BioNTech Announces Second Quarter Financial Results and Corporate Update

August 8, 2022

- *Second quarter revenues of €3.2 billion[1], net profit of €1.7 billion and fully diluted earnings per share of €6.45 ($6.87[2]) as well as first half 2022 revenues of €9.6 billion, net profit of €5.4 billion and fully diluted earnings per share of €20.69 ($18.92[2])*
- *Reiterates BioNTech COVID-19 2022 vaccine revenue guidance of €13 billion to €17 billion*
- *Preparing for potential launch of two variant-adapted bivalent COVID-19 vaccines containing the original strain and Omicron BA.1 or BA.4/5 spike protein as recommended by U.S. Food and Drug Administration (FDA), European Medicines Agency (EMA) and other regulators; expect to be able to begin delivering Omicron-adapted vaccines as early as October 2022, subject to regulatory approval*
- *Signed agreement with U.S. government to provide additional 105 million doses of COVID-19 vaccine with option for another 195 million doses*
- *Received U.S. Emergency Use Authorization (EUA) for COVID-19 vaccine in children six months through four years of age and for a booster dose in children five through 11 years of age*
- *Continued pipeline expansion with initiation of two new Phase 1 clinical trials (BNT116 and BNT142) to 18 clinical-stage oncology programs in 23 ongoing clinical trials; BNT211, first-in-class CAR-T program targeting CLDN6, receives EMA Priority Medicines (PRIME) designation*
- *Commenced construction of first BioNTainer mRNA vaccine manufacturing facility in Africa*

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

MAINZ, Germany, August 8, 2022 (GLOBE NEWSWIRE) -- BioNTech SE (Nasdaq: BNTX, “BioNTech” or the "Company") today reported financial results for the three and six months ended June 30, 2022 and provided an update on its corporate progress.

“In the first half of 2022, we achieved important milestones as we have further strengthened our COVID-19 vaccine leadership and have expanded our broad pipeline and accelerated its maturation. Our COVID-19 product pipeline includes variant-adapted and next-generation vaccine candidates, aimed at prolonged and broad protection,” said **Prof. Ugur Sahin, M.D., CEO and Co-Founder of BioNTech.** “In oncology, we have presented encouraging data updates for our individualized mRNA cancer vaccine candidate BNT122 in pancreatic cancer and our novel CAR-T cell therapy candidate BNT211 in solid tumors, leading to our first PRIME designation by EMA. We drive toward the preparation of registrational trials as well as the delivery of our first BioNTainers to Africa, aiming to provide access to novel medicines.”

Key Second Quarter Financial Results

in millions, except per share data	**Second Quarter 2022**	**Second Quarter 2021**	**First Half 2022**	**First Half 2021**
Total Revenues[1]	€3,196.5	€5,308.5	€9,571.1	€7,356.9
Net Profit	€1,672.0	€2,787.2	€5,370.8	€3,915.3
Diluted Earnings per Share	€6.45	€10.77	€20.69	€15.14

“With our strong performance year to date, we believe to be well on track to achieve our previous financial guidance for the ongoing financial year,” said **Jens Holstein, CFO of BioNTech.** “With our initiatives around variant-adapted COVID-19 vaccine candidates, we expect an uptake in demand in our key markets in the fourth quarter of 2022, subject to regulatory approval. We will continue to invest heavily in research and development in 2022 and beyond and remain focused on furthering our oncology pipeline as well as driving our leadership in COVID-19 vaccine development. We are driving toward potential launches of multiple innovative products to address diseases with high unmet medical need in the coming three to five years.”

Outlook for the 2022 Financial Year Reiterated

The Company reiterates its prior 2022 financial year outlook, which 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	€13 billion - €17 billion

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.

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	~28%

Detailed Second Quarter Financial Results

- *Revenues*: Total revenues reported were €3,196.5 million[1] for the three months ended June 30, 2022, compared to €5,308.5 million[1] for the comparative prior year period. For the six months ended June 30, 2022, total revenues were €9,571.1 million[1], compared to €7,356.9 million[1] for the comparative prior year period. BioNTech believes the development of the pandemic remains dynamic, causing a re-phasing of orders and with this leading to fluctuations in quarterly revenues. This revenue fluctuation caused by the re-phasing of orders is expected to remain over the rest of the financial year with an uptake in demand in key markets in the fourth quarter of 2022 related to the Omicron-adapted bivalent vaccine, subject to regulatory approval. 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 June 30, 2022, BioNTech’s commercial revenues included €1,987.4 million[1] gross profit share (€3,923.7 million[1] gross profit share and €168.6 million[1] sales milestones during the comparative prior year period). For the six months ended June 30, 2022, BioNTech's commercial revenues included €6,574.2 million[1] gross profit share (€5,428.4 million[1] gross profit share and €415.8 million[1] sales milestones during the comparative prior year period). BioNTech’s share of the collaboration partners’ gross profit is based on COVID-19 vaccine sales in Pfizer’s and Fosun Pharma’s territories and represents a net figure. In addition, during the three and six months ended June 30, 2022, BioNTech recognized €557.0 million and €1,720.1 million of direct COVID-19 vaccine sales to customers in BioNTech’s territory, Germany and Turkey, as well as €608.3 million and €1,211.5 million from sales of products manufactured by BioNTech for its collaboration partners. During the comparative prior year periods, €1,035.6 million and €1,235.4 million were recognized from sales to customers in BioNTech’s territory as well as €138.1 million and €202.0 million from sales of products manufactured by BioNTech for its collaboration partners, respectively.
- *Cost of Sales:* Cost of sales were €764.6 million for the three months ended June 30, 2022, compared to €883.8 million for the comparative prior year period. For the six months ended June 30, 2022, cost of sales were €2,058.7 million, compared to €1,116.9 million for the comparative prior year period. 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 its collaboration partner Pfizer. In addition, cost of sales was impacted by expenses arising from inventory write-offs and expenses for production capacities derived from contracts with contract manufacturing organizations.
- *Research and Development Expenses*: Research and development expenses were €399.6 million for the three months ended June 30, 2022, compared to €201.1 million for the comparative prior year period. For the six months ended June 30, 2022, research and development expenses were €685.4 million, compared to €417.3 million for the comparative prior year period. The increase was mainly due to recognizing costs related to the manufacturing of pre-launch Omicron vaccine candidates as research and development expenses in the period incurred and an increase in headcount.
- *General and Administrative Expenses*: General and administrative expenses were €130.0 million for the three months ended June 30, 2022, compared to €47.8 million for the comparative prior year period. For the six months ended June 30, 2022, general and administrative expenses were €220.8 million, compared to €86.7 million for the comparative prior year period. The increase was mainly due to recognizing increased expenses for purchased external services as well as an increase in headcount.
- *Income Taxes*: Income taxes were accrued with an amount of €647.3 million for the three months ended June 30, 2022, compared to €1,235.6 million for the comparative prior year period. For the six months ended June 30, 2022, income taxes were accrued in an amount of €1,966.6 million, compared to €1,749.8 million for the comparative prior year period. The derived effective income tax rate for the six months ended June 30, 2022 was 26.8%.
- *Net Profit*: Net profit was €1,672.0 million for the three months ended June 30, 2022, compared to €2,787.2 million for the comparative prior year period. For the six months ended June 30, 2022, net profit was €5,370.8 million, compared to €3,915.3 million for the comparative prior year period.
- *Cash, Cash Deposits and Trade Receivables*: As of June 30, 2022, cash and cash equivalents were €9,334.8 million. In addition, trade receivables remained outstanding as of June 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 first quarter of 2022 (as defined by the contract) for which the settlement payment was received subsequent to the end of the reporting period in July 2022. Of the total trade receivables of €10,382.9 million which were outstanding as of June 30, 2022, €5,581.1 million were received in cash as of July 15, 2022. The total cash and cash equivalents amounted to €14,884.5 million as of July 15, 2022.

- *Shares Outstanding*: Shares outstanding as of June 30, 2022, were 242,685,401.

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]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 six months ended June 30, 2022, filed as an exhibit to BioNTech's Current Report on Form 6-K filed on August 8, 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 six months ended June 30, 2022, respectively as published by the German Central Bank (*Deutsche Bundesbank*).

Second Quarter 2022 and Subsequent Program Updates

COVID-19 Vaccine Program – BNT162

BioNTech and Pfizer continue to build on their global COVID-19 vaccine leadership with further label expansions as well as development of a diverse pipeline of follow-on and next generation vaccine candidates. Subject to regulatory approval, Omicron-adapted vaccine launches and clinical trial starts, including trials for next generation vaccines, are expected to begin in the second half of 2022.

Commercial updates

As of the beginning of July 2022, BioNTech and Pfizer have delivered in total more than 3.6 billion doses to 180 countries or territories. The companies have signed orders for approximately 2.5 billion doses for 2022, and, in the first half of the year, invoiced approximately 1.2 billion doses. The cumulative share of doses[3] increased in the period between January 1, 2022 to July 20, 2022 from approximately 52% to 63% in all markets[4,5]. In developed markets[6], the share of doses for the same time period increased from approximately 59% to 68%.
As part of BioNTech and Pfizer's 2-billion-doses-pledge to support equitable access to medicines, the companies have delivered more than 1.5 billion doses of the companies' COVID-19 vaccine in total to low- and middle-income countries.

- In May 2022, BioNTech and Pfizer announced an agreement with the European Commission, or EC, to amend their originally agreed contractual delivery schedules for the COVID-19 vaccine. The amendment rephases planned deliveries to help support the EC and Member States' ongoing immunization programs and is aligned to the companies' commitment to working collaboratively to identify pragmatic solutions to address the evolving pandemic needs. Doses scheduled for delivery in June through August 2022 will now be delivered in September through to the fourth quarter of 2022. This change of delivery schedule did not impact the companies' full-year 2022 revenue guidance or the full-year commitment of doses to be delivered to EC Member States in 2022.
- In June 2022, BioNTech and Pfizer entered into a new vaccine supply agreement with the U.S. government. Under the terms of the agreement, the U.S. government will receive 105 million doses, including 30 µg, 10 µg and 3 µg doses, potentially including the Omicron-adapted adult vaccine, subject to granting of U.S. FDA Emergency Use Authorization, or EUA. The U.S. government also has the option to purchase up to an additional 195 million doses, bringing the potential total to 300 million vaccine doses. Delivery of the vaccine doses is scheduled to begin in late summer 2022 and will continue into the fourth quarter of this year. The U.S. government will pay the two companies $3.2 billion after receiving the first 105 million doses of vaccine.

[3] Market share data includes only those markets in which Pfizer operates and that report market share data
[4] Incl. all markets in Developed Markets (5) plus Emerging Markets (Argentina, Chile, Ecuador, Hong Kong, Nepal, Peru, South Africa, Uruguay)
[5] Includes the U.S., EU/EEA, other Int'l Developed markets (Japan, South Korea, Switzerland, Ukraine)
[6] Starting date of January 1, 2022 for this data set is from Q1 2022 earnings presentation

Manufacturing updates

BioNTech and Pfizer's global COVID-19 vaccine supply chain and manufacturing network includes 20 manufacturing facilities spanning four continents.

- BioNTech and Pfizer have started to manufacture bivalent Omicron BA.1- and BA.4/5-adapted vaccines. Pending regulatory approval, the companies expect to deliver the updated vaccines as soon as October 2022 and plan to supply both vaccines in time for fall booster campaigns.

Clinical development and regulatory updates

BioNTech and Pfizer's COVID-19 vaccine has received multiple regulatory approvals including expansions of authorizations for booster and pediatric vaccinations.

- In May 2022, the U.S. FDA expanded the EUA to include a booster dose in children five through 11 years of age. The EUA was granted based on data from the Phase 2/3 clinical trial demonstrating a high immune response following a booster dose after completion of the primary series of BNT162b2 in this age group. Data demonstrated that a booster dose given approximately six months after the second dose of the 10 µg primary series increased neutralizing antibodies by six-fold against the SARS-CoV-2 wild-type strain compared to levels observed after two doses. The vaccine was well

tolerated with no new safety signals observed. The data were also submitted to the EMA for a variation of the Conditional Marketing Authorization (CMA), in the European Union to include a booster dose in this age group and are being filed with other regulatory authorities worldwide.

- In June 2022, the U.S. FDA amended the EUA to include children six months of age through four years of age. The EUA was granted based on safety, immunogenicity and vaccine efficacy topline data from a Phase 2/3 study evaluating a third 3 µg dose in 1,678 children in this age group. Following a third dose in this age group, the vaccine elicited a strong immune response with a favorable safety profile similar to placebo. The vaccine met all immunobridging criteria required for an EUA, based on an immunogenicity analysis conducted on a subset of study participants one month following the third dose in this age group, compared to the second dose in the 16- to 25-year-old population. Further data on this age group will be shared in the coming weeks. The data were also submitted to the EMA for a line extension of the CMA in the European Union in this age group and are expected to be filed with other regulatory authorities in the coming weeks.
- In July 2022, the U.S. FDA also approved the supplemental Biologics License Application, or sBLA, to include individuals 12 through 15 years of age in the approved indication, expanding licensure of the vaccine to this age group, which was previously included under U.S. EUA.

BNT162b2 has demonstrated a high level of protection against several variants of concern, including Alpha, Beta, and Delta and continues to offer protection against severe disease, hospitalization and death for circulating Omicron-variants. BioNTech and Pfizer continue to monitor protection offered by BNT162b2 against emerging SARS-CoV-2 variants.

The companies are currently evaluating variant-adapted COVID-19 vaccines, including monovalent and bivalent vaccines directed against Omicron subvariants and other strains of SARS-CoV-2. Data from these studies were presented to regulatory agencies in June and July 2022, which supported the regulators' discussions for the development of Omicron-adapted vaccines and definition of the most appropriate regulatory pathways. BioNTech and Pfizer will continue to submit available data to regulatory authorities worldwide. In June 2022, the U.S. FDA advised vaccine manufacturers to develop modified vaccines that add an Omicron BA.4/5 spike protein encoding component to the current vaccine composition to create a bivalent booster vaccine.

- In June 2022, BioNTech and Pfizer announced positive safety, tolerability and immunogenicity data for two Omicron BA.1-adapted vaccine candidates, including data on a monovalent and a bivalent vaccine candidate combining the existing vaccine and a vaccine candidate targeting the Omicron variant BA.1 spike protein. Results from this Phase 2/3 trial in 1,234 subjects aged 56 years or older show that booster doses of 30 µg and 60 µg of both Omicron BA.1-adapted monovalent and bivalent vaccine candidates elicit significantly higher neutralizing antibody responses against Omicron BA.1 compared to BNT162b2, consistent with the regulatory requirements for superiority. The monovalent Omicron-adapted vaccine 30 µg and 60 µg achieved the regulatory requirement of super superiority. One month after administration, a booster dose of the Omicron BA.1-adapted monovalent candidates increased neutralizing geometric mean titers, or GMTs, against Omicron BA.1 13.5- and 19.6-fold above pre-booster dose levels. Booster vaccination with the bivalent Omicron BA.1-adapted vaccine candidates resulted in a 9.1- and 10.9-fold increase in neutralizing GMTs against Omicron BA.1, respectively. Both vaccine candidates demonstrated a favorable safety and tolerability profile similar to BNT162b2. In preclinical studies in mice, both monovalent and bivalent Omicron BA.4/5-adapted vaccine candidates were observed to substantially increase Omicron neutralization responses against all Omicron sublineages, including BA.1, BA.4/5 and the wild-type strain. Given the FDA guidance, BioNTech and Pfizer plan to distribute a bivalent vaccine encoding for the spike protein of the original strain as well as of the BA.4/BA.5 Omicron sublineage to be used as a booster, subject to regulatory authorizations. In addition, BioNTech and Pfizer plan to initiate a clinical trial in August 2022 to generate immunogenicity and safety data for an Omicron BA.4/5-adapted bivalent vaccine.
- In July 2022, BioNTech and Pfizer completed the submission to the EMA for an Omicron-adapted bivalent COVID-19 vaccine, based on the BA.1 sublineage, for individuals 12 years of age and older. This application follows guidance from the EMA to move forward with introducing an Omicron-adapted bivalent vaccine candidate to address the continued evolution of the SARS-CoV-2 virus. The companies are preparing to initiate the submission of pre-clinical and Chemistry, Manufacturing and Controls (CMC) data for a bivalent vaccine candidate encoding Omicron BA.4/5 spike protein to EMA beginning in August 2022.
- In a recent preprint publication (bioRxiv. Omicron BA.2 breakthrough infection enhances cross-neutralization of BA.2.12.1 and BA.4/BA.5; August 2022) BioNTech reported data demonstrating that sera from triple mRNA-vaccinated individuals who experienced Omicron sublineage BA.2 breakthrough infection demonstrated broad neutralizing activity against variants of concern, including Omicron BA.2 derived variants BA.2.12.1, BA.4/BA.5. In addition, the data showed that neutralization of BA.2 and BA.4/BA.5 sublineages by BA.2 convalescent sera is driven to a large extent by antibodies targeting the N-terminal domain, or NTD, of the spike glycoprotein. In comparison, neutralization by Omicron BA.1 convalescent sera depends on antibodies targeting the receptor binding domain. These findings suggest that Omicron BA.2 triggers significant NTD specific recall responses in vaccinated individuals, which enhances the neutralization of BA.4/BA.5 sublineages. Given the current epidemiology with a predominance of BA.2 derived sublineages like BA.4/BA.5 and rapidly ongoing evolution, these findings will increase current understanding on Omicron immune escape mechanisms and the effects of immunization on variant cross-neutralization, and thus will help guide further vaccine development.

BioNTech and Pfizer are investigating and identifying novel next-generation vaccine approaches to maintain a broad and longer lasting immune

response and high levels of protection against SARS-CoV-2 as it evolves. The long-term strategy takes a multipronged approach devised to develop and test multiple engineered vaccine candidates to achieve the goal of delivering a pan-SARS-CoV-2-type vaccine that will ultimately help to better manage upcoming variants of concern. The companies expect that scientific data derived from those different approaches will support the vaccine candidate selected 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. These next-generation vaccine approaches the companies plan to evaluate include an enhanced SARS-CoV-2 spike antigen and a T cell enhancing vaccine candidate.

- In July 2022, as a first step of BioNTech and Pfizer's long-term strategy of developing a next-generation COVID-19 vaccine, a randomized, active-controlled, observer-blind, Phase 2 study was initiated to evaluate the safety, tolerability, and immunogenicity of a 30 µg dose of an enhanced spike antigen vaccine candidate. This first of multiple candidates with an engineered design, BNT162b5, consists of RNAs encoding for a sequence-modified spike protein of the SARS-CoV-2 ancestral strain and the Omicron BA.2 variant. The enhanced prefusion spike protein in BNT162b5 has been modified with the aim to increase the magnitude and breadth of antibody neutralization response to better protect against COVID-19.
- Additionally, in the second half of 2022, BioNTech and Pfizer anticipate progressing T cell enhancing and pan-SARS-CoV-2 vaccine candidates into the clinic.

Additional Infectious Disease Programs

BioNTech is on track to initiate two first-in-human clinical trials in the second half of 2022 that include mRNA-based product candidates designed to address shingles (in collaboration with Pfizer), and herpes simplex virus type 2 (HSV 2; BNT163).

First-in-human clinical trials for tuberculosis (BNT164) and malaria (BNT165) are now expected to start in the second half of 2022 or early 2023.

Influenza Vaccine Program

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

- A Phase 1/2 trial to evaluate BNT161, a quadrivalent nucleoside-modified RNA (modRNA) vaccine candidate, is ongoing and a dose-finding study for a self-amplifying RNA (saRNA) vaccine candidate has started.
- In July 2022, data were reported from the Phase 2 expansion study of BNT161 in subjects 65 years of age and older showing first evidence of substantial induction of strain specific CD4+ and CD8+ responses. At day seven after vaccination with BNT161, the geometric mean fold rise, or GMFR, for CD4+ T cells was more than two-fold for all four encoded strains. For strain specific CD8+ T cells, the GMFR was more than two-fold for the Victoria B subtype and influenza B subtype (H3N2). The GMFR was higher compared to the control quadrivalent influenza vaccine for both CD4+ and CD8+ strain specific T cell responses. Based on these encouraging T cell responses and observed seroconversion, a Phase 3 study of the quadrivalent modified mRNA influenza vaccine is planned to initiate in the second half of 2022.

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. The Company's oncology pillars 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 18 product candidates in 23 ongoing clinical trials including five in 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). BNT116, a FixVac program for non-small cell lung cancer (NSCLC) and BNT142, a RiboMab program targeting CD3 on T cells and Claudin-6 (CLDN6) in solid tumors, have recently entered first-in-human clinical testing.

BioNTech expects continued pipeline advancement and expansion, as well as further data readouts from the ongoing trials, for the remainder of 2022.

mRNA programs

FixVac

BioNTech's off-the-shelf cancer immunotherapy approach, FixVac, leverages the Company's proprietary uridine mRNA (uRNA) backbone for full actualization of the intrinsic adjuvanticity of RNA that encodes cancer-specific shared antigens for intravenous administration using the proprietary RNA-LPX formulation and aiming for induction of strong antigen-specific immune responses. FixVac product candidates may be of clinical utility in combination with anti-PD1 in patients with lower mutational burden tumors, including those who have already experienced checkpoint inhibitor (CPI) therapy.

Two FixVac programs are in ongoing Phase 2 trials: BNT111 in PD1 inhibitor refractory/relapsed melanoma (in collaboration with Regeneron Pharmaceuticals, Inc., "Regeneron") and BNT113 in HPV16+ PDL1+ head and neck cancer.

BNT116 is being evaluated in a Phase 1 clinical trial. It is designed to elicit an immune response to six tumor-associated antigens that cover up to 100% of patients in all major histologic subtypes of non-small cell lung cancer.

- 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 in patients with advanced or metastasized NSCLC. The trial will comprise several cohorts and is intended to establish a safe dose for BNT116 monotherapy as well as for BNT116 in combination with cemiplimab (Regeneron's Libtayo®) 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.

Individualized neoantigen specific immunotherapy (iNeST)

BioNTech's individualized cancer immunotherapy approach (iNeST) is also based on a pharmacologically optimized uridine mRNA (uRNA) backbone delivered in the Company's proprietary RNA-LPX formulation.

BioNTech's lead iNeST product candidate, autogene cevumeran (BNT122), is being developed together with Genentech, Inc. ("Genentech") as part of a co-development and co-commercialization collaboration.

Each patient is treated with a vaccine informed by the mutation profile of their personal cancer and manufactured on-demand. The RNA encodes a unique composition of the patient's own tumor mutations and results in generation of neoantigen specific CD4+ and CD8+ T cell responses . BioNTech believes this modality is well-suited for use in early-stage cancers and the adjuvant setting.

- A randomized Phase 2 trial of autogene cevumeran in the adjuvant treatment of circulating tumor DNA (ctDNA) positive, surgically resected Stage II (high-risk)/Stage III colorectal cancer is ongoing.
- A data update from the ongoing randomized Phase 2 trial of autogene cevumeran combined with pembrolizumab in patients with first-line metastatic melanoma is now expected in the first half of 2023.
- In June 2022, initial data from an investigator-initiated Phase 1 clinical trial of autogene cevumeran evaluating safety and tolerability in combination with the anti-PD-L1 immune checkpoint inhibitor atezolizumab and chemotherapy in patients with surgically removed pancreatic ductal adenocarcinoma, or PDAC, was presented at the 2022 American Society of Clinical Oncology (ASCO) Annual Meeting. 16 patients had their tumor surgically removed, were subsequently treated with a single dose of atezolizumab and received autogene cevumeran. Preliminary data from these 16 treated patients showed that autogene cevumeran was well tolerated. *De novo* neoantigen-specific T cell responses of high magnitude were induced in 50% (eight out of 16) of patients. After an early median follow-up of 18 months, patients with this type of immune response had a significantly longer recurrence-free survival, or RFS, than those without a high magnitude vaccine-induced immune response. Based on these data, BioNTech and Genentech are planning a randomized study to further evaluate the efficacy and safety of autogene cevumeran in combination with atezolizumab and chemotherapy in patients with resected PDAC.

RiboMabs

BioNTech's RiboMab product candidates, BNT141 and BNT142, are based on mRNA and designed to encode cancer cell targeting antibodies. These product candidates leverage the Company's proprietary optimized mRNA technology combining nucleoside modifications to minimize immunogenicity with modifications in the mRNA backbone with the aim of maximizing protein expression. RiboMabs may address the limitations of recombinant antibodies, including avoidance of protein manufacturing challenges and short plasma half-life.

BNT141 encodes an antibody targeting Claudin-18.2, expressed in high unmet medical need tumors, including multiple epithelial solid tumors, such as gastric, biliary and pancreatic cancers.

BNT142 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.

- BNT142 – In July 2022, the first participant 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.

Cell therapies

CAR-T cell immunotherapy

BNT211, BioNTech's first chimeric antigen receptor, or CAR-T cell product candidate, targets CLDN6-positive solid tumors in combination with a CAR-T cell-amplifying RNA vaccine, or CARVac, encoding CLDN6. CARVac is also based on a pharmacologically optimized uridine mRNA (uRNA) backbone delivered in the Company's proprietary RNA-LPX formulation. CLDN-6 CAR-T cells are equipped with a second-generation CAR of high sensitivity and specificity for the tumor-specific carcino-embryonic antigen CLDN6. CARVac drives *in vivo* expansion of transferred CAR-T cells, aiming to increase their persistence and efficacy. BNT211 is designed to overcome CAR-T cell therapy limitations in patients with solid tumors.

- BNT211 – A Phase 1/2 open-label dose escalation and dose expansion trial evaluating BNT211 in patients with CLDN6-positive solid tumors is ongoing. Data from the ongoing trial were presented at the American Association for Cancer Research (AACR) Conference in April 2022 and at the annual meeting of the Association for Cancer Immunotherapy (CIMT) in May 2022. The preliminary efficacy data showed encouraging signs of clinical activity with a disease control rate of 86% and an overall response rate of 43%. The results also demonstrated an encouraging safety profile as adverse

events and dose limiting toxicities were manageable. Another data update from the ongoing Phase 1/2 trial is expected in the second half of 2022.
- In June 2022, the EMA granted Priority Medicines (PRIME) designation to BNT211 for the third- or later-line treatment of testicular germ cell tumors. The PRIME status is granted to drug candidates that may offer a major therapeutic advantage over existing treatments and provides early and proactive EMA support to developers of medicines that target an unmet medical need. BNT211 will benefit from this interaction with the EMA through the next development phase.

Antibodies

Next generation immunomodulators

In August 2022, BioNTech announced the expansion of its global strategic collaboration with Genmab A/S ("Genmab") for the joint development of BNT313 (GEN1053), a CD27 antibody, applying Genmab's proprietary HexaBody® technology. Under this 50/50 collaboration, the development costs and potential future profits for BNT313 will be shared equally.

- BNT313 (GEN1053) – A Phase 1 trial to evaluate the safety, tolerability, and preliminary efficacy of BNT313 on malignant solid tumors as monotherapy is expected to be initiated in the second half of 2022. The trial will consist of two parts. The dose escalation part will explore the safety of escalating doses of BNT313 as monotherapy. The expansion part is planned to provide additional safety and initial antitumor activity information on the selected dose regimen for BNT313 monotherapy in selected tumor indications, as well as more detailed data related to the mode of action.

Corporate Updates

A key component of BioNTech's corporate strategy is strengthening the Company's technology platforms, digital capabilities and infrastructure through select strategic partnerships and acquisitions. In April 2022, BioNTech was granted a pandemic preparedness contract by the Federal Republic of Germany and the Company entered into an exclusive research collaboration with Matinas BioPharma Holdings, Inc. ("Matinas BioPharma").

- In June 2022, BioNTech began construction of its first Africa-based mRNA vaccine manufacturing facility in Kigali, Rwanda, with a target for the first set of manufacturing BioNTainers to be delivered to the site by the end of 2022. The facility will initially include two BioNTainers equipped to manufacture a range of mRNA-based vaccines targeted to the needs of the African Union member states, including potentially the COVID-19 vaccine and investigational malaria and tuberculosis vaccine candidates if approved or authorized by regulatory authorities. The Company believes the estimated initial annual capacity of, for example, the COVID-19 vaccine may be as high as approximately 50 million doses and manufacturing in the BioNTainers could commence as soon as approximately 12 to 18 months after their installation.

BioNTech also provides an update on key Supervisory Board developments and the status of the return of capital to shareholders

- In June 2022, at the Annual General Meeting (AGM) the Company's shareholders voted to reappoint Helmut Jeggle as a member of the Supervisory Board and appointed two additional Supervisory Board members, Prof. Dr. Anja Morawietz and Prof. Dr. Rudolf Staudigl. In a meeting following the AGM, the Supervisory Board re-elected Helmut Jeggle as its Chairman. All three members will serve in their roles until the 2026 AGM.
- In June 2022, at the Annual General Meeting, the Company's shareholders approved the proposed special cash dividend of €2.00 per ordinary share (including those held in the form of ADSs), which led to an aggregate payment of €484.3 million.
- During the three months ended June 30, 2022, 2,078,207 American Depositary Shares (ADSs) were repurchased under the Company's share repurchase program at an average price of $145.65, for total consideration of $302.7 million (€286.9 million).

In light of the potential energy supply issues in Europe, BioNTech is evaluating its ongoing mitigation efforts to ensure business continuity.

- BioNTech monitors the natural gas supply situation as part of its regular business continuity management and is evaluating possible additional energy supply measures. BioNTech's commercial production of its COVID-19 vaccine is currently 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 are currently dependent on gas, and the Company is putting measures in place to mitigate related risks. BioNTech is also currently evaluating the impact to its partners, including Pfizer, suppliers and other service providers. BioNTech is proactively engaging with collaboration partners and governmental authorities to mitigate adverse impacts from any potential energy shortage.

Environmental, Social, and Governance (ESG)

The rating agency ISS ESG, part of the Institutional Shareholder Services group (ISS) reiterated BioNTech's "Prime" ESG rating. BioNTech improved its rating from "C+" to "B-" compared to the previous year and remains in the top 10% of the biopharmaceutical industry, according to the ISS ESG Rating.

Conference Call and Webcast Information

BioNTech invites investors and the general public to join a conference call and webcast with investment analysts on the same day at 8.00 a.m. EDT (2.00 p.m. CEST) to report its financial results and provide a corporate update for the second 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. It is recommended to register at least a day in advance.
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.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 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 BNT162b2 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 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 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 vaccine revenues, and projections of estimated research and development expenses, selling, general and administrative expenses, capital expenditures, and income taxes; 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 quarter ended June 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 June 30,		Six months ended June 30,	
(in millions, except per share data)	**2022** *(unaudited)*	**2021** *(unaudited)*	**2022** *(unaudited)*	**2021** *(unaudited)*
Revenues				
Commercial revenues	€3,166.3	€5,280.5	€9,528.5	€7,3 08.0
Research & development revenues	30.2	28.0	42.6	48.9
Total revenues	**€3,196.5**	**€5,308.5**	**€9,571.1**	**€7,356.9**
Cost of sales	(764.6)	(883.8)	(2,058.7)	(1,116.9)
Research and development expenses	(399.6)	(201.1)	(685.4)	(417.3)
Sales and marketing expenses	(17.8)	(13.3)	(32.1)	(22.0)
General and administrative expenses	(130.0)	(47.8)	(220.8)	(86.7)
Other operating expenses	(240.7)	(0.3)	(309.5)	(0.9)
Other operating income	565.8	36.2	697.7	147.5
Operating income	**€2,209.6**	**€4,198.4**	**€6,962.3**	**€5,860.6**
Finance income	115.5	0.3	387.6	24.8
Finance expenses	(5.8)	(175.9)	(12.5)	(220.3)
Profit before tax	**€2,319.3**	**€4,022.8**	**€7,337.4**	**€5,665.1**
Income taxes	(647.3)	(1,235.6)	(1,966.6)	(1,749.8)
Profit for the period	**€1,672.0**	**€2,787.2**	**€5,370.8**	**€3,915.3**
Earnings per share				
Basic profit for the period per share	€6.86	€11.42	€22.00	€16.07
Diluted profit for the period per share	€6.45	€10.77	€20.69	€15.14

Interim Condensed Consolidated Statements of Financial Position

(in millions)	**June 30, 2022** *(unaudited)*	**December 31, 2021**
Assets		
Non-current assets		
Intangible assets	€221.4	€202.4
Property, plant and equipment	420.4	322.5
Right-of-use assets	243.7	197.9
Other financial assets	51.5	21.3
Other assets	0.9	0.8
Deferred expenses	9.4	13.6
Total non-current assets	**€947.3**	**€758.5**
Current assets		
Inventories	367.7	502.5
Trade and other receivables	10,382.9	12,381.7
Other financial assets	0.1	381.6
Other assets	46.6	64.9
Income tax assets	0.4	0.4
Deferred expenses	75.6	48.5
Cash and cash equivalents	9,334.8	1,692.7
Total current assets	**€20,208.1**	**€15,072.3**
Total assets	**€21,155.4**	**€15,830.8**
Equity and liabilities		
Equity		
Share capital	248.6	246.3
Capital reserve	1,689.8	1,674.4

Treasury shares	(5.9)	(3.8)
Retained earnings	14,769.4	9,882.9
Other reserves	128.8	93.9
Total equity	**€16,830.7**	**€11,893.7**
Non-current liabilities		
Loans and borrowings	206.6	171.6
Other financial liabilities	6.1	6.1
Income tax liabilities	6.8	4.4
Provisions	7.3	184.9
Contract liabilities	55.9	9.0
Other liabilities	17.9	12.8
Deferred tax liabilities	100.4	66.7
Total non-current liabilities	**€401.0**	**€455.5**
Current liabilities		
Loans and borrowings	32.3	129.9
Trade payables	291.1	160.0
Other financial liabilities	807.3	1,190.4
Government grants	3.0	3.0
Refund liabilities	—	90.0
Income tax liabilities	1,417.9	1,568.9
Provisions	596.2	110.2
Contract liabilities	656.3	186.1
Other liabilities	119.6	43.1
Total current liabilities	**€3,923.7**	**€3,481.6**
Total liabilities	**€4,324.7**	**€3,937.1**
Total equity and liabilities	**€21,155.4**	**€15,830.8**

Interim Condensed Consolidated Statements of Cash Flows

	Three months ended June 30,		**Six months ended June, 30**	
	2022	**2021**	**2022**	**2021**
(in millions)	*(unaudited)*	*(unaudited)*	*(unaudited)*	*(unaudited)*
Operating activities				
Profit for the period	€1,672.0	€2,787.2	€5,370.8	€3,915.3
Income taxes	647.3	1,235.6	1,966.6	1,749.8
Profit before tax	**€2,319.3**	**€4,022.8**	**€7,337.4**	**€5,665.1**
Adjustments to reconcile profit before tax to net cash flows:				
Depreciation and amortization of property, plant, equipment, intangible assets and right-of-use assets	33.2	16.4	60.8	29.4
Share-based payment expense	12.6	22.0	22.0	39.3
Net foreign exchange differences	(344.6)	(70.1)	(338.5)	(101.3)
Gain on disposal of property, plant and equipment	0.2	0.2	0.2	0.4
Finance income	(1.5)	(0.3)	(218.8)	(0.6)
Finance expense	5.8	175.6	12.5	220.3
Movements in government grants	—	(20.9)	—	(88.8)
Net loss on derivative instruments at fair value through profit or loss	86.5	—	84.6	—
Working capital adjustments:				
Decrease / (increase) in trade and other receivables, contract assets and other assets	3,174.8	(4,651.0)	2,771.3	(6,751.5)
Decrease / (increase) in inventories	91.6	(158.5)	134.8	(241.3)
(Decrease) / increase in trade payables, other financial liabilities, other liabilities, contract liabilities, refund liabilities and provisions	(663.1)	565.5	194.4	821.0
Interest received	1.5	0.3	2.2	0.6
Interest paid	(5.8)	(2.1)	(12.2)	(3.9)
Income tax paid	(791.4)	(0.2)	(2,081.4)	(0.3)
Net cash flows from / (used in) operating activities	**€3,919.1**	**€(100.3)**	**€7,969.3**	**€(411.6)**
Investing activities				
Purchase of property, plant and equipment	(70.6)	(25.9)	(114.7)	(47.6)
Proceeds from sale of property, plant and equipment	—	0.3	—	1.2
Purchase of intangible assets and right-of-use assets	(4.8)	(4.2)	(21.5)	(11.7)

Purchase of financial instruments	(3.0)	—	(30.0)	—
Proceeds from maturity of other financial assets	—	—	375.2	—
Net cash flows from / (used in) investing activities	**€(78.4)**	**€(29.8)**	**€209.0**	**€(58.1)**
Financing activities				
Proceeds from issuance of share capital and treasury shares, net of costs	—	160.9	110.5	160.9
Proceeds from loans and borrowings	0.2	—	0.2	—
Repayment of loans and borrowings	—	(0.7)	(18.8)	(1.4)
Payments related to lease liabilities	(10.5)	(7.3)	(21.9)	(11.1)
Share repurchase program	(286.9)	—	(286.9)	—
Dividends	(484.3)	—	(484.3)	—
Net cash flows from / (used in) financing activities	**€(781.5)**	**€152.9**	**€(701.2)**	**€148.4**
Net increase / (decrease) in cash and cash equivalents	3,059.2	22.8	7,477.1	(321.3)
Change in cash and cash equivalents resulting from exchange rate differences	111.5	(0.2)	165.0	25.2
Cash and cash equivalents at the beginning of the period	6,164.1	891.5	1,692.7	1,210.2
Cash and cash equivalents at June 30	**€9,334.8**	**€914.1**	**€9,334.8**	**€914.1**