

BioNTech Announces Fourth Quarter and Full Year 2023 Financial Results and Corporate Update

- Advanced oncology pipeline in mid- and late-stage with plans to have ten or more potentially registrational oncology trials running by the end of 2024
- Aiming for first oncology launch in 2026 and ten indication approvals by 2030 as part of BioNTech's strategy to develop combinatorial and synergistic therapeutic approaches
- Entered strategic collaborations with Biotheus, DualityBio, Medilink and OncoC4 to complement clinical oncology pipeline with innovative antibody-drug conjugate (ADC) and immuno-modulatory programs
- Annemarie Hanekamp appointed as Chief Commercial Officer effective July 1, 2024
- Delivered over 400 million COVID-19 vaccine doses worldwide in 2023, including successfully launched XBB.1.5 variant-adapted monovalent COVID-19 vaccine
- Progressed three infectious disease vaccine candidates into clinical evaluation, leveraging BioNTech's mRNA technology and expertise
- Fourth quarter and full year 2023 revenues of €1.5 billion and €3.8 billion, respectively
- Full year net profit of €0.9 billion and fully diluted earnings per share of €3.83 (\$4.14¹)
- Strong financial position with €17.7 billion in cash, cash equivalents and security investments
- 2024 revenue guidance of €2.5 billion to €3.1 billion

Conference call and webcast scheduled for March 20, 2024, at 8:00 a.m. ET (1:00 p.m. CET)

MAINZ, Germany, March 20, 2024 (GLOBE NEWSWIRE) -- [BioNTech SE](#) (Nasdaq: BNTX, "BioNTech" or "the Company") today reported financial results for the three months and full year ended December 31, 2023, and provided an update on its corporate progress.

"2023 was another year of good performance for BioNTech. We have maintained our leading position in the COVID-19 vaccine market which lays the foundation for establishing a sustainable respiratory vaccines business. In oncology, we have strengthened our core competencies by entering into several partnerships and have made numerous clinical advances. Today, our oncology pipeline encompasses multiple candidates in mid- and late-stage clinical development, including investigational ADCs, mRNA vaccines and innovative immunotherapies," **said Prof. Ugur Sahin, M.D., CEO and Co-Founder of BioNTech.** "Our goal is to achieve product approvals in ten oncological indications by 2030 and with this improve the treatment options for patients around the globe."

Financial Review for the Fourth Quarter and Full Year 2023 Financial Results

<i>in millions €, except per share data</i>	Fourth Quarter 2023	Fourth Quarter 2022	Full Year 2023	Full Year 2022
Total Revenues	1,479.0	4,278.3	3,819.0	17,310.6
Net Profit	457.9	2,278.7	930.3	9,434.4
Diluted Earnings per Share	1.90	9.26	3.83	37.77

Total revenues reported were €1,479.0 million for the three months ended December 31, 2023, compared to €4,278.3 million for the comparative prior year period. For the year ended December 31, 2023, total revenues were €3,819.0 million, compared to €17,310.6 million for the comparative prior year period. Inventory write-downs by BioNTech's collaboration partner Pfizer, Inc. ("Pfizer") reduced BioNTech's revenues by €291.3 million and €906.7 million for the three and twelve months ended December 31, 2023, respectively.

Cost of sales were €179.1 million for the three months ended December 31, 2023, compared to €183.5 million for the comparative prior year period. For the year ended December 31, 2023, cost of sales were €599.8 million, compared to €2,995.0 million for the comparative prior year period. The change was mainly caused by the decrease in COVID-19 vaccine sales.

Research and development (R&D) expenses were €577.8 million for the three months ended December 31, 2023, compared to €509.8 million for the comparative prior year period. For the year ended December 31, 2023, research and development expenses were €1,783.1 million, compared to €1,537.0 million for the comparative prior year period. R&D expenses are mainly influenced by progressing clinical studies for pipeline candidates as well as by our newly acquired product

candidates and the development of variant-adapted COVID-19 vaccines. The increase was further driven by an increase in wages, benefits and social security expenses resulting from an increase in headcount.

General and administrative (G&A) expenses reached €124.3 million for the three months ended December 31, 2023, compared to €119.9 million for the comparative prior year period. For the year ended December 31, 2023, G&A expenses were €495.0 million, compared to €481.7 million for the comparative prior year period. G&A expenses were mainly influenced by increased expenses for IT services as well as by wages, benefits and social security expenses resulting from an increase in headcount.

Income taxes were accrued in an amount of €205.3 million for the three months ended December 31, 2023, compared to €893.9 million accrued for the comparative prior year period. For the year ended December 31, 2023, income taxes were accrued with an amount of €255.8 million, compared to €3,519.7 million accrued for the comparative prior year period. The derived annual effective income tax rate for the year ended December 31, 2023, was 21.6%.

Net profit was €457.9 million for the three months ended December 31, 2023, compared to €2,278.7 million for the comparative prior year period. For the year ended December 31, 2023, net profit was €930.3 million, compared to €9,434.4 million net profit for the comparative prior year period.

Cash and cash equivalents as well as security investments² as of December 31, 2023, reached €17,653.4 million, comprising €11,663.7 million cash and cash equivalents and €5,989.0 million security investments, respectively.

Diluted earnings per share was €1.90 for the three months ended December 31, 2023, compared to diluted earnings per share of €9.26 for the comparative prior year period. For the year ended December 31, 2023, diluted earnings per share were €3.83, compared to €37.77 diluted earnings per share for the comparative prior year period.

Shares outstanding as of December 31, 2023, were 237,725,735, excluding 10,826,465 shares held in treasury.

In March 2023, the Management Board and Supervisory Board authorized the 2023 share repurchase program, under which BioNTech was permitted to purchase ADSs, each representing one ordinary share, with a value of up to \$0.5 billion, which started June 2, 2023, and concluded on September 18, 2023. During the three months ended December 31, 2023, 114,513 ADSs were repurchased under the share repurchase program at an average price of \$112.22 (€105.07), for total consideration of \$12.9 million (€12.0 million). For the year ended December 31, 2023, a total of 4,646,965 ADSs were repurchased related to the 2023 program at an average price of \$107.58 (€98.24), for total consideration of \$0.5 billion (€456.5 million).

“In 2023, we strengthened our financial position while concurrently progressing our clinical pipeline of immunotherapies and executing acquisitions and collaborations. Looking ahead to 2024, we will maintain a prudent capital allocation strategy as we invest and execute in our maturing pipeline and prepare for our first potential oncology launches,” **said Jens Holstein, CFO of BioNTech.** “Our COVID-19 vaccine franchise is expected to remain an important cash contributor in 2024. We believe our solid financial position will enable us to push forward with our long-term strategy to develop novel therapies against cancer, infectious and other severe diseases thereby generating added value for patients, society, investors and the Company.”

Outlook for the 2024 Financial Year

The Company's outlook contains the following components:

Total revenues for the 2024 financial year	€2.5 billion - €3.1 billion
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BioNTech expects group revenue for the full 2024 financial year to be in the range of €2.5 - €3.1 billion. The range reflects certain assumptions, including, but not limited to, expectations regarding: the timing and grant of regulatory approvals and recommendations, COVID-19 vaccine

uptake and price levels, inventory write-downs by BioNTech's collaboration partner Pfizer that would negatively influence the Company's revenues, seasonal variations in SARS-CoV-2 circulation and vaccination uptake which are expected to lead to demand peaks in the autumn and winter compared to other seasons, revenues from a pandemic preparedness contract with the German government as well as revenues from BioNTech Group service businesses, namely InstaDeep, JPT Peptide Technologies GmbH and in Idar-Oberstein at BioNTech Innovative Manufacturing Services GmbH. Generally, the Company continues to remain largely dependent on revenues generated in its collaboration partner's territories in 2024.

Planned 2024 Financial Year Expenses and Capex³:

R&D expenses ⁴	€2.4 billion - €2.6 billion
SG&A expenses ⁵	€700 million - €800 million
Capital expenditures for operating activities	€400 million - €500 million

BioNTech expects to continue to focus investments on R&D and scaling the business for commercial readiness in oncology, while continuing to be cost disciplined. Strategic capital allocation will continue to be an important driver of the Company's trajectory. As part of BioNTech's strategy, the Company may continue to evaluate appropriate corporate development opportunities with the aim of driving sustainable long-term growth and create future value.

The full audited consolidated financial statements as of and for the year ended December 31, 2023, can be found in BioNTech's Annual Report on Form 20-F for the period ended December 31, 2023, filed today with the United States Securities and Exchange Commission ("SEC") and available at <https://www.sec.gov/> (the "Annual Report").

Endnotes

¹ Calculated applying the average foreign exchange rate for the year ended December 31, 2023, as published by the German Central Bank (Deutsche Bundesbank).

² The contractual settlement of the gross profit share has a temporal offset of more than one calendar quarter. As Pfizer's financial quarter for subsidiaries outside the United States differs from BioNTech's, it creates an additional time lag between the recognition of revenues and the payment receipt.

³ Numbers reflect current base case projections and are calculated based on constant currency rates, and exclude external risks that are not yet known and/or quantifiable, including, but not limited to, the effects of ongoing and/or future legal disputes or related activity.

⁴ Numbers include effects identified from additional collaborations or potential M&A transactions to the extent disclosed and are subject to update due to future developments.

⁵ Anticipated expenses related to external legal advice in connection with certain legal litigations are not reflected in SG&A but in other operating expenses. Guidance does not include and may be impacted by potential payments resulting from the outcomes of ongoing or future legal disputes or related activity, such as judgments or settlements.

Operational Review of the Fourth Quarter 2023, Key Post Period-End Events and 2024 Outlook

Omicron XBB.1.5-adapted Monovalent COVID-19 Vaccine (COMIRNATY®)

- BioNTech and Pfizer developed, manufactured and delivered their Omicron XBB.1.5-adapted monovalent COVID-19 vaccine, which has received multiple regulatory approvals, including full approvals, authorizations for emergency or temporary use, or marketing authorizations in more than 40 countries and regions. In 2023, BioNTech and Pfizer delivered more than 400 million COVID-19 vaccine doses worldwide.

COVID-19 – Influenza Combination Vaccine Program

BNT162b2 + BNT161 is an mRNA-based combination vaccine program against COVID-19 and influenza being developed in collaboration with Pfizer.

- Topline data from the Phase 1/2 trial ([NCT05596734](https://clinicaltrials.gov/ct2/show/study/NCT05596734)) demonstrated robust immune responses to influenza A, influenza B, and SARS-CoV-2 strains and that the safety profile of the candidates

was consistent with that of the companies' COVID-19 vaccine. A Phase 3 clinical trial ([NCT06178991](#)) was initiated in December 2023.

Select Oncology Pipeline Highlights

BioNTech's vision for oncology is to bring novel therapies to patients and address the continuum of cancer treatment, from early to late lines. Addressing root causes of cancer treatment failure such as cancer heterogeneity and interindividual variability is the core of its strategy. To augment anti-tumor activity and to counteract resistance mechanisms, BioNTech seeks to combine compounds with non-overlapping, synergistic mechanisms of action.

In 2023, the Company's pipeline continued to mature, with various programs advancing towards later stages of development. BioNTech's oncology pipeline currently contains 10 ongoing Phase 2 and 3 trials. In 2024, the Company expects to continue building its pipeline towards its planned first oncology launch in 2026. BioNTech aims to have ten indication approvals by 2030.

Antibody-Drug Conjugate (ADC) Programs

BNT323/DB-1303 is an ADC candidate targeting Human Epidermal Growth Factor 2 (HER2) that is being developed in collaboration with Duality Biologics (Suzhou) Co. Ltd. ("DualityBio").

- An ongoing randomized, multi-center, open-label Phase 3 clinical trial ([NCT06018337](#)) is recruiting to evaluate BNT323/DB1303 versus the investigator's choice of chemotherapy in advanced or metastatic Hormone Receptor (HR)+, HER2-low breast cancer subjects whose disease has progressed on at least two lines of prior endocrine therapy or within six months of first-line endocrine therapy + cyclin-dependent kinase 4/6 (CDK4/6) inhibitor therapy without prior chemotherapy. The first patient was dosed in January 2024 and the trial aims to enroll 532 patients.
- A potentially registrational single-arm trial enrolling HER2-expressing (immunohistochemistry score ("IHC") 3+, 2+, 1+ or in situ hybridization ("ISH")-positivet) patients with endometrial carcinoma is ongoing and plans to enroll 140 patients.
- In December 2023, the U.S. Food and Drug Administration ("FDA") granted Breakthrough Therapy designation for BNT323/DB-1303 for the potential treatment of advanced endometrial cancer in patients whose disease progressed on or after treatment with immune checkpoint inhibitors.
- First-in-human data from the ongoing Phase 1/2 trial ([NCT05150691](#)) were presented at medical conferences in 2023, indicating a manageable safety profile and anti-tumor activity in patients with heavily pretreated HER2-expressing solid tumors, including breast and endometrial cancer. Data from this trial informed the decision to further evaluate this candidate in these indications in the aforementioned studies.
- Additional trials with registrational potential are planned to be initiated in 2024.

BNT325/DB-1305 is an ADC candidate targeting Trophoblast Cell-surface Antigen 2 ("TROP2") that is being developed in collaboration with DualityBio.

- Data from the ongoing Phase 1/2 clinical trial ([NCT05438329](#)) were presented at the 2023 European Society for Medical Oncology ("ESMO") Annual Meeting. The dose range with manageable safety profile was determined. Encouraging preliminary activity was observed in heavily pretreated patients with advanced/metastatic solid tumors.
- In November 2023, two new cohorts were added to the study: one to evaluate BNT325/DB-1305 monotherapy in cervical cancer, and one to assess the combination of BNT325/DB-1305 with pembrolizumab in non-small cell lung cancer ("NSCLC").
- In January 2024, BioNTech and DualityBio received Fast Track designation for BNT325/DB-1305 from the FDA for the treatment of patients with platinum-resistant ovarian epithelial, fallopian tube, or primary peritoneal cancer who have received one to three prior systemic treatment regimens.

Next-Generation Immune Checkpoint Immunomodulator Programs

BNT316/ONC-392 (gotistobart) is an anti-CTLA-4 monoclonal antibody candidate being developed in collaboration with OncoC4, Inc. ("OncoC4").

- In June 2023, a Phase 3 clinical trial ([NCT05671510](#)) was initiated to evaluate BNT316/ONC-392 (monotherapy in patients with metastatic NSCLC whose disease progressed on anti-PD-1/PD-L1 antibody-based therapy).
- In November 2023, clinical data from the ongoing Phase 1/2 trial ([NCT04140526](#)) were presented at the Society for Immunotherapy of Cancer ("SITC") Annual Meeting in which BNT316/ONC-392 was observed to have a manageable safety profile. The data also included encouraging clinical activity observations in patients with immunotherapy-resistant NSCLC, which informed the decision to proceed the Phase 3 clinical trial.
- In December 2023, the first patient was dosed in a Phase 1/2 clinical trial ([NCT05682443](#)) to evaluate the efficacy and safety of BNT316/ONC-392 in combination with the radioligand therapy, lutetium (¹⁷⁷Lu) vipivotide tetraxetan in patients with metastatic castration-resistant prostate cancer ("mCRPC") who have progressed on an androgen receptor pathway inhibitor.

BNT311/GEN1046 (acasunlimab) is a potential first-in-class bispecific antibody candidate combining PD-L1 checkpoint inhibition with 4-1BB costimulatory activation that is being developed in collaboration with Genmab S/A ("Genmab").

- Based on emerging clinical data, the companies are engaging with health authorities on the design of a Phase 3 trial in second-line NSCLC. The companies intend to share initial data at a medical conference in the first half of 2024 from an ongoing Phase 2 randomized, open-label clinical trial ([NCT05117242](#)) evaluating BNT311/GEN1046 as monotherapy and in combination with pembrolizumab in patients with relapsed/refractory metastatic NSCLC and a tumor PD-L1 expression of tumor proportion score of ≥1% after treatment with standard-of-care therapy with an immune checkpoint inhibitor. The primary endpoint is objective response rate according to Response Evaluation Criteria in Solid Tumors ("RECIST v1.1"). Secondary endpoints include duration of response, time to response, progression-free survival, overall survival and safety.

BNT312/GEN1042 is a potential first-in-class bispecific antibody candidate designed to induce conditional immune activation by crosslinking CD40 and 4-1BB positive cells that is being developed in collaboration with Genmab.

- The companies intend to share updated data at a medical conference in the second half of 2024 from an ongoing Phase 1/2 dose-escalation clinical trial ([NCT04083599](#)) with expansion cohorts evaluating safety and anti-tumor activity of BNT312/GEN1042 as monotherapy and in combination therapies in patients with solid tumors. The companies also expect to determine next steps for this program in 2024.

BNT327/PM8002 is an anti-VEGF-A antibody candidate fused to a humanized anti-PD-L1 VHH that is being developed in collaboration with Biotheus Inc. ("Biotheus"). BNT327/PM8002 is currently being evaluated in Phase 1 and Phase 2/3 clinical trials in China to assess the efficacy and safety of the candidate as a monotherapy or in combination with chemotherapy in various indications, including in first line small-cell lung cancer ("SCLC") and second-line Epidermal Growth Factor Receptor ("EGFR")-mutated NSCLC.

- Data from a Phase 1/2 clinical trial in advanced solid tumors presented in 2023 indicate that BNT327/PM8002 monotherapy may have antitumor activity and a manageable safety profile.
- Data from Phase 2 trials in patients with SCLC and triple-negative breast cancer ("TNBC") presented in 2023 indicate that BNT327/PM8002 in combination with chemotherapy may have encouraging antitumor activity and an acceptable toxicity profile as second and first-line therapy, respectively.
- An Investigational New Drug ("IND") application has been accepted by the FDA for further studies in the United States. Global trials are planned to start in 2024.

Cancer Vaccine Programs

BNT116 is based on BioNTech's FixVac platform, and is a wholly owned, systemically administered, off-the-shelf uridine mRNA-lipoplex based cancer vaccine candidate encoding six shared lung cancer associated antigens. BNT116 is being evaluated for the treatment of advanced NSCLC.

- A randomized, controlled Phase 2 clinical trial ([NCT05557591](#)) is ongoing to evaluate BNT116 in combination with cemiplimab versus cemiplimab alone as first-line treatment in patients with advanced NSCLC whose tumors express PD-L1 in ≥ 50% of tumor cells.

- In November 2023, data from the ongoing Phase 1 clinical trial ([NCT05142189](#)) evaluating the safety, tolerability and preliminary efficacy of BNT116 alone and in combination with cemiplimab or chemotherapy were presented at the 2023 SITC Annual Meeting. BNT116 was observed to be generally well tolerated with an expected safety profile as monotherapy and in combination with cemiplimab. In heavily pretreated NSCLC patients, early clinical activity was observed for treatment with BNT116 with the addition of cemiplimab from cycle 3 onward.
- Additional data from a different cohort of this Phase 1 clinical trial evaluating BNT116 in combination with docetaxel in patients with NSCLC that progressed on prior anti-PD(L)-1 therapy will be presented at the 2024 American Association of Cancer Research ("AACR") Annual Meeting in April 2024.

Autogene cevumeran (BNT122) is an uridine mRNA-lipoplex based cancer vaccine candidate for individualized neoantigen-specific immunotherapy ("iNeST") being developed in collaboration with Genentech, Inc. ("Genentech"), a member of the Roche Group ("Roche").

- In October 2023, BioNTech announced the initiation of a Phase 2 trial ([NCT05968326](#)) evaluating the efficacy and safety of BNT122 in combination with the anti-PD-L1 immune checkpoint inhibitor atezolizumab and standard-of-care chemotherapy in patients with resected pancreatic ductal adenocarcinoma ("PDAC").
- Follow-up data from the investigator-initiated Phase 1 trial in patients with resected PDAC, which informed and motivated the Phase 2 trial, are due to be presented at the AACR Annual Meeting in April 2024. The results of the Phase 1 trial were published in *Nature* ([Rojas et al., Nature 2023](#)).
- An additional Phase 2 clinical trial is planned to be initiated as early as 2024.

Cell Therapy Programs

BNT211 is a CAR-T cell product candidate targeting Claudin-6 ("CLDN6")-positive solid tumors that is combined with a CAR-T cell-amplifying RNA vaccine ("CARVac") encoding CLDN6.

- An open-label, multi-center Phase 1/2 dose escalation and dose expansion basket trial ([NCT04503278](#)) evaluating CLDN6 CAR-T cells with or without a CLDN6 CARVac in CLDN6-positive relapsed or refractory advanced solid tumors, including ovarian and testicular cancers, is ongoing. Data from this trial were reported at several conferences, including ASCO and ESMO 2023. Encouraging signs of activity were observed. In several patients treated with CARVac, an increased persistence of CLDN6 CAR-T cells was observed. The rate of treatment-dependent adverse event was dose-dependent and further evaluation is ongoing to determine the CLDN6 CAR-T dose with manageable safety.
- A pivotal Phase 2 clinical trial in relapsed/refractory germ cell tumors is planned to start in 2024.

Select Infectious Disease Pipeline Highlights

Beyond BioNTech's portfolio of variant-adapted, next-generation and combination respiratory programs, the Company is developing vaccine modalities against multiple pathogens that pose a threat to public health and have a significant global health burden.

In 2023, BioNTech initiated three first-in-human Phase 1 clinical trials leveraging its proprietary mRNA prophylactic vaccine technology. These trials are for vaccine candidates addressing shingles ([NCT05703607](#)), tuberculosis ([NCT05537038](#), Germany, and [NCT05547464](#), Republic of South Africa) and mpox ([NCT05988203](#)).

Corporate Update for 2023 and Key Post Period-End Events

In 2023, BioNTech strategically forged a series of complementary agreements and collaborations, including:

- The acquisition of its long-time strategic collaboration partner, InstaDeep Ltd ("InstaDeep"), which provides BioNTech with capabilities to leverage artificial intelligence (AI) and machine learning (ML) technologies across its therapeutic platforms and operations. With this acquisition, BioNTech has added industry-leading AI and ML capabilities and approximately 290 highly skilled professionals to its organization. InstaDeep is operating as a London-based subsidiary of BioNTech.

- New collaborations with DualityBio and MediLink Therapeutics (Suzhou) Co., Ltd. (“MediLink”), which expanded BioNTech’s technology base into ADCs, and collaborations with OncoC4 and Biotheus that have complemented the Company’s pipeline with mid-to-late-stage novel immunomodulators.
- A strategic partnership with the Government of the United Kingdom (“UK”) aiming to lead to personalized mRNA cancer immunotherapies reaching up to 10,000 patients by 2030. BioNTech also plans to invest in a research and development hub in Cambridge, UK, which is expected to employ more than 70 additional highly skilled scientists.
- A multi-year strategic partnership with the State of Victoria, Australia, to set up and operate a clinical-scale mRNA manufacturing facility through its BioNTainers, BioNTech’s modular, state-of-the-art mRNA manufacturing solution, and to establish an mRNA Innovation Center in Melbourne.

Over the last 12 months, BioNTech expanded its organization in Asia, Africa, North America, Australia and Europe. The Company increased its research and development and production capabilities and completed construction of its first proprietary plasmid DNA manufacturing facility in Marburg, Germany. BioNTech also delivered and set up the first BioNTainer for its site in Kigali, Rwanda.

In February 2024, BioNTech entered into a strategic collaboration with Autolus Therapeutics plc (“Autolus”) aimed at advancing both companies’ autologous CAR-T programs towards commercialization, pending regulatory authorizations. The collaboration also grants BioNTech the option to access a suite of Autolus’ target binders and cell programming technologies to support BioNTech’s development of *in vivo* cell therapy and ADC candidates.

In March 2024, BioNTech announced that Sean Marett, Chief Business and Commercial Officer, will retire as planned from the Management Board of BioNTech. As of July 1, 2024, Sean Marett will continue as a specialist advisor to the Company at least until the end of the year. As announced earlier today, Annemarie Hanekamp will be joining the Company’s Management Board as Chief Commercial Officer on July 1, 2024. Sean Marett’s responsibilities as Chief Business Officer are being gradually transferred to James Ryan, Ph.D., Chief Legal Officer, who joined the Management Board in September 2023 and who will also take on the role as Chief Business Officer of BioNTech at the end of the transition phase and upon Sean Marett’s retirement.

Environmental, Social, and Governance (ESG)

In February 2024, the Company’s near-term science-based emissions reduction targets were approved by the Science Based Targets initiative (“SBTi”). This validation underscores the ambitious nature of BioNTech’s scope 1 and scope 2 climate targets and is intended to align with the United Nations’ Paris Climate Agreement to limit global warming to 1.5 degrees Celsius above pre-industrial levels. More information on BioNTech’s Scope 1, 2 and 3 targets can be found in the [Company’s press release dated February 12, 2024](#).

BioNTech’s performance on environmental, social, and governance matters is regularly assessed by external rating agencies. The Institutional Shareholder Services Group (“ISS”) currently assigns BioNTech a “Prime” ESG rating: the Company has received an overall corporate rating of B-, which is among the top 10% of all rated companies in the pharmaceutical and biotechnology sector. In the ISS Governance Quality Score, BioNTech stands at 5 on a risk scale of 1 (low risk) to 10 (high risk). S&P Global Ratings has rated BioNTech in the S&P Corporate Sustainability Assessment 2023 (“CSA”) with an S&P Global CSA score of 45 (2022: 32) out of 100. Morningstar Sustainability has given BioNTech a Sustainalytics ESG rating of 24.1 (2022: 22.3), which corresponds to a “medium risk”, the third of five risk levels (negligible, low, medium, high and severe).

BioNTech publishes its ESG report (Sustainability Report 2023) today, March 20, 2024. The report is being made available on the Investors’ section of BioNTech’s website.

Upcoming Investor and Analyst Events

- Annual General Meeting: May 17, 2024
- Innovation Series (Digital & AI Day): October 1, 2024
- Innovation Series: November 14, 2024

Conference Call and Webcast Information

BioNTech invites investors and the general public to join a conference call and webcast with investment analysts today, March 20, 2024, at 8:00 a.m. ET (1:00 p.m. CET) to report its financial results and provide a corporate update for the fourth quarter and financial year 2023.

To access the live conference call via telephone, please register [via this link](#). Once registered, dial-in numbers and a pin number will be provided.

The slide presentation and audio of the webcast will be available [via this link](#).

Participants may also access the slides and the webcast of the conference call via the “Events & Presentations” page of the Investors' section of the Company's website at <https://biontech.com>. 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 global next generation immunotherapy company pioneering novel therapies for cancer and other serious diseases. BioNTech 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 (CAR) T cells, several protein-based therapeutics, including bispecific immune checkpoint modulators, targeted cancer antibodies and antibody-drug conjugate (ADC) therapeutics, as well as 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 and specialized pharmaceutical collaborators, including Biotheus, DualityBio, Fosun Pharma, Genentech, a member of the Roche Group, Genevant, Genmab, OncoC4, Pfizer and Regeneron.

For more information, please visit www.BioNTech.com.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, including, but not limited to, statements concerning: BioNTech's expected revenues and net profit related to sales of BioNTech's COVID-19 vaccine, referred to as COMIRNATY where approved for use under full or conditional marketing authorization, in territories controlled by BioNTech's collaboration partners, particularly for those figures that are derived from preliminary estimates provided by BioNTech's partners; the rate and degree of market acceptance of BioNTech's COVID-19 vaccine and, if approved, BioNTech's investigational medicines; expectations regarding anticipated changes in COVID-19 vaccine demand, including changes to the ordering environment and expected regulatory recommendations to adapt vaccines to address new variants or sublineages; 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, enrollment, and completion of studies or trials and related preparatory work and the availability of results, and the timing and outcome of applications for regulatory approvals and marketing authorizations; BioNTech's expectations with respect to its intellectual property; the impact of BioNTech's collaboration and licensing agreements and its acquisition of InstaDeep Ltd.; the development, nature and feasibility of sustainable vaccine production and supply solutions; and BioNTech's estimates of revenues, research and development expenses, cost of sales, general and administrative expenses, and capital expenditures for operating activities. 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.

These risks and uncertainties include, but are not limited to: BioNTech's pricing and coverage negotiations regarding its COVID-19 vaccine 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 timing of and BioNTech's ability to obtain and maintain regulatory approval for BioNTech's product candidates; the ability of BioNTech's COVID-19 vaccines 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 potential claims that are alleged to arise from the use of BioNTech's COVID-19 vaccine and other products and product candidates developed or manufactured by BioNTech; BioNTech's and its collaborators' ability to commercialize and market BioNTech's COVID-19 vaccine and, if approved, its product candidates; BioNTech's ability to manage its development and expansion; regulatory developments in the United States and other countries; BioNTech's ability to effectively scale its production capabilities and manufacture its products, including target COVID-19 vaccine production levels, and product candidates; risks relating to the global financial system and markets; and other factors not known to BioNTech at this time.

You should review the risks and uncertainties described under the heading "Risk Factors" in BioNTech's Annual Report on Form 20-F for the year ended December 31, 2023 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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Statements of Profit or Loss

	Three months ended December 31,		Years ended December 31,		
	2023	2022	2023	2022	2021
<i>(in millions €, except per share data)</i>	<i>(unaudited)</i>	<i>(unaudited)</i>			
Revenues					
Commercial revenues	1,478.9	4,271.3	3,815.5	17,194.6	18,874.0
Research & development revenues	0.1	7.0	3.5	116.0	102.7
Total revenues	1,479.0	4,278.3	3,819.0	17,310.6	18,976.7
Cost of sales	(179.1)	(183.5)	(599.8)	(2,995.0)	(2,911.5)
Research and development expenses	(577.8)	(509.8)	(1,783.1)	(1,537.0)	(949.2)
Sales and marketing expenses	(18.0)	(14.6)	(62.7)	(59.5)	(50.4)
General and administrative expenses	(124.3)	(119.9)	(495.0)	(481.7)	(276.8)
Other operating expenses ⁽¹⁾	(57.6)	(379.2)	(293.0)	(410.0)	(103.4)
Other operating income ⁽¹⁾	4.0	221.6	105.0	815.3	598.4
Operating income	526.2	3,292.9	690.4	12,642.7	15,283.8
Finance income	162.2	38.8	519.6	330.3	67.7
Finance expenses	(25.2)	(159.1)	(23.9)	(18.9)	(305.1)
Profit before tax	663.2	3,172.6	1,186.1	12,954.1	15,046.4
Income taxes	(205.3)	(893.9)	(255.8)	(3,519.7)	(4,753.9)
Profit for the period	457.9	2,278.7	930.3	9,434.4	10,292.5
Earnings per share					
Basic earnings for the period per share	1.91	9.38	3.87	38.78	42.18
Diluted earnings for the period per share	1.90	9.26	3.83	37.77	39.63

⁽¹⁾ Adjustments to prior-year figures due to change in functional allocation of general and administrative expenses and other operating expenses

Statements of Financial Position

<i>(in millions €)</i>	December 31, 2023	December 31, 2022
Assets		
Non-current assets		
Goodwill	362.5	61.2
Other intangible assets	804.1	158.5
Property, plant and equipment	757.2	609.2
Right-of-use assets	214.4	211.9
Other financial assets	1,176.1	80.2
Other non-financial assets	83.4	6.5
Deferred tax assets	81.3	229.6
Total non-current assets	3,479.0	1,357.1
Current assets		
Inventories	357.7	439.6
Trade and other receivables	2,155.7	7,145.6
Contract assets	4.9	—
Other financial assets	4,885.3	189.4
Other non-financial assets	280.9	271.9
Income tax assets	179.1	0.4
Cash and cash equivalents	11,663.7	13,875.1
Total current assets	19,527.3	21,922.0
Total assets	23,006.3	23,279.1
Equity and liabilities		
Equity		
Share capital	248.6	248.6
Capital reserve	1,229.4	1,828.2
Treasury shares	(10.8)	(5.3)
Retained earnings	19,763.3	18,833.0
Other reserves	(984.6)	(848.9)
Total equity	20,245.9	20,055.6
Non-current liabilities		
Lease liabilities, loans and borrowings	191.0	176.2
Other financial liabilities	38.8	6.1
Income tax liabilities	—	10.4
Provisions	8.8	8.6
Contract liabilities	398.5	48.4
Other non-financial liabilities	13.1	17.0
Deferred tax liabilities	39.7	6.2
Total non-current liabilities	689.9	272.9
Current liabilities		
Lease liabilities, loans and borrowings	28.1	36.0
Trade payables and other payables	354.0	204.1
Other financial liabilities	415.2	785.1
Refund liabilities	—	24.4
Income tax liabilities	525.5	595.9
Provisions	269.3	367.2
Contract liabilities	353.3	77.1
Other non-financial liabilities	125.1	860.8
Total current liabilities	2,070.5	2,950.6
Total liabilities	2,760.4	3,223.5
Total equity and liabilities	23,006.3	23,279.1

Statements of Cash Flows

	Three months ended December 31,		Years ended December 31,		
	2023 (unaudited)	2022 (unaudited)	2023	2022	2021
<i>(in millions €)</i>					
Operating activities					
Profit for the period	457.9	2,278.7	930.3	9,434.4	10,292.5
Income taxes	205.3	893.9	255.8	3,519.7	4,753.9
Profit before tax	663.2	3,172.6	1,186.1	12,954.1	15,046.4
Adjustments to reconcile profit before tax to net cash flows:					
Depreciation and amortization of property, plant, equipment, intangible assets and right-of-use assets	78.8	29.0	183.4	123.3	75.2
Share-based payment expenses	14.2	22.2	51.4	108.6	93.9
Net foreign exchange differences	66.3	847.8	(298.0)	625.5	(387.5)
Loss on disposal of property, plant and equipment	0.2	0.2	3.8	0.6	4.6
Finance income excluding foreign exchange differences	(162.2)	(38.8)	(519.6)	(265.3)	(1.5)
Finance expense excluding foreign exchange differences	3.4	2.1	7.9	18.9	305.2
Movements in government grants	5.4	0.3	2.4	0.3	(89.0)
Net (gain) / loss on derivative instruments at fair value through profit or loss	(21.2)	(323.3)	175.5	(241.0)	57.3
Working capital adjustments:					
Decrease / (increase) in trade and other receivables, contract assets and other assets	(288.0)	(646.8)	5,374.0	4,369.9	(11,808.1)
Decrease / (increase) in inventories	58.0	(144.8)	81.9	62.9	(438.4)
Increase in trade payables, other financial liabilities, other liabilities, contract liabilities, refund liabilities and provisions	412.8	(674.6)	118.9	85.7	1,516.1
Interest received and realized gains from cash and cash equivalents	91.8	22.8	258.2	29.3	1.2
Interest paid and realized losses from cash and cash equivalents	(1.7)	(5.0)	(5.4)	(21.5)	(12.2)
Income tax paid	(65.1)	(1,387.4)	(482.9)	(4,222.1)	(3,457.9)
Share-based payments	(5.0)	(47.1)	(766.2)	(51.8)	(13.4)
Net cash flows from operating activities	850.9	829.2	5,371.4	13,577.4	889.7
Investing activities					
Purchase of property, plant and equipment	(83.8)	(136.6)	(249.4)	(329.2)	(127.5)
Proceeds from sale of property, plant and equipment	0.1	0.2	(0.7)	0.6	3.4
Purchase of intangible assets and right-of-use assets	(106.5)	(7.9)	(455.4)	(34.1)	(26.5)
Acquisition of subsidiaries and businesses, net of cash acquired	—	—	(336.9)	—	(20.8)
Investment in other financial assets	(3,418.2)	(16.7)	(7,128.4)	(47.8)	(19.5)
Proceeds from maturity of other financial assets	913.3	—	1,216.3	375.2	(375.2)
Net cash flows used in investing activities	(2,695.1)	(161.0)	(6,954.5)	(35.3)	(566.1)
Financing activities					
Proceeds from issuance of share capital and treasury shares, net of costs	—	—	—	110.5	160.9
Proceeds from loans and borrowings	0.2	0.2	0.3	0.8	—
Repayment of loans and borrowings	—	—	(0.1)	(18.8)	(52.6)
Payments related to lease liabilities	(12.3)	(9.2)	(40.3)	(41.1)	(14.1)
Share repurchase program	(0.8)	(55.7)	(738.5)	(986.4)	—
Dividends	—	—	—	(484.3)	—
Net cash flows from / (used in) financing activities	(12.9)	(64.7)	(778.6)	(1,419.3)	94.2
Net increase / (decrease) in cash and cash equivalents	(1,857.1)	603.5	(2,361.7)	12,122.8	417.8

Change in cash and cash equivalents resulting from exchange rate differences	(15.4)	(152.1)	(14.5)	60.1	64.7
Cash and cash equivalents at the beginning of the period	13,495.8	13,423.7	13,875.1	1,692.7	1,210.2
Cash and cash equivalents as of December 31	11,663.7	13,875.1	11,663.7	13,875.1	1,692.7