BioNTech Announces Third Quarter 2022 Financial Results and Corporate Update

November 7, 2022

- *BioNTech and Pfizer continue to build on global COVID-19 vaccine leadership with first-to-market Original/Omicron BA.4/BA.5-adapted bivalent vaccine launches across multiple countries and regions worldwide*
- *Approximately 300 million doses of the Original/Omicron BA.1- and BA.4/BA.5-adapted bivalent vaccines invoiced as of mid-October 2022*
- *In infectious diseases, Phase 1 trial initiated with a combination vaccine candidate, incorporating the Pfizer-BioNTech Omicron BA.4/BA.5-adapted bivalent COVID-19 vaccine and Pfizer's quadrivalent modified RNA (modRNA) influenza vaccine candidate, both based on BioNTech's proprietary mRNA platform*
- *Continued oncology pipeline expansion with three new first-in-human trial starts for BNT116, BNT142, and BNT313*
- *Presented positive follow-up data from the Phase 1/2 trial evaluating the Company's novel CAR-T cell therapy candidate, BNT211, in patients with relapsed or refractory solid tumors at ESMO 2022*
- *For the nine months ended September 30, 2022, revenues of €13.0 billion[1] (9M 2021: €13.4 billion[1]), net profit of €7.2 billion (9M 2021: €7.1 billion) and fully diluted earnings per share of €27.70 or $29.47[2] (9M 2021: €27.46 or $32.85[2])*
- *Strong liquidity of €13.4 billion cash and cash equivalents plus total trade receivables of €7.3 billion outstanding as of September 30, 2022; €3.2 billion of the €7.3 billion trade receivables were received in cash as of October 15, 2022*
- *BioNTech raises the lower end of its 2022 full year financial guidance to include estimated COVID-19 vaccine revenue of €16 - 17 billion*

Conference call and webcast scheduled for November 7, 2022, at 8:00 am ET (2:00 pm CET)

MAINZ, Germany, November 7, 2022 (GLOBE NEWSWIRE) -- BioNTech SE (Nasdaq: BNTX, "BioNTech" or the "Company") today reported financial results for the three and nine months ended September 30, 2022 and provided an update on its corporate progress.

"I would like to thank our growing BioNTech team for their outstanding performance in the first nine months of 2022 which allowed us to be the first Company to provide access to a BA.4/BA.5 variant adapted bivalent vaccine at an unprecedented speed. We are working to leverage this experience and apply the lessons learned from the development of Omicron-adapted vaccines to other disease areas and product candidates," said **Prof. Ugur Sahin, M.D., CEO and Co-founder of BioNTech**. "The next chapter of BioNTech's evolution is becoming tangible; we continue to expand our COVID-19 vaccine and infectious disease portfolio and advance our oncology pipeline. We reaffirm our commitment to improving the health of people worldwide by developing immunotherapies that utilize the full potential of the immune system to fight cancer, infectious and other serious diseases."

Financial Review for the Third Quarter and First Nine Months of 2022

in millions, except per share data	**Third Quarter 2022**	**Third Quarter 2021**	**First Nine Months 2022**	**First Nine Months 2021**
Total Revenues[1]	€3,461.2	€6,087.3	€13,032.3	€13,444.2
Net Profit	€1,784.9	€3,211.0	€7,155.7	€7,126.3
Diluted Earnings per Share	€6.98	€12.35	€27.70	€27.46

Total revenues reported were €3,461.2 million[1] for the three months ended September 30, 2022 (Q3 2021: €6,087.3 million[1]). As expected, the course of the pandemic remains dynamic and led to fluctuations in quarterly revenues. For the nine months ended September 30, 2022, total revenues were €13,032.3 million[1] (9M 2021: €13,444.2 million[1]).

Under the collaboration agreements, territories have been allocated between BioNTech, Pfizer Inc. ("Pfizer") and Shanghai Fosun Pharmaceutical (Group) Co., Ltd. ("Fosun Pharma") based on marketing and distribution rights:

- During the three months ended September 30, 2022, BioNTech's commercial revenues included €2,554.2 million [1] gross profit share (Q3 2021: €4,358.5 million[1]). For the nine months ended September 30, 2022, BioNTech's commercial revenues included €9,128.4 million[1] gross profit share (9M 2021: €10,202.7 million[1]). 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, 2022, BioNTech recognized €564.5 million and €2,284.6 million of direct COVID-19 vaccine sales to customers in BioNTech's territory, Germany and Turkey, as well as €259.4 million and €1,470.9 million from sales of products manufactured by BioNTech for its collaboration partners. During the comparative prior year periods, €1,350.8 million and €2,586.2 million were recognized from sales to customers in BioNTech's territory as well as €312.3 million and €514.3 million from sales of products manufactured by BioNTech for its collaboration partners respectively.

Cost of sales were €752.8 million for the three months ended September 30, 2022 (Q3 2021: €1,211.4 million). For the nine months ended September 30, 2022, cost of sales were €2,811.5 million (9M 2021: €2,328.3 million). The change in cost of sales resulted mainly from the recognition

of costs related to BioNTech's COVID-19 vaccine revenues which included the share of gross profit owed to the Company's collaboration partner Pfizer. In addition, cost of sales were impacted by expenses arising from inventory write-offs and expenses for production capacities derived from contracts with contract manufacturing organizations.

Research and development expenses were €341.8 million for the three months ended September 30, 2022 (Q3 2021: €260.4 million). For the nine months ended September 30, 2022, research and development expenses were €1,027.2 million (9M 2021: €677.7 million). The increase was mainly due to increased headcount and higher expenses in the context of the share-based payments.

General and administrative expenses were €141.0 million for the three months ended September 30, 2022 (Q3 2021: €68.2 million). For the nine months ended September 30, 2022, general and administrative expenses were €361.8 million (9M 2021: €154.9 million), mainly due to recognizing increased expenses for purchased external services as well as an increase in headcount.

Income taxes were accrued with an amount of €659.2 million for the three months ended September 30, 2022 (Q3 2021: €1,456.4 million). For the nine months ended September 30, 2022, income taxes were accrued in an amount of €2,625.8 million (9M 2021: €3,206.2 million). The derived effective income tax rate for the nine months ended September 30, 2022 was 26.8%.

Net profit was €1,784.9 million for the three months ended September 30, 2022 (Q3 2021: €3,211.0 million). For the nine months ended September 30, 2022, net profit was €7,155.7 million (9M 2021: €7,126.3 million).

As of September 30, 2022, **cash and cash equivalents** were €13,423.7 million. Trade receivables remained outstanding as of September 30, 2022, 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. Trade receivables for example include the gross profit share for the second quarter of 2022 (as defined by the contract) for which the settlement payment was received subsequent to the end of the reporting period in October 2022. Of the total trade receivables of €7,309.4 million which were outstanding as of September 30, 2022, €3,185.9 million were received in cash as of October 15, 2022.

"Thanks to our strong execution in the third quarter of 2022, we updated our COVID-19 vaccine revenue guidance for the year 2022 to the upper end of the original range. We started shipments of our Omicron-adapted bivalent vaccines early in September and we expect to carry on with our deliveries throughout the fourth quarter of 2022," said **Jens Holstein, CFO of BioNTech**. "We believe in the potential of our COVID-19 franchise and plan to build on our leading position with ongoing innovations in this field. The power of our scientific innovation combined with our strong financial position allows us to accelerate and expand our diversified clinical pipeline and to create future growth in the interest of all stakeholders."

Updated Outlook for the 2022 Financial Year:

Raised COVID-19 vaccine revenue target to upper end of original guidance. Reiterate planned expenses and capex. Updated the estimated annual effective income tax rate.

The Company's outlook includes the following components:

BioNTech COVID-19 Vaccine Revenues for the 2022 Financial Year:

Estimated BioNTech COVID-19 vaccine revenues for the full 2022 financial year	€16 billion - €17 billion (previously €13 billion - €17 billion)

BioNTech updates its 2022 financial guidance, raising its COVID-19 vaccine revenue estimate to the upper end of the original range: €16 - 17 billion (previously: €13 - 17 billion). The updated guidance reflects the shipment of the Omicron-adapted bivalent vaccine boosters, which started early in September and is expected to continue throughout the fourth quarter of 2022 as well as higher prices and a positive foreign currency effect.

This revenue estimate reflects expected revenues related to BioNTech's share of gross profit from COVID-19 vaccine sales in the collaboration partners' territories, from direct COVID-19 vaccine sales to customers in BioNTech's territory and expected revenues generated from products manufactured by BioNTech and sold to collaboration partners. BioNTech's COVID-19 vaccine gross profit share from Pfizer is impacted by inventory write-offs. Pfizer inventory write-offs for COVID-19 products reduce BioNTech's gross profit share and therefore, reduce BioNTech's vaccine revenues.

Planned 2022 Financial Year Expenses and Capex:

R&D expenses	€1,400 million - €1,500 million
SG&A expenses	€450 million - €550 million
Capital expenditures	€450 million - €550 million

The ranges reflect current base case projections and do not include potential effects caused by or driven from additional collaborations or potential merger and acquisition transactions.

Estimated 2022 Financial Year Tax Assumptions:

BioNTech Group estimated annual effective income tax rate	~27% (previously ~28%)

Operational Review of the Third Quarter 2022 and Key Post Period-End Events

COVID-19 Vaccine Programs – BNT162 *(*COMIRNATY)

BioNTech and Pfizer continue to build on their global COVID-19 vaccine leadership with first-to-market Original/Omicron BA.4/BA.5-adapted vaccine launches. The Companies have now three commercial stage COVID-19 vaccine products on the market that include the original COVID-19 vaccine and two Omicron adapted vaccines: Original/BA.1- and BA.4/5.-adapted bivalent vaccines. BioNTech's flexible mRNA platform and production

infrastructure supported rapid development and manufacturing of variant-adapted vaccines at an unprecedented speed. BioNTech will continue to innovate to advance a diverse pipeline of follow-on and next generation product candidates. BioNTech believes its COVID-19 vaccine franchise will remain a long-term sustainable business opportunity.

Commercial updates

Following regulatory approvals, BioNTech and Pfizer immediately began shipping Original/Omicron BA.1 and BA.4/BA.5-adapted bivalent COVID-19 vaccines in September 2022 in time for fall and winter booster campaigns. Shipments in the United States began approximately two months after the U.S. Food and Drug Administration (FDA) provided its guidance for the BA.4/BA.5-adapted bivalent COVID-19 vaccine.

As of mid-October 2022, BioNTech and Pfizer have invoiced approximately 300 million doses of Original/Omicron-adapted bivalent vaccine.

As part of BioNTech and Pfizer's 2-billion-doses-pledge to support equitable access to medicines, the companies have delivered approximately 1.6 billion doses of the companies' COVID-19 vaccine in total to low- and middle-income countries in line with the demand.

BioNTech expects to invoice up to 2.1 billion doses of the COVID-19 vaccine in 2022. Some dose deliveries have been shifted into 2023 due to the evolving dynamics of demand.

BioNTech believes that it and Pfizer are well positioned to supply the quantities required by global market demand.

Clinical development and regulatory updates

During the third quarter of 2022, BioNTech and Pfizer's COVID-19 vaccine received multiple regulatory approvals and authorizations, including for Omicron-adapted bivalent vaccines, label expansions for pediatric vaccinations and ongoing conversions from conditional or emergency approvals to full regulatory approvals across various regions worldwide. The companies' Original/Omicron BA.4/BA.5-adapted bivalent vaccine has received approvals in more than 45 countries and regions, as of October 25, 2022.

Adapted bivalent vaccine boosters

- In August 2022, BioNTech and Pfizer started a randomized Phase 2/3 trial evaluating the safety, tolerability and immunogenicity of the Original/Omicron BA.4/BA.5-adapted bivalent vaccine in individuals aged 12 years and older. First data from this trial were reported in October 2022. A 30-µg booster dose of the vaccine demonstrated a substantial increase in the Original/Omicron BA.4/BA.5 neutralizing antibody response above pre-booster levels based on sera taken seven days after administration, with similar responses seen across individuals aged 18 to 55 years and those older than 55 years of age (40 participants in each age group). The Omicron BA.4/BA.5-adapted bivalent vaccine was well tolerated with early data indicating a favorable safety profile, similar to that of the original vaccine.
- On August 31, 2022, BioNTech and Pfizer received U.S. FDA Emergency Use Authorization (EUA) for a 30-µg booster dose of the Original/Omicron BA.4/BA.5-adapted bivalent vaccine for individuals aged 12 years and older.
- On September 1, 2022, BioNTech and Pfizer received a positive European Medicines Agency (EMA) Committee for Medicinal Products for Human Use (CHMP) opinion and subsequent EC approval for the Original/Omicron BA.1-adapted bivalent vaccine and on September 12, 2022 for a 30-µg booster dose of the Original/Omicron BA.4/BA.5-adapted bivalent COVID-19 vaccine for individuals aged 12 years and older.
- In September 2022, BioNTech and Pfizer initiated a Phase 1/2/3 study to evaluate the safety, tolerability and immunogenicity of different doses and dosing regimens of the Original/Omicron BA.4/BA.5-adapted bivalent vaccine in children 6 months through 11 years of age. This pediatric study follows a previous Phase 1/2/3 trial in these age groups that demonstrated the original vaccine is well-tolerated and offers a high level of protection against COVID-19.
- In September 2022, BioNTech and Pfizer submitted a request to the U.S. FDA for EUA for Original/Omicron BA.4/BA.5-adapted bivalent vaccine booster and also completed a submission for conditional Marketing Authorization (cMA) in the European Union for children 5 through 11 years of age.
- In October 2022, the companies received U.S. FDA EUA for a 10-µg booster dose of the Original/Omicron BA.4/BA.5-adapted bivalent vaccine in children 5 through 11 years of age.
- The Centers for Disease Control and Prevention has added COVID-19 vaccines to the agency's lists of recommended regular immunizations and recommends that people ages 5 years and older receive one updated bivalent booster if it has been at least 2 months since their last COVID-19 vaccine dose.
- In November 2022, BioNTech and Pfizer reported updated 30-day clinical data from the randomized Phase 2/3 trial evaluating the safety, tolerability and immunogenicity of the companies' Original/Omicron BA.4/BA.5-adapted bivalent COVID-19 vaccine, given as a 30-µg booster dose, which started in August 2022. The data demonstrate a robust and broadly neutralizing immune response one month after a 30-µg booster dose. Immune responses were markedly higher for those who received the bivalent vaccine compared to the original COVID-19 vaccine, with similar favorable safety and tolerability profile demonstrated between both vaccines. Clinical data demonstrated that Omicron BA.4/BA.5-neutralizing antibody titers rose 13.2-fold from pre-booster levels in adults over 55 years and 9.5-fold for adults 18 to 55 years, one month post bivalent booster compared to 2.9-fold rise in titers elicited in the same time frame by the original vaccine booster. These results reinforce the early clinical data measured seven days after a booster dose of the bivalent vaccine, as well as the pre-clinical data, and suggest that a 30-µg booster dose of the Original/Omicron BA.4/BA.5 bivalent vaccine may induce higher level of protection against the Omicron BA.4 and BA.5 subvariants than the original vaccine. BioNTech and Pfizer have shared these data with the U.S. FDA and plan to share with the EMA and other global health authorities

as soon as possible.

Original COVID-19 vaccine

- In August 2022, BioNTech and Pfizer announced updated efficacy data from a Phase 2/3 trial evaluating a 3-µg dose series of the original COVID-19 vaccine in children 6 months through 4 years of age. Vaccine efficacy, a secondary endpoint in the trial, was 73.2% in children without evidence of prior COVID-19 infection, during a period of circulating Omicron BA.2. The vaccine previously received EUA from the U.S. FDA and the companies submitted for extension of the cMA in the European Union for this age group.
- In September 2022, BioNTech and Pfizer were granted approval in the European Union for COMIRNATY as a 10-µg booster (third) dose of the original vaccine given at least six months after completion of a primary series for children 5 through 11 years of age.
- In October 2022, BioNTech and Pfizer received EC approval for the conversion of the cMA to full Marketing Authorization (MA). The conversion applies to all existing and upcoming indications and formulations of the COMIRNATY product group authorized in the European Union, including Original/BA.1 and BA.4/BA.5-adapted bivalent vaccines as booster doses for individuals aged 12 years and older.
- In October 2022, BioNTech and Pfizer received EC approval for full MA for a 3-µg dose of COMIRNATY as a three-dose series for children aged 6 months through 4 years.
- In October 2022, BioNTech and Pfizer received EC approval for a fourth dose booster of COMIRNATY in individuals 12 years of age and older at an interval of at least three months between the administration of COMIRNATY and the last prior dose of a COVID-19 vaccine.

The COVID-19 vaccine continues to offer protection post booster vaccination against severe disease, hospitalization and deaths for circulating Omicron sublineages.

BioNTech and Pfizer continue to monitor protection offered by the original and Original/Omicron adapted bivalent vaccines against emerging SARS-CoV-2 variants.

Recently published data (Muik et al. Exposure to BA.4/BA.5 Spike glycoprotein drives pan-Omicron neutralization in vaccine-experienced humans and mice; bioRxiv 2022.09.21.508818) suggest that when administered as boosters, mono- and bivalent Original/Omicron BA.4/BA.5-adapted vaccines may enhance neutralization breadth against Omicron sublineages BA.1, BA.2, BA.2.12.1, and BA.4/BA.5. The preclinical data support the assumption that boosting with an Original/Omicron BA.4/5-adapted bivalent vaccine is a suitable strategy to confer a broader neutralization and address both currently circulating Omicron variants as well as potential future emerging Omicron sublineages or new variants of concern that are closer to the wild-type strain.

Next generation COVID-19 vaccine

In addition to variant adapted vaccines, BioNTech and Pfizer are identifying and investigating novel next generation vaccine approaches to maintain a broad and longer lasting immune response and high levels of protection against COVID-19 as SARS-CoV-2 evolves. The long-term strategy takes a multipronged approach devised to develop multiple engineered vaccine candidates with the aim of delivering a pan-SARS-CoV-2-type vaccine that will help to better manage future variants of concern. The companies expect that scientific data derived from those different approaches will support the selection of the vaccine candidate for evaluation in a pivotal trial.

BioNTech and Pfizer plan to test several novel vaccine constructs that have been engineered to engage multiple arms of the immune system, including antibodies and T cells.

- In July 2022, BioNTech and Pfizer started a Phase 2 study with a first enhanced spike antigen vaccine candidate.
- The first T cell enhancing SARS-CoV-2 vaccine product candidate (BNT164b4) in combination with the Original/Omicron BA.4/BA.5-adapted bivalent COVID-19 vaccine is expected to enter the clinic in the fourth quarter of 2022.

COVID-19 – Influenza Combination mRNA Vaccine Program (BNT162b2 + BNT161)
In October 2022, BioNTech and Pfizer initiated a Phase 1 open-label, dose-finding study to evaluate the safety, tolerability and immunogenicity of a combination of the COVID-19 and influenza mRNA vaccines to help protect individuals against two severe respiratory viral diseases. The combination vaccine consists of Original/Omicron BA.4/BA.5-adapted bivalent COVID-19 vaccine and quadrivalent modRNA influenza vaccine candidate and will be tested at different dose levels in approximately 180 healthy adults 18 to 64 years of age. The companies are building on the experiences made in the BNT161 program, which pursues development of an influenza vaccine based on BioNTech's suite of mRNA platforms.

Influenza Vaccine Program (BNT161)

BNT161 - BioNTech is collaborating with Pfizer to develop an influenza vaccine based on BioNTech's suite of mRNA platforms.

- In July 2022, positive immunogenicity data from the Phase 2 expansion study of BNT161 were reported.
- In September 2022, Pfizer announced that the first participants have been dosed in a pivotal Phase 3 clinical trial to evaluate the efficacy, safety, tolerability and immunogenicity of a quadrivalent modRNA influenza vaccine candidate in approximately 25,000 healthy U.S. adults. Upon potential approval and commercialization, BioNTech is eligible to receive milestone payments and a royalty on Pfizer’s worldwide sales.

Shingles Vaccine Program

BioNTech is collaborating with Pfizer to develop the first mRNA-based shingles vaccine candidate. A clinical trial is expected to start in the fourth quarter of 2022.

Further Infectious Disease Programs

BioNTech is applying its validated mRNA vaccine platform across multiple high-need infectious diseases.

BioNTech is on track to initiate a first-in-human clinical trial in the fourth quarter of 2022 for mRNA-based product candidate BNT163, designed to address herpes simplex virus type 2 (HSV 2). A first-in-human clinical trial of an mRNA vaccine to protect against malaria (BNT165) is expected to start in the fourth quarter of 2022 or early 2023. A first-in-human clinical trial of an mRNA vaccine to protect against tuberculosis (BNT164) is expected to start early 2023.

In 2023, BioNTech expects to start up to five vaccine clinical trials in infectious diseases.

Oncology

BioNTech's immuno-oncology strategy is based on pioneering approaches that harness the immune response to treat cancer. The Company has multiple clinical stage assets across different therapeutic classes which may have the potential to tackle tumors using complementary strategies, either by targeting tumor cells directly or by modulating the immune response against the tumor. These drug classes include mRNA therapeutic vaccines, cell therapies (CAR-, TCR-, and neoantigen-specific T-cell therapies), mRNA-encoded effector molecules (RiboMabs and RiboCytokines), next generation immune checkpoint inhibitors and agonists, anti-tumor antibodies and immune-modulatory small molecules. Many product candidates have the potential to be combined with other pipeline assets or already approved therapies.

BioNTech's clinical stage oncology pipeline includes a total of 19 product candidates in 24 ongoing clinical trials including five randomized Phase 2 clinical trials: two FixVac programs (BNT111 and BNT113), two indications for the iNeST product candidate autogene cevumeran (BNT122/RO7198457) and the bispecific antibody immune checkpoint modulator BNT311 (GEN1046).

In the third quarter of 2022, BioNTech started three first-in-human clinical trials: BNT116, a FixVac program for non-small cell lung cancer (NSCLC), BNT142, a bispecific RiboMab targeting CD3 on T cells and Claudin-6 (CLDN6) in solid tumors and, most recently, BNT313, a HexaBody targeting CD27, a new product candidate from BioNTech's collaboration with Genmab A/S being evaluated in solid tumors.

BioNTech expects continued pipeline advancement and expansion as well as one more data readout from an ongoing trial for the remainder of 2022. In 2023, BioNTech expects to provide up to ten clinical trial updates in oncology.

Third Quarter 2022 Clinical Oncology Pipeline Update

BNT116, BioNTech's FixVac product candidate for the treatment of advanced or metastatic non-small cell lung cancer (NSCLC), encodes for six tumor-associated antigens that cover up to 100% of patients in all major histologic subtypes of NSCLC and aims to elicit a tumor-antigen-specific immune response. FixVac is an off-the-shelf cancer immunotherapy approach based on BioNTech's uridine mRNA lipoplex technology targeting shared non-mutated antigens.

- In July 2022, the first participant was dosed in a first-in-human clinical trial evaluating the safety, tolerability and preliminary efficacy of BNT116 alone and in combination with cemiplimab (anti-PD-1, Regeneron's Libtayo) in patients with advanced or metastasized NSCLC. The trial is intended to establish a safe dose for BNT116 monotherapy as well as for BNT116 in combination with cemiplimab in patients who have progressed on prior PD-1 inhibitor treatment or are not eligible for chemotherapy, and in combination with docetaxel in patients who have received prior platinum-based chemotherapy.
- A second trial evaluates BNT116 alone and in combination with cemiplimab as first-line treatment of patients with advanced NSCLC whose tumors express programmed cell death ligand-1 (PD-L1) in ≥ 50% of tumor cells. The primary objective of the Phase 1/2 trial is to assess the safety and tolerability as well as the overall response rate (ORR) and tumor burden reduction. The trial is expected to dose the first patient in the fourth quarter of 2022 and is sponsored by Regeneron Pharmaceuticals, Inc.

BNT142, BioNTech's second RiboMab product candidate, is an mRNA that encodes a bispecific T cell engaging antibody that targets CD3, a T cell receptor component, and CLDN6, an oncofetal cell surface antigen found in solid tumors such as testicular and ovarian cancers.

- In July 2022, the first patient was dosed in an open-label, multi-center Phase 1/2 dose escalation, safety and pharmacokinetic trial of BNT142 followed by expansion cohorts in patients with CLDN6-positive advanced solid tumors. The trial is evaluating BNT142 as monotherapy in patients that have exhausted therapy or are not eligible for standard of care therapy. After dose escalation, BNT142 will be evaluated in expansion cohorts in testicular cancer, ovarian cancer and non-squamous NSCLC.

BNT211 is a CAR directing T cells against the novel target CLDN6 that is tested alone and in combination with a CAR-T cell-amplifying RNA vaccine, or CARVac, encoding CLDN6. CARVac drives *in vivo* expansion of transferred CAR-T cells, aiming to increase their persistence and efficacy. BNT211 aims to overcome CAR-T cell therapy limitations in patients with solid tumors.

- In September 2022, BioNTech presented follow-up data from its ongoing Phase 1/2 trial evaluating the safety and preliminary efficacy of BNT211 in patients with relapsed or refractory solid tumors at the European Society for Medical Oncology (ESMO) Congress 2022. Signs of anti-tumor activity were observed and the safety profile remained manageable for the two tested dose levels. Efficacy assessment of the 21 evaluable patients showed a best ORR of 33% and a DCR of 67% with one complete response, six partial responses and seven patients with stable disease. In line with the earlier data presented, encouraging clinical responses were seen in patients with testicular cancer treated with dose level 2 after

lymphodepletion (n=7), where one complete response, three partial responses and two stable diseases were observed, representing an ORR of 57% and a disease control rate (DCR) of 85%.

BNT312/GEN1042, is a first-in-class bispecific antibody designed to induce conditional immune activation by crosslinking CD40 and 4-1BB positive cells. BNT312 is partnered with Genmab as part of a 50/50 collaboration in which development costs and future profit are shared.

- A Phase 1/2 trial in patients with solid tumors is ongoing. Expansion cohorts in melanoma, NSCLC, pancreatic and head and neck carcinoma are recruiting for combination regimens of BNT312 in these indications. Safety and preliminary efficacy data of BNT312 combination therapy in patients with advanced solid tumors are planned to be presented at the ESMO-Immuno-Oncology annual congress in December 2022.

BNT313/GEN1053 is a monospecific antibody candidate targeting CD27 to address malignant solid tumors. It is based on Genmab's HexaBody technology and is engineered to induce clustering of CD27 on the plasma membrane of T cells with the aim to enhance T cell activation, proliferation and differentiation without depleting T cells. BNT313 is partnered with Genmab as part of a 50/50 collaboration in which development costs and potential future profits for BNT313 will be shared equally.

- In November 2022, a Phase 1 trial was initiated to evaluate the safety, tolerability and preliminary efficacy of BNT313 as a monotherapy for the treatment of malignant solid tumors. The dose escalation part will explore the safety of escalating doses of BNT313. The expansion part is planned to provide additional safety and initial antitumor activity information on the selected dose regimen in selected tumor indications, as well as more detailed data related to the mode of action.
- At the 37th Annual Meeting of the Society for Immunotherapy of Cancer (SITC) in November 2022, BioNTech intends to present preclinical data that characterize the mechanism of action of HexaBody-CD27. In the *in vitro* experiments, HexaBody-CD27 exhibited CD27 agonist activity independently of Fc gamma receptor-mediated crosslinking. HexaBody-CD27 enhanced activation, proliferation, and proinflammatory cytokine secretion of human CD4+ and CD8+ T cells as well as CD8+ T -cell mediated cytotoxic activity towards tumor cells *in vitro*. In mice expressing human CD27 protein, it enhanced expansion and IFN-γ secretion of antigen-specific CD8+ T cells *in vivo*. Overall, the data demonstrated a unique potential mechanism of action that distinguishes HexaBody-CD27 from benchmark monoclonal antibodies targeting CD27.

Corporate Updates

- BioNTech continues to facilitate equitable access to its medicines. As part of this commitment, construction of BioNTech's first Africa-based mRNA vaccine manufacturing facility in Kigali, Rwanda is progressing with the first BioNTainer being ready for shipment by the end of 2022. The facility is planned to be able to manufacture a range of mRNA-based vaccines targeted to the needs of the African Union member states, such as the COVID-19 vaccine and investigational malaria and tuberculosis vaccine candidates pending authorization by respective regulatory authorities. Implementation of a Rwandan manufacturing team is also advancing with first senior team members already onboarded.
- In October 2022, BioNTech signed a Letter of Intent with the State of Victoria in Australia for a strategic partnership to collaborate on the research and development of potential mRNA-based vaccines and therapies. The parties will establish a research and innovation center in Melbourne where BioNTech plans to set up a clinical scale end-to-end mRNA manufacturing facility based on its BioNTainer solution to support the design, manufacture and clinical testing of product candidates.
- BioNTech values and respects valid and enforceable intellectual property rights of others and remains confident in its intellectual property. During the course of the third quarter of 2022, CureVac AG and ModernaTX, Inc. filed patent infringement lawsuits against BioNTech and its partner, Pfizer. BioNTech is evaluating these lawsuits and intends to determine the appropriate action in response to these lawsuits.
- BioNTech continues to monitor the natural gas supply situation as part of its regular business continuity management and continues to evaluate possible additional energy supply measures. BioNTech has evaluated its ongoing mitigation efforts to ensure business continuity in light of potential energy supply issues in Europe and elsewhere.
  BioNTech's manufacturing supply chain remains stable, and the Company does not anticipate energy-related disruptions. BioNTech's commercial production of its COVID-19 vaccine continues to run on natural gas, but the Company expects that it could be powered by alternative fuel sources without interruption, if needed. According to the Company's most recent information and analyses, commercial mRNA manufacturing in BioNTech's facilities is not expected to be impacted by a natural gas shortage, such as the current one. Nonetheless, the Company cannot predict with certainty the impact that a continuing or more severe natural gas shortage would have on its operations. BioNTech's R&D and clinical development activities continue to be dependent on gas, and the Company is putting measures in place to mitigate related risks. BioNTech continues to evaluate the impact to its partners, including Pfizer, suppliers and other service providers.
- The first tranche of BioNTech's share repurchase program of ADSs, with a value of up to $1.0 billion, was executed from May 2, 2022 to October 10, 2022. In the first tranche of the share repurchase program, BioNTech repurchased 6,945,513 ADSs at an average price of $143.98.
  In November 2022, BioNTech's Management Board and Supervisory Board authorized the second tranche of the Company's share repurchase program of ADSs, with a value of up to $0.5 billion, commencing on December 7, 2022.

The full unaudited interim 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/.

Endnotes

[1] BioNTech's profit share is estimated based on preliminary data shared between Pfizer and BioNTech as further described in BioNTech's Annual Report on Form 20-F for the year ended December 31, 2021 as well as its Quarterly Report as of and for the three and nine months ended September 30, 2022, filed as an exhibit to BioNTech's Current Report on Form 6-K filed on November 7, 2022. Any changes in the estimated share of the collaboration partner's gross profit will be recognized prospectively.

[2] Calculated applying the average foreign exchange rates for the three and nine months ended September 30, 2021 and 2022, respectively, as published by the German Central Bank (Deutsche Bundesbank).

Conference Call and Webcast Information

BioNTech invites investors and the general public to join a conference call and webcast with investment analysts on November 7, 2022 at 8.00 a.m. EDT (2.00 p.m. CEST) to report its financial results and provide a corporate update for the third quarter of 2022.
To access the live conference call via telephone, please register via this link. Once registered, dial-in numbers and a pin number will be provided. The slide presentation and audio of the webcast will be available via this link.

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.

About BioNTech

Biopharmaceutical New Technologies (BioNTech) 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 immune checkpoint 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, Genentech, a member of the Roche Group, Regeneron, Genevant, Fosun Pharma and Pfizer.

For more information, please visit www.BioNTech.com

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 future commercial demand and medical need for initial or booster doses of a COVID-19 vaccine; 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, including those relating to additional formulations of BioNTech's COVID-19 vaccine, 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 ability of BioNTech's COVID-19 vaccine to prevent COVID-19 caused by emerging virus variants; BioNTech's and its counterparties' ability to manage and source necessary energy resources; 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 potential personal injury or death arising from the use of BioNTech's COVID-19 vaccine and other products and product candidates developed or manufactured by BioNTech; 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 development of sustainable vaccine production and supply solutions on the African continent, including its BioNTainers, 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, and 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 BioNTech's 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 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 quarterly report on Form 6-K for the three and nine months ended September 30, 2022 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.

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Interim Condensed Consolidated Statements of Profit or Loss

	Three months ended September 30,		Nine months ended September 30,	
(in millions, except per share data)	**2022** *(unaudited)*	**2021** *(unaudited)*	**2022** *(unaudited)*	**2021** *(unaudited)*
Revenues				
Commercial revenues	€3,394.8	€6,040.1	€12,923.3	€13,348.1
Research & development revenues	66.4	47.2	109.0	96.1
Total revenues	**€3,461.2**	**€6,087.3**	**€13,032.3**	**€13,444.2**
Cost of sales	(752.8)	(1,211.4)	(2,811.5)	(2,328.3)
Research and development expenses	(341.8)	(260.4)	(1,027.2)	(677.7)
Sales and marketing expenses	(12.8)	(10.5)	(44.9)	(32.5)
General and administrative expenses	(141.0)	(68.2)	(361.8)	(154.9)
Other operating expenses	(285.1)	(26.4)	(594.6)	(27.3)
Other operating income	459.8	213.1	1,157.5	360.6
Operating income	**€2,387.5**	**€4,723.5**	**€9,349.8**	**€10,584.1**
Finance income	60.9	26.6	448.5	51.4
Finance expenses	(4.3)	(82.7)	(16.8)	(303.0)
Profit before tax	**€2,444.1**	**€4,667.4**	**€9,781.5**	**€10,332.5**
Income taxes	(659.2)	(1,456.4)	(2,625.8)	(3,206.2)
Profit for the period	**€1,784.9**	**€3,211.0**	**€7,155.7**	**€7,126.3**
Earnings per share				
Basic profit for the period per share	€7.43	€13.14	€29.47	€29.22
Diluted profit for the period per share	€6.98	€12.35	€27.70	€27.46

Interim Condensed Consolidated Statements of Financial Position

(in millions)	**September 30, 2022** *(unaudited)*	**December 31, 2021**
Assets		
Non-current assets		
Intangible assets	€226.2	€202.4
Property, plant and equipment	488.5	322.5
Right-of-use assets	272.0	197.9
Other financial assets	52.8	21.3
Other assets	1.1	0.8
Deferred expenses	7.5	13.6
Deferred tax assets	343.7	—
Total non-current assets	**€1,391.8**	**€758.5**
Current assets		

Inventories	294.8	502.5
Trade and other receivables	7,309.4	12,381.7
Other financial assets	4.8	381.6
Other assets	162.7	64.9
Income tax assets	0.4	0.4
Deferred expenses	73.0	48.5
Cash and cash equivalents	13,423.7	1,692.7
Total current assets	**€21,268.8**	**€15,072.3**
Total assets	**€22,660.6**	**€15,830.8**
Equity and liabilities		
Equity		
Share capital	248.6	246.3
Capital reserve	1,050.4	1,674.4
Treasury shares	(10.3)	(3.8)
Retained earnings	16,554.3	9,882.9
Other reserves	523.3	93.9
Total equity	**€18,366.3**	**€11,893.7**
Non-current liabilities		
Loans and borrowings	237.0	171.6
Other financial liabilities	6.1	6.1
Income tax liabilities	8.0	4.4
Provisions	7.3	184.9
Contract liabilities	53.8	9.0
Other liabilities	17.4	12.8
Deferred tax liabilities	7.0	66.7
Total non-current liabilities	**€336.6**	**€455.5**
Current liabilities		
Loans and borrowings	37.0	129.9
Trade payables	296.5	160.0
Other financial liabilities	686.9	1,190.4
Government grants	3.0	3.0
Refund liabilities	—	90.0
Income tax liabilities	1,387.5	1,568.9
Provisions	768.1	110.2
Contract liabilities	673.9	186.1
Other liabilities	104.8	43.1
Total current liabilities	**€3,957.7**	**€3,481.6**
Total liabilities	**€4,294.3**	**€3,937.1**
Total equity and liabilities	**€22,660.6**	**€15,830.8**

Interim Condensed Consolidated Statements of Cash Flows

	Three months ended September 30,		NineSix months ended September, 30	
(in millions)	**2022** *(unaudited)*	**2021** *(unaudited, restated)*	**2022** *(unaudited)*	**2021** *(unaudited, restated)*
Operating activities				
Profit for the period	€1,784.9	€3,211.0	€7,155.7	€7,126.3
Income taxes	659.2	1,456.4	2,625.8	3,206.2
Profit before tax	**€2,444.1**	**€4,667.4**	**€9,781.5**	**€10,332.5**
Adjustments to reconcile profit before tax to net cash flows:				
Depreciation and amortization of property, plant, equipment, intangible assets and right-of-use assets	33.5	19.8	94.3	49.2
Share-based payment expense	59.7	23.1	81.7	62.4
Net foreign exchange differences	116.2	(194.2)	(222.3)	(295.5)
Loss on disposal of property, plant and equipment	0.2	—	0.4	0.4
Finance income	(7.7)	(0.6)	(226.5)	(1.2)
Finance expense	4.3	82.7	16.8	303.0

Movements in government grants	—	(20.8)	—	(109.6)
Net (gain) / loss on derivative instruments at fair value through profit or loss	(2.3)	24.9	82.3	24.9
Working capital adjustments:				
Decrease / (increase) in trade and other receivables, contract assets and other assets	2,245.4	(3,343.9)	5,016.7	(10,095.4)
Decrease / (increase) in inventories	72.9	(88.0)	207.7	(329.3)
Increase in trade payables, other financial liabilities, other liabilities, contract liabilities, refund liabilities and provisions	565.9	332.9	760.3	1,153.9
Interest received	4.3	0.4	6.5	1.0
Interest paid	(4.3)	(2.2)	(16.5)	(6.1)
Income tax paid	(753.3)	(0.7)	(2,834.7)	(1.0)
Net cash flows from operating activities	**€4,778.9**	**€1,500.8**	**€12,748.2**	**€1,089.2**
Investing activities				
Purchase of property, plant and equipment	(77.9)	(40.5)	(192.6)	(88.1)
Proceeds from sale of property, plant and equipment	0.4	0.2	0.4	1.4
Purchase of intangible assets and right-of-use assets	(4.7)	(0.8)	(26.2)	(12.5)
Purchase of financial instruments	(1.1)	—	(31.1)	—
(Investment) / proceeds from maturity of other financial assets	—	(367.0)	375.2	(367.0)
Net cash flows from / (used in) investing activities	**€(83.3)**	**€(408.1)**	**€125.7**	**€(466.2)**
Financing activities				
Proceeds from issuance of share capital and treasury shares, net of costs	—	—	110.5	160.9
Proceeds from loans and borrowings	0.4	—	0.6	—
Repayment of loans and borrowings	—	(0.5)	(18.8)	(1.9)
Payments related to lease liabilities	(10.0)	(4.8)	(31.9)	(15.9)
Share repurchase program	(643.8)	—	(930.7)	—
Dividends	—	—	(484.3)	—
Net cash flows from / (used in) financing activities	**€(653.4)**	**€(5.3)**	**€(1,354.6)**	**€143.1**
Net increase in cash and cash equivalents	4,042.2	1,087.4	11,519.3	766.1
Change in cash and cash equivalents resulting from exchange rate differences	46.7	24.2	211.7	49.4
Cash and cash equivalents at the beginning of the period	9,334.8	914.1	1,692.7	1,210.2
Cash and cash equivalents at September 30	**€13,423.7**	**€2,025.7**	**€13,423.7**	**€2,025.7**