BioNTech Announces Third Quarter 2021 Financial Results and Corporate Update

November 9, 2021

- *Delivered more than 2 billion doses of COMIRNATY/BNT162b2 in 2021 as of November 2nd*
- *Demonstrated progress in expanding access to COVID-19 vaccine globally, including Biologics License Application (BLA) approval by U.S. FDA, regulatory authorizations of booster doses in multiple populations and first U.S. Emergency Use Authorization (EUA) in children for a COVID-19 vaccine*
- *Expansion of clinical oncology portfolio with first patient dosed in Phase 2 trial of mRNA-based individualized immunotherapy autogene cevumeran (BNT122, RO7198457) in circulating tumor DNA positive high-risk colorectal cancer patients after adjuvant treatment*
- *Positive clinical data from BioNTech's oncology pipeline to be highlighted in seven presentations at SITC 36th Annual Meeting; currently 15 product candidates in 19 ongoing trials*

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

MAINZ, Germany, November 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 third quarter and first nine months of 2021 ended September 30, 2021.

"We continue to work diligently to respond to global vaccine needs with a commitment to ensure equitable vaccine access. Our robust clinical and regulatory strategy has led to recent approvals that expand access to additional age groups, highlighted by the first EUA for a COVID-19 vaccine in children 5 to under 12 years of age in the United States, and authorizations for booster doses for multiple populations," said **Ugur Sahin, M.D., CEO and Co-Founder of BioNTech**. "We also had a strong quarter with regard to our oncology pipeline. Our approach to oncology addresses each patient's unique needs by leveraging multiple therapeutic platforms with combination potential. With the recent dosing of the first patient with autogene cevumeran in high-risk colorectal cancer patients after adjuvant treatment, we now have four programs in Phase 2 development, as our pipeline advances into later-stage trials. We are reporting positive clinical data across 6 of our oncology programs at the upcoming SITC conference, including favorable safety profiles and robust immune responses."

Third Quarter 2021 and Subsequent Updates

Infectious disease

Infectious disease is a growth pillar for BioNTech, and the company is developing vaccine candidates to address multiple pathogens that pose significant global public health challenges.

COVID-19 Vaccine Program – BNT162b2
BNT162b2 clinical development updates

Multiple clinical trials are ongoing to expand COVID-19 vaccine reach and explore booster doses to address waning immunity. Clinical data to date support a third dose booster of the vaccine in adults to augment vaccine protection over time. A third booster dose of BNT162b2 confers high neutralizing antibody titers against SARS-CoV-2 ancestral virus and the Beta and Delta variants. The titers following a booster dose are higher than the levels observed after the two-dose primary series.
Additionally, studies are underway evaluating variant-specific versions of the vaccine to generate data to inform BioNTech and Pfizer's strategy to address emerging SARS-CoV-2 variants. While to date, there is no clinical data suggesting the need for a variant-specific version of the vaccine, the companies are establishing a preemptive prototype approach to evaluate the development, manufacturing and regulatory processes for variant specific vaccines. This prototype approach is aimed to be substantiated by broad clinical data that are being prepared for submission to regulatory authorities.

- In August 2021, BioNTech and Pfizer started a clinical trial to evaluate the safety and immunogenicity of variant-encoding vaccine candidates, including a multivalent vaccine against two variants of concern. The study will enroll approximately 1,200 adults 18 to 85 years of age. Participants will receive a third 30 µg dose of a multivalent Delta and Alpha version of the vaccine, or monovalent Delta or Alpha versions administered six months after the second dose of the two-dose primary series of BNT162b2. Vaccine- and SARS-CoV-2-naïve participants in the study will receive two doses of the multivalent Delta and Alpha vaccine administered 21 days apart. First data from this study are anticipated in the fourth quarter of 2021.
- On September 6, 2021, BioNTech and Pfizer announced data from a Phase 3 safety and immunogenicity clinical trial of 306 participants 18 to 55 years of age who received a booster dose approximately six months after completing the two-dose primary regimen, with a median follow-up time of 2.6 months post-third dose. The booster dose elicited significantly higher SARS-CoV-2 neutralizing antibody titers against the ancestral strain compared to the levels observed after the two-dose primary series with titers against ancestral virus more than 5 times as high at 1 month after the third dose compared to 1 month after the two-dose primary series. The safety profile was favorable and similar to the safety profile after dose two of the primary series and generally consistent with other clinical data for BNT162b2. Previously reported Phase 1 data showed a similar pattern of third dose responses against the ancestral strain, Beta and Delta

variants. Based on these data a third dose booster of BNT162b2 for emergency use in certain population groups was authorized by the U.S. Food and Drug Administration (FDA) and the Conditional Marketing Authorization (CMA) in the European Union was updated upon approval from the European Commission (EC) following a positive opinion from the European Medicines Agency (EMA) for a booster dose of the COVID-19 vaccine from BioNTech and Pfizer. The data are also being submitted to other regulatory authorities worldwide.

- On September 20, 2021, BioNTech and Pfizer announced positive topline results from a Phase 2/3 trial in children demonstrating strong immune response one month after the second dose in 2,268 children aged 5 to under 12 years. The vaccine showed a favorable safety profile and robust neutralizing antibody responses in this cohort using a two-dose regimen of 10 µg administered 21 days apart. Antibody responses were comparable to those in a previous study in people 16 to 25 years of age immunized with 30 µg doses. One month after the second dose, the geometric mean ratio of SARS-CoV-2 neutralizing titers in the children aged 5 to under 12 years to those in people 16 to 25 years of age was 1.04, meeting the predefined immunobridging success criteria. These data compare immune responses between a vaccine candidate and an approved vaccine. These data were recently submitted for publication in a peer-reviewed journal.
- Subsequently, on October 26, 2021, the companies reported further results from the Phase 2/3 trial in children that included an additional 2,379 children, from the supplemental safety group, bringing the total to approximately 4,500. In this analysis, BNT162b2 showed a favorable safety profile, robust immune responses as well as a vaccine efficacy rate of 90.7% in participants without prior SARS-CoV-2 infection, measured 7 days after the second dose, during a period when Delta was the prevalent strain. Topline readouts for the other two age cohorts from the trial – children 2 to <5 years of age and children 6 months to <2 years of age – are expected as soon as the fourth quarter of 2021 or early first quarter 2022.
- On October 21, 2021, BioNTech and Pfizer announced topline results from a Phase 3 clinical trial to evaluate the safety, tolerability and efficacy of a 30 µg booster dose versus placebo in more than 10,000 participants aged 16 years and older who previously received two doses of BNT162b2 at least six months prior to randomization. These first results from a randomized, controlled COVID-19 vaccine booster dose trial demonstrated that a booster dose restored vaccine protection to the high levels achieved after the second dose, showing a relative vaccine efficacy of 95.6% compared to those who did not receive a booster dose. Multiple subgroup analyses showed efficacy was consistent irrespective of age, sex, race, ethnicity and co-morbidities. The adverse event profile was consistent with previous clinical safety data. The companies plan to share these data with the FDA, EMA, and other regulatory agencies and submit detailed results for publication in a peer-reviewed journal.
- A global Phase 2/3 trial to evaluate the safety, tolerability and immunogenicity of BNT162b2 in preventing COVID-19 in healthy pregnant women 18 years of age and older is ongoing. The study will also assess safety in infants of vaccinated pregnant women and the transfer of potentially protective antibodies to their infants.

Regulatory updates

BioNTech and Pfizer have made progress on the regulatory front, including Biologics License Application (BLA) approval in the United States, as well as U.S. Emergency Use Authorization (EUA) for booster doses for many populations at high risk of severe COVID-19-disease. The EMA issued a positive opinion on the administration of BNT162b2 as a booster dose in adults and as a third dose in immunocompromised people.

- In August 2021, the U.S. FDA and the EMA authorized the extension of the shelf-life of the COVID-19 vaccine from six to nine months when stored at -90 to -60 degrees C.
- On August 23, 2021, the U.S. FDA approved the BLA for BNT162b2 to prevent COVID-19 in individuals 16 years of age and older based on a comprehensive data package that included longer-term follow-up data from the Phase 3 trial. BNT162b2 is the first COVID-19 vaccine to be granted full approval by the FDA.
- On September 22, 2021, the U.S. FDA authorized a third dose booster for emergency use in individuals 65 years of age and older, individuals 18 through 64 years of age at high risk of severe COVID-19, and individuals 18 through 64 years of age whose frequent institutional or occupational exposure to SARS-CoV-2 puts them at high risk of serious complications from COVID-19 including severe COVID-19. The booster dose, which is the same formulation and dosage as used in the primary series, is to be administered at least six months after completion of the primary series. A third dose was authorized on August 12, 2021, under the EUA for administration to individuals at least 12 years of age who have undergone solid organ transplantation, or who are diagnosed with conditions that are considered to have an equivalent level of immunocompromise.
- On October 5, 2021, the EC granted a variation to the CMA for the administration of a third dose booster of BNT162b2 at least six months after the second dose in individuals 18 years of age and older. This followed a positive opinion from the Committee for Medicinal Products for Human Use (CHMP) of the EMA. The positive opinion follows the companies' submission of a variation to the EMA requesting to update the CMA with data supporting a booster dose to prevent COVID-19 in individuals 16 years of age and older. The CHMP also recommended that people with severely weakened immune systems should be given a third dose of the vaccine at least 28 days after their second dose.
- In October 2021, BioNTech and Pfizer announced the submission of data supporting the vaccination of children 5 to under 12 years of age to the EMA for a variation of the CMA in the European Union. The variation request includes data from the Phase 2/3 study, which is enrolling children 6 months to under 12 years of age. The data will also be filed with other regulatory authorities in the coming weeks.

- On October 29, 2021, BioNTech and Pfizer received the first U.S. FDA EUA of a COVID-19 vaccine in children ages 5 through 11 years of age based on data from a Phase 2/3 randomized, controlled trial. This EUA follows the FDA's Vaccines and Related Biological Products Advisory Committee (VRBPAC) vote on October 26, 2021, recommending that the FDA grant EUA in this population.
- In November 2021, the EC authorized a new formulation of BNT162b2, that further simplifies vaccine handling. This decision followed a positive opinion from the EMA CHMP. The new formulation also allows for longer storage, as vials can be stored for 10 weeks at refrigerator temperatures from 2°C to 8°C, and after first puncture, can be stored and transported at 2°C to 30°C and used within 12 hours.

Commercial updates

BioNTech and Pfizer have delivered an aggregate of over 2 billion doses of BNT162b2 vaccine to more than 152 countries and territories around the world as of November 2, 2021.
Further discussions for additional dose commitments are ongoing for 2022 and beyond.

- On September 22, 2021, BioNTech and Pfizer announced plans to expand the existing agreement with the U.S. government by providing an additional 500 million doses at a not-for-profit price for donation to low- and lower-middle-income countries and the organizations that support them. This expanded agreement brings the total number of doses to be supplied to the U.S. government for donation to one billion. The companies are committed to working toward equitable and affordable access to COVID-19 vaccines for all people around the world, actively working with governments and health partners worldwide, and have pledged to provide two billion doses to low- and middle-income countries in 2021 and 2022.
- In October 2021, the Japanese government agreed to purchase another 120 million doses starting in January 2022, bringing the total number of doses purchased to 314 million.
- On October 28, 2021, BioNTech and Pfizer announced that the U.S. government purchased an additional 50 million doses to continue to support preparedness for pediatric vaccinations, including securing vaccines for children under 5 years of age. With this purchase, the U.S. government has exercised its final purchase option under the existing supply agreement, bringing the total number of doses secured under the agreement to 600 million, excluding the one billion doses to be supplied at a not-for-profit price for donation.

Manufacturing Updates

BioNTech and Pfizer expect to manufacture 2.7 billion to 3 billion doses by the end of 2021 and anticipate capacity to manufacture up to four billion doses in 2022. The companies have developed a global COVID-19 vaccine supply chain and manufacturing network, which now spans four continents and includes more than 20 manufacturing facilities.

- On August 26, 2021, BioNTech and Pfizer announced the signing of a letter of intent with Eurofarma Laboratórios SA, a Brazilian biopharmaceutical company, to manufacture vaccine for distribution within Latin America. Eurofarma will obtain drug product from facilities in the United States, and manufacturing of finished doses is expected to commence in 2022. At full operational capacity, annual production is expected to exceed 100 million finished COVID-19 doses.

Influenza Vaccine Program

- BNT161 – On September 27, 2021, the first participants were dosed in a Phase 1 clinical trial to evaluate the safety, tolerability and immunogenicity of a single dose quadrivalent mRNA vaccine (BNT161) against influenza in healthy adults 65 to 85 years of age, with an FDA-approved standard quadrivalent influenza vaccine as a control. BNT161 encodes World Health Organization recommended strains. Data from the trial is expected in the first half of 2022. BNT161 is partnered with Pfizer.

Other Infectious Disease

BioNTech is committed to developing vaccines and sustainable end-to-end vaccine production on the African continent and to provide affordable access to low- and lower-middle-income countries. The company has continued its efforts to establish the necessary infrastructure and to grow its infectious disease pipeline.

- On July 26, 2021, BioNTech announced plans to develop sustainable solutions to address infectious diseases on the African continent. BioNTech aims to develop an mRNA-based malaria vaccine and the initiation of a clinical trial is expected by end of 2022.
- On October 26, 2021, BioNTech announced that construction of the first mRNA manufacturing facility in Africa is expected to begin in mid-2022, following the signing of a Memorandum of Understanding with the Rwandan government and the Institut Pasteur de Dakar (Senegal). BioNTech believes this facility could become the first node in a decentralized and robust African end-to-end manufacturing network with an expected annual manufacturing capacity of several hundreds of million mRNA vaccine doses to provide sustainable vaccine supply on the African continent.
- The company also announced that clinical trials for its first tuberculosis vaccine candidate are planned to begin by end of 2022, just two years after the program was initiated. BioNTech has collaborated with the Bill and Melinda Gates Foundation since 2019 to develop preclinical vaccine and immunotherapy candidates to prevent HIV and tuberculosis infection.

Oncology

BioNTech is advancing the development of a broad oncology pipeline, which spans multiple anti-tumor and immune-modulating approaches. BioNTech's clinical pipeline now includes randomized Phase 2 clinical trials for FixVac programs, BNT111 and BNT113, and for iNeST product candidate autogene cevumeran (BNT122, RO7198457), bringing the company's clinical programs to a total of 15 product candidates in 19 ongoing clinical trials including four phase 2 randomized clinical trials.
BioNTech expects to further advance its oncology pipeline in the fourth quarter of 2021 with one preclinical program expected to move into a first-in-human Phase 1 trial.
Seven updates (from 6 oncology programs) with positive clinical and preclinical data supporting BioNTech's oncology pipeline will be presented at the Society for Immunotherapy of Cancer's (SITC) 36th Annual Meeting which takes place on November 10–14, 2021. The information below regarding the SITC presentations reflects data in submitted abstracts and supplemental data may be presented at the conference.

mRNA programs
FixVac

These product candidates leverage the company's proprietary pharmacologically optimized uridine mRNA and its proprietary intravenous lipoplex formulation.

- BNT111 – A global, three-arm Phase 2 trial evaluating BNT111 in combination with cemiplimab (Regeneron and Sanofi's Libtayo®), versus both agents as monotherapy, in patients with anti-PD1-refractory/relapsed unresectable Stage III or IV melanoma is ongoing. The trial is being conducted in collaboration with Regeneron.

On September 15, 2021, the U.S. FDA granted Orphan Drug Designation to BNT111 for the treatment of Stage IIB through IV melanoma.
At SITC, BioNTech intends to present additional data from the ongoing Phase 1 trial evaluating the safety and tolerability of BNT111 in patients with advanced melanoma. Data demonstrated that the immunogenicity and safety profile of BNT111 as a monotherapy were comparable in patients grouped as having evidence of disease (ED) and in patients with no evidence of disease (NED). As of May 24, 2021, 14 of 22 (64%) patients with ED and 19 of 28 (68%) patients with NED demonstrated BNT111-induced T-cell responses against at least one tumor-associated antigen (TAA). In NED patients, clinical efficacy was promising with median disease-free survival of 34.8 months.

- BNT112 – At SITC, BioNTech intends to present data from the ongoing Phase 1/2 trial of BNT112 as a monotherapy and in combination with cemiplimab in patients with metastatic castration-resistant prostate cancer (mCRPC) and newly diagnosed high-risk localized prostate cancer (LPC). Overall, as of June 22, 2021, the data suggest that BNT112 as monotherapy and in combination with a PD-1 inhibitor (cemiplimab) is well-tolerated in mCRPC. Additionally, data suggest that BNT112 induces robust immune responses, as de novo induction and expansion of pre-existing antigen-specific T-cell responses was observed in all patients with available Post-IVS-ELISpot.
- BNT113 – A 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 is ongoing.

Individualized neoantigen specific immunotherapy (iNeST)

- Autogene Cevumeran (BNT122) – BioNTech's iNeST product candidate autogene cevumeran is also based on the company's proprietary pharmacologically optimized uridine mRNA and its proprietary intravenous lipoplex formulation, and is partnered with Genentech. In October 2021, BioNTech announced that the first patient was dosed in a randomized Phase 2 trial in the adjuvant treatment of circulating tumor DNA (ctDNA) positive, surgically resected Stage II (high-risk)/Stage III colorectal cancer. The trial plans to enroll about 200 patients to evaluate the efficacy of autogene cevumeran compared to watchful waiting after surgery and chemotherapy, the current standard of care for these high-risk patients. The primary endpoint for the study is disease-free survival. Secondary objectives include overall survival and safety. The trial has been initiated in the United States, Germany, Spain and Belgium.

The medical need for novel therapies to treat colorectal cancer, the second deadliest cancer worldwide, remains high. The current standard of care in this indication is watchful waiting to see if tumors recur after removal of the primary tumor and adjuvant chemotherapy. A proportion of these patients are expected to have a recurrence of their tumor within 2 to 3 years after their surgery. For this clinical trial, patients at high risk for recurrence will be selected by means of a highly sensitive blood test detecting ctDNA.

RiboMabs

BioNTech's RiboMab product candidates, BNT141 and BNT142, are designed to encode secreted antibodies. These product candidates leverage the company's proprietary nucleoside-modified mRNA which is designed to minimize the immunomodulatory activity of the mRNA.

- BNT141 – BioNTech plans to start a Phase 1 clinical trial for BNT141 in the fourth quarter of 2021.
- BNT142 – BioNTech now plans to start a Phase 1 clinical trial for BNT142 in the first half of 2022.

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 1/2 trial with multiple expansion cohorts in patients with solid tumors is ongoing.

At SITC, BioNTech intends to present exploratory pharmacodynamic analyses and potential biomarkers of response in an expansion cohort of patients with metastatic or unresectable NSCLC who had multiple lines of prior systemic therapy, including a checkpoint inhibitor. As of May 2021, 40 patients were enrolled and BNT311 elicited pharmacodynamic effects consistent with its proposed mechanism of action. In addition, relationships between disease control and PD-L1 tumoral expression, as well as time from last prior anti-PD-1 therapy were observed.
A Phase 2 trial of BNT311 as monotherapy and in combination with pembrolizumab in patients with recurrent/refractory metastatic non-small cell lung cancer is planned to start in the fourth quarter of 2022.

- BNT312/GEN1042 – A Phase 1/2 trial with multiple expansion cohorts in patients with solid tumors is ongoing.

At SITC, BioNTech intends to report, in a mini-oral presentation, clinical data from the dose escalation part of the ongoing Phase 1/2 trial. Overall the data demonstrated a favorable safety profile in patients with advanced solid tumors, as well as biologic and early antitumor activity. As of June 11, 2021, disease control was achieved in 25 of 49 (51%) patients, including two confirmed partial responses per RECIST1.1 in melanoma and neuroendocrine lung cancer.

Cell therapies
CAR-T cell immunotherapy

- BNT211 – A first-in-human Phase 1/2 open-label dose escalation and dose expansion trial evaluating BNT211 in patients with Claudin-6-positive solid tumors is ongoing.

At SITC, BioNTech intends to present data from this trial. Overall, as of July 23, 2021, Claudin-6 CAR-T cells dosed as monotherapy and in combination with Claudin-6 CARVac showed a favorable safety profile at doses tested with encouraging signs of efficacy. At the first tumor assessment six weeks after adoptive T-cell transfer for the five evaluable patients, four patients showed stable disease (SD) and one patient showed progressive disease (PD). Three patients showed initial tumor shrinkage per RECIST1.1.

Neoantigen-targeting T-cell therapy

- BNT221 – A first-in-human Phase 1 dose escalation trial evaluating BNT221 in patients with checkpoint inhibitor unresponsive or refractory metastatic melanoma is ongoing. At SITC, preclinical data demonstrating NEOSTIM's ability to induce CD8+ and CD4+ T-cell responses using peripheral blood mononuclear cells from patients with ovarian cancer will be presented. These responses were polyfunctional, specific and have the capacity to degranulate.

Small molecule immunomodulators
Toll-like receptor binding agonist

- BNT411 – A Phase 1/2 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.

At SITC, BioNTech intends to present preliminary clinical data from the Phase 1/2 trial. Overall, as of July 1, 2021, BNT411 demonstrated an acceptable safety profile at all doses tested as a monotherapy and in combination with atezolizumab, carboplatin and etoposide. Pharmacodynamic signals were encouraging and showed a strong induction of type 1 interferon-dominated cytokines in line with the proposed mechanism of action. BNT411 has shown early signal of prolonging stable disease even in heavily pre-treated patients including post-anti-PD-1. Both pharmacodynamics and anti-tumor responses warrant further expansion in various indications either as a monotherapy or in combination with other standard-of-care treatments.

Corporate Updates

- In October 2021, BioNTech expanded its infectious disease portfolio capabilities by acquiring PhagoMed Biopharma GmbH, an Austrian biotechnology company, specialized in the development of a new class of antibacterials.

Third Quarter 2021 Financial Results

Revenues: Total revenues were estimated to be €6,087.3 million[1] for the three months ended September 30, 2021, compared to €67.5 million for the three months ended September 30, 2020. For the nine months ended September 30, 2021, total revenues were estimated to be €13,444.2 million[1] compared to €136.9 million for the comparative prior year period. The increase was mainly due to rapid increases in the supply and sales of the 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 September 30, 2021, BioNTech's commercial revenues included an estimated amount of €4,341.5 million[1] gross profit share and €17.0 million of sales milestones. During the nine months ended September 30, 2021, BioNTech's commercial revenues included an estimated amount of €9,769.9 million [1] gross profit share and €432.8 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 nine months ended September 30, 2021, respectively, €312.3 million and €514.3 million sales to BioNTech's collaboration partners of products manufactured by BioNTech as well as €1,350.8 million and €2,586.2 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 €1,211.4 million[1] for the three months ended September 30, 2021, compared to €6.8 million for the three months ended September 30, 2020. For the nine months ended September 30, 2021, cost of sales were estimated to be €2,328.3 million[1], compared to €18.3 million for the comparative prior year period. During the three and nine months ended September 30, 2021, estimated cost of sales of €1,194.8 million[1] and €2,290.1 million[1], 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 €260.4 million for the three months ended September 30, 2021, compared to €227.7 million for the three months ended September 30, 2020. For the nine months ended September 30, 2021, research and development expenses were €677.7 million, compared to €388.0 million for the comparative prior year period. The increase was mainly due to an increase in research and development expenses from the BNT162 program. The increase was further driven by an increase in wages, benefits and social security expenses following an increase in headcount, the recognition of inventor compensation expenses as well as expenses incurred under share-based-payment arrangements.

General and Administrative Expenses: General and administrative expenses were €68.2 million for the three months ended September 30, 2021, compared to €23.5 million for the three months ended September 30, 2020. For the nine months ended September 30, 2021, general and administrative expenses were €154.9 million, compared to €58.1 million for the comparative prior year period. The increase was mainly due to an increase in wages, benefits and social security expenses following an increase in headcount and expenses incurred under the share-based-payment arrangements, increased expenses for purchased management consulting and legal services as well as higher insurance premiums caused by the increased business volume.

Income Taxes: Interim income taxes were accrued in an amount of €1,456.4 million and €3,206.2 million for the three and nine months ended September 30, 2021, respectively, and were recognized using the estimated annual effective income tax rate of approximately 31%.
Net Profit/(Loss): Net profit was €3,211.0 million for the three months ended September 30, 2021, compared to €210.0 million net loss for the three months ended September 30, 2020. For the nine months ended September 30, 2021, net profit was €7,126.3 million, compared to €351.7 million net loss for the comparative prior year period.

Cash Position: Cash and cash equivalents as of September 30, 2021 were €2,392.7 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, these trade receivables which are subject to this temporal offset and were outstanding as of September 30, 2021 were received as payments in October 2021, improving BioNTech's cash position.

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

Updated Outlook for the 2021 Financial Year
Update on COVID-19 Vaccine Planned Deliveries for the 2021 Financial Year:

- Estimated BioNTech COMIRNATY/COVID-19 vaccine revenues for the full 2021 financial year based on up to 2.5 billion doses: ~€16 billion to €17 billion[2]

- 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

Planned 2021 Financial Year Expenses and Capex[2]:

- Previous cost guidance maintained for the full 2021 financial year

R&D expenses	€950 million - €1,050 million
SG&A expenses	€250 million - €300 million
Capital expenditures	€175 million - €225 million

- Further ramp-up of R&D investment in Q4 2021 planned to expand and accelerate the pipeline development

- Ranges reflect current base case projections

Estimated 2021 Financial Year 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 Report on Form 6-K, filed today with the SEC and available at https://www.sec.gov/.

[1]Estimated 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 Nine Months Ended September 30, 2021, 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.
[2]Figures have been estimated at constant foreign exchange rates.

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: BioNTech's expected revenues and net profit related to sales of BioNTech's COVID-19 vaccine, referred to as COMIRNATY® where approved for use under full or conditional marketing authorization, in territories controlled by BioNTech's collaboration partners, particularly for those figures that are derived from preliminary estimates provided by BioNTech's partners; BioNTech's pricing and coverage negotiations with governmental authorities, private health insurers and other third-party payors after BioNTech's initial sales to national governments; the extent to which initial or booster doses of a COVID-19 vaccine continue to be necessary in the future; competition from other COVID-19 vaccines or related to BioNTech's 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 BioNTech's COVID-19 vaccine and, if approved, BioNTech's investigational medicines; the initiation, timing, progress, results, and cost of BioNTech's research and development programs and BioNTech's 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 BioNTech's research and development programs; the timing of and BioNTech's ability to obtain and maintain regulatory approval for BioNTech's 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; BioNTech's ability to identify research opportunities and discover and develop investigational medicines; the ability and willingness of BioNTech's third-party collaborators to continue research and development activities relating to BioNTech's development candidates and investigational medicines; the impact of the COVID-19 pandemic on BioNTech's development programs, supply chain, collaborators and financial performance; unforeseen safety issues and claims for personal injury or death arising from the use of BioNTech's COVID-19 vaccine and other products and product candidates developed or manufactured by us; BioNTech's ability to progress BioNTech's Malaria, Tuberculosis and HIV programs, including 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; BioNTech's estimates of research and development revenues, commercial revenues, cost of sales, research and development expenses, sales and marketing expenses, general and administrative expenses, capital expenditures, income taxes, shares outstanding; BioNTech's ability and that of BioNTech's collaborators to commercialize and market BioNTech's product candidates, if approved, including BioNTech's COVID-19 vaccine; BioNTech's ability to manage BioNTech's development and expansion; regulatory developments in the United States and foreign countries; BioNTech's ability to effectively scale BioNTech's production capabilities and manufacture BioNTech's products, including BioNTech's target COVID-19 vaccine production levels, and oBioNTech'sur product candidates; and other factors not known to BioNTech 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 BioNTech's quarterly report for the three and nine months ended September 30, 2021 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 September 30,		Nine months ended September 30,	
	2021	2020	2021	2020
(in millions, except per share data)	*(unaudited)*	*(unaudited)*	*(unaudited)*	*(unaudited)*
Revenues				

Research & development revenues	€47.2	€59.7	€96.1	€113.4
Commercial revenues	6,040.1	7.8	13,348.1	23.5
Total revenues	**€6,087.3**	**€67.5**	**€13,444.2**	**€136.9**
Cost of sales	(1,211.4)	(6.8)	(2,328.3)	(18.3)
Research and development expenses	(260.4)	(227.7)	(677.7)	(388.0)
Sales and marketing expenses	(10.5)	(4.3)	(32.5)	(7.8)
General and administrative expenses	(68.2)	(23.5)	(154.9)	(58.1)
Other operating expenses	(26.4)	(0.4)	(27.3)	(1.3)
Other operating income	213.1	8.8	360.6	10.0
Operating income / (loss)	**€4,723.5**	**€(186.4)**	**€10,584.1**	**€(326.6)**
Finance income	26.6	0.5	51.4	1.1
Finance expenses	(81.9)	(21.1)	(301.0)	(24.5)
Interest expenses related to lease liabilities	(0.8)	(0.5)	(2.0)	(1.4)
Profit / (loss) before tax	**€4,667.4**	**€(207.5)**	**€10,332.5**	**€(351.4)**
Income taxes	(1,456.4)	(2.5)	(3,206.2)	(0.3)
Profit / (loss) for the period	**€3,211.0**	**€(210.0)**	**€7,126.3**	**€(351.7)**
Earnings per share				
Basic profit / (loss) for the period per share	€13.14	€(0.88)	€29.22	€(1.51)
Diluted profit / (loss) for the period per share	€12.35	€(0.88)	€27.46	€(1.51)

Interim Condensed Consolidated Statements of Financial Position

(in millions)	**September 30, 2021** *(unaudited)*	**December 31, 2020**
Assets		
Non-current assets		
Intangible assets	€162.9	€163.5
Property, plant and equipment	294.4	227.0
Right-of-use assets	147.7	99.0
Other assets	0.9	1.0
Deferred tax assets	75.3	161.2
Total non-current assets	**€681.2**	**€651.7**
Current assets		
Inventories	393.4	64.1
Trade and other receivables	10,603.9	165.5
Other financial assets	1.8	137.2
Other assets	109.3	61.0
Income tax assets	0.9	0.9
Deferred expenses	49.4	28.0
Cash and cash equivalents	2,392.7	1,210.2
Total current assets	**€13,551.4**	**€1,666.9**
Total assets	**€14,232.6**	**€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)	6,716.7	(409.6)
Other reserves	77.9	25.4
Total equity	**€8,711.5**	**€1,371.8**
Non-current liabilities		
Interest-bearing loans and borrowings	267.7	231.0
Other financial liabilities	324.9	31.5
Provisions	5.7	5.5

Contract liabilities	10.5	71.9
Other liabilities	9.7	0.6
Deferred tax liabilities	—	0.3
Total non-current liabilities	**€618.5**	**€340.8**
Current liabilities		
Interest-bearing loans and borrowings	19.0	9.1
Trade payables	258.9	102.3
Other financial liabilities	924.5	74.1
Government grants	3.1	92.0
Income tax liabilities	3,118.4	—
Provisions	189.7	0.9
Contract liabilities	284.2	299.6
Other liabilities	104.8	28.0
Total current liabilities	**€4,902.6**	**€606.0**
Total liabilities	**€5,521.1**	**€946.8**
Total equity and liabilities	**€14,232.6**	**€2,318.6**

Interim Condensed Consolidated Statements of Cash Flows

	Three months ended September 30,		Nine months ended September 30,	
	2021	**2020**	**2021**	**2020**
(in millions)	*(unaudited)*	*(unaudited)*	*(unaudited)*	*(unaudited)*
Operating activities				
Profit / (loss) for the period	€3,211.0	€(210.0)	€7,126.3	€(351.7)
Income taxes	1,456.4	2.5	3,206.2	0.3
Profit / (loss) before tax	**€4,667.4**	**€(207.5)**	**€10,332.5**	**€(351.4)**
Adjustments to reconcile profit / (loss) before tax to net cash flows:				
Depreciation and amortization of property, plant, equipment and intangible assets	19.8	8.8	49.2	26.2
Share-based payment expense	23.1	8.1	62.4	24.8
Net foreign exchange differences	(194.2)	0.1	(295.5)	—
Gain on disposal of property, plant and equipment	—	0.6	0.4	0.7
Finance income	(0.6)	(0.5)	(1.2)	(1.1)
Interest on lease liability	0.8	0.5	2.0	1.4
Finance expense	81.9	7.1	301.0	7.3
Movements in government grants	(20.8)	(8.5)	(109.6)	(8.5)
Other non-cash income	24.9	—	24.9	(0.2)
Working capital adjustments:				
Increase in trade and other receivables, contract assets and other assets	(3,343.9)	(45.1)	(10,095.4)	(54.9)
Increase in inventories	(88.0)	(3.7)	(329.3)	(0.5)
Increase in trade payables, other financial liabilities, other liabilities, contract liabilities and provisions	332.9	47.8	1,153.9	94.5
Interest received	0.4	0.2	1.0	0.8
Interest paid	(2.2)	(0.6)	(6.1)	(1.6)
Income tax received / (paid), net	(0.7)	0.2	(1.0)	(0.2)
Net cash flows from / (used in) operating activities	**€1,500.8**	**€(192.5)**	**€1,089.2**	**€(262.7)**
Investing activities				
Purchase of property, plant and equipment	(40.5)	(19.3)	(88.1)	(40.7)
Proceeds from sale of property, plant and equipment	0.2	—	1.4	—
Purchase of intangibles assets and right-of-use assets	(0.8)	(1.0)	(12.5)	(5.2)
Acquisition of subsidiaries and businesses, net of cash acquired	—	—	—	0.9
Net cash flows used in investing activities	**€(41.1)**	**€(20.3)**	**€(99.2)**	**€(45.0)**
Financing activities				
Proceeds from issuance of share capital and treasury shares, net of costs	—	532.3	160.9	680.1

Proceeds from loans and borrowings	—	99.5	—	102.4
Repayment of loans and borrowings	(0.5)	(0.6)	(1.9)	(0.9)
Payments related to lease liabilities	(4.8)	(1.0)	(15.9)	(3.2)
Net cash flows from / (used in) financing activities	**€(5.3)**	**€630.2**	**€143.1**	**€778.4**
Net increase in cash and cash equivalents	1,454.4	417.4	1,133.1	470.7
Change in cash and cash equivalents resulting from exchange rate differences	24.2	0.1	49.4	0.7
Cash and cash equivalents at the beginning of the period	914.1	573.0	1,210.2	519.1
Cash and cash equivalents at September 30	**€2,392.7**	**€990.5**	**€2,392.7**	**€990.5**