk Factors</u>	45

Interim Condensed Consolidated Financial Statements

Interim Condensed Consolidated Statements of Financial Position

(in thousands)	Note	June 30, 2020 (unaudited)	December 31, 2019
Assets			
Non-current assets			
Intangible assets	7	€183,281	€89,434
Property, plant and equipment	8	112,829	93,044
Right-of-use assets		54,905	55,018
Other assets		1,316	-
Total non-current assets		€352,331	€237,496
Current assets			
Inventories		8,615	11,722
Trade receivables	9	7,679	11,913
Contract assets		1,621	-
Other financial assets	9	1,953	1,680
Other assets		16,329	9,069
Income tax assets		1,012	756
Deferred expense		10,896	5,862
Cash and cash equivalents		573,011	519,149
Total current assets		€621,116	€560,151
Total assets		€973,447	€797,647
Equity and liabilities			
Equity			
Share capital	10	238,198	232,304
Capital reserve	10	918,174	686,714
Treasury shares	10	(5,525)	(5,525)
Accumulated losses		(566,509)	(424,827)
Other reserves	11	17,596	4,826
Total equity		€601,934	€493,492
Non-current liabilities			
Financial liabilities	9	70,289	68,904
Other liabilities		431	-
Contract liabilities		86,793	97,109
Deferred tax liabilities		5,434	-
Total non-current liabilities		€162,947	€166,013
Current liabilities			
Tax provisions		150	150
Provisions		833	762
Financial liabilities	9	2,591	1,823
Trade payables	9	35,690	20,498
Contract liabilities		117,661	93,583
Other financial liabilities	9	33,763	13,836
Other liabilities		17,878	7,490
Total current liabilities		€208,566	€138,142
Total liabilities		€371,513	€304,155
Total equity and liabilities		€973,447	€797,647

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

Interim Condensed Consolidated Statements of Operations

(in thousands, except per share data)	Note	Three months ended June 30,		Six months ended June 30,	
		2020 (unaudited)	2019	2020 (unaudited)	2019
Revenues from contracts with customers	4	€41,762	€25,785	€69,425	€51,939
Cost of sales		(5,662)	(5,489)	(11,504)	(8,694)
Gross profit		€36,100	€20,296	€57,921	€43,245
Research and development expenses		(95,189)	(53,402)	(160,311)	(110,643)
Sales and marketing expenses		(3,054)	(678)	(3,540)	(1,238)
General and administrative expenses		(18,813)	(14,623)	(34,628)	(23,899)
Other operating income		773	660	1,198	991
Other operating expenses		(759)	(120)	(859)	(158)
Operating loss		€(80,942)	€(47,867)	€(140,219)	€(91,702)
Finance income*		205	425	593	1,876
Finance expenses*		(9,300)	(2,204)	(3,374)	(151)
Interest expense related to lease liability		(465)	(425)	(880)	(850)
Loss before tax		€(90,502)	€(50,071)	€(143,880)	€(90,827)
Income taxes	6	2,206	(13)	2,198	(19)
Loss for the period		€(88,296)	€(50,084)	€(141,682)	€(90,846)
Attributable to:					
Equity holders of the parent		(88,296)	(50,084)	(141,682)	(90,730)
Non-controlling interests		-	-	-	(116)
Earnings per share		€(88,296)	€(50,084)	€(141,682)	€(90,846)
<i>in EUR</i>					
Basic & diluted, loss per share for the period attributable to equity holders of the parent**		€(0.38)	€(0.24)	€(0.62)	€(0.45)

* Foreign exchange differences on a cumulative basis are either shown as finance income or expenses and might switch between those two positions during the year-to-date reporting periods.

** Numbers of shares for calculating the earnings per share for the three and six months ended June 30, 2019 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 interim consolidated financial statements.

Interim Condensed Consolidated Statements of Comprehensive Loss

(in thousands)	Note	Three months ended June 30,		Six months ended June 30,	
		2020	2019 (unaudited)	2020	2019 (unaudited)
Loss for the period		€(88,296)	€(50,084)	€(141,682)	€(90,846)
Other comprehensive income <i>Other comprehensive income that may be reclassified to profit or loss in subsequent periods (net of tax)</i>		(3,367)	2	(3,493)	6
Net other comprehensive income that may be reclassified to profit or loss in subsequent periods		(3,367)	2	(3,493)	6
Other comprehensive income for the period, net of tax		(3,367)	2	(3,493)	6
Comprehensive loss for the period, net of tax		€(91,663)	€(50,082)	€(145,175)	€(90,840)
Attributable to:					
Equity holders of the parent		(91,663)	(50,082)	(145,175)	(90,724)
Non-controlling interests		-	-	-	(116)
Comprehensive loss for the period, net of tax		€(91,663)	€(50,082)	€(145,175)	€(90,840)

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

Interim Condensed Consolidated Statements of Changes in Stockholders' Equity

Six months ended June 30, 2020

		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, 2020		€232,304	686,714	(5,525)	(424,827)	4,762	64	493,492	-	493,492
Loss for the period		-	-	-	(141,682)	-	-	(141,682)	-	(141,682)
Other comprehensive loss		-	-	-	-	-	(3,493)	(3,493)	-	(3,493)
Total comprehensive loss		-	-	-	(141,682)	-	(3,493)	(145,175)	-	(145,175)
Issuance of share capital	10	5,894	233,113	-	-	-	-	239,007	-	239,007
Transaction costs	10	-	(1,653)	-	-	-	-	(1,653)	-	(1,653)
Share-based payments	11	-	-	-	-	16,263	-	16,263	-	16,263
June 30, 2020 <i>(unaudited)</i>		€238,198	918,174	(5,525)	(566,509)	21,025	(3,429)	601,934	-	601,934

Six months ended June 30, 2019
Attributable to the 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		-	-	-	(90,730)	-	-	(90,730)	(116)	(90,846)
Other comprehensive income		-	-	-	-	-	6	6	-	6
Total comprehensive income / (loss)		-	-	-	(90,730)	-	6	(90,724)	(116)	(90,840)
Issuance of share capital	10	5,088	(5,078)	-	-	-	-	10	-	10
Capital increase Series B	10	11,990	178,845	-	-	-	-	190,835	-	190,835
Acquisition of non-controlling interest	10	2,375	(1,644)	-	-	-	-	731	(731)	-
Transaction costs	10	-	(501)	-	-	-	-	(501)	-	(501)
Share based payments	11	-	-	-	-	17,986	-	17,986	-	17,986
As of June 30, 2019 <i>(unaudited)</i>		€212,749	515,737	-	(336,501)	(7,488)	(7)	384,490	-	384,490

* 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 interim condensed consolidated financial statements.

Interim Condensed Consolidated Statements of Cash Flows

	Six months ended June 30,	
(in thousands)	2020 (unaudited)	2019
Operating activities		
Loss for the period	€(141,682)	€(90,846)
Income taxes	(2,198)	19
Loss before tax	€(143,880)	€(90,827)
Adjustments to reconcile loss before tax to net cash flows:		
Depreciation and amortization of property, plant, equipment and intangible assets	17,425	15,595
Share-based payment expense	16,263	17,986
Net foreign exchange differences	(50)	143
Loss on disposal of property, plant and equipment	80	9
Finance income	(593)	(769)
Interest on lease liability	880	850
Finance expense	208	151
Other non-cash income	(151)	-
Working capital adjustments:		
Decrease/(Increase) in trade receivable and contract assets	(9,770)	9,715
Decrease/(Increase) in inventories	3,246	(1,355)
(Decrease)/Increase in trade payables, other liabilities, contract liabilities and provisions	46,918	(36,936)
Interest received	576	769
Interest paid	(985)	(1,001)
Income tax paid	(375)	(19)
Net cash flows used in operating activities	€(70,208)	€(85,689)
Investing activities		
Purchase of property, plant and equipment	(21,396)	(10,608)
Proceeds from sale of property, plant and equipment	2	557
Purchase of intangibles assets	(4,174)	(29,665)
Acquisition of subsidiaries and businesses, net of cash acquired	891	(6,050)
Net cash flows used in investing activities	€(24,677)	€(45,766)
Financing activities		
Proceeds from issuance of share capital, net of costs	147,806	175
Proceeds from loans and borrowings	2,899	6,035
Repayment of loans and borrowings	(319)	-
Payments related to lease liabilities	(2,173)	(1,291)
Net cash flows from financing activities	€148,213	€4,919
Net increase/(decrease) in cash and cash equivalents	53,328	(126,536)
Change in cash resulting from exchange rate differences	534	(69)
Cash and cash equivalents at January 1	519,149	411,495
Cash and cash equivalents at June 30	€573,011	€284,890

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

Selected Explanatory Notes to the Interim Condensed 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 have been publicly traded on the 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, or IFRS, unaudited interim condensed consolidated financial statements present the financial position and the results of operation of BioNTech SE and its subsidiaries, hereinafter also referred to as "BioNTech" or the "Group" and have been prepared on a going concern basis in accordance with the IFRS as issued by the International Accounting Standards Board, or IASB.

BioNTech combines decades of groundbreaking research in immunology, cutting-edge therapeutic platforms and a suite of patient profiling and bioinformatic tools to develop immunotherapies for cancer and 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. The breadth of BioNTech's immunotherapy technologies and expertise has enabled the Group to develop therapies to address a range of rare and infectious diseases, and BioNTech has recently rapidly mobilized these with the aim of addressing the COVID-19 pandemic.

On May 6, 2020 BioNTech SE acquired Neon Therapeutics, Inc., Cambridge, Massachusetts, United States (formerly Nasdaq: NTGN), or Neon. Under the merger agreement by and among BioNTech, Neon and BioNTech's wholly owned subsidiary, Endor Lights, Inc., New York, United States, Endor Lights, Inc. merged with and into Neon. The new subsidiary operates under the name BioNTech US Inc., a wholly owned subsidiary of BioNTech SE, and serves as BioNTech's headquarters in the United States. All BioNTech entities are included in the Group's unaudited interim condensed consolidated financial statements.

These unaudited interim condensed consolidated financial statements of the Group as of and for the three and six months ended June 30, 2020 were authorized for issuance in accordance with a resolution of the audit committee on August 10, 2020.

2 Basis of Preparation, Significant Accounting Policies and further Accounting Topics

Basis of Preparation

These unaudited interim condensed consolidated financial statements as of and for the three and six months ended June 30, 2020 have been prepared in accordance with IAS 34 Interim Financial Reporting.

The unaudited interim condensed consolidated financial statements do not include all the information and disclosures required in the consolidated financial statements and should be read in conjunction with the Group's consolidated financial statements as of and for the year ended December 31, 2019.

BioNTech prepares and presents its unaudited interim condensed consolidated financial statements in Euros. Due to rounding, numbers presented throughout this document may not add up precisely to the totals provided and percentages may not precisely reflect the absolute figures.

Significant Accounting Policies

The accounting policies adopted in the preparation of the unaudited interim condensed consolidated financial statements are consistent with those followed in the preparation of the Group's consolidated financial statements for the year ended December 31, 2019. The standards applied for the first time as of January 1, 2020, as disclosed in the notes to the consolidated financial statements as of December 31, 2019, had no impact on the unaudited interim condensed consolidated financial statements of the Group as of June 30, 2020.

Impact of COVID-19

On March 11, 2020, the World Health Organization declared the outbreak of COVID-19 as a pandemic, which continues to spread throughout the United States, the European Union and around the world.

In response, BioNTech's BNT162 program is evaluating at least four experimental vaccines aimed at preventing COVID-19 infection. As part of the program, BioNTech executed two strategic collaborations with large pharmaceutical companies to globally develop BioNTech's vaccine candidates and supply an approved vaccine globally. BioNTech and Pfizer Inc. (NYSE: PFE), or Pfizer, aim to accelerate the development of BNT162 worldwide, excluding China, which is covered by BioNTech's strategic alliance with Shanghai Fosun Pharmaceutical (Group) Co., Ltd (Stock Symbol: 600196.SH, 02196.HK), or Fosun Pharma.

As BioNTech advances its clinical programs, it is in close contact with its principal investigators and clinical sites, which are located in jurisdictions affected by the COVID-19 pandemic, and is assessing the impact of the COVID-19 pandemic on its clinical trials, expected timelines and costs on an ongoing basis. In light of recent developments relating to the COVID-19 pandemic, the primary focus of healthcare providers and hospitals remains on fighting the novel coronavirus. BioNTech has also modified its business practices, in response to the spread of COVID-19, including restricting employee travel, developing social distancing plans for employees and cancelling physical participation in meetings, events and conferences. In addition, for certain earlier stage programs, including BNT141 and BNT142 (RiboMabs), BNT151 and BNT152/153 (RiboCytokines), BNT161 (Influenza), BNT171 (Rare Disease) and BNT411 (TLR7), BioNTech has delayed commencement of trials, experienced slowed patient enrollment or experienced other delays as a result of the COVID-19 pandemic. This partial disruption, even temporary, may severely impact BioNTech's operations and overall business by delaying the progress of its clinical trials and preclinical studies. Such factors were evaluated and considered carefully when preparing these unaudited interim condensed consolidated financial statements. BioNTech will continue to evaluate potential effects of the COVID-19 pandemic and will provide updates as appropriate.

3 Segment Information

For the three and six months ended June 30, 2020 and 2019, respectively, the following tables present revenue and operating results for the Group's operating segments consistent with the presentation in the notes to the consolidated financial statements as of December 31, 2019:

(in thousands)	Biotech Business Unit					External Services Business Unit	Total	Adjustments	Group
	Clinical	Technology Platform	Manufacturing	Business Service	Product Sales & External Services				
Three months ended June 30, 2020									
Revenues									
Collaboration Revenues	€12,154	€5,479	€14,952	-	-	€32,585	-	-	€32,585
Revenues from other sales transactions	-	88	-	-	9,089	9,177	-	-	9,177
Cost of sales	-	-	-	-	(4,779)	(4,779)	(883)	(883)	(5,662)
Gross Profit	€12,154	€5,567	€14,952	-	€4,310	€36,983	€(883)	€(883)	€36,100
Income / Expenses									
Research and development expenses	(37,111)	(35,905)	(21,026)	(1,883)	(147)	(96,072)	883	883	(95,189)
Sales and marketing expenses	-	-	-	(2,459)	(595)	(3,054)	-	-	(3,054)
General and administrative expenses	-	(5)	(1,018)	(16,956)	(835)	(18,814)	1	1	(18,813)
Other result	(2)	13	30	(16)	(11)	14	-	-	14
Segment operating income / (loss)	€(24,959)	€(30,330)	€(7,062)	€(21,314)	€2,722	€(80,943)	€1	€1	€(80,942)

(in thousands)	Biotech Business Unit					External Services Business Unit	Total	Adjustments	Group
	Clinical	Technology Platform	Manufacturing	Business Service	Product Sales & External Services				
Three months ended June 30, 2019									
Revenues									
Collaboration Revenues	€9,141	-	€10,984	-	-	€20,125	-	-	€20,125
Revenues from other sales transactions	-	323	2	8	5,327	5,660	-	-	5,660
Cost of sales	-	-	-	-	(5,501)	(5,501)	12	12	(5,489)
Gross Profit	€9,141	€323	€10,986	€8	€(174)	€20,284	€12	€12	€20,296
Income / Expenses									
Research and development expenses	(19,359)	(19,813)	(12,315)	(1,725)	(177)	(53,389)	(13)	(13)	(53,402)
Sales and marketing expenses	-	-	-	(283)	(395)	(678)	-	-	(678)
General and administrative expenses	-	-	(1,117)	(12,860)	(646)	(14,623)	-	-	(14,623)
Other result	151	146	8	(24)	256	537	3	3	540
Segment operating loss	€(10,067)	€(19,344)	€(2,438)	€(14,884)	€(1,136)	€(47,869)	€2	€2	€(47,867)

(in thousands)	Biotech Business Unit					External Services Business Unit			
	Clinical	Technology Platform	Manufacturing	Business Service	Product Sales & External Services		Total	Adjustments	Group
Six months ended June 30, 2020									
Revenues									
Collaboration Revenues	€18,963	€7,425	€27,358	-	-	€53,746	-	€53,746	
Revenues from other sales transactions	103	245	-	-	15,331	15,679	-	15,679	
Cost of sales	-	-	-	-	(10,434)	(10,434)	(1,070)	(11,504)	
Gross profit	€19,066	€7,670	€27,358	-	€4,897	€58,991	€(1,070)	€57,921	
Income / Expenses									
Research and development expenses	(58,444)	(62,704)	(36,855)	(3,070)	(308)	(161,381)	1,070	(160,311)	
Sales and marketing expenses	-	-	-	(2,623)	(917)	(3,540)	-	(3,540)	
General and administrative expenses	-	(5)	(2,176)	(30,974)	(1,473)	(34,628)	-	(34,628)	
Other result	(15)	68	42	230	14	339	-	339	
Segment operating income / (loss)	€(39,393)	€(54,971)	€(11,631)	€(36,437)	€2,213	€(140,219)	-	€(140,219)	

(in thousands)	Biotech Business Unit					External Services Business Unit			
	Clinical	Technology Platform	Manufacturing	Business Service	Product Sales & External Services		Total	Adjustments	Group
Six months ended June 30, 2019									
Revenues									
Collaboration Revenues	€18,431	-	€23,592	-	-	€42,023	-	€42,023	
Revenues from other sales transactions	-	463	2	8	9,443	9,916	-	9,916	
Cost of sales	-	-	-	-	(8,603)	(8,603)	(91)	(8,694)	
Gross profit	€18,431	€463	€23,594	€8	€840	€43,336	€(91)	€43,245	
Income / Expenses									
Research and development expenses	(43,686)	(38,214)	(26,237)	(2,335)	(262)	(110,734)	91	(110,643)	
Sales and marketing expenses	-	-	-	(569)	(669)	(1,238)	-	(1,238)	
General and administrative expenses	-	-	(1,858)	(20,696)	(1,345)	(23,899)	-	(23,899)	
Other result	260	288	14	26	245	833	-	833	
Segment operating loss	€(24,995)	€(37,463)	€(4,487)	€(23,566)	€(1,191)	€(91,702)	-	€(91,702)	

The segments are managed based on external sales and operating profit/loss, which represents the operating profit/loss incurred within 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 cost incurred. 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 other results that are not directly attributable to one of the segments are allocated to Business Service.

In order to reconcile the segment figures to the Group's unaudited interim condensed financial statements, some of the research and development expenses are reclassified to cost of sales.

Revenue at BioNTech is differentiated between revenues resulting from collaboration and license agreements and revenues from other sales transactions. The Company collaborates with pharmaceutical and healthcare companies and several global academic collaborators. During the three and six months ended June 30, 2020, revenue generated from the Genentech, Inc., or Genentech, and Pfizer collaboration agreements each represented more than 10% of BioNTech's overall revenue resulting from collaboration and license agreements. Revenues were partly recorded in the Clinical and the Manufacturing segment and, with respect to Pfizer, in the Technology Platform segment as well. During the three months ended June 30, 2019, only revenue generated from the Genentech collaboration agreement represented more than 10% of BioNTech's overall revenue from collaboration and license agreements. Revenues were partly recorded in the Clinical as well as the Manufacturing segment. During the six months ended June 30, 2019, revenue generated from the Genentech and Pfizer collaboration agreements each represented more than 10% of BioNTech's overall revenue from collaboration and license agreements and were recorded in the Clinical segment and, with respect to Genentech, in the Manufacturing segment. Total amounts of revenues from these collaboration and license agreements in the periods presented are disclosed in Note 4.

Revenues from other sales transactions are 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 while manufacturing facilities and sales offices are located and managed in Germany. External sales originate in Germany.

4 Revenues from Contracts with Customers

Disaggregated revenue information

Set out below is the disaggregation of the Group's revenues from contracts with customers:

(in thousands)	Three months ended June 30,		Six months ended June 30, 2019	
	2020	2019	2020	2019
Revenues resulting from collaboration and license agreements				
<i>Genentech Inc.</i>	€32,585	€20,125	€53,746	€42,023
<i>Pfizer Inc.</i>	11,258	15,619	26,886	31,750
<i>Sanofi S.A.</i>	20,613	3,587	24,200	7,174
<i>Shanghai Fosun Pharmaceutical (Group) Co., Ltd</i>	257	919	1,759	3,099
Revenues from other sales transactions	457	-	901	-
Total	9,177	5,660	15,679	9,916
Total	€41,762	€25,785	€69,425	€51,939

During the three and six months ended June 30, 2020, revenues from BioNTech's two new collaboration agreements aimed at developing a COVID 19 vaccine were recognized for the first time.

On March 13, 2020, BioNTech entered into a collaboration and license agreement with Fosun Pharma. Fosun Pharma paid BioNTech a non-refundable upfront cash payment of k€901 (k\$1,000) upon signing the agreement in addition to an equity investment of k€45,568 (k\$50,000) (see Note 10 for the capital contribution). BioNTech is eligible to receive future milestone payments of up to k\$84,000 for potential aggregate consideration of k\$135,000.

On April 9, 2020, BioNTech entered into a collaboration and license agreement with Pfizer. Pfizer agreed to pay BioNTech k€170,146 (k\$185,000), including an equity investment of k€103,890 (k\$113,000) (see Note 10 for the capital contribution) and a non-refundable upfront cash payment of k€66,256 (k\$72,000) which were received in late April 2020 and May 2020, respectively. BioNTech is eligible to receive future milestone payments of up to k\$563,000 for potential aggregate consideration of k\$748,000. Pfizer and BioNTech share development costs equally. Initially, Pfizer will fund 100% of the development costs, and BioNTech will repay Pfizer its 50% share of these costs if success-based milestones are reached, or with proceeds generated from the commercialization of the vaccine, if approved. If the vaccine program is not successful or does not generate sufficient proceeds, BioNTech will not be required to pay back its 50% share of the development costs incurred.

During the three months ended March 31, 2020, k€444 of the upfront payment from Fosun Pharma was recognized as revenue during the three months ended March 31, 2020. The remaining k€457 was recognized as revenue during the three months ended June 30, 2020. During the three months ended June 30, 2020, revenue from Pfizer was initiated to be recognized from the non-refundable upfront cash payment which has a restricted purpose by being dedicated to activities to be performed under the collaboration and license agreement. Based on cost incurred, k€20,613 revenue was recognized of which k€14,258 were directly incurred by BioNTech and k€6,356 have been accrued based on BioNTech's 50% share of the shared development costs incurred. As services are performed under a collaboration agreement, revenue recognition will be continued in future periods in accordance with our accounting policy as described in "—Critical Accounting Policies and Use of Estimates" and Note 2.3.4 to our consolidated financial statements included in our Annual Report on Form 20-F for the year ended December 31, 2019.

Product sales included within revenue from other sales transactions are displayed below:

<i>(in thousands)</i>	Three months ended June 30,		Six months ended June 30,	
	2020	2019	2020	2019
Product sales of JPT Peptide Technologies GmbH	€5,884	€3,009	€9,037	€5,835

5 Business Combinations

BioNTech US Inc. (formerly Neon Therapeutics, Inc.)

On May 6, 2020, BioNTech acquired Neon, a biotechnology company developing novel neoantigen-based T-cell therapies ("the Merger"). Through the acquisition, BioNTech will be able to leverage Neon's expertise in the development of neoantigen therapies, with both vaccine and T cell capabilities.

Based on the acquisition date share price, the aggregate value of the merger consideration was k€89,890 (k\$97,144) financed by issuing 1,935,488 American Depository Shares representing BioNTech's ordinary shares as a stock transaction and including a de minimis cash consideration which was paid to settle Neon's outstanding stock options.

The provisional fair values and values in accordance with IFRS 3 of the identifiable net assets of BioNTech US Inc. as at the date of acquisition were as follows:

	Fair value recognized on acquisition BioNTech US Inc.
(in thousands)	
Assets	
Intangible assets	€29,867
Property, plant and equipment	5,617
Right-of-use assets	6,896
Other assets non-current and current	2,704
Cash	7,749
Total assets	€52,833
Liabilities	
Trade payables	1,723
Deferred tax liability	8,043
Other liabilities non-current and current	17,793
Total liabilities	€27,559
Total identifiable net assets at fair value	€25,274
Provisional goodwill from the acquisition	64,616
Consideration transferred	€89,890
Consideration	
Shares issued, at fair value	89,548
Cash paid	342
Total consideration	€89,890

During the measurement period, further considerations will be made especially with respect to the recoverability of tax losses carried forward. This will potentially have an impact on the identifiable net assets and the respective goodwill.

The interim condensed consolidated statement of operations includes the result of BioNTech US since the acquisition date. From the date of acquisition through June 30, 2020, BioNTech US contributed k€7,353 to the operating loss in all biotech business unit operating segments of the Group, primarily in the Technology Platform segment. If the transaction had occurred at the beginning of the reporting period, k€38,643 would have contributed to the operating loss. This amount includes expenses resulting from the Merger and should not necessarily be considered representative of the future consolidated results of operations or financial condition on a consolidated basis. From the date of acquisition, BioNTech US did not generate any revenue and no revenue would have been generated if the transaction had occurred at the beginning of the reporting period.

Provisional goodwill recognized is primarily attributable to the expected synergies and other benefits from combining two organizations with a common culture of pioneering translational science and a shared vision for the future of cancer immunotherapy as described above. The provisional goodwill resulting from the BioNTech US acquisition during the six months ended June 30, 2020 was provisionally allocated to the Technology Platform segment.

Transaction costs of k€1,044 relating to the acquisition have been expensed and are included in the general and administrative expenses in the interim condensed consolidated statement of operations. To the extent that costs have already been invoiced and paid, k€1,007, they are included in cash flows used in operating activities in the interim condensed consolidated statement of cash flows. The attributable costs of the issuance of the shares of k€1,320 were recorded in equity as a deduction from the capital reserve and are included in cash flows from financing activities in the interim condensed consolidated statement of cash flows.

Lipocalyx GmbH

In December 2019, BioNTech Delivery Technologies GmbH (previously BioNTech Protein Therapeutics GmbH), or 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, or Lipocalyx, and its related parties in exchange for a total consideration of cash at an amount of k€6,516 and additional contingent consideration estimated at the closing date of January 6, 2020 at an amount of k€572. The employees of Lipocalyx were transferred automatically to BioNTech Delivery Technologies with effect as of the closing date.

The Group acquired the assets of Lipocalyx and its related parties to combine the acquired technologies and the related know-how with already existing product candidates of the Group to improve their functionality and performance.

The final fair values of the identifiable net assets of Lipocalyx as at the date of acquisition were:

	Fair value recognized on acquisition
(in thousands)	
Assets	
Goodwill	€896
Other intangible assets	5,978
Property, plant and equipment	75
Inventories	139
Total identifiable net assets at fair value	€7,088
 Consideration	
Cash paid	€6,516
Contingent consideration liability	572
Total consideration	€7,088

The interim condensed consolidated statement of operations includes the result of Lipocalyx since the acquisition date. From the date of acquisition, Lipocalyx contributed k€707 to operating loss in the Technology Platform business segment of the Group. From the date of acquisition through June 30, 2020, Lipocalyx generated k€176 in revenues. Given the timing of closing, the contribution to operating loss and revenues, if the transaction had occurred at the beginning of the reporting period, would not differ materially. Goodwill recognized is primarily attributed to the expected synergies and other benefits from combining the assets and activities of Lipocalyx with those of the Group. The goodwill resulting from the Lipocalyx acquisition during the six months ended June 30, 2020 was allocated to the Technology Platform segment.

Transaction costs of k€17 relating to the acquisition have been expensed and are included in the general and administrative expenses in the interim condensed consolidated statement of operations and are included in cash flows used in operating activities in the interim condensed consolidated statement of cash flows.

The purchase agreement with Lipocalyx includes the following contingent cash considerations to the previous owners:

- k€1,000 upon successful completion of a Phase 1 clinical trial designed to show and establish a sufficient safety margin justifying further development of the first pharmaceutical product relating to acquired technologies formulated in a manner covered by a valid granted claim in a major country of a patent within the assigned IP rights; and
- k€1,000 upon successful completion of the first Phase 2 clinical trial of the first pharmaceutical product relating to acquired technologies formulated in a manner covered by a valid granted claim in a major country of a patent within the assigned IP rights.

At the acquisition date, the fair value of the contingent consideration was k€572. The contingent consideration is presented in ‘non-current financial liabilities’ in the interim condensed consolidated statements of financial position.

6 Income Tax

The Group calculates the interim income tax expense using the tax rate that would be applicable to the expected total annual earnings. Deferred tax assets on tax losses of subsidiaries incorporated in Germany have not been capitalized as there is not sufficient probability that there will be future taxable profits against which the unused tax losses can be utilized. Deferred tax assets calculated from tax losses of subsidiaries incorporated in the United States incurred since the acquisition of BioNTech US have been recorded in an amount of k€2,317. Deferred tax assets have been offset with deferred tax liabilities recognized as part of the acquisition of BioNTech US (see Note 5) given that the conditions to offset were fulfilled. Accumulated tax losses relate to Germany and the United States. There is no expiration date for any of the accumulated tax losses under German tax law. With respect to accumulated losses incurred at the level of BioNTech USA Holding LLC and BioNTech Research and Development Inc. since their incorporation and tax losses of BioNTech US since the acquisition of BioNTech US there is no expiration date under U.S. tax law.

7 Intangible Assets

During the six months ended June 30, 2020, the Group acquired intangible assets with a cost of k€4,175 (six months ended June 30, 2019: k€10,451), excluding intangible assets acquired through business combinations (see Note 5). The acquisitions during the six months ended June 30, 2020 mainly related to advance payments (k€2,957) as well as concessions, licenses, in-process R&D and similar rights (k€1,218). During the six months ended June 30, 2019, the acquisitions mainly related to concessions, licenses, in-process R&D and similar rights (k€7,029) as well as to advance payments (k€3,422).

8 Property, Plant and Equipment

During the six months ended June 30, 2020, the Group acquired property, plant and equipment with a cost of k€21,396 (six months ended June 30, 2019: k€10,609), excluding property, plant and equipment acquired through business combinations (see Note 5). The acquisitions during the six months ended June 30, 2020 were related to construction in progress and advance payments (k€14,780), equipment, tools and installations (k€4,201) as well as land and buildings (k€2,415). During the six months ended

June 30, 2019, the acquisitions were related to equipment, tools and installations (k€5,743), construction in progress and advance payments (k€4,224) as well as land and buildings (k€642).

9 Financial Assets and Financial Liabilities

Set out below, is an overview of financial assets, other than cash and cash equivalents, held by the Group as of June 30, 2020 and December 31, 2019:

Financial assets at amortized cost

	June 30, 2020	December 31, 2019
Purchased services		
Trade receivables	€7,679	€11,913
Other financial assets	1,953	1,680
Total	€9,632	€13,593
Total current	9,632	13,593
Total non-current	-	-

Set out below, is an overview of financial liabilities held by the Group as of June 30, 2020 and December 31, 2019:

Financial liabilities at amortized cost (including interest-bearing loans and borrowings)

	Maturity	June 30, 2020	December 31, 2019
Purchased services			
Trade payables		€35,690	€20,498
Lease liabilities		57,750	57,612
2.15% € 10,000,000 secured bank loan	12/30/2027	9,731	9,000
2.08% € 9,450,000 secured bank loan	09/30/2028	9,508	7,600
Other financial liabilities		29,654	10,351
Total		€142,333	€105,061
Total current		72,044	36,157
Total non-current		70,289	68,904

Risk management activities

No changes have occurred regarding the Group's risk management activities as disclosed in the notes to the consolidated financial statements as of December 31, 2019.

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 June 30, 2020 and December 31, 2019, the carrying value approximates their fair values as there have been no significant changes in relevant interest rates since inception of the respective loans.

Manufacturing Financing

BioNTech entered into an agreement with the European Investment Bank (EIB) for a €100 million credit facility to partially support the development of BNT162 and fund expansion of BioNTech's manufacturing capacity to provide worldwide supply of BNT162 in response to the COVID-19 pandemic.

Under this arrangement, the EIB agreed to provide BioNTech with a credit in an amount up to €100 million to partially finance such development and expansion. The credit consists of (i) a term loan in the amount of €50 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 €50 million that may be drawn in a single tranche (Credit B). 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. The closing of the financing agreement, subject to achieving certain milestone events, was not fulfilled before June 30, 2020 and had no accounting impact within the three and six months ended June 30, 2020.

June 2020 Private Placement

On June 29, 2020, BioNTech announced the signing of a private investment of €223.9 million (\$250.7 million; this and the following amounts calculated using the exchange rate in effect as of June 30, 2020 as published by the German Central Bank (*Deutsche Bundesbank*)) by a fund associated with Temasek Capital Management Pte. Ltd., or Temasek, and another accredited investor, which investment BioNTech refers to as the June 2020 Private Placement. The private placement includes an investment of approximately €123.9 million (\$138.7 million) in ordinary shares and a €100.0 million (\$112.0 million) investment in 4-year mandatory convertible notes. Upon the closing of the June 2020 Private Placement, the investors will receive an aggregate of 2,595,996 ordinary shares in BioNTech, which will be subject to a 180-day lock-up agreement. The four-year mandatory convertible note will have a coupon of 4.5% per annum and a conversion premium of 20% above the reference price. The closing of the investment, subject to customary closing conditions, was not fulfilled before June 30, 2020 and had no accounting impact within the three and six months ended June 30, 2020.

10 Issued Capital and Reserves

On September 18, 2019, BioNTech effected a 1:18 share split by issuing 206,595,492 shares by way of a capital increase from its own funds; thus, no outside proceeds were received. This capital increase came into effect upon registration with the commercial register (*Handelsregister*). The accompanying unaudited interim condensed consolidated financial statements and notes to the unaudited interim condensed consolidated financial statements give retroactive effect to the share split for all periods presented.

Capital transactions during the six months ended June 30, 2020

During the six months ended June 30, 2020, the issued share capital of BioNTech increased by k€5,894. Each share has a nominal value of €1.00. As a result of the financing transactions the capital reserve increased by k€233,113. Costs of k€1,653 related to these equity transactions were recorded in equity as deduction from the capital reserve. The financing transactions that occurred during the six months ended June 30, 2020, were as follows:

Shanghai Fosun Pharmaceuticals (Group) Co., Ltd

As part of the BNT162 program, BioNTech entered a strategic alliance with Fosun Pharma to develop COVID-19 vaccine candidates in China. Fosun Pharma agreed to make an equity investment of k€45,568 (k\$50,000) for 1,580,777 ordinary shares in BioNTech via Fosun Industrial Co., Limited, Hong Kong. The increase in share capital with a nominal amount of k€1,581 was subject to execution of share subscription documentation and approval from regulatory authorities in China and became effective with the registration with the commercial register (*Handelsregister*) on April 23, 2020. As result of the transaction the capital reserve increased by k€43,987.

Pfizer Inc., New York, New York, United States

As part of the collaboration between BioNTech and Pfizer, for the co-development of BNT162, Pfizer agreed to make an equity investment of k€103,890 (k\$113,000). The issuance of 2,377,446 ordinary

shares with the nominal amount of k€ 2,377 was registered with the commercial register (*Handelsregister*) on May 5, 2020. As result of the transaction the capital reserve increased by k€101,513.

Neon Therapeutics, Inc., Cambridge, Massachusetts, United States

BioNTech acquired Neon by issuing 1,935,488 American Depository Shares representing BioNTech's ordinary shares with the nominal amount of k€ 1,935 to former stockholders of Neon in the Merger. The capital increase was registered with the commercial register (*Handelsregister*) on May 8, 2020. As result of the transaction the capital reserve increased by k€87,613.

Capital transactions during the six months ended June 30, 2019

During the comparative period of six months ended June 30, 2019, the issued share capital of BioNTech increased by k€19,453. Each share has a par value of €1.00. Of the amount issued in 2019, k€11,990 relates to a new financing round (referred to as the Series B round) with existing and new investors. As a result of the Series B financing, the capital reserve increased during the six months ended June 30, 2019 by k€178,845. As of March 14, 2019, BioNTech acquired the remaining 5.5% of non-controlling interests in BioNTech Cell & Gene Therapies GmbH previously held by Eli Lilly Nederland B.V. in exchange for issuing 2,374,794 new ordinary shares with an imputed nominal value 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 in 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. Costs of k€501 related to the equity transactions that occurred during the six months ended June 30, 2019, were recorded in equity as deduction from the capital reserve.

11 Share-Based Payments

Management Board Grant (Cash-Settled)

Since the beginning of 2020, the first year following the completion of BioNTech's initial public offering ("IPO"), the current service agreements with BioNTech's Management Board have provided for a short-term incentive compensation of up to a maximum of fifty percent of the annual base salary for the years 2020, 2021 and 2022. The amount of such short-term incentive compensation will depend on the achievement of certain company goals in the particular fiscal year, which goals will be set uniformly for all members of the Management Board. Fifty percent of the incentive compensation will be paid promptly upon achievement of the applicable company goals (first installment), with the remaining amount payable one year later, subject to adjustment relative to the performance of the price of the American Depository Shares representing BioNTech's ordinary shares during that year (second installment).

For each of the three yearly awards, the second installment of the short-term incentive compensation that is dependent on the price of the American Depository Shares representing BioNTech's ordinary shares, represents a cash-settled share-based payment arrangement. The fair values of the liabilities are recognized over the award's vesting period beginning as of the service commencement date (January 1, 2020) until each separate determination date and are remeasured until settlement date.

During the three months ended June 30, 2020, the Group recognized share-based payment expenses of k€83 as research & development expenses and of k€124 as general & administrative expenses in the interim condensed consolidated statement of operations (three months ended June 30, 2019: Nil).

During the six months ended June 30, 2020, the Group recognized share-based payment expenses of k€165 as research & development expenses and of k€248 as general & administrative expenses in the interim condensed consolidated statement of operations (six months ended June 30, 2019: Nil).

Management Board Grant (Equity-Settled)

From the beginning of 2020, the first year following the completion of BioNTech's IPO, until the end of the term of the Management Board member's employment agreement, the service agreements with BioNTech's Management Board provide for a long-term incentive compensation in terms of a yearly grant of options to purchase BioNTech shares. The right to receive options in 2020, 2021 and 2022 represents an equity-settled share-based payment arrangement.

The options allocated each year will be subject to the terms, conditions, definitions and provisions of the Employee Stock Ownership Plan ("ESOP") and the applicable option agreement thereunder. The number of options to be allocated 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. The value used to calculate the number of options for Ryan Richardson increases to €280,000 for the year 2022.

The allocation of the number of options to be received in 2020 took place on February 13, 2020 (allocation date). The allocations of the number of options to be received in 2021 and 2022 are estimated to take place on the first and second anniversary of the allocation date (estimated allocation dates).

The share options allocated and expected to be allocated to BioNTech's Management Board as of the dates indicated are presented in the tables below.

Allocation date February 13, 2020	Share options outstanding	Weighted-average exercise price (€)
Prof. Ugur Sahin, M.D.	97,420	28.32
Sean Marett	38,968	28.32
Dr. Sierk Poetting	38,968	28.32
Dr. Özlem Türeci	38,968	28.32
Ryan Richardson	33,772	28.32

Estimated allocation date February 13, 2021	Share options expected to be allocated	Weighted-average exercise price (€)
Prof. Ugur Sahin, M.D.	44,830	59.75*
Sean Marett	17,932	59.75*
Dr. Sierk Poetting	17,932	59.75*
Dr. Özlem Türeci	17,932	59.75*
Ryan Richardson	15,541	59.75*

* Valuation parameter derived from the Monte-Carlo simulation model

Estimated allocation date February 13, 2022	Share options expected to be allocated	Weighted-average exercise price (€)
Prof. Ugur Sahin, M.D.	44,516	60.17*
Sean Marett	17,806	60.17*
Dr. Sierk Poetting	17,806	60.17*
Dr. Özlem Türeci	17,806	60.17*
Ryan Richardson	16,619	60.17*

* Valuation parameter derived from the Monte-Carlo simulation model

For the awards with estimated allocation dates, the numbers of awards expected to be allocated have been calculated using the valuation parameter derived from the Monte-Carlo simulation model. The numbers will be adjusted until the actual allocation has occurred and the number of options granted has ultimately been determined. The options will vest annually in equal installments over four years commencing on the first anniversary of the allocation date and will be exercisable four years after the allocation date.

The options will be subject to the terms, conditions, definitions and provisions of the ESOP and the applicable option agreement thereunder. The vested options 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 ordinary shares outstanding immediately following the initial public offering (other than ordinary shares owned by BioNTech), and (b) for each twelve-month period starting on the fifth or subsequent anniversary of the allocation date, 107% of the target share price applicable for the prior twelve-month period); and (iii) the closing price for the fifth trading day prior to the start of the relevant exercise window is higher than the exercise price by at least the same percentage by which the Nasdaq Biotechnology Index or a comparable successor index as of such time is higher than such index was as of the last trading day before the allocation date. The options 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 values at the (estimated) allocation dates of the Management Board Grant. This model incorporates the impact of the performance criteria regarding share price and index development described above. The parameters used for measuring the fair values as of the respective (estimated) allocation dates were as follows:

	Allocation date February 13, 2020	Estimated allocation date February 13, 2021	Estimated allocation date February 13, 2022
Weighted average fair value*	€10.83	€22.15	€21.51
Weighted average share price	€28.20	€59.60*	€59.60*
Exercise price	€28.32	€59.75*	€60.17*
Expected volatility (%)	36.6%	35.2%	35.0%
Expected life (years)*	4.75	5.45	6.49
Risk-free interest rate (%)	1.61 %	0.62%	0.62%

* Valuation parameter derived from the Monte-Carlo simulation model

The exercise of the option rights in accordance with the terms of the ESOP gives the Management Board members the right to obtain shares against payment of the exercise price. The per share exercise price of the options is the Euro equivalent of the arithmetic mean of the closing prices of the ten last trading days prior to the allocation date. For the award allocated as of February 13, 2020 the exercise price has been determined to be \$30.78 (€28.32). The exercise prices for the awards with estimated allocation dates as of February 13, 2021 and February 13, 2022 have been derived from the Monte-Carlo simulation model. Expected volatility was based on an evaluation of the historical volatilities of comparable companies over the historical period commensurate with the expected option term. The expected term was based on general optionholder behavior for employee options.

The share options allocated and expected to be allocated under the Management Board Grant were as follows:

	Share options (expected to be allocated)	Weighted- average exercise price (€)
As of January 1, 2020	-	-
Granted as of allocation date February 13, 2020	248,096	28.32
Expected to be allocated as of estimated allocation date February 13, 2021	114,167	59.75*
Expected to be allocated as of estimated allocation date February 13, 2022	114,553	60.17*
As of June 30, 2020	476,816	43.50

* Valuation parameter derived from the Monte-Carlo simulation model

As of June 30, 2020, the share options allocated and expected to be allocated had a remaining weighted-average expected life of 5.30 years.

The expenses recognized for employee services received during the three and six months ended June 30, 2020 are shown in the following table:

<i>(in thousands)</i>	Three months ended June 30,	Six months ended June 30,
	2020	2020
Research and development expenses	€349	€718
General and administrative expenses	287	591
Total	€636	€1,309

Chief Executive Officer Grant (Equity-Settled)

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. As disclosed in the notes to the consolidated financial statements as of December 31, 2019, the option will be subject to the terms, conditions, definitions and provisions of the ESOP and the applicable option agreement thereunder.

During the three and six months ended June 30, 2020, no further options were granted or forfeited.

As of June 30, 2020, the share options outstanding had a remaining expected life of 4.62 years.

During the three months ended June 30, 2020 the Group has recognized k€3,208 of share-based payment expenses as research & development expenses in the interim condensed consolidated statement of operations (three months ended June 30, 2019: Nil).

During the six months ended June 30, 2020 the Group has recognized k€6,416 of share-based payment expenses as research & development expenses in the interim condensed consolidated statement of operations (six months ended June 30, 2019: Nil).

Employee Stock Ownership Plan (Equity-Settled)

On November 15, 2018, the Group established a share option program that grants selected employees options to receive shares in the company. The program is designed as an Employee Stock Ownership Plan (ESOP) as disclosed in the notes to the consolidated financial statements as of December 31, 2019. The amounts disclosed in this note have been retrospectively adjusted to reflect the share split as described in note 10.

Set out below is an overview of changes to share options outstanding and number of ordinary shares underlying these options that occurred during the six months ended June 30, 2020.

	Share options outstanding	Number of ordinary shares underlying options	Weighted- average exercise price (€)
As of January 1, 2020	655,383	11,796,894	10.23
Forfeited	(8,971)	(161,478)	10.82
As of June 30, 2020	646,412	11,635,416	10.23

During the six months ended June 30, 2020 no further options were granted but 8,971 share options were forfeited.

As of June 30, 2020, the share options outstanding had a remaining weighted-average expected life of 4.23 years.

The expenses recognized for employee services received during the three and six months ended June 30, 2020 and June 30, 2019 are shown in the following table:

(in thousands)	Three months ended June 30,		Six months ended June 30,	
	2020	2019	2020	2019
Cost of sales	€213	€228	€426	€456
Research and development expenses	2,787	2,733	5,573	14,503
Sales and marketing expenses	27	27	55	55
General and administrative expenses	1,242	1,502	2,484	2,972
Total	€4,269	€4,490	€8,538	€17,986

12 Related Party Disclosures

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 consummated transactions with the Group during the period.

BioNTech has 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., BioNTech's co-founder and Chief Executive Officer, is a significant shareholder of TRON.

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

(in thousands)	Three months ended June 30,		Six months ended June 30,	
	2020	2019	2020	2019
Consulting services / patent assignment	€6	€9	€6	€15
Purchases of various goods and services from TRON	1,602	1,566	3,835	4,163
Total	€1,608	€1,575	€3,841	€4,178

The outstanding balances of transactions related to key management personnel were as follows as of the dates indicated:

(in thousands)	June 30, 2020	December 31, 2019
TRON	€861	€1,843
Total	€861	€1,843

Other Related Party Transactions

ATHOS KG, Holzkirchen, Germany owns 100% of shares in AT Impf GmbH, Munich, Germany and is the beneficial owner of BioNTech SE. AT Impf GmbH, Munich, Germany is the parent company of the Group. Entities controlled by ATHOS KG mainly provide rental and property management activities and sell property, plant and equipment to BioNTech. The total amount of transactions with ATHOS KG or entities controlled by them was as follows for the periods indicated:

(in thousands)	Three months ended		Six months ended	
	June 30, 2020	2019	June 30, 2020	2019
Purchases of various goods and services from entities controlled by ATHOS KG	€961	€738	€1,450	€1,272
Purchases of property and other assets from entities controlled by ATHOS KG	2,349	-	2,349	-
Total	€3,310	€738	€3,799	€1,272

The outstanding balances of transactions with ATHOS KG or entities controlled by them were as follows as of the dates indicated:

(in thousands)	June 30, 2020	December 31, 2019
ATHOS KG	€565	€51
Total	€565	€51

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

13 Events after the Reporting Period

On July 20, 2020, BioNTech and Pfizer entered into a binding term sheet for a supply agreement with the United Kingdom. Pursuant to the term sheet, BioNTech and Pfizer expect to supply 30 million doses of BNT162, if approved, to the United Kingdom. Under the terms of the binding term sheet, BioNTech and Pfizer are eligible to receive a fully refundable advance payment per dose upon signing of a definitive supply agreement. The advance payment will be treated as a prepayment towards the total cost of the contracted number of doses of BNT162, with the remainder of the contracted price per dose to be paid upon delivery of the contracted doses.

On July 27, 2020, BioNTech's underwritten offering (the "Underwritten Offering") of 5,500,000 American Depository Shares ("ADSs"), each representing one of BioNTech's ordinary shares, closed at a public offering price of \$93.00 per ADS, for gross proceeds of \$511.5 million. The Underwritten Offering is part of a Global Offering that includes the Underwritten Offering and a rights offering (the

“Rights Offering”). In addition, a selling shareholder granted the underwriters a 30-day option to purchase up to 825,000 additional ADSs at the same public offering price, which has not yet been exercised. BioNTech will not receive any of the proceeds from sale of ADSs by the selling shareholder.

On July 31, 2020, BioNTech entered into a strategic collaboration with Regeneron for a clinical trial combining BioNTech’s BNT111 FixVac product candidate and Libtayo® (cemiplimab), a fully human anti-PD-1 therapy, for the treatment of melanoma. The companies plan to jointly conduct a randomized Phase 2 study in patients with anti-PD1-refractory/relapsed, unresectable Stage III or IV cutaneous melanoma.

Operating and Financial Review and Prospects

In this report, unless stated or the context otherwise requires, references to the “Company,” “BioNTech,” “we,” “us” and “our” refer to BioNTech SE and its consolidated subsidiaries. The following “Operating and Financial Review and Prospects” should be read together with the unaudited interim condensed consolidated financial statements and related notes as presented above. 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” in our Annual Report on Form 20-F for the year ended December 31, 2019 as well as the “Risk Factors” described in the respective section further below. Please also see “Forward-Looking Statements” included in Exhibit 99.1 of the Form 6-K of which this exhibit forms a part.

Operating Results

Overview

BioNTech was founded in 2008 on the understanding that every cancer patient’s tumor is unique and that in order to effectively address this challenge, we must create individualized treatments for each patient. To realize this vision, we combine decades of groundbreaking research in immunology, cutting-edge therapeutic platforms and a suite of patient profiling and bioinformatic tools to develop immunotherapies for cancer and 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. The breadth of our immunotherapy technologies and expertise has also enabled us to develop therapies to address a range of rare and infectious diseases, and we have recently rapidly mobilized these with the aim of addressing the COVID-19 pandemic. 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 12 have entered into 13 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 500 patients across 17 tumor types to date. Our immunotherapy drug classes consist of messenger ribonucleic acid, or mRNA, therapeutics, 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 1,400 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, Bayer AG, or Bayer, Pfizer Inc., or Pfizer, Shanghai Fosun Pharmaceutical (Group) Co., Ltd., or Fosun Pharma, and Regeneron Pharmaceuticals, Inc., or Regeneron. We have built out comprehensive, highly automated, on-demand in-house manufacturing capabilities that complement the development of our individualized immunotherapies.

The following table shows our consolidated statements of operations for each period presented:

(in thousands)	Three months ended June 30,		Six months ended June 30,	
	2020	2019	2020	2019
	(unaudited)	(unaudited)		
Revenues from contracts with customers	€41,762	€25,785	€69,425	€51,939
Cost of sales	(5,662)	(5,489)	(11,504)	(8,694)
Gross profit	€36,100	€20,296	€57,921	€43,245
Research and development expenses	(95,189)	(53,402)	(160,311)	(110,643)
Sales and marketing expenses	(3,054)	(678)	(3,540)	(1,238)
General and administrative expenses	(18,813)	(14,623)	(34,628)	(23,899)
Other operating income	773	660	1,198	991
Other operating expenses	(759)	(120)	(859)	(158)
Operating loss	€(80,942)	€(47,867)	€(140,219)	€(91,702)
Finance income	205	425	593	1,876
Finance expenses	(9,300)	(2,204)	(3,374)	(151)
Interest expense related to lease liability	(465)	(425)	(880)	(850)
Loss before tax	€(90,502)	€(50,071)	€(143,880)	€(90,827)
Income taxes	2,206	(13)	2,198	(19)
Loss for the period	€(88,296)	€(50,084)	€(141,682)	€(90,846)

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)	Three months ended June 30,		Six months ended June 30,	
	2020	2019	2020	2019
	(unaudited)	(unaudited)		
Revenues from contracts with customers				
Revenues resulting from collaboration and license agreements	€32,585	€20,125	€53,746	€42,023
Revenues from other sales transactions	9,177	5,660	15,679	9,916
Total revenues from contracts with customers	€41,762	€25,785	€69,425	€51,939

The following table summarizes our collaboration revenue for the periods indicated:

<i>(in thousands)</i>	Three months ended June 30,		Six months ended June 30,	
	2020	2019 (unaudited)	2020	2019 (unaudited)
Revenues resulting from collaboration and license agreements				
Genentech Inc.	€11,258	€15,619	€26,886	€31,750
Pfizer Inc.	20,613	3,587	24,200	7,174
Sanofi S.A.	257	919	1,759	3,099
Shanghai Fosun Pharmaceutical (Group) Co., Ltd	457	-	901	-
Total revenues resulting from collaboration and license agreements	€32,585	€20,125	€53,746	€42,023

Our collaboration revenue consists of milestone payments, upfront licensing payments and reimbursement of development expenses. Certain of these payments are initially recorded as contract liabilities on our statement of financial position and are subsequently recognized as revenue in accordance with our accounting policy as described in “—Critical Accounting Policies and Use of Estimates” and Note 2.3.4 to our consolidated financial statements included in our Annual Report on Form 20-F for the year ended December 31, 2019.

From the three months ended June 30, 2019 to the three months ended June 30, 2020, total revenues resulting from collaboration and license agreements increased from €20.1 million to €32.6 million. Total revenues resulting from collaboration and license agreement for the six months ended June 30, 2020 increased from €42.0 million for the comparative prior year period to €53.7 million.

During the three and six months ended June 30, 2020, revenues from our two new collaboration agreements were recognized for the first time. As part of the BNT162 program, our vaccine program against COVID-19, we collaborate with Pfizer and Fosun Pharma. The BNT162 program is evaluating at least four experimental vaccines, each of which represent a unique combination of messenger RNA format and target antigen. During the three months ended March 31, 2020, upon signing the agreement, a non-refundable upfront cash payment of €0.9 million was received from Fosun Pharma, of which €0.4 million was recognized as revenue during the three months ended March 31, 2020 and the remaining €0.5 million was recognized as revenue during the three months ended June 30, 2020. During the three months ended June 30, 2020, a non-refundable upfront cash payment of €66.3 million was received from Pfizer which has a restricted purpose by being dedicated to activities to be performed under the collaboration and license agreement. Based on costs incurred, €20.6 million revenue was recognized of which €14.2 million were directly incurred by us and €6.4 million have been accrued based on our 50% share of the shared development costs incurred. As services are performed under a collaboration agreement, revenue recognition will be continued in future periods in accordance with our accounting policy.

In light of recent developments relating to the COVID-19 pandemic, the primary focus of healthcare providers and hospitals remains on fighting the novel coronavirus. For certain of our earlier stage programs we have delayed commencement of trials, experienced slowed patient enrollment or experienced other delays as a result of the COVID-19 pandemic. Accordingly, during the three and six months ended June 30, 2020, revenues from our collaboration programs with Genentech, Sanofi and from the non-COVID-19 collaboration with Pfizer have decreased compared to the prior year periods. We will continue to monitor this temporary partial disruption and will continue to evaluate potential effects of the COVID-19 pandemic. Our collaborations with Bayer, Genevant and Genmab did not generate any revenue in the three and six months ended June 30, 2020 and 2019.

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. During the three and six months ended June 30, 2020, those revenues increased due to increased orders.

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. We do not expect revenue from pharmaceutical product sales before the fourth quarter of 2020. Our ability to generate sales revenue from our BNT162 program is subject to regulatory authorization or approval. If the vaccine candidate is approved, we and our collaboration partner Pfizer expect to manufacture up to 100 million doses by the end of 2020 and potentially more than 1.3 billion doses by the end of 2021. 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.

Cost of Sales

Our cost of sales includes wages, benefits and 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:

(in thousands)	Three months ended		Six months ended	
	June 30,		June 30,	
	2020	2019 (unaudited)	2020	2019 (unaudited)
Cost of sales				
Wages, benefits and social security expense	€3,327	€2,101	€6,023	€3,783
Laboratory supplies	449	1,837	1,969	2,024
Purchased services	658	527	1,270	1,009
Depreciation and amortization	388	349	773	694
Other	840	675	1,469	1,184
Total cost of sales	€5,662	€5,489	€11,504	€8,694

From the three months ended June 30, 2019 to the three months ended June 30, 2020, cost of sales slightly increased from €5.5 million to €5.7 million. Cost of sales for the six months ended June 30, 2020 increased from €8.7 million for the comparative prior year period to €11.5 million. The increase was mainly due to an increase in headcount leading to higher wages, benefits and social security expenses as well as an increase in expenses for contract manufacturing services.

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)	Three months ended June 30,		Six months ended June 30,	
	2020	2019 (unaudited)	2020	2019 (unaudited)
Research and development expenses				
Wages, benefits and social security expense	€32,408	€19,143	€59,517	€44,447
Purchased services	39,609	14,893	58,038	30,313
Laboratory supplies	13,026	9,928	21,177	18,294
Depreciation and amortization	6,818	6,493	13,911	12,351
IT costs	1,062	597	2,429	869
Lease and lease related cost	674	703	1,665	1,263
Transport costs	483	282	819	520
Travel costs	115	281	433	572
Other	994	1,082	2,322	2,014
Total research and development expenses	€95,189	€53,402	€160,311	€110,643

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.

From the three months ended June 30, 2019 to the three months ended June 30, 2020, research and development expenses increased from €53.4 million to €95.2 million. Research and development expenses for the six months ended June 30, 2020 increased from €110.6 million for the comparative prior year period to €160.3 million. The increase was mainly due to an increase in headcount leading to higher

wages, benefits and social security expenses as well as an increase in expenses for purchased research and development services, especially with respect to our BNT162 program, our vaccine program against COVID-19. In addition, from May 6, 2020, the date of acquisition, our new U.S.-based subsidiary, BioNTech US Inc., contributed €5.8 million to the research and development expenses of the Group.

Sales and Marketing Expenses

Our sales and marketing expenses mainly consist of personnel-related costs and expenses for purchased services. 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.

From the three months ended June 30, 2019 to the three months ended June 30, 2020, sales and marketing expenses increased from €0.7 million to €3.1 million. Sales and marketing expenses for the six months ended June 30, 2020 increased from €1.2 million for the comparative prior year period to €3.5 million. The increase was mainly due to increased marketing consulting expenses.

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:

(in thousands)	Three months ended June 30,		Six months ended June 30,	
	2020	2019 (unaudited)	2020	2019 (unaudited)
General and administrative expenses				
Wages, benefits and social security expense	€7,680	€5,253	€14,194	€9,550
Purchased services	4,110	1,890	8,288	3,116
IT and office equipment	1,366	1,140	2,710	2,092
Depreciation and amortization	1,619	1,558	2,723	2,530
Insurance premiums	862	37	1,614	75
Lease and lease related cost	561	384	910	810
Travel costs	80	687	475	931
Other	2,535	3,674	3,714	4,795
Total general and administrative expenses	€18,813	€14,623	€34,628	€23,899

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

From the three months ended June 30, 2019 to the three months ended June 30, 2020, general and administrative expenses increased from €14.6 million to €18.8 million. General and administrative expenses for the six months ended June 30, 2020 increased from €23.9 million for the comparative prior year period to €34.6 million. The increase was mainly influenced by higher expenses for purchased management consulting and legal services as well as an increase in headcount leading to higher wages, benefits and social security expenses. In addition, from May 6, 2020, the date of acquisition, our new

U.S.-based subsidiary, BioNTech US Inc. contributed €1.6 million to the general and administrative expenses of the Group.

Other Operating Income / Expenses

Other operating income for the three months ended June 30, 2020 amounted to €0.8 million compared to €0.7 million for the three months ended June 30, 2019. Other operating income for the six months ended June 30, 2020 amounted to €1.2 million compared to €1.0 million for the comparative prior year period. The amount mainly included income from collecting certain withholding tax payments for intellectual property licenses related to prior years. Other operating expenses for the three months ended June 30, 2020 amounted to €0.8 million compared to €0.1 million for the three months ended June 30, 2019. Other operating expenses for the six months ended June 30, 2020 amounted to €0.9 million compared to €0.2 million for the comparative prior year period.

Finance Income / Expenses

Our finance income and expenses consist of interest income and interest expenses on cash as well as foreign exchange gains and losses. Foreign exchange differences on a cumulative basis, are either shown as finance income or expenses and might switch between those two positions during the year-to-date reporting periods.

Finance income for the six months ended June 30, 2020 amounted to €0.6 million compared to €1.9 million for the six months ended June 30, 2019. The latter included €1.1 million attributable to unrealized foreign exchange gains. Finance expenses for the six months ended June 30, 2020 amounted to €3.4 million compared to €0.2 million for the six months ended June 30, 2019. The former included €3.2 million attributable to unrealized foreign exchange losses.

Tax Losses

We calculate the interim income tax expense using the tax rate that would be applicable to the expected total annual earnings. Deferred tax assets on tax losses of subsidiaries incorporated in Germany have not been capitalized as there is not sufficient probability that there will be future taxable profits against which the unused tax losses can be utilized. Deferred tax assets calculated from tax losses of subsidiaries incorporated in the United States incurred since the acquisition of BioNTech US have been recorded in an amount of k€2,317. Deferred tax assets have been offset with deferred tax liabilities recognized as part of the acquisition of BioNTech US given that the conditions to offset were fulfilled. Accumulated tax losses relate to Germany and the United States. There is no expiration date for any of the accumulated tax losses under German tax law. With respect to accumulated losses incurred at the level of BioNTech USA Holding LLC and BioNTech Research and Development Inc. since their incorporation and tax losses of BioNTech US since the acquisition of BioNTech US there is no expiration date under 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 us 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:

(in thousands)	Three months ended June 30, 2020		Six months ended June 30, 2020	
	2020	2019 (unaudited)	2020	2019 (unaudited)
Revenues	€32,673	€20,458	€54,094	€42,496
Gross profit	€32,673	€20,458	€54,094	€42,496
Research and development expenses	(95,925)	(53,212)	(161,073)	(110,472)
Sales and marketing expenses	(2,459)	(283)	(2,623)	(569)
General and administrative expenses	(17,979)	(13,977)	(33,155)	(22,554)
Other result	25	281	325	588
Operating loss	€(83,665)	€(46,733)	€(142,432)	€(90,511)

Comparison of the three and six months ended June 30, 2020 and 2019

Revenue

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

(in thousands)	Three months ended June 30, 2020		Change	
	2020	2019 (unaudited)	€	%
Revenues				
Clinical	€12,154	€9,141	€3,013	33
Technology Platform	5,567	323	5,244	1,624
Manufacturing	14,952	10,986	3,966	36
Business Service	-	8	(8)	(100)
Total unit revenues	€32,673	€20,458	€12,215	60

(in thousands)	Six months ended June 30,		€ %	Change %
	2020 (unaudited)	2019		
Revenues				
Clinical	€19,066	€18,431	€635	3
Technology Platform	7,670	463	7,207	1,557
Manufacturing	27,358	23,594	3,764	16
Business Service	-	8	(8)	(100)
Total unit revenues	€54,094	€42,496	€11,598	27

Revenue of our biotech business unit increased by €12.2 million, or 60%, to €32.7 million in the three months ended June 30, 2020 from €20.5 million in the three months ended June 30, 2019 as well as by €11.6 million, or 27%, to €54.1 million in the six months ended June 30, 2020 from €42.5 million in the six months ended June 30, 2019. The increase was primarily driven by the increased revenues of the Technology Platform segment accompanied by increased revenues in the Manufacturing segment.

During the six months ended June 30, 2020, revenues from our two new collaboration agreements were recognized for the first time. As part of the BNT162 program, our vaccine program against COVID-19, we collaborate with Pfizer and Fosun Pharma. The BNT162 program is evaluating at least four experimental vaccines, each of which represent a unique combination of messenger RNA format and target antigen. The revenue recognized from the collaboration agreement with Pfizer was recorded in all three operating segments since the underlying costs were also recorded in these segments. The revenue recognized from the collaboration with Fosun affected the Technology Platform segment.

These effects were offset by decreased revenues from our collaboration programs with Genentech, Sanofi and from the collaboration with Pfizer to develop mRNA-based immunotherapies for the prevention of influenza. This is due to the fact that in light of recent developments relating to the COVID-19 pandemic, the primary focus of healthcare providers and hospitals is currently on fighting the novel coronavirus. For certain of our earlier stage programs we have delayed commencement of trials, experienced slowed patient enrollment or experienced other delays as a result of the COVID-19 pandemic.

As summarized above, the increase in revenue in our Clinical segment of €3.1 million from €9.1 million in the three months ended June 30, 2019 to €12.2 million in the three months ended June 30, 2020 as well as the increase of €0.7 million from €18.4 million in the six months ended June 30, 2019 to €19.1 million in the six months ended June 30, 2020 is mainly derived from the first time recognition of revenue from our Pfizer collaboration agreement to co-develop our potential first-in-class COVID-19 mRNA vaccine program. The effect offsets the decreased revenues from our collaboration agreements with Genentech and Sanofi which are also recorded in the Clinical segment.

Likewise, the increase in revenue in our Technology Platform segment of €5.3 million from €0.3 million in the three months ended June 30, 2019 to €5.6 million in the three months ended June 30, 2020 as well as the increase of €7.2 million from €0.5 million in the six months ended June 30, 2019 to €7.7 million in the six months ended June 30, 2020 is due to the first time recognition of revenues under our two new collaboration agreements aiming at preventing COVID-19 as well as revenue recorded from our Sanofi collaboration.

The increase in revenue in our Manufacturing segment of €4.0 million from €11.0 million in the three months ended June 30, 2019 to €15.0 million in three months ended June 30, 2020, as well as the increase in revenue of €3.8 million from €23.6 million in the six months ended June 30, 2019 to €27.4 million in six months ended June 30, 2020, results from the first time recognition of revenue from our Pfizer collaboration agreement to co-develop our potential first-in-class COVID-19 mRNA vaccine

program, offsetting the decreased revenue from our Genentech collaboration program due to the reasons mentioned above.

Research and Development Expenses

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

<i>(in thousands)</i>	Three months ended			Change € %	
	June 30,		2019 (unaudited)		
	2020	2019			
Research and development expenses					
Clinical	€37,111	€19,359	€17,752	92	
Technology Platform	35,905	19,813	16,092	81	
Manufacturing	21,026	12,315	8,711	71	
Business Service	1,883	1,725	158	9	
Total unit research and development expenses	€95,925	€53,212	€42,713	80	

<i>(in thousands)</i>	Six months ended			Change € %	
	June 30,		2019 (unaudited)		
	2020	2019			
Research and development expenses					
Clinical	€58,444	€43,686	€14,758	34	
Technology Platform	62,704	38,214	24,490	64	
Manufacturing	36,855	26,237	10,618	40	
Business Service	3,070	2,335	735	31	
Total unit research and development expenses	€161,073	€110,472	€50,601	46	

Research and development expenses of our biotech business unit increased by €42.7 million, or 80%, to €95.9 million in the three months ended June 30, 2020 from €53.2 million in the three months ended June 30, 2019 as well as by €50.6 million, or 46%, to €161.1 million in the six months ended June 30, 2020 from €110.5 million in the six months ended June 30, 2019. The increase was mainly due to an increase in headcount leading to higher wages, benefits and social security expenses as well as an increase in expenses for purchased research and development services, especially with respect to our BNT162 program, our vaccine program against COVID-19. In addition, from May 6, 2020, the date of acquisition, our new U.S.-based subsidiary, BioNTech US Inc., contributed €5.8 million to the research and development expenses of the Group.

The following table summarizes our clinical research and development expenses, broken down by drug class and selected platforms, for each period presented:

(in thousands)	Three months ended				
	June 30,		€	Change	
	2020	2019 (unaudited)		%	
Clinical research and development expenses					
mRNA					
FixVac	€4,295	€2,610	€1,685	65	
iNeST	7,447	3,778	3,669	97	
Infectious Disease Vaccines*	11,544	892	10,652	1,194	
Other mRNA	3,729	6,335	(2,606)	(41)	
Total mRNA	27,015	13,614	13,401	98	
Cell Therapies	1,865	68	1,797	2,643	
Antibodies	7,178	3,511	3,667	104	
Small Molecule Immunomodulators	800	606	194	32	
Other	253	1,560	(1,307)	(84)	
Total clinical research and development expenses	€37,111	€19,359	€17,752	92	

*Infectious Disease Vaccines was previously included in other mRNA

(in thousands)	Six months ended				
	June 30,		€	Change	
	2020	2019 (unaudited)		%	
Clinical research and development expenses					
mRNA					
FixVac	€6,336	€4,379	€1,957	45	
iNeST	14,076	8,323	5,753	69	
Infectious Disease Vaccines*	13,097	2,197	10,900	496	
Other mRNA	8,426	10,301	(1,875)	(18)	
Total mRNA	41,935	25,199	16,736	66	
Cell Therapies	2,748	118	2,630	2,229	
Antibodies	11,997	6,905	5,092	74	
Small Molecule Immunomodulators	1,252	798	454	57	
Other	512	10,666	(10,154)	(95)	
Total clinical research and development expenses	€58,444	€43,686	€14,758	34	

*Infectious Disease Vaccines was previously included in other mRNA

During the three months ended June 30, 2020, other mRNA expenses mainly included €1.3 million Intratumoral Immunotherapy costs, €0.8 million RiboCytokines costs, €0.6 million RiboMabs costs and €0.5 million Protein Replacement Therapy costs. Other mRNA expenses during the three months ended June 30, 2019 mainly included €2.7 million RiboCytokines costs, €1.5 million RiboMabs costs, €1.3 million Intratumoral Immunotherapy costs and €0.5 million Protein Replacement Therapy costs.

During the six months ended June 30, 2020, other mRNA expenses mainly included €2.8 million Intratumoral Immunotherapy costs, €1.8 million RiboCytokines costs, €1.6 million RiboMabs costs and €1.2 million Protein Replacement Therapy costs. Other mRNA expenses during the six months ended June 30, 2019 mainly included €4.2 million RiboCytokines costs, €2.6 million Intratumoral Immunotherapy costs, €2.0 million RiboMabs costs and €0.9 million Protein Replacement Therapy costs.

Sales and Marketing Expenses

Sales and marketing expenses of our biotech business unit increased by €2.2 million to €2.5 million in the three months ended June 30, 2020 from €0.3 million in the three months ended June 30, 2019 as well as by €2.0 million, or 361%, to €2.6 million in the six months ended June 30, 2020 from €0.6

million in the six months ended June 30, 2019. The increase was mainly due to increased marketing consulting expenses.

General and Administrative Expenses

General and administrative expenses of our biotech business unit increased by €4.0 million, or 29%, to €18.0 million in the three months ended June 30, 2020 from €14.0 million in the three months ended June 30, 2019 as well as by €10.6 million, or 47%, to €33.2 million in the six months ended June 30, 2020 from €22.6 million in the six months ended June 30, 2019. The increase was mainly influenced by higher expenses for purchased management consulting and legal services as well as an increase in headcount leading to higher wages, benefits and social security expenses. In addition, from May 6, 2020, the date of acquisition, our new U.S.-based subsidiary, BioNTech US Inc. contributed €1.6 million to the general and administrative expenses of the Group.

Other Result

The other result of our biotech business unit decreased by €0.3 million, or 91%, to €0.03 million in the three months ended June 30, 2020 from €0.3 million in the three months ended June 30, 2019.

The other result of our biotech business unit decreased by €0.3 million, or 45%, to €0.3 million in the six months ended June 30, 2020 from €0.6 million in the six months ended June 30, 2019.

External Services Business Unit

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

(in thousands)	Three months ended June 30,		Six months ended June 30, 2019	
	2020	2019 (unaudited)	2020	2019 (unaudited)
Revenues	€9,089	€5,327	€15,331	€9,443
Cost of sales	(4,779)	(5,501)	(10,434)	(8,603)
Gross profit	€4,310	€(174)	€4,897	€840
Research and development expenses	(147)	(177)	(308)	(262)
Sales and marketing expenses	(595)	(395)	(917)	(669)
General and administrative expenses	(835)	(646)	(1,473)	(1,345)
Other result	(11)	256	14	245
Operating income (loss)	€2,722	€(1,136)	€2,213	€(1,191)

In the three and six months ended June 30, 2019, our external services business unit generated an operating loss of €1.1 million and €1.2 million, respectively. The unit was able to turn the result around mainly by increasing revenues due to increased orders and generated an operating income of €2.7 million and €2.2 million in the three and six months ended June 30, 2020, respectively.

Related Party Transactions

Related party transactions that occurred during the three and six months ended June 30, 2020 and 2019 are explained in Note 12 to the unaudited interim condensed consolidated financial statements.

Merger Agreement with BioNTech US Inc. (formerly Neon Therapeutics, Inc.)

On May 6, 2020, we acquired Neon Therapeutics, Inc. (formerly Nasdaq: NTGN), or Neon, a biotechnology company developing novel neoantigen-based T-cell therapies, through a stock transaction and including de minimis cash consideration, or the Merger. The Merger was first announced on January 16, 2020. Neon, now BioNTech US Inc., or BioNTech US, is operated as a wholly owned subsidiary of BioNTech SE. The new subsidiary is based in Cambridge, Massachusetts and serves as our U.S. headquarters.

The transaction combines two organizations with a common culture of pioneering translational science and a shared vision for the future of cancer immunotherapy. Through the acquisition, we leverage Neon's deep expertise in the development of neoantigen therapies, with both vaccine and T-cell capabilities. Our most advanced program acquired in the Merger is BNT221 (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. We also acquired a precision T-cell therapy program targeting shared neoantigens in genetically defined patient populations. The lead program from this approach, BNT222 (NEO-STC-01), is a T-cell therapy candidate targeting shared RAS neoantigens. In addition, Neon had assembled libraries of high-quality TCRs against various shared neoantigens across common HLAs. This pipeline is underpinned by Neon's platform technologies including RECON®, its machine-learning bioinformatics platform, and NEO-STIM™, its proprietary process to directly prime, activate and expand neoantigen-targeting T-cells *ex vivo*.

Based on the acquisition date share price, the implied aggregate value of the merger consideration was €89.9 million (\$97.1 million) financed by issuing 1,935,488 ordinary shares as a stock transaction and including a de minimis cash consideration which was paid to settle Neon's outstanding stock options.

Impact of COVID-19

On March 11, 2020, the World Health Organization declared the outbreak of COVID-19 as a pandemic, which continues to spread throughout the United States, the European Union and around the world. As we advance our clinical programs, we are in close contact with our principal investigators and clinical sites, which are located in jurisdictions affected by the COVID-19 pandemic, and are assessing the impact of the COVID-19 pandemic on our clinical trials, expected timelines and costs on an ongoing basis. In light of recent developments relating to the COVID-19 pandemic, the primary focus of healthcare providers and hospitals remains on fighting the novel coronavirus. We have also modified our business practices, in response to the spread of COVID-19, including restricting employee travel, developing social distancing plans for our employees and cancelling physical participation in meetings, events and conferences. In addition, for certain of our earlier stage programs, including BNT141 and BNT142 (RiboMabs), BNT151 and BNT152/153 (RiboCytokines), BNT161 (Influenza), BNT171 (Rare Disease) and BNT411 (TLR7), we have delayed commencement of trials, experienced slowed patient enrollment or experienced other delays as a result of the COVID-19 pandemic. This partial disruption, even temporary, may severely impact our operations and overall business by delaying the progress of our clinical trials and preclinical studies.

COVID-19 Collaboration

Aiming at preventing COVID-19 infection, our BNT162 program is evaluating at least four experimental vaccines. As part of the program, we entered into two strategic collaborations with large pharmaceutical companies to globally develop our vaccine candidates and supply an approved vaccine globally. BioNTech and Fosun Pharma aim to develop COVID-19 vaccine candidates in China. BioNTech and Pfizer aim to accelerate the development of BNT162 worldwide (excluding China).

Under the terms of the agreement, Pfizer agreed to pay us \$185 million in upfront payments, including an equity investment of €103.9 million (\$113.0 million) and a cash payment of €66.3 million (\$72.0 million) which were received in late April 2020 and May 2020, respectively. The issuance of 2,377,446 ordinary shares with the nominal amount of € 2.4 million was registered with the commercial register

(Handelsregister) on May 5, 2020. We are eligible to receive future milestone payments of up to \$563 million for potential aggregate consideration of \$748 million. Pfizer and we share development costs equally. Initially, Pfizer will fund 100% of the development costs, and we will repay Pfizer our 50% share of these costs if success-based milestones are reached, or with proceeds generated from the commercialization of the vaccine, if approved. If the vaccine program is not successful or does not generate sufficient proceeds, we will not be required to pay back our 50% share of the development costs incurred.

We and Pfizer are jointly conducting clinical trials for four COVID-19 vaccine candidate variants initially in the United States and Europe, across multiple sites. In late April 2020, we and Pfizer announced that the German regulatory authority, the Paul-Ehrlich-Institut, approved the Phase 1/2 clinical trial and the first patients in the first cohort of the Phase 1/2 clinical trial were dosed shortly thereafter. In early May 2020, Pfizer and we initiated a clinical trial for BNT162 in the United States and the first participants were dosed shortly thereafter.

On July 1, 2020, we and Pfizer announced preliminary data from the ongoing U.S. Phase 1/2 trial of BNT162b1.

On July 13, 2020, we and Pfizer announced that BNT162b1 and BNT162b2 received Fast Track designation from the U.S. Food and Drug Administration (“FDA”).

On July 20, 2020, we and Pfizer announced preliminary data from the ongoing German Phase 1/2 trial of BNT162b1.

During the clinical development stage, we and our partners will provide clinical supply of the vaccine from our and our partners’ GMP-certified mRNA manufacturing facilities in Europe. We and Pfizer are working together to scale-up manufacturing capacity at risk to provide worldwide supply in response to the pandemic. If the vaccine candidate is approved, we and Pfizer would also work jointly to commercialize the vaccine worldwide (excluding China which is covered by the collaboration with Fosun Pharma).

On July 20, 2020, we announced that we and Pfizer entered into a binding term sheet for a supply agreement with the United Kingdom. Pursuant to the term sheet, we and Pfizer expect to supply 30 million doses of BNT162, if approved, to the United Kingdom. Under the terms of the binding term sheet, we and Pfizer are eligible to receive a fully refundable advance payment per dose upon signing of a definitive supply agreement. The advance payment will be treated as a prepayment towards the total cost of the contracted number of doses of BNT162, with the remainder of the contracted price per dose to be paid upon delivery of the contracted doses.

On July 22, 2020, we announced that the U.S. government agreed to purchase an initial order of 100 million doses of BNT162 and has the option to acquire up to 500 million additional doses from us and Pfizer. The U.S. government agreed to pay \$1.95 billion upon the receipt of the first 100 million doses, following FDA authorization or approval.

We are also in late-stage discussions with other governments and governmental bodies related to the establishment of supply agreements for BNT162, if approved. We expect that we and Pfizer will enter into further binding and non-binding agreements to supply additional doses of BNT162 as early as 2020 and 2021. Certain of the agreements may also provide an option to purchase additional doses, under specified circumstances.

On July 27, 2020 we and Pfizer announced the start of a global (except for China) Phase 2/3 safety and efficacy clinical study to evaluate a single nucleoside-modified messenger RNA candidate from their BNT162 mRNA-based vaccine program, against SARS-CoV-2. After extensive review of preclinical and clinical data from Phase 1/2 clinical trials, and in consultation with the U.S. Food and Drug Administration’s Center for Biologics Evaluation and Research and other global regulators, we and Pfizer

announced that we chose to advance the BNT162b2 vaccine candidate into the Phase 2/3 study, at a 30 µg dose level in a 2 dose regimen.

On July 31, 2020, we and Pfizer announced that the government of Japan has agreed to purchase 120 million doses of BNT162 from us and Pfizer, if approved. As requested by the Government of Japan, deliveries of the vaccine candidate are planned for the first half of 2021, subject to clinical success and regulatory approval.

On August 5, 2020, we and Fosun Pharma announced the start of the clinical trial of BNT162b1 in China and the dosing of the first 72 participants with BNT162b1 following IND approval by the Chinese regulatory authority, National Medical Products Administration (NMPA).

On August 5, 2020, we and Pfizer announced an agreement with the Government of Canada to supply our BNT162 mRNA-based vaccine candidate against SARS-CoV-2, subject to clinical success and Health Canada approval. As requested by the Government of Canada, deliveries of the vaccine candidate are planned over the course of 2021.

Critical Accounting Policies and Use of Estimates

Our unaudited interim condensed consolidated financial statements for the three and six months ended June 30, 2020 have been prepared in accordance with IFRS, as issued by the IASB.

The preparation of the consolidated financial statements in accordance with IFRS requires 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 respective reporting period. 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 base our assumptions and estimates on parameters available when the consolidated financial statements are 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.

Our critical accounting policies are those related to revenue recognition, share-based compensation, fair value measurement of share-based awards as well as taxes. Our critical accounting policies are discussed further in Item 5 of our Annual Report on Form 20-F for the year ended December 31, 2019 as well as Note 2.3 to our consolidated financial statements included in that Annual Report. Actual results in these areas could differ from management's estimates.

Liquidity and Capital Resources

We have historically funded our operations primarily from private placements of our ordinary shares, from issuing ordinary shares in connection with our initial public offering, proceeds from collaborators and services and proceeds from secured bank loans. As of June 30, 2020, we had cash and cash equivalents of €573.0 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 buildouts of our JPT Peptide Technologies GmbH facility and Innovative Manufacturing Services GmbH 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. The loan is repayable in equal quarterly installments of k€322.6 commencing on June 30,

2020. As of June 30, 2020, the full amount under this facility is drawn down and the first scheduled repayment has occurred. 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. The loan is repayable by quarterly installments of k€286.4 commencing on September 30, 2020. As of June 30, 2020, the full amount under this facility is drawn down. Each of these facilities is secured by liens over our property.

In December 2019, we 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 us 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.

In June 2020, we entered into an agreement with the EIB for a €100 million credit facility to partially support the development of BNT162 and fund expansion of our manufacturing capacity to provide worldwide supply of BNT162 in response to the COVID-19 pandemic. Under this arrangement, the EIB agreed to provide us with a credit in an amount up to €100 million to partially finance such development and expansion. The credit consists of (i) a term loan in the amount of €50 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 €50 million that may be drawn in a single tranche (Credit B). 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. The closing of the financing agreement, subject to achieving certain milestone events, was not fulfilled before June 30, 2020.

On June 29, 2020, we announced the signing of a private investment of €223.9 million (\$250.7 million; this and the following amounts calculated using the exchange rate in effect as of June 30, 2020 as published by the German Central Bank (*Deutsche Bundesbank*)) by a fund associated with Temasek Capital Management Pte. Ltd., or Temasek, and another accredited investor, which investment we refer to as the June 2020 Private Placement. The June 2020 Private Placement consisted of approximately €123.9 million (\$138.7 million) in ordinary shares and a €100.0 million (\$112.0 million) four-year mandatory convertible note. Upon the closing of the June 2020 Private Placement, the investors will receive an aggregate of 2,595,996 of our ordinary shares and will be subject to a 180-day lock-up agreement. The four-year mandatory convertible note will have a coupon of 4.5% per annum and a conversion premium of 20% above the reference price. The closing of the investment, subject to customary closing conditions, was not fulfilled before June 30, 2020.

On July 21, 2020 and July 23, 2020, we announced a rights offering (the “Rights Offering”) and the terms of the Rights Offering, respectively, of rights to subscribe for up to 7,505,596 ordinary shares, including ordinary shares represented by ADSs, extended to existing holders of its ordinary shares and

ADSs. The Rights Offering is part of a Global Offering that includes the Rights Offering and the underwritten offering (the “Underwritten Offering”). The ADS rights exercise period expires at 12:01 a.m. (New York City time) on August 14, 2020 and the ordinary share rights exercise period expires one minute after 11:59 p.m. (Mainz, Germany time) on August 14, 2020. Certain ordinary shareholders representing 74.83% of our outstanding ordinary shares irrevocably agreed not to transfer or exercise their rights in the Rights Offering, and the shares underlying those rights were offered in the Underwritten Offering. ADSs purchased in the Underwritten Offering were not entitled to receive rights in the Rights Offering.

On July 27, 2020, our Underwritten Offering of 5,500,000 American Depository Shares (“ADSs”), each representing one of our ordinary shares, closed at a public offering price of \$93.00 per ADS, for gross proceeds of \$511.5 million. In addition, a selling shareholder granted the underwriters a 30-day option to purchase up to 825,000 additional ADSs at the same public offering price, which has not yet been exercised. We will not receive any of the proceeds from sale of ADSs by the selling shareholder.

Cash Flow

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

(in thousands)	Three months ended June 30,		Six months ended June 30,	
	2020	2019 (unaudited)	2020	2019 (unaudited)
Net cash flows from (used in):				
Operating activities	€(15,522)	€(54,472)	€(70,208)	€(85,689)
Investing activities	(9,744)	(12,598)	(24,677)	(45,766)
Financing activities	146,203	3,960	148,213	4,919
Total cash inflow (outflow)	€120,937	€(63,110)	€53,328	€(126,536)

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 three months ended June 30, 2020 was €15.5 million, comprising a loss before tax of €90.5 million, non-cash adjustments of €17.4 million, and a net positive change in assets and liabilities of €58.0 million. Non-cash items primarily included depreciation and amortization as well as share-based compensation expenses. The net positive change in assets and liabilities was primarily based on the upfront payment received from Pfizer as part of the BNT162 program, our vaccine program against COVID-19, which was recorded as contract liability and subsequently only started to be recognized as revenue.

Net cash used in operating activities for the three months ended June 30, 2019 was €54.5 million, comprising a loss before tax of €50.1 million, non-cash adjustments of €13.1 million, and a net negative change in assets and liabilities of €17.4 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.

Net cash used in operating activities for the six months ended June 30, 2020 was €70.2 million, comprising a loss before tax of €143.9 million, non-cash adjustments of €34.1 million, and a net positive change in assets and liabilities of €40.4 million. Non-cash items primarily included depreciation and

amortization as well as share-based compensation expenses. Also on a year-to-date basis, the net positive change in assets and liabilities was primarily based on the upfront payment received from Pfizer as part of the BNT162 program, which was recorded as contract liability and subsequently only started to be recognized as revenue.

Net cash used in operating activities for the six months ended June 30, 2019 was €85.7 million, comprising a loss before tax of €90.8 million, non-cash adjustments of €34.0 million, and a net negative change in assets and liabilities of €28.6 million. Non-cash items primarily included depreciation and amortization as well as share-based compensation expenses. Also on a year-to-date basis, the net positive change in assets and liabilities was primarily due to a decrease in contract liabilities.

The decrease in net cash used in operating activities from the three months ended June 30, 2019 to the three months ended June 30, 2020 as well as from the six months ended June 30, 2019 to the six months ended June 30, 2020 was primarily due to the fact that the upfront payment received from Pfizer as part of the BNT162 program overcompensated the increase in amounts spent for wages, benefits and social security expenses as headcount increases and higher research and development expenditures.

Investing Activities

Net cash used in investing activities for the three months ended June 30, 2020 was €9.7 million, of which €2.1 million was attributable to the purchase of intangible assets and €15.1 million was attributable to the purchase of property, plant and equipment, mainly including the amounts spent with respect to the new buildings at our BioNTech IMFS facility in Idar-Oberstein. The total cash used in investing activities was partially offset by the positive effect attributable to the acquisition of Neon of €7.4 million. As part of the transaction, the amount of cash acquired exceeded the consideration paid given that the acquisition was financed by issuing American Depository Shares representing our ordinary shares as a stock transaction and only included a de minimis cash consideration paid to settle Neon's outstanding stock options.

Net cash used in investing activities for the three months ended June 30, 2019 was €12.6 million, of which €2.3 million was attributable to the purchase of intangible assets, €4.3 million was attributable to the purchase of property, plant and equipment and €6.1 million was 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 six months ended June 30, 2020 was €24.7 million, of which €4.2 million was attributable to the purchase of intangible assets, €21.4 million was attributable to the purchase of property, plant and equipment, mainly including the amounts spent with respect to the new buildings at our BioNTech IMFS facility in Idar-Oberstein. The net cash used attributable to the acquisition of assets, employees and proprietary know-how of Lipocalyx GmbH and its related parties based in Halle, Germany was offset by the net cash acquired attributable to the acquisition of Neon.

Net cash used in investing activities for the six months ended June 30, 2019 was €45.8 million of which €29.7 million was attributable to the purchase of intangible assets, including the final installment payment for the license agreement for the CellScript patent and €10.6 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 €0.6 million. In addition, €6.1 million was attributable to the acquisition of MAB Discovery GmbH's operational antibody generation unit based near Munich, Germany.

Financing Activities

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

During the three months ended June 30, 2020, we generated cash from financing activities of €146.2 million, primarily from proceeds from the issuance of shares in the amount of €147.8million

received from Fosun Pharma via Fosun Industrial Co., Limited, Hong Kong and Pfizer, net of transaction costs related to all financing transactions that occurred during the three months ended June 30, 2020. The amount was offset by the first scheduled repayment of €0.3 million made with respect to the secured credit facility, entered into with Deutsche Bank by our subsidiary BioNTech Innovative Manufacturing Services GmbH as well as payments made related to lease liabilities of €1.3 million.

During the three months ended June 30, 2019, we generated cash from financing activities of €4.0 million, primarily from proceeds from loans and borrowings in the amount of €4.5 million, partially offset by payments made related to lease liabilities of €0.7 million.

During the six months ended June 30, 2020, we generated cash from financing activities of €148.2 million, primarily from proceeds from the issuance of shares in the amount of €147.8 million received from Fosun Pharma via Fosun Industrial Co., Limited, Hong Kong and Pfizer, net of transaction costs related to all financing transactions that occurred during the six months ended June 30, 2020. The €2.6 million proceeds from loans and borrowings were partially offset by the payments made related to lease liabilities of €2.2 million.

During the six months ended June 30, 2019, we generated cash from financing activities of €4.9 million, primarily from proceeds from loans and borrowings in the amount of €6.0 million, partially offset by payments made related to lease liabilities of €1.3 million.

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 €566.5 million as of June 30, 2020 and €424.8 million as of June 30, 2019. 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. As a result of increased spending related to our BNT162 program, we now expect the net cash used in operating activities and for investments into property, plant and equipment to be between €450 million and €600 million in the full year 2020. We anticipate that existing cash and cash equivalents, the net proceeds from the recent Underwritten Offering and the expected net proceeds from the private investment announced in June 2020 will enable us to fund our operating expenses and capital requirements through at least the next 24 months.

Our future funding requirements will depend on many factors, including, but not limited to:

- the initiation, progress, timing, costs and results of preclinical or nonclinical studies and clinical trials for our product candidates;
- the results of research and our other platform activities;
- the clinical development plans we establish for our product candidates;
- the terms of any agreements with our current or future collaborators;
- the number and characteristics of product candidates that we develop or may in-license;
- the outcome, timing and cost of meeting regulatory requirements established by the FDA, European Medicines Agency 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.

Risk Factors

Our business is subject to various risks, including those described below as well as in “Risk Factors” in our Annual Report on Form 20-F for the year ended December 31, 2019, which we strongly encourage you to review. You should consider carefully the risks and uncertainties described below and in our Form 20-F. If any of the following risks are realized, our business, financial condition, results of operations and prospects could be materially and adversely affected. Additionally, risks and uncertainties not currently known to us or that we currently deem to be immaterial also may materially adversely affect our business, financial condition, results of operations and/or prospects.

Risks Related to Our COVID-19 Vaccine Development Program and Our Intellectual Property

We may experience significant volatility in the market price of the ADSs representing our ordinary shares following announcements and data releases regarding our ongoing development of BNT162 as a potential COVID-19 vaccine.

Biopharmaceutical companies that are developing potential therapeutics and vaccines to combat COVID-19 and SARS-CoV-2, including BioNTech SE, have experienced significant volatility in the price of their securities upon publication of preclinical and clinical data as well as news about their

development programs. For example, following the announcement of our collaborations with Pfizer and Fosun Pharma relating to the development of BNT162, our vaccine candidate program for the prevention of COVID-19, the last reported sales price of the ADSs representing our ordinary shares on the Nasdaq Global Select Market increased from \$30.93 on March 13, 2020, the day before the announcement, to \$92.00 on March 18, 2020, before decreasing to \$46.50 on March 20, 2020. In addition to the preclinical and clinical data we and Pfizer have already disclosed in connection with our BNT162 development program, we and Pfizer intend over the coming months to make public several additional COVID-19 vaccine data readouts and clinical updates. We also expect to announce data, in due course, for the other three vaccine candidate variants that we are currently testing for the prevention of COVID-19 as part of our BNT162 program. On July 20, 2020, we announced that we and Pfizer have entered into a binding term sheet for a supply agreement with the United Kingdom, on July 22, 2020, we announced that the U.S. government has agreed to purchase doses of BNT162 from us and Pfizer, on July 31 we announced that we and Pfizer had agreed to supply doses of BNT162 to Japan and on August 5, 2020, we and Pfizer announced an agreement with the Government of Canada. In addition, we are in late-stage discussions with other governments and governmental bodies related to the establishment of supply agreements for BNT162, if approved. We cannot predict public reaction or the impact on the market price of the ADSs representing our ordinary shares once the terms of any or all of these supply arrangements are announced. We also cannot guarantee that the ultimate supply agreements we enter into, if any, will be for the number of doses we currently estimate and that aggregate consideration to be received under any such supply agreements will ultimately be what we currently expect. Given the attention being paid to the COVID-19 pandemic and the public scrutiny of COVID-19 development announcements and data releases to date, we expect that the public announcements we and Pfizer intend to make in the coming months regarding the ongoing development of BNT162 will attract significant attention and scrutiny and that, as a result, the price of the ADSs representing our ordinary shares may be particularly volatile during this time.

We are currently developing multiple candidate variants in our BNT162 program, which rely on different mechanisms of action, and the efficacy or safety of one variant is not indicative or predictive of the efficacy or safety of another variant.

We are currently developing four vaccine candidate variants for the prevention of COVID-19 as part of our BNT162 program. The first, which is the variant for which we and Pfizer announced Phase 1/2 data on July 1 and July 20, 2020, is BNT162b1, which utilizes nucleoside-modified mRNA (modRNA) and encodes the receptor binding domain antigen. Two of our four vaccine candidate variants, including BNT162b1, include a modRNA, one includes a uridine containing mRNA (uRNA), and the fourth variant utilizes self-amplifying mRNA (saRNA). Each mRNA format is combined with a lipid nanoparticle (LNP) formulation. The larger spike sequence is included in two of the vaccine candidate variants and the smaller optimized receptor binding domain from the spike protein is included in the other two candidate variants. Each variant has a distinct mechanism of action, and, as a result, clinical activity or safety results observed from one variant may not be indicative or predictive of the efficacy or safety profile or results observed of another variant. For example, on July 27, 2020 we announced that we had selected our BNT162b2 candidate variant to advance into our Phase 3 trial. The data we recently announced for our BNT162b1 variant may differ in material respects from the safety or efficacy profile of the other vaccine candidate variants and should not be considered predictive of the safety or efficacy of our other vaccine candidate variants.

We cannot guarantee that the BNT162 variant we chose to advance into late stage clinical development will perform better than any of the variants we did not choose to advance. Further, even if we demonstrate a sufficient safety profile for BNT162 we may not be able to demonstrate sufficient efficacy in subsequent trials to obtain regulatory approval.

Based on preclinical and clinical data observed to-date, we and Pfizer have progressed our BNT162 program into a Phase 2b/3 trial which commenced in late July 2020. For the initial Phase 2b/3 trial, we have selected our modRNA vaccine candidate variant targeting the 2P-mutated full spike protein, BNT162b2. Both the BNT162b1, for which we have already released data publicly, and the BNT162b2

vaccine candidates have received Fast Track status from the FDA. Since clinical evaluation of the BNT162b2 candidate started several weeks later than BNT162b1, only preliminary clinical data are currently available for the BNT162b2 candidate. A set of data obtained for a cohort of subjects aged to 18-55 years immunized with 10 μ g of BNT162b2 indicates that BNT162b2 may induce strong virus neutralizing antibody responses with titers in a similar range as observed for BNT162b1. The preliminary observations are subject to further data collection and analysis. Assessment of dose dependent immune response and safety profile as well as analysis of T-cell responses is currently pending. On the basis of data collected and analyzed for BNT162b1 and BNT162b2, including the overall observed safety, tolerability and immunogenicity profiles for each vaccine candidate at different dose levels, along with input from the FDA, we selected BNT162b2 as our lead candidate to take into a Phase 2b/3 trial.

We cannot guarantee that the candidate variant that we have selected will ultimately prove to be the optimal variant. We and Pfizer chose the variant to advance based on our scientific judgment in light of the preclinical and clinical data available to us at the time as to which variant has the best chance for success. It is possible that subsequent data regarding the variant we chose could prove to be less favorable or subsequent data from a variant that is not advanced could prove to be more favorable.

Regardless of the variant we selected for Phase 2b/3, we cannot guarantee that the results from subsequent data analyses and announcements will be in line with the data that we have previously published. In addition, the total number of patients evaluated in Phase 1 is small relative to the number we intend to evaluate in Phase 2b/3 and may not be indicative of the safety or immunogenicity of BNT162 in a larger and more diverse patient population. Similarly, the samples of convalescent sera, or blood samples from people who have recovered from COVID-19, used to benchmark the level of antibodies produced by subjects receiving BNT162 in clinical studies, have been taken from a small number of people and may not be representative of the antibody levels in a broader population of people who have recovered from COVID-19. Future results in clinical trials of BNT162 may not be as positive when compared to the antibody levels in other samples of convalescent sera.

Furthermore, because the assays being used to measure and analyze the effectiveness of COVID-19 vaccines have only recently been developed and are continuing to evolve, indications of immunogenicity and the duration of immunity observed in our Phase 1/2 trials may not be predictive of the achievement of clinically relevant endpoints.

In addition, by definition our Phase 1/2 clinical trials are designed to evaluate only safety and not efficacy. Positive results from these Phase 1/2 trials do not guarantee we will be able to demonstrate in our Phase 2b/3 trial that BNT162 is efficacious. More specifically, we do not yet know the levels of immunity required to prevent COVID-19 infection, and have not yet tested the ability of our vaccine candidates to prevent infection in humans. Failure to adequately demonstrate safety or to eventually demonstrate sufficient efficacy of BNT162 could delay or prevent us from receiving regulatory approval of BNT162 and there can be no assurance that BNT162 will be approved in a timely manner, if at all.

The development of our BNT162 program may divert resources from the clinical development of our other product candidates and we may not recoup our investments in the program.

Although we believe that our BNT162 program could result in an effective COVID-19 vaccine, clinical trials involve a lengthy and expensive process with an uncertain outcome. Given the severity and urgency of the COVID-19 pandemic, we have committed significant capital and resources to fund and supply the development of BNT162. However, the development of BNT162 will require us to expend financial, personnel and other resources and may cause delays in or otherwise negatively impact our other development programs, despite uncertainties surrounding the longevity and extent of COVID-19 as a global health concern. Furthermore, our business could be negatively impacted by our allocation of significant resources to a global health threat that is unpredictable and could rapidly dissipate or against which our vaccine, if developed, may not be partially or fully effective.

If we are successful in producing a vaccine against COVID-19, we may need to devote significant resources to its scale-up and development.

If any clinical trials for BNT162 are perceived to be successful, we may need to work toward the large scale technical development, manufacturing scale-up and larger scale deployment of this vaccine candidate through a variety of government mechanisms such as an Emergency Use Authorization program in the United States. We may also need to access facilities capable of rapidly manufacturing BNT162 in the volumes necessary to support large-scale clinical trials or commercial sales. If we are unable to conduct production and manufacturing activities or if our vaccine requires more doses to achieve sufficient efficacy than we expect, we may not complete our product development or commercialization efforts in a timely manner. In addition, during a global health crisis, such as the COVID-19 pandemic, where the spread of a disease needs to be controlled, closed or heavily regulated national borders will create challenges and potential delays in our development and production activities and may necessitate that we pursue strategies to develop and produce our vaccine candidate variants within self-contained national or international borders, at potentially much greater expense and with longer timeframes for public distribution.

There can be no assurance that BNT162, even if approved, would ever become profitable, due to government interest and public perception regarding a vaccine.

As a result of the emergency situations in many countries, there is a heightened risk that a COVID-19 vaccine may be subject to adverse governmental actions in certain countries, including intellectual property expropriation, compulsory licenses, strict price controls or other actions. Additionally, we may need to, or we may be required by governmental or non-governmental authorities to, set aside specific quantities of doses of BNT162 for designated purposes or geographic areas. We are likely to face challenges related to the allocation of supply of BNT162, particularly with respect to geographic distribution. Thus, even if BNT162 is approved, such governmental actions may limit our ability to recoup our current and future expenses.

Furthermore, public sentiment regarding commercialization of a COVID-19 vaccine may limit or negate our ability to generate revenues from sales of BNT162. Given that COVID-19 has been designated as a pandemic and represents an urgent public health crisis, we are likely to face significant public attention and scrutiny over any future business models and pricing decisions with respect to BNT162. If we are unable to successfully manage these risks, we could face significant reputational harm, which could negatively affect the price of the ADSs representing our ordinary shares.

The regulatory pathway for BNT162 is highly dynamic and continues to evolve and may result in unexpected or unforeseen challenges.

To date, BNT162 has moved rapidly through the regulatory review process of the FDA and foreign regulatory authorities. The speed at which all parties are acting to create and test many therapeutics and vaccines for SARS-CoV-2 and COVID-19 is unusual, and evolving or changing plans or priorities within the FDA and foreign regulatory authorities, including changes based on new knowledge of COVID-19 and how the disease affects the human body, may significantly affect the regulatory timeline for BNT162. Results from clinical testing may raise new questions and require us to redesign proposed clinical trials, including revising proposed endpoints or adding new clinical trial sites or cohorts of subjects.

For example, the FDA on June 30, 2020 adopted guidance outlining the FDA's current recommendations regarding the data needed to facilitate clinical development and licensure of vaccines to prevent COVID-19. In particular, the June 30, 2020 guidance suggests that the primary efficacy endpoint estimate for a placebo-controlled efficacy trial should be at least 50%. The guidance also includes discussion of chemical, manufacturing and controls and safety concerns. Although we intend to design any future clinical trials for BNT162 in accordance with this guidance, we cannot be certain that, as the regulatory pathway continues to evolve, we will be able to complete a clinical trial in accordance with the FDA's guidance and regulations then in effect. A failure to complete a clinical trial in accordance with guidance and regulations then in effect could impair our ability to obtain approval for BNT162,

which may adversely affect our operating results, reputation and ability to raise capital and enter into or maintain collaborations to advance our other product candidates.

Additionally, the FDA has the authority to grant an Emergency Use Authorization to allow unapproved medical products to be used in an emergency to diagnose, treat, or prevent serious or life-threatening diseases or conditions when there are no adequate, approved, and available alternatives. If we are granted an Emergency Use Authorization for BNT162, we would be able to commercialize BNT162 prior to FDA approval. However, the FDA may revoke an Emergency Use Authorization where it is determined that the underlying health emergency no longer exists or warrants such authorization, and we cannot predict how long, if ever, an Emergency Use Authorization would remain in place. Such revocation could adversely impact our business in a variety of ways, including if BNT162 is not yet approved by the FDA and if we and our manufacturing partners have invested in the supply chain to provide BNT162 under an Emergency Use Authorization.

Even if regulatory approval is received for a BNT162 vaccine candidate, the later discovery of previously unknown problems associated with BNT162 may result in restrictions, including withdrawal of the product from the market, and lead to significant liabilities and reputational damage.

Because the path to marketing approval of any vaccine against COVID-19 is unclear, we may have a widely used vaccine in circulation in the United States or another country prior to our receipt of marketing approval. Unexpected safety issues, including any that we have not yet observed in our Phase 1/2 clinical trials for BNT162, could lead to significant reputational damage for BioNTech and our technology platforms going forward and other issues, including delays in our other programs, the need for re-design of our clinical trials and the need for significant additional financial resources.

We also may be restricted or prohibited from marketing or manufacturing a BNT162 vaccine, even after obtaining product approval, if previously unknown problems with the product or its manufacture are subsequently discovered. We cannot provide assurance that newly discovered or developed safety issues will not arise following regulatory approval. With the use of any vaccine by a wide patient population, serious adverse events may occur from time to time that did not arise in the clinical trials of the product or that initially appeared to be unrelated to the vaccine itself and only with the collection of subsequent information were found to be causally related to the product. Any such safety issues could cause us to suspend or cease marketing of our approved products, possibly subject us to substantial liabilities, and adversely affect our ability to generate revenue and our financial condition.

We may be unable to produce a successful COVID-19 vaccine and establish a competitive market share for our vaccine before a competitor or before the COVID-19 outbreak is effectively contained or the risk of coronavirus infection is significantly diminished.

A large number of vaccine manufacturers, academic institutions and other organizations currently have programs to develop COVID-19 vaccine candidates. While we are not aware of all of our competitors' efforts, we believe that the University of Oxford/AstraZeneca plc, CanSino Biologics Inc., Sanofi/GlaxoSmithKline plc Inovio Pharmaceuticals, Inc., China National Pharmaceutical Group (Sinopharm)/Beijing Institute of Biological Products and Wuhan Institute of Biological Products, Moderna, Inc., Johnson & Johnson, Novavax, Inc. and other companies are all in the early stages of developing vaccine candidates against COVID-19. Our competitors pursuing vaccine candidates may have greater financial, product candidate development, manufacturing and marketing resources than we do. Larger pharmaceutical and biotechnology companies have extensive experience in clinical testing and obtaining regulatory approval for their products, and may have the resources to heavily invest to accelerate discovery and development of their vaccine candidates.

Our efforts to develop BNT162 for regulatory approval and commercialization may fail if competitors develop and commercialize one or more COVID-19 vaccines before we are able to do so, or if they develop and commercialize one or more COVID-19 vaccines that are safer, more effective, produce longer immunity against COVID-19, require fewer administrations, have fewer or less severe side effects, have broader market acceptance, are more convenient or are less expensive than any vaccine candidate that we may develop.