BioNTech Announces Fourth Quarter and Full Year 2021 Financial Results and Corporate Update

March 30, 2022

- *Fourth quarter and full year revenues of €5.5 billion[1] and €19.0 billion[1], respectively*
- *Full year net income of €10.3 billion and fully diluted earnings per share of €39.63 ($46.87[2])*
- *Expect to authorize a share repurchase program of up to $1.5 billion over the next two years and will propose a special cash dividend of €2.00 per share, pending approval at the Annual General Meeting*
- *Approximately 2.6 billion doses of COMIRNATY®/BNT162b2 delivered to more than 165 countries and regions worldwide in 2021, including more than 1 billion doses to low- and middle-income countries*
- *Reiterate BioNTech COVID-19 2022 vaccine revenue guidance of €13 billion to €17 billion*
- *Signed orders for 2022 delivery increased to 2.4 billion COVID-19 vaccine doses*
- *Expanded clinical stage oncology pipeline to 16 clinical programs with initiation of nine clinical trials, including four randomized Phase 2 trials*
- *Initiated expansion of Phase 3 clinical trials to include Omicron-based vaccine candidates, and expanded mRNA vaccine pipeline with multiple preclinical programs addressing high-need infectious diseases expected to advance into the clinic this year*
- *Focused on driving further transformation in 2022 by reinvesting COVID-19 vaccine profits to accelerate oncology and infectious disease programs, broaden pipeline and scale-up business*

Conference call and webcast scheduled for March 30, 2022 at 8:00 am ET (2:00 pm CET)

MAINZ, Germany, March 30, 2022 (GLOBE NEWSWIRE) -- BioNTech SE (Nasdaq: BNTX, "BioNTech" or "the Company") today reported financial results for the three months and full year ended December 31, 2021 and provided an update on its corporate progress.

"Looking back, 2021 was an exceptional year during which BioNTech had a momentous impact on human health and the global economy with our first approved vaccine based on our mRNA technology," said **Ugur Sahin, M.D., CEO and Co-Founder of BioNTech**. "To continue our industry leadership, we intend to build on our 2021 success and rapidly advance multiple programs, including our mRNA-based immunotherapies, cell therapies, and bi-specific antibodies. At the same time, we are investing in our second growth pillar, infectious diseases, and intend to advance our influenza and shingles vaccine candidates together with our partner Pfizer. In parallel, we also intend to invest heavily in regenerative medicine and autoimmune diseases with the aim to develop further therapeutic innovations addressing high unmet medical need. Our core vision remains the foundation for all our activities: harnessing the power of the immune system to improve the health and lives of billions of people worldwide."

Key Fourth Quarter and Full Year 2021 Financial Results

in millions, except per share data	**Fourth Quarter 2021**	**Fourth Quarter 2020**	**Full Year 2021**	**Full Year 2020**
Total Revenues[1]	€5,532.5	€345.4	€18,976.7	€482.3
Net Profit	€3,166.2	€366.9	€10,292.5	€15.2
Diluted Earnings per Share	€12.18	€1.43	€39.63	€0.06

"Driven by the continued global delivery of our COVID-19 vaccine, we are delighted to report a strong financial performance in both the fourth quarter and for the full year of 2021. Our 2021 COVID-19 vaccine revenues were significantly influenced by the extraordinary circumstances of the ongoing pandemic," said **Jens Holstein, CFO of BioNTech**. "The financial success of 2021 allows us to redeploy meaningful investments into our R&D engine in the years to come. We expect to spend €1.4 billion to €1.5 billion in R&D during the 2022 financial year, which represents an increase of about 50%[3] compared to 2021. In subsequent years we intend to increase R&D investments further to continue to exploit the many prophylactic and therapeutic opportunities offered by our technologies. Moreover, we expect to initiate a share repurchase program of up to $1.5 billion as we would like to share our successes with our shareholders and provide for upcoming settlement obligations under share-based payment arrangements. In addition, we will propose a special cash dividend of €2.00 per share at our forthcoming 2022 Annual General Meeting."

Outlook for the Full Year 2022

The Company's full year 2022 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	€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 M&A transactions.

Estimated 2022 Financial Year Tax Assumptions:

BioNTech Group estimated annual effective income tax rate	~28%

Capital Allocation Framework

The broad success of BioNTech's COVID-19 vaccine has paved the way to a new era of mRNA technology and synthetic biology. The Company's position today reflects a rich pipeline including multiple potentially first-in-class approaches positioning BioNTech to potentially redesign the therapeutic landscape, enable personalized and individualized therapeutic solutions, and drive superior patient outcomes across diseases.
The current capital allocation of BioNTech places the Company in an exceptional position to drive a multi-platform strategy and continue to build a fully integrated global biotechnology company, supported by the following goals:

R&D activities

- Develop next generation COVID-19 vaccines to maintain leadership and pandemic preparedness as well as broaden label and access to vaccine
- Scale-up Global Development Organization with clinical and regulatory expertise
- Accelerate clinical development, bolstering mid- and late-stage oncology presence
- Broaden pipeline through start of new programs in oncology and infectious diseases
- Diversify therapeutic area footprint to fully leverage potential of all technology platforms across autoimmune diseases, inflammatory diseases, cardiovascular disease, neurodegenerative diseases, and regenerative medicines

M&A and business development

- Strengthen technology platforms and digital capabilities through select strategic partnerships and acquisitions
- Enhance capabilities through complementary acquisitions, technologies, infrastructure and manufacturing

Corporate and infrastructure

- Grow organization and expand team while developing global footprint in key regions including Europe, the United States, Asia and Africa
- Invest in manufacturing capabilities for key technologies
- Deploy pandemic response capabilities

Return capital to shareholders

- The Management Board and Supervisory Board expect to authorize a share repurchase program of ADSs, pursuant to which the Company may repurchase ADSs in the amount of up to $1.5 billion over the next two years. The Company expects to use all or a portion of the ADSs it repurchases and holds in treasury to satisfy upcoming settlement obligations under its share-based payment arrangements.
- Given that BioNTech had an extraordinary year 2021, the Management Board and Supervisory Board will propose a special cash dividend of €2.00 per ordinary share (including those held in the form of ADSs), which corresponds to an aggregate of approximately €486.0 million, based on the shares outstanding as of March 30, 2022, pending approval at the Annual General Meeting to be held in June 2022, which the Company expects to serve as the record date for the dividend.

Detailed Fourth Quarter and Full Year 2021 Financial Results

- *Revenues*: Total revenues reported were €5,532.5 million[1] for the three months ended December 31, 2021, compared to €345.4 million[1] for the comparative prior year period. For the year ended December 31, 2021, total revenues reported reached €18,976.7 million[1] compared to €482.3 million[1] for the comparative prior year period. The increase was mainly due to the high demand for BioNTech's COVID-19 vaccine.
  Under the collaboration agreements, territories have been allocated between BioNTech, Pfizer and Fosun Pharma based on marketing and distribution rights. During the three months ended December 31, 2021, BioNTech's commercial revenues included €4,582.2 million[1] gross profit share and €43.8 million of sales milestones. During the year ended December 31, 2021, €14,352.1 million[1] gross profit share and €476.6 million of sales milestones were included in BioNTech's commercial revenues. 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 months and the year ended December 31, 2021, respectively, €456.6 million and €970.9 million sales of products manufactured by BioNTech for its collaboration partners, as well as €421.0 million and €3,007.2 million direct COVID-19 vaccine sales to customers in BioNTech's territory, Germany and Turkey, have been recognized.

- *Cost of Sales:* Cost of sales was €583.2 million for the three months ended December 31, 2021, compared to €41.0 million for the comparative prior year period. For the year ended December 31, 2021, cost of sales was €2,911.5 million, compared to €59.3 million for the comparative prior year period. During the three and 12 months ended December 31, 2021, cost of sales of €565.5 million and €2,855.6 million, respectively, was recognized with respect to BioNTech's COVID-19 vaccine sales and include the share of gross profit that BioNTech owes to its collaboration partner Pfizer based on its sales.
- *Research and Development Expenses*: Research and development expenses were €271.5 million for the three months ended December 31, 2021, compared to €257.0 million for the comparative prior year period. For the year ended December 31, 2021, research and development expenses were €949.2 million, compared to €645.0 million for the comparative prior year period. The increase was mainly due to increased research and development expenses from the BNT162 COVID-19 vaccine clinical trials initiated and conducted in the year ended December 31, 2021. The increase was further driven by an increase in wages, benefits and social security expenses resulting from an increase in headcount, recording expenses incurred under BioNTech's share-based-payment arrangements as well as from recognizing inventor remuneration expenses.
- *General and Administrative Expenses*: General and administrative expenses were €130.9 million for the three months ended December 31, 2021, compared to €35.9 million for the comparative prior year period. For the year ended December 31, 2021, general and administrative expenses were €285.8 million, compared to €94.0 million for the comparative prior year period. The increase was mainly due to an increase in wages, benefits and social security expenses resulting from an increase in headcount and expenses incurred under the share-based-payment arrangements, increased expenses for purchased management consulting and legal services as well as higher insurance premiums caused by the increased business volume. The Company's M&A and business development transactions also contributed to the increase in general and administrative expenses.
- *Income Taxes*: Income taxes were accrued in an amount of €1,547.7 million of tax expenses for the three months ended December 31, 2021, compared to €161.3 million of tax income for the comparative prior year period. For the year ended December 31, 2021, income taxes accrued were €4,753.9 million of tax expenses, compared to €161.0 million of tax income for the comparative prior year period. The derived annual effective income tax rate for the year ended December 31, 2021 was 31.6%.
- *Net Profit*: Net profit was €3,166.2 million for the three months ended December 31, 2021, compared to €366.9 million for the comparative prior year period. For the year ended December 31, 2021, net profit was €10,292.5 million, compared to €15.2 million for the comparative prior year period.
- *Cash, Cash Deposits and Trade Receivables*: As of December 31, 2021, cash and cash equivalents were €1,692.7 million and cash deposits, which were returned to cash in January and February 2022, were €375.2 million. In addition, trade receivables remained outstanding as of December 31, 2021 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 third quarter of 2021 (as defined by the contract) for which the settlement payment was received subsequent to the end of the reporting period in January 2022. Of the total trade receivables of €12,381.7 million which were outstanding as of December 31, 2021, €4,693.6 million were received in cash by January 16, 2022.
- *Shares Outstanding*: Shares outstanding as of December 31, 2021 were 242,521,489.

The full audited consolidated financial statements can be found in BioNTech's 20F, 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 the Annual Report on Form 20-F for the year ended December 31, 2021. Any changes in the estimated share of the collaboration partner's gross profit will be recognized prospectively.

[2]Calculated applying the average foreign exchange rate for the year ended December 31, 2021 as published by the German Central Bank (*Deutsche Bundesbank*).

[3]Comparing R&D expenses planned for the 2022 financial year to the R&D expenses incurred during the 2021 financial year.

Fourth Quarter 2021 and Subsequent Program Updates

COVID-19 Vaccine Program – BNT162b2

BNT162b2, the first ever approved mRNA-based product, is ushering in a new class of medicines. This was one of the fastest pharmaceutical products ever developed and one of the most successful pharmaceutical product launches. BioNTech's efforts resulted in more than one billion people being vaccinated with BNT162b2 around the globe. BioNTech and Pfizer continue to execute on plans for global COVID-19 vaccine leadership with multiple new product launches, including label expansions, pediatric dosage forms and potentially variant-based vaccines.

Commercial updates

As of the beginning of March 2022, BioNTech and Pfizer delivered more than 3.1 billion doses of BNT162b2 to more than 170 countries and regions around the world. By early March 2022, as part of BioNTech and Pfizer's commitment towards equitable and affordable access to COVID-19 vaccines globally, approximately 1.3 billion doses had been delivered to low- and middle-income countries. As of mid-March 2022, BioNTech and Pfizer have signed orders for approximately 2.4 billion doses in 2022. Further discussions for additional dose commitments are ongoing for 2022 and beyond.

- BioNTech and Pfizer launched a new product formulation of their COVID-19 vaccine that simplifies vaccine handling and has improved storage and transport conditions. Vials can be stored for 10 weeks at refrigerator temperatures from 2°C to 8°C, and after first puncture, can be stored and transported at 2°C to 30°C and used within 12 hours. The new formulation was rolled out in November 2021 in the United States and in December 2021 in the European Union. To date, this formulation has been delivered to more than 50 countries.
- In December 2021, BioNTech and Pfizer announced an agreement with the European Commission (EC) and its member states, pursuant to which the EC exercised its option to purchase more than 200 million additional doses of vaccine. The 200 million doses are in addition to the 450 million doses already planned to be delivered in 2022, based on an agreement signed in May 2021. The number of doses to be delivered to EC member states in 2022 will now total more than 650 million doses. In sum, the total number of potential doses delivered to the EC, inclusive of all agreements, is expected to be up to 2.4 billion by end of 2023.

Manufacturing updates

The companies' global COVID-19 vaccine supply chain and manufacturing network includes 20 manufacturing facilities spanning four continents.

Clinical development and research updates

In 2021 and 2022 to-date, BioNTech and Pfizer generated clinical data to expand COVID-19 vaccination to broader populations, including children. The companies are conducting a robust booster development program to address waning efficacy, and partial escape variants and to ensure continued protection by the vaccine.
Additionally, BioNTech and Pfizer continue to monitor protection offered by BNT162b2 against emerging SARS-CoV-2 variants. BNT162b2 offers a high level of protection against variants of concern, including Alpha, Beta, and Delta, and recent laboratory studies published in *Science* demonstrated three doses of BNT162b2 neutralize the SARS-CoV-2 Omicron variant.
BioNTech and Pfizer are evaluating variant-based versions of the vaccine, including Omicron-based candidates, and are also evaluating bivalent vaccines, directed against the Omicron and Wuhan strains of SARS-CoV-2. The studies are part of ongoing efforts to assess durability of efficacy and to determine the need for variant-based vaccines.

- In November 2021, BioNTech and Pfizer announced longer-term follow-up data from a pivotal Phase 3 clinical trial in 2,228 individuals 12 to under 16 years of age where 100% efficacy was observed from seven days to four months after the second dose. This was during a time when the Delta variant was the dominant circulating strain. The adverse event profile was favorable and generally consistent with other clinical safety data for the vaccine.
- In December 2021, after review by the Independent Data Monitoring Committee, the trial in children 6 months to under 5 years of age was amended to include a third dose of 3µg at least two months after the two-dose series to provide high protection in this age group. The companies expect to have three dose protection data in this age group available in April 2022. The data will be submitted to the U.S. Food and Drug Administration (FDA) and other regulators to support expansion of authorizations and approvals for this age group.
  BioNTech and Pfizer are also evaluating a third dose of the 10µg formulation in children 5 to under 12 years of age.
- In January 2022, BioNTech and Pfizer announced the initiation of clinical trials to evaluate the safety, tolerability, and immunogenicity of an Omicron-based vaccine in healthy adults 18 to less than 56 years of age and adults greater than 55 years of age. The study is evaluating approximately 2,150 participants across multiple cohorts examining different regimens of the current COVID-19 vaccine or an Omicron-based vaccine in both vaccine experienced and naive subjects. The study was expanded to include multiple new cohorts, including a cohort evaluating combination of an Omicron-based vaccine and BNT162b2, as well as an exploratory cohort evaluating a bivalent Omicron vaccine. BioNTech has scaled-up manufacturing and has started producing its Omicron-based vaccine at risk. The trial recruitment is on track and the Company expects to publish data in April 2022 supporting potential regulatory submissions for an Omicron-adapted vaccine. In addition, BioNTech intends to continue to evaluate other follow-on COVID-19 vaccines candidates, including combination and bivalent vaccines.

Regulatory updates

BioNTech and Pfizer's COVID-19 vaccine has received multiple regulatory approvals worldwide including label expansions, a new formulation, and updated storage conditions. The label expansions include use as a booster dose in individuals 12 years and older and pediatric vaccinations in children 5 years and older.

- In November 2021, the U.S. FDA expanded the Emergency Use Authorization (EUA) to include a booster dose of the companies' COVID-19 vaccine in individuals 18 years of age and older given six months after the second dose of the primary regimen.
- In November 2021, the EC approved a variation to the Conditional Marketing Authorization (CMA) for the use of the companies' COVID-19 vaccine in children 5 to less than 12 years of age, following a positive European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP) opinion. The approval was based on results from a Phase 2/3 trial that included approximately 4,500 children 5 to less than 12 years of age. BNT162b2 showed a favorable safety profile, robust immune responses as well as a vaccine efficacy rate of 90.7% in participants without prior SARS-CoV-2 infection, during a period when Delta was the prevalent strain.
- In December 2021, BioNTech and Pfizer announced that the U.S. FDA expanded the EUA to include a booster dose for

individuals 16 years of age and older given at least six months after completion of the primary series.

- In January 2022, BioNTech and Pfizer announced that the U.S. FDA expanded the EUA to include a booster dose for individuals 12 years of age and older, to be given at least 5 months following completion of the primary series.
- The EUA was also expanded to include administration of a third primary series dose at least 28 days following the second dose for immunocompromised individuals 5 to less than 12 years of age.
- In February 2022, BioNTech and Pfizer announced that, following a request from the U.S. FDA, the companies initiated a rolling submission seeking to amend the EUA to include children 6 months to less than 5 years of age in response to the urgent public health need in this population. The application is for the authorization of a three-dose primary series in this age group.
- In February 2022, the EC approved a variation to the CMA to include the administration of BNT162b2 as a booster dose (30µg) at least six months after the second dose in adolescents 12 to less than 18 years of age.
- In February 2022, the EU Product Information of COMIRNATY® was updated to include the use of the vaccine during pregnancy. A large amount of data from pregnant women showed no increase in pregnancy complications. Although data in the first trimester of pregnancy are more limited, no increased risk of miscarriage was seen. The EU Product Information was also updated to include the use during breast-feeding. Data from women who were breast-feeding after vaccination have not shown a risk of adverse effects in breast-fed babies.
- In March 2022, BioNTech and Pfizer announced that the U.S. FDA expanded the EUA for the COVID-19 vaccine to include a second booster dose for individuals aged 50 years and older who have previously received a booster of any authorized or approved COVID-19 vaccine. The U.S. FDA also authorized a second booster dose for individuals 12 years of age and older who have been determined to have certain kinds of immunocompromise and who have received a first booster dose of any authorized or approved COVID-19 vaccine. The second booster is to be administered at least four months after the first booster and is the same formulation and strength as prior doses.

Additional Infectious Disease programs

Infectious diseases are a long-term growth pillar for BioNTech. The Company's objective is to be a leader in mRNA vaccines for infectious diseases. With investments in multiple programs to address diseases with major impact on global population health and on people in lower income countries, the Company is advancing its pipeline of mRNA vaccines and therapeutics to address multiple high-need indications, including influenza, shingles (herpes zoster), malaria, tuberculosis, herpes simplex virus 2 (HSV 2), and HIV.

Influenza Vaccine Program

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

- BNT161 – BioNTech and Pfizer expect data from the Phase 1 clinical trial of BNT161, a modified mRNA vaccine, to evaluate the safety, tolerability and immunogenicity of a single dose quadrivalent mRNA influenza vaccine in the first half of 2022.
- BioNTech and Pfizer also plan to start a clinical study to develop a self-amplifying mRNA, or saRNA, influenza vaccine. This planned dose-finding study will evaluate safety, tolerability, and immunogenicity in healthy adults 18 to less than 50 years of age.

Shingles Vaccine Program

In January 2022, Pfizer and BioNTech signed a new global agreement to develop the first mRNA-based shingles vaccine candidate. Under the terms of the agreement the companies will leverage a proprietary antigen technology identified by Pfizer's scientists and BioNTech's proprietary mRNA platform used in the companies' COVID-19 vaccine. The goal is to develop an mRNA vaccine with a favorable safety profile and high efficacy, utilizing a scalable manufacturing technology to support global access.
Clinical trials are planned to start in the second half of 2022.

Malaria Vaccine Program

BioNTech plans to develop an mRNA vaccine candidate to potentially prevent malaria and disease-associated mortality. The Company will assess several vaccine candidates, featuring known targets such as circumsporozoite protein (CSP) as well as newly discovered antigens.
A clinical trial for an mRNA-based malaria vaccine is planned to start in the second half of 2022.

Tuberculosis Vaccine Program - BNT164

BioNTech has collaborated with the Bill and Melinda Gates Foundation since 2019 to develop vaccine candidates aimed at preventing tuberculosis infection and disease.
There is still a high unmet medical need for a safe, effective, and durable vaccine to prevent the development and spread of pulmonary tuberculosis. The collaboration will initially develop first mRNA vaccine candidates targeting tuberculosis. A clinical trial for a tuberculosis vaccine candidate is planned to begin in the second half of 2022, just two years after the tuberculosis program was initiated.

HSV 2 Vaccine Program

BioNTech is developing an HSV 2 vaccine candidate under a preclinical collaboration with the University of Pennsylvania.
A clinical trial is expected to start in the second half of 2022.

Oncology

BioNTech's immuno-oncology strategy is based on pioneering approaches to modulate the immune response to treat cancer. BioNTech has multiple assets across different therapeutic classes with 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, CAR-T immunotherapies, cell therapies, individualized neoantigen specific immunotherapies, RiboMabs, next-generation checkpoint immunomodulators, anti-tumor antibodies and small molecules. Many product candidates have the potential to be combined with other pipeline assets or previously approved therapies.
This diverse toolkit of different technologies and modes of action has potential to address a broad range of solid tumors in different disease stages, using both off-the-shelf and individualized approaches. BioNTech has assembled libraries of more than 300 proprietary or known shared antigens and has developed predictive algorithms capable of efficiently identifying multiple neoantigens on an individualized basis for any patient.
BioNTech drove strong clinical execution in 2021 with the advancement of four immuno-oncology programs into randomized Phase 2 studies, and five first in human trial starts, bringing the Company's clinical pipeline to a total of 16 product candidates in 20 ongoing clinical trials. BioNTech's clinical stage oncology pipeline now includes 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 checkpoint immunomodulator BNT311 (GEN1046). Also, a first-in-human trial was started in January 2022 for the first product candidate from BioNTech's RiboMabs program, BNT141. BioNTech expects continued pipeline advancement and expansion in 2022.

mRNA programs

FixVac

BioNTech's off-the-shelf FixVac product candidates leverage the Company's proprietary immunogenic mRNA backbone encoding cancer-specific shared antigens in a proprietary RNA-LPX delivery formulation for intravenous administration. FixVac product candidates may be of clinical utility in combination with anti-PD1 in patients with a lower mutational burden, including those who have already experienced checkpoint inhibitor (CPI) therapy.
In 2021, two FixVac programs moved into Phase 2 trials: BNT111 in checkpoint inhibitor refractory/relapsed (CPI-R/R) melanoma and BNT113 in HPV16+ PDL1+ head and neck cancer. In addition, a Phase 1/2 trial is ongoing for BNT112 program in localized and metastatic castrate-resistant prostate cancer.

- BNT111 – A global, three-arm Phase 2 trial evaluating BNT111 in combination with cemiplimab (Regeneron and Sanofi's Libtayo®), versus both agents as monotherapy, in patients with anti-PD1-refractory/relapsed, unresectable Stage III or IV melanoma, is ongoing. The trial is being conducted in collaboration with Regeneron.
  In November 2021, the FDA granted Fast Track Designation for BNT111 for the treatment of advanced melanoma. Previously, the FDA granted Orphan Drug Designation for BNT111 for the treatment of Stage IIB through IV melanoma.
- BNT116 – In March 2022, BioNTech announced the expansion of its strategic collaboration with Regeneron. Under the agreement, the combination of BNT116 and Libtayo is expected to be advanced into clinical development for the treatment of advanced non-small-cell lung cancer (NSCLC). The first-in-human clinical trial to evaluate the safety, tolerability and preliminary efficacy of BNT116 alone and in combination with Libtayo is expected to be initiated in the second half of 2022.

Individualized neoantigen specific immunotherapy (iNeST)

iNeSTs are individualized cancer immunotherapies that target patient-specific neoantigens present in the tumor. BioNTech's iNeST immunotherapy contains pharmacologically optimized uridine mRNA delivered in the Company's proprietary RNA-LPX formulation.

- Autogene Cevumeran (BNT122) – BioNTech's lead iNeST product candidate, autogene cevumeran, is being developed by BioNTech and Genentech as part of a co-development and co-commercialization collaboration.
  Individual mRNA cancer vaccines use the patient's own tumor mutations to generate neoantigen specific CD4 and CD8 T cell responses *in vivo.* BioNTech believes this modality is well-suited for use in early-stage cancers and in the adjuvant setting.
  - In October 2021, BioNTech announced that the first patient was dosed in 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. The trial is expected to enroll about 200 patients to evaluate the efficacy of autogene cevumeran compared to watchful waiting after surgery and chemotherapy, the current standard of care for these high-risk patients. The primary endpoint for the study is disease-free survival. Secondary objectives include overall survival and safety. The trial has been initiated in the United States, Germany, Spain and Belgium.
  - A data update from the ongoing randomized Phase 2 trial of autogene cevumeran combined with pembrolizumab in patients with 1L metastatic melanoma is expected in the second half of 2022.

RiboMabs

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

- BNT141 – encodes a secreted antibody targeting Claudin-18.2, expressed in high unmet medical need tumors, including multiple epithelial solid tumors, such as gastric and pancreatic cancers.
  In January 2022, the first participant was dosed in an open-label, multi-site, Phase 1/2 dose escalation, safety, and pharmacokinetic trial of BNT141 followed by expansion cohorts in patients with Claudin (CLDN)-18.2-positive tumors. The

trial evaluates dose escalation as monotherapy in patients with unresectable or metastatic cancers, followed by dose escalation in combination with standard of care in patients with advanced unresectable or metastatic CLDN18.2-positive pancreatic adenocarcinoma or cholangiocarcinoma who are eligible for treatment with standard of care. After dose escalation, expansion cohorts will be evaluated.

- BNT142 – encodes bispecific antibodies that target CD3, a T cell receptor component that plays a key role in the activation of T cells, and Claudin-6, a highly specific oncofetal cell surface antigen found in solid tumors.
  BioNTech plans to start a Phase 1 clinical trial for BNT142 in the first half of 2022.

Antibodies

Next-generation checkpoint immunomodulators

BioNTech's next generation immunomodulators are designed to prime and activate anti-tumor T-cell and Natural Killer cell function. BioNTech is developing two bispecific antibody checkpoint immunomodulators, BNT311 and BNT312, as part of a 50/50 collaboration with Genmab in which development costs and future profit are shared.

- BNT311/GEN1046 – In December 2021, the first patient was dosed in a Phase 2, multicenter, randomized, open-label trial of BNT311 as monotherapy and in combination with pembrolizumab in subjects with relapsed/refractory metastatic NSCLC after treatment with standard of care therapy with an immune checkpoint inhibitor. This three-arm trial is expected to enroll up to 132 patients with histologically or cytologically confirmed diagnosis of Stage 4 NSCLC with tumor PD-L1 expression of tumor proportion score (TPS) ≥1% and at least one prior line of systemic therapy containing an anti-PD-1/PD-L1 monoclonal antibody and has progressed. The primary endpoint of the study is objective response rate (ORR) according to RECIST v1.1.
  10 expansion cohorts in the Phase 1/2 study are currently ongoing, including patients with NSCLC, triple negative breast cancer (TNBC), urothelial cancer, squamous cell carcinoma of the head and neck (SCCHN), and cervical cancer.

- BNT312/GEN1042 – 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.

Cell therapies

CAR-T cell immunotherapy

BNT211, BioNTech's first CAR-T product candidate, targets CLDN6+ solid tumors in combination with a CAR-T cell-Amplifying RNA Vaccine, or CARVac, encoding the antigen CLDN6. Claudin-6 CAR-T cells are equipped with a second-generation chimeric antigen receptor of high sensitivity and specificity for the tumor-specific carcino-embryonal antigen Claudin-6. CARVac drives *in vivo* expansion of transferred CAR-T cells, increasing 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 Claudin-6-positive solid tumors is ongoing.
  At ESMO-IO in December 2021, BioNTech presented a data update from the ongoing Phase 1/2 trial. As of November 18, 2021, 15 patients have been treated, including patients with testicular, ovarian, endometrial, and fallopian tube cancers, as well as sarcoma. Nine patients received CAR-T cell monotherapy and five patients received CAR-T cells plus CARVac vaccine combination therapy. Overall, the safety profile for monotherapy and combination therapy was tolerable at the dose levels evaluated. Cytokine release syndrome (CRS) was observed in four patients in the monotherapy treatment arm and three patients in the combination treatment arm. CRS cases were all Grade one or two, accompanied by IL-6 elevation, and manageable with tocilizumab if needed.
  Robust engraftment of CAR-T cells, resulting in approximately 10^9 CAR-T cells, was achieved in most patients and suggests the potential for clinical activity. Nine of ten patients evaluable for efficacy assessment showed initial disease control, including four partial responses and five stable disease cases, of which four showed signs of clinical activity with shrinkage of target lesions.
  An oral presentation was accepted at the American Association for Cancer Research (AACR) conference 2022.
  Another data update from the ongoing Phase 1/2 trial is expected in the second half of 2022.

Corporate Updates

- In January 2022, BioNTech announced the design, development and successful testing of an Early Warning System (EWS) in collaboration with InstaDeep. Based on a new computational method, the EWS analyzes worldwide available sequencing data and predicts high-risk variants of SARS-CoV-2. The advanced computational methods developed use artificial intelligence (AI) calculated immune escape and fitness metrics and allow to analyze sequence information of the spike protein and rank new variants according to their predicted immune escape and ACE2 binding score. Results from a study testing the EWS underline that it is capable of evaluating new variants in minutes and risk monitoring variant lineages nearly in real-time. It is also fully scalable as new variant data becomes available.
  This initiative is a cornerstone of BioNTech's objective to drive digital transformation in medicine, bringing together scientific and medical understanding with machine learning. Leveraging this combined expertise will further allow the Company to

differentiate its research and discovery capabilities.

- In January 2022, BioNTech entered into a multi-target discovery collaboration with Crescendo Biologics Ltd. to develop novel immunotherapies for the treatment of patients with cancer and other diseases. Crescendo will contribute its proprietary, transgenic platform to deliver fully human heavy-chain antibody domains (Humabody® VH) against targets nominated by BioNTech.
- In February 2022, BioNTech entered into an asset purchase and option agreement in addition to a multi-target research collaboration with Medigene AG to develop novel T cell receptor-based immunotherapies against cancer. BioNTech will hold exclusive worldwide development and commercialization rights to all T cell receptor (TCR) therapies arising from the collaboration. The initial term of the collaboration is three years.

Environmental, Social, and Governance (ESG) Overview

BioNTech's commitment to social responsibility, responsible governance, environmental and climate protection, respecting human rights, and providing equitable access to medicines is intrinsic to the vision of the Company. To that end, several initiatives to democratize access to our innovative medicines are underway.

- In 2022, BioNTech plans to construct state-of-the-art mRNA manufacturing sites initially in Africa and Asia to establish sustainable local supply that will help to increase the Company's manufacturing capacity in the future.
- In February 2022, BioNTech announced its turnkey manufacturing solution, named "BioNTainer," which is designed to enable scalable mRNA vaccine production in bulk. The novel approach utilizes a modular manufacturing unit made up of state-of-the-art manufacturing containers. BioNTainers will be equipped to manufacture a range of mRNA-based vaccines, which can be targeted to local infectious disease needs. With their scalable and modular approach, BioNTainers are intended to enable production of high-quality mRNA vaccine manufacturing worldwide. The establishment of the first modular mRNA manufacturing facility in the African Union is expected to start in mid-2022 with the first BioNTainer expected to arrive in Africa in the second half of 2022.

BioNTech will publish its second ESG report (Sustainability Report 2021) in the coming days. The report can be found in the Investor Relations section of BioNTech's website.

Key ESG highlights:

- BioNTech's ethical business practices include good corporate governance, social and societal responsibility, and sustainability. BioNTech has signed the United Nations Global Compact. Furthermore, the Management Board variable compensation is linked to the achievement of ESG targets, including maintaining a "Prime" rating from the Institutional Shareholder Services (ISS) ESG rating agency.
- A resolution from the Management Board set climate protection targets fulfilling the requirements of the Science Based Targets Initiative (the "SBTi"). For Scope 1 & 2, the Company targets a greenhouse gas (GHG) emissions absolute reduction of 42% by 2030 against base year 2021. For Scope 3, a supplier engagement target is set to cover at least 2/3 of BioNTech's Scope 3 GHG emissions by 2026, at the latest.
- The Company pursues continuous enhancement of safety, health and environmental management (SHE).
- BioNTech is committed to continuous strengthening of employee recruiting and development. The Company is well diversified with employees from more than 60 countries.
- As part of BioNTech's pledge to equitable access to medicines, the Company expects to supply more than two billion doses of COVID-19 vaccine to low- and middle-income countries by the end of 2022.

Upcoming investor and analyst events

- The Annual General Meeting will take place on June 1, 2022.
- BioNTech today announced that it will host a Capital Markets Day for analysts and investors on June 29, 2022.

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 checkpoint immuno-modulators, targeted cancer antibodies and small molecules. Based on its deep expertise in mRNA vaccine development and in-house manufacturing capabilities, BioNTech and its collaborators are developing multiple mRNA vaccine candidates for a range of infectious diseases alongside its diverse oncology pipeline. BioNTech has established a broad set of relationships with multiple global pharmaceutical collaborators, including Genmab, Sanofi, Genentech, a member of the Roche Group, Regeneron, Genevant, Fosun Pharma and Pfizer.

For more information, please visit www.BioNTech.de

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, including, but not limited to, statements concerning: BioNTech's expected revenues and net profit related to sales of BioNTech's COVID-19 vaccine, referred to as COMIRNATY® where approved for use under full or conditional marketing authorization, in territories controlled by BioNTech's collaboration partners, particularly for those figures that are derived from preliminary estimates provided by BioNTech's partners; BioNTech's pricing

and coverage negotiations with governmental authorities, private health insurers and other third-party payors after BioNTech's initial sales to national governments; the extent to which initial or booster doses of a COVID-19 vaccine continue to be necessary in the future; competition from other COVID-19 vaccines or related to BioNTech's other product candidates, including those with different mechanisms of action and different manufacturing and distribution constraints, on the basis of, among other things, efficacy, cost, convenience of storage and distribution, breadth of approved use, side-effect profile and durability of immune response; the rate and degree of market acceptance of BioNTech's COVID-19 vaccine and, if approved, BioNTech's investigational medicines; the initiation, timing, progress, results, and cost of BioNTech's research and development programs and BioNTech's current and future preclinical studies and clinical trials, including statements regarding the timing of initiation and completion of studies or trials and related preparatory work, the period during which the results of the trials will become available and BioNTech's research and development programs; the timing of and BioNTech's ability to obtain and maintain regulatory approval for BioNTech's product candidates; the collaboration between BioNTech and Pfizer to develop a COVID-19 vaccine (including a potential booster dose of BNT162b2 and/or a potential booster dose of a variation of BNT162b2 having a modified mRNA sequence); the ability of BNT162b2 to prevent COVID-19 caused by emerging virus variants; BioNTech's ability to identify research opportunities and discover and develop investigational medicines; the ability and willingness of BioNTech's third-party collaborators to continue research and development activities relating to BioNTech's development candidates and investigational medicines; the impact of the COVID-19 pandemic on BioNTech's development programs, supply chain, collaborators and financial performance; unforeseen safety issues and claims for personal injury or death arising from the use of BioNTech's COVID-19 vaccine and other products and product candidates developed or manufactured by us; BioNTech's ability to progress BioNTech's Malaria, Tuberculosis and HIV programs, including timing for selecting clinical candidates for these programs and the commencement of a clinical trial, as well as any data readouts; the nature of the collaboration with the African Union and the Africa CDC; the nature and duration of support from WHO, the European Commission and other organizations with establishing infrastructure; the development of sustainable vaccine production and supply solutions on the African continent and the nature and feasibility of these solutions; BioNTech's estimates of research and development revenues, commercial revenues, cost of sales, research and development expenses, sales and marketing expenses, general and administrative expenses, capital expenditures, income taxes, shares outstanding; BioNTech's ability and that of BioNTech's collaborators to commercialize and market BioNTech's product candidates, if approved, including BioNTech's COVID-19 vaccine; BioNTech's ability to manage BioNTech's development and expansion; regulatory developments in the United States and foreign countries; BioNTech's ability to effectively scale BioNTech's production capabilities and manufacture BioNTech's products, including BioNTech's target COVID-19 vaccine production levels, and 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 annual report on Form 20-F for the quarter and year ended December 31, 2021 and in subsequent filings made by BioNTech with the SEC, which are available on the SEC's website at https://www.sec.gov/. Except as required by law, BioNTech disclaims any intention or responsibility for updating or revising any forward-looking statements contained in this 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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Consolidated Statements of Profit or Loss

	Three months ended December 31,		Years ended December 31,		
(in millions, except per share data)	**2021**	**2020**	**2021**	**2020**	**2019**
Revenues					
Research & development revenues	6.6	65.4	102.7	178.8	84.4
Commercial revenues	5,525.9	280.0	18,874.0	303.5	24.2
Total revenues	**€5,532.5**	**€345.4**	**€18,976.7**	**€482.3**	**€108.6**
Cost of sales	(583.2)	(41.0)	(2,911.5)	(59.3)	(17.4)
Research and development expenses	(271.5)	(257.0)	(949.2)	(645.0)	(226.5)
Sales and marketing expenses	(17.9)	(6.7)	(50.4)	(14.5)	(2.7)
General and administrative expenses	(130.9)	(35.9)	(285.8)	(94.0)	(45.5)
Other operating expenses	(67.1)	(1.1)	(94.4)	(2.4)	(0.7)
Other operating income	237.8	240.5	598.4	250.5	2.7
Operating income / (loss)	**€4,699.7**	**€244.2**	**€15,283.8**	**€(82.4)**	**€(181.5)**

Finance income	31.9	0.5	67.7	1.6	4.1
Finance expenses[1]	(17.7)	(39.1)	(305.1)	(65.0)	(2.0)
Profit / (loss) before tax	**€4,713.9**	**€205.6**	**€15,046.4**	**€(145.8)**	**€(179.4)**
Income taxes	(1,547.7)	161.3	(4,753.9)	161.0	0.2
Profit / (loss) for the period	**€3,166.2**	**€366.9**	**€10,292.5**	**€15.2**	**€(179.2)**
Attributable to:					
Equity holders of the parent	3,166.2	366.9	10,292.5	15.2	(179.1)
Non-controlling interests	—	—	—	—	(0.1)
Profit / (loss) for the period	**€3,166.2**	**€366.9**	**€10,292.5**	**€15.2**	**€(179.2)**
Earnings per share[2]					
Basic profit / (loss) for the period per share	€12.96	€1.51	€42.18	€0.06	€(0.85)
Diluted profit / (loss) for the period per share	€12.18	€1.43	€39.63	€0.06	€(0.85)

(1) Finance expenses disclosed separately in prior periods have been condensed.

(2) Capital increase due to 1:18 share split occurred on September 18, 2019. Retroactive effect is reflected in number of shares which relate to the period before the share split.

Consolidated Statements of Financial Position

(in millions)	**December 31, 2021**	**December 31, 2020**
Assets		
Non-current assets		
Intangible assets	€202.4	€163.5
Property, plant and equipment	322.5	227.0
Right-of-use assets	197.9	99.0
Other financial assets	21.3	—
Other assets	0.8	1.0
Deferred expenses	13.6	—
Deferred tax assets	—	161.2
Total non-current assets	**€758.5**	**€651.7**
Current assets		
Inventories	502.5	64.1
Trade and other receivables	12,381.7	165.5
Other financial assets	381.6	137.2
Other assets	64.9	61.0
Income tax assets	0.4	0.9
Deferred expenses	48.5	28.0
Cash and cash equivalents	1,692.7	1,210.2
Total current assets	**€15,072.3**	**€1,666.9**
Total assets	**€15,830.8**	**€2,318.6**
Equity and liabilities		
Equity		
Share capital	246.3	246.3
Capital reserve	1,674.4	1,514.5
Treasury shares	(3.8)	(4.8)
Retained earnings / (accumulated losses)	9,882.9	(409.6)
Other reserves	93.9	25.4
Total equity	**€11,893.7**	**€1,371.8**
Non-current liabilities		
Loans and borrowings	171.6	231.0
Other financial liabilities	6.1	31.5
Income tax liabilities	4.4	—
Provisions	184.9	5.5
Contract liabilities	9.0	71.9
Other liabilities	12.8	0.7
Deferred tax liabilities	66.7	0.2
Total non-current liabilities	**€455.5**	**€340.8**
Current liabilities		

Loans and borrowings	129.9	9.1
Trade payables	160.0	102.3
Other financial liabilities	1,190.4	74.1
Government grants	3.0	92.0
Refund liabilities	90.0	—
Income tax liabilities	1,568.9	—
Provisions	110.2	0.9
Contract liabilities	186.1	299.6
Other liabilities	43.1	28.0
Total current liabilities	**€3,481.6**	**€606.0**
Total liabilities	**€3,937.1**	**€946.8**
Total equity and liabilities	**€15,830.8**	**€2,318.6**

Consolidated Statements of Cash Flows

	Three months ended December 31,		Years ended December 31,		
(in millions)	**2021**	**2020**	**2021**	**2020**	**2019**
Operating activities					
Profit / (loss) for the period	€3,166.2	€366.9	€10,292.5	€15.2	€(179.2)
Income taxes	1,547.7	(161.3)	4,753.9	(161.0)	(0.2)
Profit / (loss) before tax	**€4,713.9**	**€205.6**	**€15,046.4**	**€(145.8)**	**€(179.4)**
Adjustments to reconcile profit / (loss) before tax to net cash flows:					
Depreciation and amortization of property, plant, equipment, intangible assets and right-of-use assets	26.0	12.5	75.2	38.7	33.9
Share-based payment expense	18.1	7.3	80.5	32.1	30.2
Net foreign exchange differences	(92.0)	41.3	(387.5)	41.3	0.1
Gain on disposal of property, plant and equipment	4.2	(0.1)	4.6	0.6	0.5
Finance income	(0.3)	(0.5)	(1.5)	(1.6)	(1.8)
Finance expense	2.2	13.6	305.2	22.3	2.0
Movements in government grants	20.6	100.5	(89.0)	92.0	—
Other non-cash income	(2.2)	1.9	(2.2)	1.7	—
Net loss on derivative instruments at fair value through profit or loss	32.4	—	57.3	—	—
Working capital adjustments:					
Decrease / (Increase) in trade and other receivables, contract assets and other assets	(1,712.9)	(193.0)	(11,808.1)	(247.9)	2.9
Increase in inventories	(109.1)	(49.3)	(438.4)	(49.8)	(5.8)
(Decrease) / Increase in trade payables, other financial liabilities, other liabilities, contract liabilities, refund liabilities and provisions	362.2	110.1	1,516.1	204.6	(80.6)
Interest received	0.2	0.6	1.2	1.4	1.3
Interest paid	(6.1)	(2.0)	(12.2)	(3.6)	(2.0)
Income tax received / (paid), net	(3,456.9)	0.7	(3,457.9)	0.5	0.2
Net cash flows from / (used in) operating activities	**€(199.7)**	**€249.2**	**€889.7**	**€(13.5)**	**€(198.5)**
Investing activities					
Purchase of property, plant and equipment	(39.3)	(25.3)	(127.5)	(66.0)	(38.6)
Proceeds from sale of property, plant and equipment	2.0	1.2	3.4	1.2	—
Purchase of intangibles assets and right-of-use assets	(14.0)	(14.2)	(26.5)	(19.4)	(32.5)
Acquisition of subsidiaries and businesses, net of cash acquired	(20.8)	(61.5)	(20.8)	(60.6)	(6.1)
Investment into equity instruments designated at fair value through OCI	(19.5)	—	(19.5)	—	—
Investment into cash deposit with an original term of six months	(375.2)	—	(375.2)	—	—
Net cash flows used in investing activities	€(466.8)	€(99.8)	€(566.1)	€(144.8)	€(77.2)
Financing activities					
Proceeds from issuance of share capital and treasury shares, net of costs	—	72.9	160.9	753.0	375.4
Proceeds from loans and borrowings	—	53.6	—	156.0	11.0
Repayment of loans and borrowings	(50.7)	(0.7)	(52.6)	(1.6)	—
Payments related to lease liabilities	1.8	(9.5)	(14.1)	(12.7)	(3.1)
Net cash flows from / (used in) financing activities	**€(48.9)**	**€116.3**	**€94.2**	**€894.7**	**€383.3**
Net increase / (decrease) in cash and cash equivalents	(715.4)	265.7	417.8	736.4	107.6

Change in cash and cash equivalents resulting from exchange rate differences	15.4	(46.0)	64.7	(45.3)	—
Cash and cash equivalents at the beginning of the period	2,392.7	990.5	1,210.2	519.1	411.5
Cash and cash equivalents at December 31	**€1,692.7**	**€1,210.2**	**€1,692.7**	**€1,210.2**	**€519.1**