



BioNTech Announces Second Quarter 2021 Financial Results and Corporate Update

August 9, 2021

- More than one billion doses of BNT162b2 vaccine supplied to more than 100 countries or territories worldwide as of July 21, 2021
- Signed agreements for approximately 2.2 billion doses of BNT162b2 in 2021 as of July 21, 2021
- In oncology, the first patients were dosed in randomized Phase 2 trials for two FixVac programs, BNT111 and BNT113, and first-in-human Phase 1 trials started for BNT152+153 and BNT221
- BioNTech's oncology pipeline has advanced: currently 15 product candidates in 18 ongoing trials

Conference call and webcast scheduled for August 9, 2021, at 8:00 a.m. ET (2:00 p.m. CET)

MAINZ, Germany, August 9, 2021 (GLOBE NEWSWIRE) – [BioNTech SE](#) (Nasdaq: BNTX, “BioNTech” or “the Company”), a next generation immunotherapy company pioneering novel therapies for cancer and infectious diseases, today provided an update on its corporate progress and reported financial results for the second quarter and first half-year ended June 30, 2021.

“We and our partner Pfizer have crossed the one billion mark for COVID-19 vaccine doses shipped worldwide. We are proud to have reached this great milestone after only six months and to have made a difference for people with our proprietary mRNA technology. To address the ongoing pandemic, we are expanding the supply of our COVID-19 vaccine to more than 100 countries and regions worldwide, including enhancing access to low- and middle-income countries,” said **Ugur Sahin, M.D., CEO and Co-Founder of BioNTech**. “At the same time, we further developed our oncology pipeline, including the recent initiation of randomized Phase 2 trials for two FixVac programs. We were able to advance multiple oncology programs across various technology platforms which are now entering later stage testing, providing the potential for introducing a series of product candidates to the market in the coming years.”

Second Quarter 2021 and Subsequent Updates

Infectious disease

COVID-19 Vaccine Program – BNT162b2

BNT162b2 clinical development updates

- Multiple clinical trials are ongoing to expand access to and authorization of BNT162b2 to additional regions and population groups, such as the studies in children from 6 months to 11 years of age, and in healthy pregnant women.
- On April 1, 2021, BioNTech and Pfizer announced updated topline results from the global Phase 3 trial of BNT162b2, which showed high efficacy and no serious safety concerns through up to six months following the second dose. The data were published on the medRxiv preprint server on July 29, 2021.¹ Topline efficacy was based on an analysis of 971 confirmed symptomatic cases of COVID-19 observed in the pivotal Phase 3 trial through March 13, 2021. BNT162b2 was 91.2% effective against COVID-19, measured seven days through up to six months after the second dose. The vaccine was also 95.7% effective against severe COVID-19 as defined by the Food and Drug Administration (FDA) as measured seven days after the second dose. Safety data collected demonstrated a favorable safety and tolerability profile. An additional exploratory analysis of 800 trial participants enrolled in South Africa confirmed 100% efficacy against SARS-CoV-2 lineage B.1.351 (Beta variant). These data support previous results from immunogenicity studies published in April 15 demonstrating that BNT162b2 induced a robust neutralizing antibody response to the B.1.351 lineage.² The updated results have been submitted to the regulatory authorities and are currently under review.
- A clinical trial within the global Phase 1/2/3 trial is ongoing which includes: (1) an assessment of the impact of a third dose of BNT162b2 in prolonging immunity against COVID-19 and in protecting against COVID-19 caused by potential newly emerging SARS-CoV-2 variants, and (2) an assessment of a modified, variant-specific version of BNT162b2 that targets the full spike protein of the Beta variant. The aim of these studies is to explore the development, manufacturing, and regulatory pathway that BioNTech and Pfizer would pursue if SARS-CoV-2 were to change enough to require an updated vaccine.
- On June 10, 2021, BioNTech and Pfizer published results in *Nature* from *in vitro* studies demonstrating that sera from individuals vaccinated with BNT162b2 neutralize the SARS-CoV-2 lineages B.1.617.1 (Delta variant) and B.1.525 (Eta variant, first identified in Nigeria). Neutralization against the Eta variant was comparable to the neutralization against the wild-type virus, whereas the neutralization against the Delta variant was less than that against the wild-type virus, though still efficient.³
- In July 2021, BioNTech and Pfizer provided an update on their comprehensive booster strategy. In initial data from the ongoing Phase 1/2/3 booster trial of a third dose of the current BNT162b2 vaccine the companies have observed that a booster dose given six months after the second dose has a consistent tolerability profile while eliciting high neutralization titers in both younger and older adults compared to those observed after two primary doses. The immune sera elicited neutralizing titers against the original SARS-CoV-2 wild-type strain that are more than 5 to 8-fold, and more than 15 to

21-fold against the B.1.351 lineage (Beta variant) than after two primary doses. In addition, a third dose of BNT162b2 elicited neutralizing titers against the Delta variant that are more than 5 to 11-fold than after two doses. The companies expect to publish more definitive data about the analysis and plan to submit the data to the FDA, European Medicines Agency (EMA) and other regulatory authorities in the coming weeks.

While BioNTech and Pfizer believe a third dose of BNT162b2 has the potential to preserve the highest levels of protective efficacy against all currently tested variants, including Delta, the companies are remaining vigilant and are developing and will clinically test an updated version of the COVID-19 vaccine that targets the full spike protein of the Delta variant. This trial, aimed at studying the Delta variant, is part of BioNTech's and Pfizer's comprehensive strategy to address variants should the need arise in the future. The companies anticipate the clinical study to begin in August 2021, subject to regulatory approvals.

- In July 2021, BioNTech and Pfizer began a Phase 3 clinical trial to evaluate the safety, tolerability and efficacy of a 30µg booster dose of BNT162b2 versus placebo in approximately 10,000 participants aged 16 years and older who have previously received two doses of BNT162b2 at least six months prior to randomization. Participants will be followed for up to twelve months. The trial is being conducted in the United States, Brazil and South Africa.

Regulatory updates

- In May 2021, BioNTech and Pfizer announced the expansion of emergency use authorizations, conditional marketing authorizations or equivalent for adolescents 12 years of age and older in the United States, European Union and Canada. Authorizations for adolescents 12 years of age and older have also been granted in additional countries.
- On May 17, 2021, BioNTech announced that the FDA and the EMA approved the transportation and storage of thawed, undiluted vials of BNT162b2 at fridge temperatures of 2°C to 8°C for up to one month (31 days).

On July 16, 2021, the FDA granted Priority Review designation for the Biologics License Application (BLA) for BNT162b2 to prevent COVID-19 in individuals 16 years of age and older. This follows the completion of the rolling submission of the BLA in May 2021, which includes data from the pivotal Phase 3 clinical trial of the vaccine. The Prescription Drug User Fee Act (PDUFA) goal date for a decision by the FDA is in January 2022. Additional submissions to pursue regulatory approvals in those countries where emergency use authorizations or equivalents were initially granted are ongoing or planned.

Commercial updates

As of July 21, 2021, BioNTech and Pfizer have shipped approximately one billion doses of BNT162b2 to more than 100 countries or territories around the world.

The companies have signed orders of more than 2.2 billion doses for delivery in 2021 and more than one billion doses for 2022 and beyond as of July 21, 2021. Further discussions for additional dose commitments are ongoing and the order book is expected to further grow.

- On May 20, 2021, BioNTech and Pfizer announced an agreement with the European Commission (EC) to supply 900 million doses to the European Union, with an option for the EC to request up to an additional 900 million doses. This brings the total number of potential doses delivered to the EC, inclusive of all agreements, to up to 2.4 billion. The EC also has the option to purchase an updated version of the vaccine that includes new formulations or addresses potential viral variants, if available and approved. All doses for the EC are planned to be manufactured in the European Union.
- On June 10, 2021, BioNTech and Pfizer announced plans to provide the U.S. government with 500 million doses at a not-for-profit price, of which 200 million doses will be provided in 2021 and 300 million doses will be provided in the first half of 2022. The U.S. government will donate vaccine doses to low- and lower middle-income countries and organizations that support them. These doses are part of BioNTech's and Pfizer's previously announced pledge to provide two billion doses of the COVID-19 vaccine to low- and middle-income countries over the next 18 months.
- On July 23, 2021, BioNTech and Pfizer announced that the U.S. government purchased an additional 200 million doses, bringing the total number of doses under the existing supply agreement to 500 million. The companies expect to deliver 110 million of the additional doses by December 31, 2021, and the remaining 90 million doses no later than April 20, 2022. The U.S. government also has the option to acquire an updated version of the vaccine that includes new formulations or addresses potential viral variants, if available and authorized.

Manufacturing Updates

- BioNTech and Pfizer expect BNT162b2 annual manufacturing capacity to reach three billion doses by the end of 2021 and expect to have capacity to manufacture up to four billion doses in 2022.
- In the second quarter of 2021, the EMA approved the manufacturing of BioNTech's COVID-19 vaccine drug product at its facility in Marburg, Germany. This manufacturing facility is one of the largest mRNA vaccine manufacturing sites worldwide with an annual production capacity of up to one billion doses of COVID-19 vaccine, once fully operational. The first batches of vaccines manufactured at the Marburg facility were delivered in mid-April 2021.
- On May 10, 2021, BioNTech announced plans to establish a fully-integrated mRNA manufacturing facility in Singapore with support from the Singapore Economic Development Board (EDB), as well as plans to establish its first regional headquarters for South East Asia. The new facility will leverage cutting-edge manufacturing and digital infrastructure and will be equipped to produce a range of novel mRNA vaccines and therapeutics. The envisioned site will bring highly

automated and end-to-end mRNA production capabilities. The facility, with an estimated annual capacity of several hundred million doses, will provide regional and global supply capacity, as well as a rapid response capability for South East Asia to address potential pandemic threats. BioNTech anticipates the site could be operational as early as 2023.

- On July 21, 2021, BioNTech and Pfizer announced the signing of a letter of intent with The Biovac Institute (Pty) Ltd. ("Biovac"), a Cape Town-based, South African biopharmaceutical company, for the manufacture of vaccine for distribution within the African Union. Biovac will perform fill and finish manufacturing and distribution activities within BioNTech's and Pfizer's global COVID-19 vaccine supply chain and manufacturing network. Biovac's Cape Town facility is expected to be incorporated into the vaccine supply chain by the end of 2021. At full operational capacity, the annual production will exceed 100 million finished doses annually. All doses will exclusively be distributed within the 55-member states that make up the African Union.

Influenza Vaccine Program – BNT161

BNT161 – A Phase 1 clinical trial is expected to start in the third quarter of 2021. The clinical trial will evaluate modified RNA influenza vaccine candidates based on the proven BNT162b2 COVID-19 vaccine platform. BNT161 is partnered with Pfizer.

Malaria Vaccine Program

On July 26, 2021, BioNTech announced plans to develop sustainable solutions to address infectious diseases on the African continent. As part of the plans, BioNTech aims to develop a well-tolerated and highly effective Malaria vaccine, beginning with the initiation of a clinical trial by end of 2022. BioNTech will assess multiple vaccine candidates featuring known targets such as circumsporozoite protein (CSP) as well as new antigens discovered in the pre-clinical research phase. The second objective is dedicated to the development of sustainable vaccine production and supply solutions on the African continent. To this end, BioNTech is exploring possibilities to set up state-of-the-art mRNA manufacturing facilities, either with partners or on its own. This strategy aims to expand the capacity of low- and middle-income countries to manufacture contemporary vaccines end-to-end and scale up production to increase global access. BioNTech's efforts are supported by the World Health Organization and the Africa Centers for Disease Control and Prevention. Besides the WHO, the European Commission and other organizations have been involved in the early planning phase of BioNTech's Malaria project and have offered their support to identify and set up the necessary infrastructure. BioNTech's Malaria project is part of the 'eradicateMalaria' initiative, led by the KENUP Foundation, to accelerate the eradication of Malaria.

Oncology

BioNTech is accelerating the development of a broad oncology pipeline which has now advanced 15 product candidates in 18 ongoing trials. Six clinical trials, including two randomized Phase 2 clinical trials for FixVac programs, BNT111 and BNT113, have started in 2021. In the second quarter of 2021, the Company started first-in-human Phase 1 trials for the neoantigen specific T cell therapy, BNT221, and for a second RiboCytokine program, BNT152+153. BioNTech expects to further advance its oncology pipeline in the second half of 2021 with BNT122 expected to move into a randomized Phase 2 trial, and two further preclinical programs to move into Phase 1 trials.

During the remainder of 2021, BioNTech expects at least four data updates from its ongoing clinical trials in oncology.

mRNA programs

FixVac

- BNT111 – On June 18, 2021, BioNTech announced that the first patient was dosed in a randomized global, three-arm Phase 2 trial evaluating BNT111 in combination with cemiplimab versus both agents as monotherapy, in patients with anti-PD1-refractory/relapsed unresectable Stage III or IV melanoma. Melanoma remains one of the deadliest types of skin cancer with a 5-year survival for Stage IV metastatic disease of only 22.5%. In the refractory or relapsed setting, survival can be as short as six months depending on risk factors. Up to 50% of patients progress after treatment with checkpoint inhibitors.

The open-label randomized trial is expected to enroll a total of 120 patients. The primary endpoint is overall response rate of BNT111 in combination with cemiplimab. Secondary endpoints include overall response rate in the single agent arms, duration of response, and safety.

- BNT113 – Today, BioNTech announced that the first patient was dosed in July 2021 in a potentially registrational randomized Phase 2 trial evaluating BNT113 in combination with pembrolizumab versus pembrolizumab monotherapy as a first-line treatment in patients with unresectable recurrent or metastatic HPV16+ head and neck squamous cell carcinoma (HNSCC) expressing PD-L1. HPV-associated cancers are increasing, with HPV16+ HNSCC typically occurring in younger people. Most patients with HPV16+ HNSCC are diagnosed at more advanced clinical stages. BioNTech sees a significant opportunity to improve the treatment landscape with BNT113 given that it has the potential to augment clinical responses in patients being treated with checkpoint inhibitors.

BNT113 has not previously been combined with anti-PD1 therapy, and the Phase 2 trial will start with a run-in portion (Part A) designed to demonstrate the safety of the combination of BNT113 and pembrolizumab. After approximately 12 to 18 patients have completed one cycle, safety and recommended Phase 2 dosage will be confirmed, and assuming clinical success, the trial will be advanced to Part B.

Part B is planned to enroll a total of 267 patients. Primary endpoints include safety, overall survival and objective response rate. Secondary endpoints include progression free survival, durable complete responses, duration of response, patient reported outcomes and quality of life measures.

- BNT114 – The main study phase of BNT114 Phase 1 in triple negative breast cancer (TNBC-MERIT) was completed and recently summarized in a clinical trial report. A long-term follow-up period is ongoing until 2023 for patients receiving the individualized neoantigen specific vaccine only. Treatment with an on demand manufactured BNT114-vaccine was feasible

in terms of timelines, logistics, and patient burden in a standard clinical healthcare setting. Main study data demonstrated that treatment with BNT114 had an acceptable safety and tolerability profile, which was in line with the known mode of action and was accompanied by transient increases in cytokine levels.

Individualized neoantigen specific immunotherapy (iNeST)

- BNT122 (Autogene Cevumeran) – BioNTech's iNeST product candidate is partnered with Genentech. Dosing of the first patient in the randomized Phase 2 trial in the adjuvant treatment of circulating tumor DNA positive, surgically resected Stage II (high risk)/Stage III colorectal cancer is planned for the second half of 2021. The trial is currently recruiting patients.

RiboCytokines

- BNT152+153 – In June 2021 the first patient was dosed in a first-in-human Phase 1 trial evaluating a combination of BNT152 (encoding IL-7) and BNT153 (encoding IL-2). The trial will enroll approximately 72 patients with various solid tumors. In parallel, BNT152 and BNT153 monotherapy dose escalation in Part 1 will determine the Part 2 dose of each compound. Part 2 will be the dose escalation of BNT152 and BNT153 in combination.

RiboMabs

- BNT141 – BioNTech plans to start a Phase 1 clinical trial for BNT141 in the second half of 2021.
- BNT142 – BioNTech plans to start a Phase 1 clinical trial for BNT142 in the second half of 2021.

Antibodies

Next-generation checkpoint immunomodulators

BNT311 and BNT312 are partnered with Genmab as part of a 50/50 collaboration in which development costs and future profit are shared.

- BNT311/GEN1046 – A Phase 1/2a dose escalation trial with multiple expansion cohorts in patients with solid tumors is ongoing. A data update for the trial is planned in the second half of 2021.
- BNT312/GEN1042 – A Phase 1/2a dose escalation trial with multiple expansion cohorts in patients with solid tumors is ongoing. The first data disclosure for the trial is planned in the second half of 2021.

Cell therapies

CAR-T cell immunotherapy

- BNT211 – A first-in-human Phase 1/2a open-label dose escalation and dose expansion trial evaluating BNT211 in patients with Claudin-6-positive solid tumors is ongoing. The trial evaluates Claudin-6 CAR-T cells dosed as monotherapy and in combination with Claudin-6 CARVac. A data update for this trial is planned in the second half of 2021.

Neoantigen-targeting T cell therapy

- BNT221 – In April 2021, the first patient was dosed in a first-in-human Phase 1 dose escalation trial evaluating BNT221 in patients with checkpoint inhibitor unresponsive or refractory metastatic melanoma. Part 1 of the trial consists of a monotherapy dose escalation of BNT221. In Part 2, BNT221 will be dosed in combination with anti-PD1 therapy after first-line treatment.

Small molecule immunomodulators

Toll-like receptor binding agonist

- BNT411 – A Phase 1/2a dose-escalation trial 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) is ongoing. A data update from this trial is planned in the second half of 2021.

Corporate Updates

- On July 19, 2021, BioNTech and Kite Pharma, a Gilead company, announced the companies have entered into a purchase agreement for BioNTech to acquire Kite's solid tumor neoantigen T cell receptor (TCR) R&D platform and clinical manufacturing facility in Gaithersburg, MD. The acquired facility will provide production capacity to support clinical trials in the United States and will complement BioNTech's existing cell therapy manufacturing facility in Idar-Oberstein, Germany. The facility will also support the development of BioNTech's expanding pipeline of novel cell therapies. Under the terms of the agreement, Kite received a one-time upfront payment from BioNTech. The asset acquisition closed on August 4, 2021 and is an important step in the BioNTech's goal to build a global biotechnology company for individualized cancer medicine. The acquisition further strengthens the Company's footprint in the United States.

Management Updates

- On May 18, 2021, BioNTech announced that Jens Holstein was appointed to the Management Board as Chief Financial Officer. Jens Holstein joined the Management Board on July 1, 2021 to help strengthen BioNTech on its growth trajectory as a global, fully integrated immunotherapy company. Jens Holstein takes over the CFO role from Dr. Sierk Poetting who will fully focus on his tasks as Chief Operating Officer (COO).

Second Quarter 2021 Financial Results (unaudited)

Revenues: Total revenues were estimated to be €5,308.5 million⁴ for the three months ended June 30, 2021, compared to €41.7 million for the three months ended June 30, 2020. For the six months ended June 30, 2021, total revenues were estimated to be €7,356.9 million⁴ compared to €69.4 million for the comparative prior year period. The increase was mainly due to rapid increases in the supply of COVID-19 vaccine worldwide. Under the collaboration agreements, territories have been allocated between BioNTech, Pfizer and Fosun Pharma based on marketing and distribution rights. During the three months ended June 30, 2021, BioNTech's commercial revenues included an estimated amount of €3,923.7 million⁴ gross profit share and €168.6 million of sales milestones. During the six months ended June 30, 2021, BioNTech's commercial revenues included an estimated amount of €5,428.4 million⁴ gross profit share and €415.8 million of sales milestones. BioNTech's share of the collaboration partners' gross profit is based on COVID-19 vaccine sales in Pfizer's and Fosun Pharma's territories and represents a net figure. In addition, during the three and six months ended June 30, 2021, respectively, €138.1 million and €202.0 million sales to BioNTech's collaboration partners of products manufactured by BioNTech as well as €1,035.6 million and €1,235.4 million direct COVID-19 vaccine sales to customers in BioNTech's territory, Germany and Turkey, have been recognized.

Cost of Sales: Cost of sales were estimated to be €883.8 million⁴ for the three months ended June 30, 2021, compared to €5.6 million for the three months ended June 30, 2020. For the six months ended June 30, 2021, cost of sales were estimated to be €1,116.9 million⁴, compared to €11.5 million for the comparative prior year period. During the three and six months ended June 30, 2021, estimated cost of sales of €872.1 million⁴ and €1,095.3 million⁴, respectively, were recognized with respect to BioNTech's COVID-19 vaccine sales and include the share of gross profit that BioNTech owes its collaboration partner Pfizer based on its sales.

Research and Development Expenses: Research and development expenses were €201.1 million for the three months ended June 30, 2021, compared to €95.2 million for the three months ended June 30, 2020. For the six months ended June 30, 2021, research and development expenses were €417.3 million, compared to €160.3 million for the comparative prior year period. The increase was mainly due to an increase in research and development expenses for BioNTech's BNT162 program, recorded as purchased services with respect to those expenses, which were initially incurred by Pfizer and subsequently charged to BioNTech under the collaboration agreement. The increase was further driven by an increase in wages, benefits and social security expenses due to increases in headcounts, recognizing inventor compensation expenses as well as expenses incurred under the new share-based-payment arrangements.

General and Administrative Expenses: General and administrative expenses were €47.8 million for the three months ended June 30, 2021, compared to €18.8 million for the three months ended June 30, 2020. For the six months ended June 30, 2021, general and administrative expenses were €86.7 million, compared to €34.6 million for the comparative prior year period. The increase was mainly due to an increase in wages, benefits and social security expenses from increasing headcounts and recognizing expenses incurred under the new share-based-payment arrangements, higher expenses for purchased management consulting and legal services, as well as higher insurance premiums.

Income Taxes: Interim income taxes were €1,235.6 million and €1,749.8 million for the three and six months ended June 30, 2021, respectively, and were recognized using the estimated annual effective income tax rate of approximately 31%.

Net Profit/(Loss): Net profit was €2,787.2 million for the three months ended June 30, 2021, compared to €88.3 million net loss for the three months ended June 30, 2020. For the six months ended June 30, 2021, net profit was €3,915.3 million, compared to €141.7 million net loss for the comparative prior year period.

Cash Position: Cash and cash equivalents as of June 30, 2021 were €914.1 million. In addition, trade receivables remained outstanding which is mainly due to the contractual settlement of the gross profit share under the COVID-19 collaboration with Pfizer, which has a temporal offset of more than one calendar quarter. As Pfizer's fiscal quarter for subsidiaries outside the United States differs from BioNTech's financial reporting cycle, it creates an additional time lag between the recognition of revenues and the payment receipt. Consequently, trade receivables which were outstanding as of June 30, 2021 were received as payments in July 2021, improving BioNTech's cash position.

Shares Outstanding: Shares outstanding as of June 30, 2021 were 242,516,955.

Update on current signed COVID-19 vaccine order book for the 2021 financial year:

Estimated COVID-19 vaccine revenues to BioNTech for the 2021 financial year upon delivery of currently signed supply contracts of ~2.2 billion doses as of July 21, 2021 is ~€15.9 billion⁵.

This revenue estimate reflects:

- Expected revenues from direct COVID-19 vaccine sales to customers in BioNTech's territory
- Expected revenues from sales to collaboration partners of products manufactured by BioNTech
- Expected sales milestone payments from collaboration partners
- Expected revenues related to share of gross profit from COVID-19 vaccine sales in the collaboration partners' territories

Additional revenues related to further supply contracts for deliveries in 2021 expected with first contracts already in place for 2022 and beyond.

Full year 2021 manufacturing capacity targeting 3 billion doses and up to 4 billion doses for the year 2022.

Update on 2021 Financial Outlook:

Planned Full Year 2021 Expenses and Capex⁵	
R&D expenses	€950 million – €1,050 million Ramp-up of R&D investment in the second half of 2021 planned to expand and accelerate the pipeline development
SG&A expenses	€250 million – €300 million
Capital expenditures	€175 million – €225 million
Estimated Full Year 2021 Tax Assumptions	
BioNTech Group estimated annual effective income tax rate	~31%

The full interim unaudited condensed consolidated financial statements can be found in BioNTech's Quarterly Report on Form 6-K, filed today with the SEC and available at <https://www.sec.gov/>.

¹Thomas SJ et al.. Six Month Safety and Efficacy of the BNT162b2 mRNA COVID-19 Vaccine; *medRxiv Preprint*, July 29, 2021. Available at <https://www.medrxiv.org/content/10.1101/2021.07.28.21261159v1.full.pdf>

²*N Engl J Med.* Neutralizing Activity of BNT162b2-Elicited Serum; 2021 Apr 15;384(15):1466-1468. Available at <https://www.nejm.org/doi/full/10.1056/NEJMc2102017>

³*Nature.* BNT162b2-elicited neutralization of B.1.617 and other SARS-CoV-2 variants; 2021 Jun 10. Online ahead of print.. Available at: <https://www.nature.com/articles/s41586-021-03693-y>

⁴Estimated figures based on preliminary data shared between the collaboration partner and BioNTech as fully described in the Annual Report on Form 20-F as well as the Quarterly Report as of and for the Three and Six Months Ended June 30, 2021, which is filed as an exhibit to BioNTech's Current Report on Form 6-K. Changes in the share of the collaboration partners' gross profit will be recognized prospectively.

⁵Figures have been estimated at constant foreign exchange rates and reflect current base case projections.

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, bispecific 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 revenues and net profit related to sales of our COVID-19 vaccine, referred to as COMIRNATY® in the European Union as authorized for use under conditional marketing approval, in territories controlled by our collaboration partners, particularly for those figures that are derived from preliminary estimates provided by our partners; our pricing and coverage negotiations with governmental authorities, private health insurers and other third-party payors after our initial sales to national governments; the extent to which a COVID-19 vaccine continues to be necessary in the future; competition from other COVID-19 vaccines or related to our other product candidates, including those with different mechanisms of action and different manufacturing and distribution constraints, on the basis of, among other things, efficacy, cost, convenience of storage and distribution, breadth of approved use, side-effect profile and durability of immune response; the rate and degree of market acceptance of our COVID-19 vaccine and our investigational medicines, if approved; the initiation, timing, progress, results, and cost of our research and development programs and our current and future preclinical studies and clinical trials, including statements regarding the timing of initiation and completion of studies or trials and related preparatory work, the period during which the results of the trials will become available and our research and development programs; the timing of and our ability to obtain and maintain regulatory approval for our product candidates; the collaboration between BioNTech and Pfizer to develop a COVID-19 vaccine (including a potential booster dose of BNT162b2 and/or a potential booster dose of a variation of BNT162b2 having a modified mRNA sequence); the ability of BNT162b2 to prevent COVID-19 caused by emerging virus variants; our ability to identify research opportunities and discover and develop investigational medicines; the ability and willingness of our third-party collaborators to continue research and development activities relating to our development candidates and investigational medicines; the impact of the COVID-19 pandemic on our development programs, supply chain, collaborators and financial performance; unforeseen safety issues and claims for personal injury or death arising from the use of our COVID-19 vaccine and other products and product candidates developed or manufactured by us; BioNTech's Malaria, Tuberculosis and HIV programs; timing for selecting clinical candidates for these programs and the commencement of a clinical trial, as well as any data readouts; the nature of the collaboration with the African Union and the Africa CDC; the nature and duration of support from WHO, the European Commission and other organizations with establishing infrastructure; the development of sustainable vaccine production and supply solutions on the African continent and the nature and feasibility of these solutions; our estimates of research and development revenues, commercial revenues, cost of sales, research and development expenses, sales and marketing expenses, general and administrative expenses, other operating income less expenses, finance income less expenses, income taxes, shares outstanding and basic and diluted profit for the period per share

and our needs for or ability to obtain additional financing; our ability to identify, recruit and retain key personnel; our and our collaborators' ability to protect and enforce our intellectual property protection for our proprietary and collaborative product candidates, and the scope of such protection; the development of and projections relating to our competitors or our industry; our ability and that of our collaborators to commercialize and market our product candidates, if approved, including our COVID-19 vaccine; the amount of and our ability to use net operating losses and research and development credits to offset future taxable income; our ability to manage our development and expansion; regulatory developments in the United States and foreign countries; our ability to effectively scale our production capabilities and manufacture our products, including our target COVID-19 vaccine production levels, and our product candidates; our ability to implement, maintain and improve effective internal controls; our plans for expansion in southeast Asia and China, including our planned regional headquarters and manufacturing facility in Singapore as well as the joint venture with Fosun Pharma; and other factors not known to us at this time. 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 quarterly report 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 this quarterly report 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 quarterly report 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.

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Interim Condensed Consolidated Statements of Profit or Loss

	Three months ended		Six months ended	
	June 30,		June 30,	
	2021	2020	2021	2020
<i>(in millions, except per share data)</i>	<i>(unaudited)</i>	<i>(unaudited)</i>	<i>(unaudited)</i>	<i>(unaudited)</i>
Revenues				
Research & development revenues	€28.0	€32.5	€48.9	€53.7
Commercial revenues	5,280.5	9.2	7,308.0	15.7
Total revenues	5,308.5	41.7	7,356.9	69.4
Cost of sales	(883.8)	(5.6)	(1,116.9)	(11.5)
Research and development expenses	(201.1)	(95.2)	(417.3)	(160.3)
Sales and marketing expenses	(13.3)	(3.0)	(22.0)	(3.5)
General and administrative expenses	(47.8)	(18.8)	(86.7)	(34.6)
Other operating expenses	(0.3)	(0.8)	(0.9)	(0.9)
Other operating income	36.2	0.8	147.5	1.2
Operating income / (loss)	€4,198.4	€(80.9)	€5,860.6	€(140.2)
Finance income	0.3	0.2	24.8	0.6
Finance expenses	(175.4)	(9.3)	(219.1)	(3.4)
Interest expenses related to lease liabilities	(0.5)	(0.5)	(1.2)	(0.9)
Profit / (loss) before tax	€4,022.8	€(90.5)	€5,665.1	€(143.9)
Income taxes	(1,235.6)	2.2	(1,749.8)	2.2
Profit / (Loss) for the period	€2,787.2	€(88.3)	€3,915.3	€(141.7)
Earnings per share				
Basic profit / (loss) for the period per share	€11.42	€(0.38)	€16.07	€(0.62)
Diluted profit / (loss) for the period per share	€10.77	€(0.38)	€15.14	€(0.62)

Interim Condensed Consolidated Statements of Financial Position

<i>(in millions)</i>	June 30, 2021	December 31, 2020
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Assets	<i>(unaudited)</i>	
Non-current assets		
Intangible assets	€164.1	€163.5
Property, plant and equipment	261.6	227.0
Right-of-use assets	119.5	99.0
Other assets	0.9	1.0
Deferred tax assets	163.2	161.2
Total non-current assets	€709.3	€651.7
Current assets		
Inventories	305.4	64.1
Trade and other receivables	7,051.7	165.5
Other financial assets	0.8	137.2
Other assets	113.1	61.0
Income tax assets	0.9	0.9
Deferred expenses	53.5	28.0
Cash and cash equivalents	914.1	1,210.2
Total current assets	€8,439.5	€1,666.9
Total assets	€9,148.8	€2,318.6
Equity and liabilities		
Equity		
Share capital	246.3	246.3
Capital reserve	1,674.4	1,514.5
Treasury shares	(3.8)	(4.8)
Retained earnings / (Accumulated losses)	3,505.7	(409.6)
Other reserves	60.2	25.4
Total equity	€5,482.8	€1,371.8
Non-current liabilities		
Interest-bearing loans and borrowings	242.9	231.0
Other financial liabilities	243.4	31.5
Provisions	5.6	5.5
Contract liabilities	6.1	71.9
Other liabilities	4.7	0.6
Deferred tax liabilities	-	0.3
Total non-current liabilities	€502.7	€340.8
Current liabilities		
Interest-bearing loans and borrowings	13.9	9.1
Trade payables	262.7	102.3
Other financial liabilities	698.9	74.1
Government grants	3.1	92.0
Tax provisions	1,750.6	-
Other provisions	98.0	0.9
Contract liabilities	241.0	299.6
Other liabilities	95.1	28.0
Total current liabilities	€3,163.3	€606.0
Total liabilities	€3,666.0	€946.8
Total equity and liabilities	€9,148.8	€2,318.6

Interim Condensed Consolidated Statements of Cash Flows

<i>(in millions)</i>	Three months ended June 30,		Six months ended June 30,	
	2021 <i>(unaudited)</i>	2020 <i>(unaudited)</i>	2021 <i>(unaudited)</i>	2020 <i>(unaudited)</i>
Operating activities				
Profit / (Loss) for the period	€2,787.2	€(88.3)	€3,915.3	€(141.7)
Income taxes	€1,235.6	€(2.2)	€1,749.8	€(2.2)
Profit / (loss) before tax	€4,022.8	€(90.5)	€5,665.1	€(143.9)
Adjustments to reconcile profit / (loss) before tax to net cash flows:				

Depreciation and amortization of property, plant, equipment and intangible assets	16.4	8.8	29.4	17.4
Share-based payment expense	22.0	8.3	39.3	16.7
Net foreign exchange differences	(70.1)	0.2	(101.3)	(0.1)
Gain on disposal of property, plant and equipment	0.2	-	0.4	0.1
Finance income	(0.3)	(0.2)	(0.6)	(0.6)
Interest on lease liability	0.5	0.5	1.2	0.9
Finance expense	175.1	0.1	219.1	0.2
Movements in government grants	(20.9)	-	(88.8)	-
Other non-cash income	-	(0.2)	-	(0.2)
Working capital adjustments:				
Increase in trade and other receivables, contract assets and other assets	(4,651.0)	(7.7)	(6,751.5)	(9.8)
Decrease / (Increase) in inventories	(158.5)	1.0	(241.3)	3.2
Increase in trade payables, other financial liabilities, other liabilities, contract liabilities and provisions	565.5	64.6	821.0	46.7
Interest received	0.3	0.3	0.6	0.6
Interest paid	(2.1)	(0.5)	(3.9)	(1.0)
Income tax paid	(0.2)	(0.2)	(0.3)	(0.4)
Net cash flows used in operating activities	€(100.3)	€(15.5)	€(411.6)	€(70.2)
Investing activities				
Purchase of property, plant and equipment	(25.9)	(15.1)	(47.6)	(21.4)
Proceeds from sale of property, plant and equipment	0.3	-	1.2	-
Purchase of intangibles assets and right-of-use assets	(4.2)	(2.1)	(11.7)	(4.2)
Acquisition of subsidiaries and businesses, net of cash acquired	-	7.4	-	0.9
Net cash flows used in investing activities	€(29.8)	€(9.8)	€(58.1)	€(24.7)
Financing activities				
Proceeds from issuance of share capital, net of costs	160.9	147.8	160.9	147.8
Proceeds from loans and borrowings	-	-	-	2.9
Repayment of loans and borrowings	(0.7)	(0.3)	(1.4)	(0.3)
Payments related to lease liabilities	(7.3)	(1.3)	(11.1)	(2.2)
Net cash flows from financing activities	€152.9	€146.2	€148.4	€148.2
Net increase/(decrease) in cash and cash equivalents	22.8	120.9	(321.3)	53.3
Change in cash and cash equivalents resulting from exchange rate differences	(0.2)	0.5	25.2	0.6
Cash and cash equivalents at the beginning of the period	891.5	451.6	1,210.2	519.1
Cash and cash equivalents at June 30	€914.1	€573.0	€914.1	€573.0