UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 6-K

REPORT OF FOREIGN PRIVATE ISSUER PURSUANT TO RULE 13a-16 OR 15d-16
UNDER THE SECURITIES EXCHANGE ACT OF 1934

FOR THE MONTH OF AUGUST 2022

COMMISSION FILE NUMBER 001-39081

BioNTech SE
(Translation of registrant's name into English)

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Germany
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(Address of principal executive offices)

Indicate by check mark whether the registrant files or will file annual reports under cover Form 20-F or Form 40-F: Form 20-F ☒ Form 40-F ☐

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1): ☐

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7): ☐

DOCUMENTS INCLUDED AS PART OF THIS FORM 6-K

On August 23, 2022, BioNTech SE (the "Company") and Pfizer Inc. today announced announced updated efficacy results from a Phase 2/3 trial evaluating a three 3-µg dose series of the Pfizer-BioNTech COVID-19 Vaccine in children 6 months through 4 years of age, reinforcing previously reported interim vaccine efficacy data collected in March and April 2022. The press release is attached hereto as Exhibit 99.1.

SIGNATURE

Pursuant to the requirements of the Exchange Act, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

BioNTech SE

By: /s/ Dr. Sierk Poetting

Name: Dr. Sierk Poetting

Title: Chief Operating Officer

Date: August 23, 2022

EXHIBIT INDEX

Exhibit	Description of Exhibit
99.1	Pfizer and BioNTech Announce Updated COVID-19 Vaccine Data Supporting Efficacy in Children 6 Months through 4 Years of Age

Pfizer and BioNTech Announce Updated COVID-19 Vaccine Data Supporting Efficacy in Children 6 Months through 4 Years of Age

- *Updated analysis from 34 cases occurring at least seven days following a three-dose regimen showed 73.2% vaccine efficacy among children ages 6 months through 4 years*
- *The vaccine efficacy remained consistently above 70% in both the 6 through 23 months and the 2 through 4 years age groups*
- *Sequencing of observed COVID-19 cases confirmed majority were caused by Omicron BA.2, broadening the evidence for efficacy across COVID-19 variants*
- *Sequencing of observed COVID-19 cases confirmed majority were caused by Omicron BA.2, broadening the evidence for efficacy across COVID-19 variants*

NEW YORK, USA and MAINZ, GERMANY, August 23, 2022 — Pfizer Inc. (NYSE: PFE, "Pfizer") and BioNTech SE (Nasdaq: BNTX, "BioNTech") today announced updated efficacy results from a Phase 2/3 trial evaluating a three 3-µg dose series of the Pfizer-BioNTech COVID-19 Vaccine in children 6 months through 4 years of age, reinforcing previously reported interim vaccine efficacy data collected in March and April 2022. Emergency Use Authorization (EUA) of this vaccine was granted by the U.S. Food and Drug Administration (FDA) for this age group on June 17 and an application for conditional marketing authorization in this age group is under review by the European Medicines Agency (EMA).

Participants in the study received either the Pfizer-BioNTech COVID-19 Vaccine (3-µg) as a three-dose series or placebo (2:1 randomization). Vaccine efficacy, a secondary endpoint in the trial, was 73.2% (2-sided 95% CI: 43.8%, 87.6%) among children 6 months through 4 years of age without evidence of prior COVID-19 infection. This analysis was based on 13 cases in the Pfizer-BioNTech COVID-19 Vaccine group (n=794) and 21 cases in the placebo group (n=351), diagnosed from March to June 2022. The study protocol specified that this formal efficacy analysis should be performed when at least 21 total symptomatic COVID-19 cases were identified, each at least seven days after the third dose. Consistent with the time period when the cases occurred, sequencing of viral RNA from illness visit nasal swabs indicated that observed cases were primarily caused by Omicron BA.2. Omicron BA.4 and BA.5 strains were emerging during the period of the study, with only a few cases accrued and efficacy results against these strains were inconclusive. Consistent with our approach in adults, we are working with the FDA to prepare an EUA application for an Omicron BA.4/BA.5-adapted bivalent vaccine in children 6 months through 11 years of age.

"Building on the strong safety and immunogenicity data that led to FDA authorization of our COVID-19 vaccine for children 6 months through 4 years, we are pleased to share confirmatory evidence that a full course of vaccination helps protect against symptomatic disease, particularly during a time when the Omicron BA.2 strain was predominant," said **Albert Bourla, Chairman and Chief Executive Officer, Pfizer**.

"While these results confirm that three 3-µg doses of our COVID-19 vaccine provide young children with a high level of protection at a time when the Omicron BA.2 strain was highly prevalent with a favorable safety profile, we are also developing an Omicron BA.4/BA.5-adapted bivalent vaccine in this age group to address these sublineages," said **Prof. Ugur Sahin, M.D., CEO and Co-Founder of BioNTech**.

Among children ages 6 through 23 months, the vaccine was 75.8% (2-sided 95% CI: 9.7%, 94.7%) effective at preventing COVID-19, based on 4 cases in the vaccine group (n=296) and 8 cases in the placebo group (n=147), after a median of 1.9 months (range: 0.0, 4.9) follow-up after the third dose. For children ages 2 through 4 years of age, the vaccine was 71.8% (2-sided 95% CI: 28.6%, 89.4%) effective at preventing COVID-19, based on 9 cases

in the vaccine group (n=498) and 13 cases in the placebo group (n=204), after a median of 2.4 months (range: 0.0, 4.9) follow-up after the third dose.

Three 3-µg doses of the Pfizer-BioNTech COVID-19 Vaccine continue to be well-tolerated in this age group. The majority of adverse events observed in this age group have been mild or moderate, with a safety profile similar to placebo.

On July 8, Pfizer and BioNTech submitted safety and immunogenicity data to the EMA requesting an update to the Conditional Marketing Authorization (CMA) in the European Union (EU) to include children ages 6 months through 4 years. The companies plan to submit the updated efficacy data to the FDA, EMA and other regulatory agencies around the world in the coming weeks.

The Pfizer-BioNTech COVID-19 Vaccine, which is based on BioNTech's proprietary mRNA technology, was developed by both BioNTech and Pfizer. BioNTech is the Marketing Authorization Holder for BNT162b2 (COMIRNATY®) in the United States, the EU, the United Kingdom, Canada and other countries, and the holder of emergency use authorizations or equivalents in the United States (jointly with Pfizer) and other countries. Submissions to pursue regulatory approvals in those countries where emergency use authorizations or equivalent were initially granted are planned.

About the Phase 1/2/3 Trial in Children

The Phase 1/2/3 trial has enrolled more than 10,000 children ages 6 months to under 12 years of age in the United States, Finland, Poland, Brazil and Spain from more than 90 clinical trial sites. The trial evaluated the safety, tolerability, and immunogenicity of three doses of the Pfizer-BioNTech COVID-19 Vaccine in three age groups: ages 5 to under 12 years; ages 2 to under 5 years; and ages 6 months to under 2 years. Based on the Phase 1 dose-escalation portion of the trial, children ages 5 to under 12 years received a two-dose schedule of 10 µg each while children under age 5 received a lower 3-µg dose for each injection in the Phase 2/3 study. The trial enrolled children with or without prior evidence of SARS-CoV-2 infection.

U.S. Indication & Authorized Use

Pfizer-BioNTech COVID-19 Vaccine is FDA authorized under Emergency Use Authorization (EUA) for active immunization to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 6 months of age and older.

Pfizer-BioNTech COVID-19 Vaccine is FDA authorized to provide:

Primary Series

- A 3-dose primary series to individuals 6 months through 4 years of age
- a 2-dose primary series to individuals 5 years through 11 years of age
- a 2-dose primary series to individuals 12 years of age and older
- a third primary series dose to individuals 5 years of age and older with certain kinds of immunocompromise

Booster Series

- a single booster dose to individuals 5 through 11 years of age who have completed a primary series with Pfizer-BioNTech COVID-19 Vaccine
- a first booster dose to individuals 12 years of age and older who have completed a primary series with Pfizer-BioNTech COVID-19 Vaccine or COMIRNATY® (COVID-19 Vaccine, mRNA)
- a first booster dose to individuals 18 years of age and older who have completed primary vaccination with a different authorized or approved COVID-19 vaccine. The

booster schedule is based on the labeling information of the vaccine used for the primary series
- a second booster dose to individuals 50 years of age and older who have received a first booster dose of any authorized or approved COVID-19 vaccine
- a second booster dose to individuals 12 years of age and older with certain kinds of immunocompromise and who have received a first booster dose of any authorized or approved COVID-19 vaccine

COMIRNATY® INDICATION
COMIRNATY® (COVID-19 Vaccine, mRNA) is a vaccine approved for active immunization to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 12 years of age and older.

HOW IS COMIRNATY® GIVEN?
COMIRNATY® is administered as an injection into the muscle as a 2-dose primary series, 3 weeks apart.

COMIRNATY® AUTHORIZED USES
COMIRNATY® (COVID-19 Vaccine, mRNA) is FDA authorized under Emergency Use Authorization (EUA) to provide:

Primary Series
- a third primary series dose to individuals 12 years of age and older with certain kinds of immunocompromise

Booster Dose
- a first booster dose to individuals 12 years of age and older who have completed a primary series with Pfizer-BioNTech COVID-19 Vaccine or COMIRNATY®
- a first booster dose to individuals 18 years of age and older who have completed primary vaccination with another authorized or approved COVID-19 vaccine. The booster schedule is based on the labeling information of the vaccine used for the primary series
- a second booster dose to individuals 50 years of age and older who have received a first booster dose of any authorized or approved COVID-19 vaccine
- a second booster dose to individuals 12 years of age and older with certain kinds of immunocompromise and who have received a first booster dose of any authorized or approved COVID-19 vaccine

Emergency Use Authorization
Emergency uses of the vaccine have not been approved or licensed by FDA, but have been authorized by FDA, under an Emergency Use Authorization (EUA) to prevent Coronavirus Disease 2019 (COVID 19) in individuals 6 months of age and older. The emergency uses are only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of the medical product under Section 564(b)(1) of the FD&C Act unless the declaration is terminated or authorization revoked sooner.

INTERCHANGEABILITY
FDA-approved COMIRNATY® (COVID-19 Vaccine, mRNA) and the Pfizer-BioNTech COVID-19 Vaccine FDA authorized for Emergency Use Authorization (EUA) for individuals 12

years of age and older can be used interchangeably by a vaccination provider when prepared according to their respective instructions for use.

The formulation of the Pfizer-BioNTech COVID-19 Vaccine authorized for use in individuals 6 months through 4 years of age, 5 through 11 years of age, and 12 years of age and older are different and should therefore **not** be used interchangeably.

IMPORTANT SAFETY INFORMATION

Tell your vaccination provider about all of the vaccine recipient's medical conditions, including if the vaccine recipient:

- has any allergies
- has had myocarditis (inflammation of the heart muscle) or pericarditis (inflammation of the lining outside the heart)
- has a fever
- has a bleeding disorder or is on a blood thinner
- is immunocompromised or are on a medicine that affects the immune system
- is pregnant, plan to become pregnant, or are breastfeeding
- has received another COVID-19 vaccine
- has ever fainted in association with an injection

Pfizer-BioNTech COVID-19 Vaccine or COMIRNATY® (COVID-19 Vaccine, mRNA) may not protect all vaccine recipients.

- The vaccine recipient should not receive Pfizer-BioNTech COVID-19 Vaccine or COMIRNATY® (COVID-19 Vaccine, mRNA) if the vaccine recipient has had a severe allergic reaction to any of its ingredients or had a severe allergic reaction to a previous dose of Pfizer-BioNTech COVID-19 Vaccine or COMIRNATY®

- There is a remote chance that Pfizer-BioNTech COVID-19 Vaccine or COMIRNATY® (COVID-19 Vaccine, mRNA) could cause a severe allergic reaction. A severe allergic reaction would usually occur within a few minutes to 1 hour after getting a dose of the vaccine. For this reason, your vaccination provider may ask you to stay at the place where the vaccine was administered for monitoring after vaccination. If the vaccine recipient experiences a severe allergic reaction, call 9-1-1 or go to the nearest hospital

Seek medical attention right away if the vaccine recipient has any of the following symptoms: difficulty breathing, swelling of the face and throat, a fast heartbeat, a bad rash all over the body, dizziness, and weakness

- Myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of the lining outside the heart) have occurred in some people who have received the vaccine, more commonly in males under 40 years of age than among females and older males. In most of these people, symptoms began within a few days following receipt of the second dose of the vaccine. The chance of having this occur is very low

Seek medical attention right away if the vaccine recipient has any of the following symptoms after receiving the vaccine, particularly during the 2 weeks after receiving a vaccine dose:

- Chest pain
- Shortness of breath
- Feelings of having a fast-beating, fluttering, or pounding heart

- Fainting
- Unusual and persistent irritability
- Unusual and persistent poor feeding
- Unusual and persistent fatigue or lack of energy
- Persistent vomiting
- Persistent pain in the abdomen
- Unusual and persistent cool, pale skin

Fainting can happen after getting injectable vaccines, including Pfizer-BioNTech COVID-19 Vaccine or COMIRNATY® (COVID-19 Vaccine, mRNA). Sometimes people who faint can fall and hurt themselves. For this reason, your vaccination provider may ask the vaccine recipient to sit or lie down for 15 minutes after receiving the vaccine.

Some people with weakened immune systems may have reduced immune responses to Pfizer-BioNTech COVID-19 Vaccine or COMIRNATY® (COVID-19 Vaccine, mRNA).
Additional side effects include rash, itching, hives, swelling of the face, injection site pain, tiredness, headache, muscle pain, chills, joint pain, fever, injection site swelling, injection site redness, nausea, feeling unwell, swollen lymph nodes (lymphadenopathy), decreased appetite, diarrhea, vomiting, arm pain, and fainting in association with injection of the vaccine and irritability.

These may not be all the possible side effects of the vaccine. Call the vaccination provider or healthcare provider about bothersome side effects or side effects that do not go away.

You should always ask your healthcare providers for medical advice about adverse events. Report vaccine side effects to the US Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC) Vaccine Adverse Event Reporting System (VAERS). The VAERS toll-free number is 1-800-822-7967 or report online to www.vaers.hhs.gov/reportevent.html. You can also report side effects to Pfizer Inc. at www.pfizersafetyreporting.com or by calling 1-800-438-1985

Click for Fact Sheets and Prescribing Information for individuals 5 years of age and older:

Recipients and Caregivers Fact Sheet (6 months through 4 years of age)
Recipients and Caregivers Fact Sheet (5 through 11 years of age)
Recipients and Caregivers Fact Sheet (12 years of age and older)
COMIRNATY® Full Prescribing Information (12 years of age and older), DILUTE BEFORE USE, Purple Cap
COMIRNATY® Full Prescribing Information (12 years of age and older), DO NOT DILUTE, Gray Cap
EUA Fact Sheet for Vaccination Providers (6 months through 4 years of age), DILUTE BEFORE USE, Maroon Cap
EUA Fact Sheet for Vaccination Providers (5 through 11 years of age), DILUTE BEFORE USE, Orange Cap
EUA Fact Sheet for Vaccination Providers (12 years of age and older), DILUTE BEFORE USE, Purple Cap
EUA Fact Sheet for Vaccination Providers (12 years of age and older), DO NOT DILUTE, Gray Cap

About Pfizer: Breakthroughs That Change Patients' Lives
At Pfizer, we apply science and our global resources to bring therapies to people that extend and significantly improve their lives. We strive to set the standard for quality, safety and value in the discovery, development and manufacture of health care products, including innovative medicines and vaccines. Every day, Pfizer colleagues work across developed and emerging markets to advance wellness, prevention, treatments and cures that challenge the most

feared diseases of our time. Consistent with our responsibility as one of the world's premier innovative biopharmaceutical companies, we collaborate with health care providers, governments and local communities to support and expand access to reliable, affordable health care around the world. For more than 170 years, we have worked to make a difference for all who rely on us. We routinely post information that may be important to investors on our website at www.Pfizer.com. In addition, to learn more, please visit us on www.Pfizer.com and follow us on Twitter at @Pfizer and @Pfizer News, LinkedIn, YouTube and like us on Facebook at Facebook.com/Pfizer.

Pfizer Disclosure Notice
The information contained in this release is as of August 23, 2022. Pfizer assumes no obligation to update forward-looking statements contained in this release as the result of new information or future events or developments.

This release contains forward-looking information about Pfizer's efforts to combat COVID-19, the collaboration between BioNTech and Pfizer to develop a COVID-19 vaccine, the BNT162b2 mRNA vaccine program, and the Pfizer-BioNTech COVID-19 Vaccine, also known as COMIRNATY (COVID-19 Vaccine, mRNA) (BNT162b2) (including potential in children 6 months through 4 years of age and planned and pending regulatory submissions, plans to evaluate the potential of a variant-adapted vaccine in this age group, qualitative assessments of available data, potential benefits, expectations for clinical trials, potential regulatory submissions, the anticipated timing of data readouts, regulatory submissions, regulatory approvals or authorizations and anticipated manufacturing, distribution and supply) involving substantial risks and uncertainties that could cause actual results to differ materially from those expressed or implied by such statements. Risks and uncertainties include, among other things, the uncertainties inherent in research and development, including the ability to meet anticipated clinical endpoints, commencement and/or completion dates for clinical trials, regulatory submission dates, regulatory approval dates and/or launch dates, as well as risks associated with preclinical and clinical data (including Phase 1/2/3 or Phase 4 data), including the data discussed in this release, for BNT162b2, any monovalent, bivalent or variant-adapted vaccine candidates or any other vaccine candidate in the BNT162 program in any of our studies in pediatrics, adolescents or adults or real world evidence, including the possibility of unfavorable new preclinical, clinical or safety data, including the risk that final results from the Phase 2/3 trial could differ from the topline data, and further analyses of existing preclinical, clinical or safety data; the ability to produce comparable clinical or other results, including the rate of vaccine effectiveness and safety and tolerability profile observed to date, in additional analyses of the Phase 3 trial and additional studies, in real world data studies or in larger, more diverse populations following commercialization; the ability of BNT162b2, any monovalent, bivalent or variant-adapted vaccine candidates or any future vaccine to prevent COVID-19 caused by emerging virus variants; the risk that more widespread use of the vaccine will lead to new information about efficacy, safety, or other developments, including the risk of additional adverse reactions, some of which may be serious; the risk that preclinical and clinical trial data are subject to differing interpretations and assessments, including during the peer review/publication process, in the scientific community generally, and by regulatory authorities; whether and when additional data from the BNT162 mRNA vaccine program will be published in scientific journal publications and, if so, when and with what modifications and interpretations; whether regulatory authorities will be satisfied with the design of and results from these and any future preclinical and clinical studies; whether and when submissions to request emergency use or conditional marketing authorizations for BNT162b2 in additional populations, for a potential booster dose for BNT162b2, any monovalent, bivalent or variant-adapted vaccine candidates or any potential future vaccines (including in children 6 months to under 5 years of age, potential future annual boosters or re-vaccination) and/or other biologics license and/or emergency use authorization applications or amendments to any such applications may be filed in particular jurisdictions for BNT162b2, any monovalent or bivalent vaccine candidates or any other potential vaccines that may arise from the BNT162 program, including a potential variant

based, higher dose, or bivalent vaccine, and if obtained, whether or when such emergency use authorizations or licenses will expire or terminate; whether and when any applications that may be pending or filed for BNT162b2 (including potential applications in children 6 months to under 5 years of age and any requested amendments to the emergency use or conditional marketing authorizations), any monovalent, bivalent or variant-adapted vaccine candidates, or other vaccines that may result from the BNT162 program may be approved by particular regulatory authorities, which will depend on myriad factors, including making a determination as to whether the vaccine's benefits outweigh its known risks and determination of the vaccine's efficacy and, if approved, whether it will be commercially successful; decisions by regulatory authorities impacting labeling or marketing, manufacturing processes, safety and/or other matters that could affect the availability or commercial potential of a vaccine, including development of products or therapies by other companies; disruptions in the relationships between us and our collaboration partners, clinical trial sites or third-party suppliers; the risk that demand for any products may be reduced or no longer exist which may lead to reduced revenues or excess inventory; risks related to the availability of raw materials to manufacture a vaccine; challenges related to our vaccine's formulation, dosing schedule and attendant storage, distribution and administration requirements, including risks related to storage and handling after delivery by Pfizer; the risk that we may not be able to successfully develop other vaccine formulations, booster doses or potential future annual boosters or re-vaccinations or new variant-based or next generation vaccines; the risk that we may not be able to maintain or scale up manufacturing capacity on a timely basis or maintain access to logistics or supply channels commensurate with global demand for our vaccine, which would negatively impact our ability to supply the estimated numbers of doses of our vaccine within the projected time periods as previously indicated; whether and when additional supply agreements will be reached; uncertainties regarding the ability to obtain recommendations from vaccine advisory or technical committees and other public health authorities and uncertainties regarding the commercial impact of any such recommendations; challenges related to public vaccine confidence or awareness; uncertainties regarding the impact of COVID-19 on Pfizer's business, operations and financial results; and competitive developments.

A further description of risks and uncertainties can be found in Pfizer's Annual Report on Form 10-K for the fiscal year ended December 31, 2021 and in its subsequent reports on Form 10-Q, including in the sections thereof captioned "Risk Factors" and "Forward-Looking Information and Factors That May Affect Future Results", as well as in its subsequent reports on Form 8-K, all of which are filed with the U.S. Securities and Exchange Commission and available at www.sec.gov and www.pfizer.com.

About BioNTech

Biopharmaceutical New Technologies is a next generation immunotherapy company pioneering novel therapies for cancer and other serious diseases. The Company exploits a wide array of computational discovery and therapeutic drug platforms for the rapid development of novel biopharmaceuticals. Its broad portfolio of oncology product candidates includes individualized and off-the-shelf mRNA-based therapies, innovative chimeric antigen receptor T cells, bispecific immune checkpoint modulators, targeted cancer antibodies and small molecules. Based on its deep expertise in mRNA vaccine development and in-house manufacturing capabilities, BioNTech and its collaborators are developing multiple mRNA vaccine candidates for a range of infectious diseases alongside its diverse oncology pipeline. BioNTech has established a broad set of relationships with multiple global pharmaceutical collaborators, including Genmab, Sanofi, Genentech, a member of the Roche Group, Regeneron, Genevant, Fosun Pharma, and Pfizer. For more information, please visit www.BioNTech.com.

BioNTech Forward-looking Statements

This press release contains "forward-looking statements" of BioNTech within the meaning of the Private Securities Litigation Reform Act of 1995. These forward-looking statements may

include, but may not be limited to, statements concerning: BioNTech's efforts to combat COVID-19; the collaboration between BioNTech and Pfizer including the program to develop a COVID-19 vaccine and COMIRNATY (COVID-19 vaccine, mRNA) (BNT162b2) (including updated data regarding BNT162b2 and its potential in children 6 months to under 5 years of age and planned regulatory submissions, qualitative assessments of available data, potential benefits, expectations for clinical trials, the anticipated timing of regulatory submissions, regulatory approvals or authorizations and anticipated manufacturing, distribution and supply); our expectations regarding the potential characteristics of BNT162b2 in our clinical trials, real world data studies, and/or in commercial use based on data observations to date; preclinical and clinical data (including Phase 1/2/3 or Phase 4 data), including the descriptive data discussed in this release, for BNT162b2 or any other vaccine candidate in the BNT162 program, including any monovalent, bivalent or variant-adapted vaccine candidates in any of our studies in pediatrics, adolescents or adults or real world evidence, including the possibility of unfavorable new preclinical, clinical or safety data, including the risk that final or formal results from the clinical trial could differ from the topline data; the ability of BNT162b2 or a future vaccine to prevent COVID-19 caused by emerging virus variants; the expected time point for additional readouts on efficacy data of BNT162b2 in our clinical trials; the nature of the clinical data, which is subject to ongoing peer review, regulatory review and market interpretation; widespread use of BNT162b2 will lead to new information about efficacy, safety, or other developments, including the risk of additional adverse reactions, some of which may be serious; the timing for submission of data for BNT162, or any future vaccine, in additional populations (including in children 6 months to under 5 years of age, including any monovalent, bivalent or variant-adapted vaccine and potential future annual boosters or re-vaccinations), or receipt of, any marketing approval or emergency use authorization or equivalent, including or amendments or variations to such authorizations, including making a determination as to whether the vaccine's benefits outweigh its known risks and determination of the vaccine's efficacy and, if approved, whether it will be commercially successful; the development of other vaccine formulations, booster doses or potential future annual boosters or re-vaccinations or new variant based vaccines; our contemplated shipping and storage plan, including our estimated product shelf life at various temperatures; the ability of BioNTech to supply the quantities of BNT162 to support clinical development and market demand, including our production estimates for 2022; challenges related to public vaccine confidence or awareness; decisions by regulatory authorities impacting labeling or marketing, manufacturing processes, safety and/or other matters that could affect the availability or commercial potential of a vaccine, including development of products or therapies by other companies; disruptions in the relationships between us and our collaboration partners, clinical trial sites or third-party suppliers; the risk that demand for any products may be reduced or no longer exist; the availability of raw material to manufacture BNT162 or other vaccine formulation, which may lead to reduced revenues or excess inventory; challenges related to our vaccine's formulation, dosing schedule and attendant storage, distribution and administration requirements, including risks related to storage and handling after delivery; and uncertainties regarding the impact of COVID-19 on BioNTech's trials, business and general operations. Any forward-looking statements in this press release are based on BioNTech current expectations and beliefs of future events and are subject to a number of risks and uncertainties that could cause actual results to differ materially and adversely from those set forth in or implied by such forward-looking statements. These risks and uncertainties include, but are not limited to: the ability to meet the pre-defined endpoints in clinical trials; competition to create a vaccine for COVID-19; the ability to produce comparable clinical or other results, including our stated rate of vaccine effectiveness and safety and tolerability profile observed to date, in the remainder of the trial or in larger, more diverse populations upon commercialization; the ability to effectively scale our productions capabilities; and other potential difficulties.

For a discussion of these and other risks and uncertainties, see BioNTech's quarterly report on Form 6-K for the quarter ended June 30, 2022 and in subsequent filings made by BioNTech with the SEC, which are available on the SEC's website at www.sec.gov. All

information in this press release is as of the date of the release, and BioNTech undertakes no duty to update this information unless required by law.

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