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 2024

COMMISSION FILE NUMBER 001-39081

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

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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 16, 2024, BioNTech SE and Pfizer Inc. announced top-line results from their Phase 3 clinical trial to evaluate the companies' combined mRNA vaccine candidate against influenza and COVID-19 in healthy individuals 18-64 years of age. 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/ Jens Holstein	By: /s/ Dr. Sierk Poetting
Name: Jens Holstein	Name: Dr. Sierk Poetting
Title: Chief Financial Officer	Title: Chief Operating Officer

Date: August 16, 2024

EXHIBIT INDEX

Exhibit	Description of Exhibit
99.1	Pfizer and BioNTech Provide Update on mRNA-based Combination Vaccine Program Against Influenza and COVID-19 in Individuals 18-64 Years of Age

Pfizer and BioNTech Provide Update on mRNA-based Combination Vaccine Program Against Influenza and COVID-19 in Individuals 18-64 Years of Age

- *In a Phase 3 trial, Pfizer and BioNTech's combination vaccine candidate against influenza and COVID-19 met one of its two primary immunogenicity objectives*
- *The trial did not meet one of its primary immunogenicity objectives of non-inferiority against the influenza B strain despite obtaining higher influenza A responses and comparable COVID-19 responses versus the comparator vaccines*
- *The companies are evaluating adjustments to the candidate and will discuss next steps with health authorities*
- *Pfizer also provides update on its separate Phase 2 second-generation trivalent influenza mRNA vaccine trial which showed encouraging data demonstrating robust immunogenicity against all strains compared to a standard of care influenza vaccine*

NEW YORK and MAINZ, Germany, August 16, 2024 — Pfizer Inc. (NYSE: PFE, "Pfizer") and BioNTech SE (Nasdaq: BNTX, "BioNTech") today announced top-line results from their Phase 3 clinical trial to evaluate the companies' combined mRNA vaccine candidate against influenza and COVID-19 in healthy individuals 18-64 years of age. The combination candidate consists of Pfizer's mRNA-based influenza vaccine candidate with the companies' licensed COVID-19 vaccine. The Phase 3 trial measured two primary immunogenicity objectives (immunogenicity against SARS-CoV-2 as well as immunogenicity against influenza A and B), of which one was met. In a separate Phase 2 trial, Pfizer evaluated trivalent ("tIRV") influenza mRNA standalone vaccine candidates which demonstrated robust immunogenicity in individuals 18-64 years of age. The companies are evaluating adjustments to the combination vaccine candidate aimed at improving immune responses against influenza B and will discuss next steps with health authorities.

Update on Phase 3 Pfizer and BioNTech Combination Vaccine Trial

The Phase 3 randomized, observer-blinded study (NCT06178991) enrolled more than 8,000 adults 18 through 64 years of age to evaluate the safety, tolerability, and immunogenicity of a single dose combination vaccine candidate against influenza and COVID-19. In this clinical trial, the vaccine candidate was compared to a licensed influenza vaccine and the companies' licensed COVID-19 vaccine given at the same visit. The primary immunogenicity objectives were to demonstrate that the antibody responses to influenza (hemagglutination inhibition, "HAI") and to SARS-CoV-2 (neutralizing titer, "NT") elicited by the combination vaccine candidate were non-inferior ("NI") to standard of care ("SOC"). Compared to a licensed influenza vaccine, the tIRV formulation was noteworthy for eliciting robust influenza A responses, including a continued trend of higher influenza A responses versus a licensed influenza vaccine, while it showed lower geometric mean titers ("GMT") and seroconversion against the influenza B strain. In addition, the formulation demonstrated comparable responses against SARS-CoV-2 versus the companies' licensed COVID-19 vaccine. No safety signals with the combination vaccine have been identified in an ongoing safety data review. Participants who received a licensed influenza and COVID-19 vaccine with co-administration continued to elicit robust immune responses against both influenza and COVID-19 with no safety signals identified to date.

“We are encouraged by the robust immunogenicity we saw with our combination vaccine against influenza A, which was similar to what we had seen for our initial quadrivalent influenza vaccine where we saw superior relative vaccine efficacy against a comparator flu vaccine,” said **Annaliesa Anderson, PhD, Senior Vice President and Head, Vaccine Research and Development at Pfizer**. “We are committed to developing vaccines that will reduce the burden of respiratory diseases and believe that combination vaccines are the most efficient way to do this. Today’s results provide insight and direction towards achieving this goal, and we remain optimistic about our combination COVID-19 and influenza program, for which we are evaluating the next steps.”

“We are dedicated to developing combination vaccines which provide broader protection against multiple respiratory diseases,” said **Prof. Ugur Sahin, M.D., CEO and Co-founder of BioNTech**. “The insights gained from this combination vaccine trial are highly valuable and will play a crucial role in guiding the further development of Pfizer’s and our combination vaccine program against influenza and COVID-19. We are committed to drawing on our experience in developing mRNA-based vaccine candidates against multiple antigens and believe we can successfully accomplish this task in collaboration with our partner Pfizer.”

Update on Pfizer's Phase 2 Second Generation Influenza Vaccine Trial

Pfizer’s Phase 2 trial (NCT06436703) to evaluate second-generation candidates against influenza was initiated earlier this year and enrolled 450 participants 18-64 years of age, who were randomized to receive investigational mRNA-based influenza vaccines or influenza vaccines approved by the U.S. Food and Drug Administration (“FDA”). As previously stated, Pfizer announced positive top-line Phase 3 results from its first-generation quadrivalent (“qIRV”) vaccine candidate which achieved the first and only demonstration of efficacy for an mRNA vaccine in a group of study participants 18-64 years of age. The primary endpoints for this qIRV first-generation candidate were not met in adults aged 65 and older, as statistical non-inferior relative vaccine efficacy (“rVE”) compared to a licensed influenza vaccine was not met based on the number of cases accrued. Pfizer developed second-generation candidates with the goal of improving immunogenicity and potentially breadth of protection, including new tIRV formulations that matched updated recommendations by the World Health Organization (“WHO”) and the FDA’s Vaccines and Related Biological Products Advisory Committee (“VRBPAC”). The tIRV formulations elicited robust influenza A responses and B responses, including continued trend of higher influenza A responses versus a licensed influenza vaccine. There were no safety signals reported. Data from this Phase 2 trial for adults 65 years of age and older will become available at a later date.

Pfizer will also continue to evaluate its influenza vaccine program and discuss next steps with health authorities.

About Influenza

Influenza causes an estimated 140,000 to 710,000 hospitalizations, 12,000 to 52,000 deaths[1] and about $25 billion in economic loss[2] in the U.S. each year. People 65 and older are at increased risk of serious complications from influenza, including hospitalization and death.[3] Even when a vaccine matches circulating strains well, current influenza vaccines typically confer 40% to 60% protection each year, with even lower protection in years with poor matching of strains.[4] The impact of influenza on racial and ethnic minority groups in the U.S. is even larger. Black Americans are nearly two times more likely than their white counterparts to be hospitalized for influenza while Latino and Indigenous Americans are 1.2 and 1.3 times more likely, respectively.[5]

With circulating influenza strains continually changing, predicting the best match for the next season's vaccine is difficult for global health experts as those strains are chosen more than six months before the start of the influenza season that they target. The flexibility of mRNA technology and its rapid manufacturing could potentially allow better strain matches in future years, and in a pandemic influenza situation, mRNA technology could enable rapid, large-scale manufacturing of vaccines.

INDICATION, AUTHORIZED USE AND IMPORTANT SAFETY INFORMATION

INDICATION

COMIRNATY® (COVID-19 Vaccine, mRNA) is a vaccine for use in people 12 years of age and older to protect against coronavirus disease 2019 (COVID-19).

IMPORTANT SAFETY INFORMATION

- You should **NOT** receive COMIRNATY® (COVID-19 Vaccine, mRNA) if you had a severe allergic reaction to a previous dose of COMIRNATY or any Pfizer-BioNTech COVID-19 vaccine* or to any ingredient in these vaccines.
  *COMIRNATY (2023-2024 Formula) is made the same way as Pfizer-BioNTech COVID-19 Vaccine (Original monovalent) and Pfizer-BioNTech COVID-19 Vaccine, Bivalent, but it encodes the spike protein of SARS-CoV-2 Omicron variant lineage XBB.1.5 (Omicron XBB.1.5).
- There is a remote chance that COMIRNATY could cause a severe allergic reaction. A severe allergic reaction would usually occur within a few minutes to 1 hour after getting a dose. For this reason, your vaccination provider may ask you to stay at the place where you received the vaccine for monitoring after vaccination. Signs of a severe allergic reaction can include:
  - Difficulty breathing
  - Swelling of your 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 mRNA COVID-19 vaccines, including COMIRNATY and Pfizer-BioNTech COVID-19 vaccines. Myocarditis and pericarditis following COMIRNATY have occurred most commonly in adolescent males 12 through 17 years of age. In most of these individuals, symptoms began within a few days following vaccination. The chance of having this occur is very low. You should seek medical attention right away if you or your child have any of the following symptoms after receiving the vaccine, particularly during the 2 weeks after receiving a dose of the vaccine:
  - Chest pain
  - Shortness of breath
  - Feelings of having a fast-beating, fluttering, or pounding heart

- Fainting can happen after getting injectable vaccines including COMIRNATY. Your vaccination provider may ask you to sit or lie down for 15 minutes after receiving the vaccine
- People with weakened immune systems may have a reduced immune response to COMIRNATY
- COMIRNATY may not protect all vaccine recipients

- **Before getting COMIRNATY, tell your vaccination provider about all of your medical conditions, including if you**:
  - have any allergies
  - had a severe allergic reaction after receiving a previous dose of any COVID-19 vaccine
  - have had myocarditis (inflammation of the heart muscle) or pericarditis (inflammation of the lining outside the heart)
  - have a fever
  - have a bleeding disorder or are on a blood thinner
  - are immunocompromised or are on a medicine that affects the immune system
  - are pregnant, plan to become pregnant, or are breastfeeding
  - have received another COVID-19 vaccine
  - have ever fainted in association with an injection

Additional side effects that have been reported with COMIRNATY or Pfizer-BioNTech COVID-19 vaccines include:

- Non-severe allergic reactions such as rash, itching, hives, or swelling of the face
- Injection site reactions: pain, swelling, redness, arm pain
- General side effects: tiredness, headache, muscle pain, chills, joint pain, fever, nausea, feeling unwell, lymph nodes (lymphadenopathy), decreased appetite, diarrhea, vomiting, dizziness.

These may not be all the possible side effects of COMIRNATY. Ask your healthcare provider about any side effects that concern you.
You may report side effects to the FDA/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. In addition, you can report side effects to Pfizer Inc. at 1-800-438-1985 or www.pfizersafetyreporting.com

Please click here for full Prescribing Information and Patient Information for COMIRNATY

AUTHORIZED USE

Pfizer-BioNTech COVID-19 Vaccine (2023-2024 Formula)* is FDA authorized under Emergency Use Authorization (EUA) to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 6 months through 11 years of age.
*Hereafter referred to as Pfizer-BioNTech COVID-19 Vaccine

EMERGENCY USE AUTHORIZATION

Pfizer-BioNTech COVID-19 Vaccine has not been approved or licensed by FDA, but has been authorized for emergency use by FDA, under an EUA to prevent Coronavirus Disease 2019 (COVID-19) for use in individuals aged 6 months through 11 years of age. The emergency use of this product is 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.

IMPORTANT SAFETY INFORMATION

- A person should **NOT** get Pfizer-BioNTech COVID-19 Vaccine if they had a severe allergic reaction after a previous dose of any Pfizer-BioNTech COVID-19 vaccine or to any ingredients in these vaccines
- There is a remote chance that the vaccine could cause a severe allergic reaction. A severe allergic reaction would usually occur within a few minutes to one hour after getting a dose of the vaccine. For this reason, the vaccination provider may ask you to stay at the place where you received the vaccine for monitoring after vaccination. **If your child experiences a severe allergic reaction, call 9-1-1, or go to the nearest hospital**. Signs of a severe allergic reaction can include:
    - difficulty breathing, swelling of the face and throat, a fast heartbeat, a bad rash all over the body, or 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 mRNA COVID-19 vaccines. Myocarditis and pericarditis following Pfizer-BioNTech COVID-19 vaccines have occurred most commonly in adolescent males 12 through 17 years of age. In most of these individuals, symptoms began within a few days following vaccination. The chance of having this occur is very low. **Seek medical attention right away if your child has any of the following symptoms after receiving the vaccine, particularly during the 2 weeks after receiving a dose of the vaccine**:
    - Chest pain
    - Shortness of breath or difficulty breathing
    - Feelings of having a fast-beating, fluttering, or pounding heart

Additional symptoms, particularly in children, may include:

- 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. For this reason, your vaccination provider may ask you to stay at the place where you received the vaccine for monitoring after vaccination
- People with weakened immune systems may have a reduced immune response to Pfizer-BioNTech COVID-19 Vaccine
- Pfizer-BioNTech COVID-19 Vaccine may not protect everyone
- **Tell your vaccination provider about all of your child's medical conditions, including if your child**:
    - 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 is on a medicine that affects the immune system
    - is pregnant or is breastfeeding
    - has received another COVID-19 vaccine
    - has ever fainted in association with an injection

- Side effects that have been reported with Pfizer-BioNTech COVID-19 vaccines include:
    - Severe allergic reactions
    - Non-severe allergic reactions such as rash, itching, hives, or swelling of the face
    - Myocarditis (inflammation of the heart muscle)
    - Pericarditis (inflammation of the lining outside the heart)
    - Injection site pain/tenderness
    - Tiredness
    - Headache
    - Muscle pain
    - Arm pain
    - Fainting in association with injection of the vaccine
    - Chills
    - Joint pain
    - Fever
    - Injection site swelling
    - Injection site redness
    - Nausea
    - Feeling unwell
    - Swollen lymph nodes (lymphadenopathy)
    - Decreased appetite
    - Diarrhea
    - Vomiting
    - Dizziness
    - Irritability

These may not be all the possible side effects. Serious and unexpected side effects may occur. Call the vaccination provider or healthcare provider about bothersome side effects or side effects that do not go away.

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. Please include “Pfizer-BioNTech COVID-19 Vaccine (2023-2024 Formula) EUA” in the first line of box #18 of the report form.

In addition, individuals can report side effects to Pfizer Inc. at www.pfizersafetyreporting.com or by calling 1-800-438-1985.

Please click here for Pfizer-BioNTech COVID-19 Vaccine Healthcare Providers Fact Sheet and Vaccine Recipient and Caregiver EUA Fact Sheet.

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 175 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 X 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 16, 2024. 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 investigational modified RNA (modRNA) influenza vaccine candidates, potential next-generation mRNA flu and combination vaccine formulations, Pfizer's and BioNTech's mRNA-based combination vaccine candidate for influenza and COVID-19, the flu and COVID/flu combination programs, Pfizer's respiratory vaccines portfolio and mRNA technology, including their potential benefits, that involves 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 our clinical trials, regulatory submission dates, regulatory approval dates and/or launch dates, as well as the possibility of unfavorable new clinical data and further analyses of existing clinical data, including uncertainties regarding the outcome of the ongoing Phase 2 trial of Pfizer's second-generation influenza vaccine candidates in adults 65 years of age and older; uncertainties regarding the future development of Pfizer's mRNA influenza vaccine candidates, potential next-generation mRNA flu and combination vaccine formulations and Pfizer's and BioNTech's mRNA-based combination vaccine candidate for influenza and COVID-19, including whether or when any such candidates will advance to future studies or phases of development; the risk that clinical trial data are subject to differing interpretations and assessments by regulatory authorities; whether regulatory authorities will be satisfied with the design of and results from our clinical studies; whether and when biologic license applications may be filed in any jurisdictions for Pfizer's mRNA influenza vaccine candidates, potential next-generation mRNA flu or combination vaccine formulations or Pfizer's and BioNTech's mRNA-based combination vaccine candidate for influenza and COVID-19 for any potential indications or for any other potential vaccine or product candidates; whether and when any such applications may be approved by regulatory authorities, which will depend on myriad factors, including making a determination as to whether the product's benefits outweigh its known risks and determination of the product's efficacy and, if approved, whether Pfizer's mRNA influenza vaccine candidates, potential next-generation mRNA flu or combination vaccine formulations, Pfizer's and BioNTech's mRNA-based combination vaccine candidate for influenza and COVID-19 or any such other potential vaccine or product candidates will be commercially successful; decisions by regulatory authorities impacting labeling, manufacturing processes, safety and/or other matters that could affect the availability or commercial potential of Pfizer's mRNA influenza vaccine candidates, potential next-generation mRNA flu or combination vaccine formulations, Pfizer's and BioNTech's mRNA-based combination vaccine candidate for influenza and COVID-19 or any such other potential vaccine or product candidates, including development of products or therapies by other companies; uncertainties regarding the ability to obtain recommendations from vaccine advisory or technical committees and other public health authorities regarding Pfizer's mRNA influenza vaccine candidates, potential next-generation mRNA flu or combination vaccine formulations, Pfizer's and BioNTech's mRNA-based combination vaccine candidate for influenza and COVID-19 or any such other potential vaccine or product candidates and uncertainties regarding the commercial impact of any such recommendations; disruptions in the relationships between us and our collaboration partners, clinical trial sites or third-party suppliers, including our relationship with BioNTech; the risk that we may not be able to successfully develop other

vaccine formulations or combination vaccines; 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, 2023 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 (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, MediLink, OncoC4, Pfizer and Regeneron.

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

BioNTech 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 be limited to, statements concerning: the collaboration between BioNTech and Pfizer, including Pfizer's investigational modified RNA (modRNA) influenza vaccine candidates, potential next-generation mRNA flu and combination vaccine formulations, and Pfizer's and BioNTech's mRNA-based combination vaccine candidate for influenza and COVID-19, and mRNA technology;; qualitative assessments of available data and expectations of potential benefits, ; regulatory submissions and regulatory approvals or authorizations and expectations regarding manufacturing, distribution and supply; expectations regarding anticipated changes in vaccine demand, including changes to the ordering environment; and expected regulatory recommendations to adapt vaccines to address new strains, variants or sublineages. 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: 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 the data discussed in this release, and including the possibility of unfavorable new preclinical, clinical or safety data and further analyses of existing preclinical, clinical or safety data; the nature of the clinical data, which is subject to

ongoing peer review, regulatory review and market interpretation; uncertainties regarding potential next-generation mRNA flu and combination vaccine formulations and Pfizer's and BioNTech's mRNA-based combination vaccine candidate for influenza and COVID-19, including whether or when any such candidates will advance to future studies or phases of development; the future commercial demand and medical need for an mRNA-based combination vaccine candidate for influenza and COVID-19; the availability of raw materials to manufacture a vaccine; vaccine formulation, dosing schedule and attendant storage, distribution and administration requirements, including risks related to storage and handling after delivery; competition from other 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 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; 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; unforeseen safety issues and potential claims that are alleged to arise from the use of products and product candidates developed or manufactured by BioNTech and/or its collaborators; BioNTech's and its collaborators' ability to commercialize and market products and, if approved, 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 production capabilities; 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 Report on Form 6-K for the period ended June 30, 2024, and in subsequent filings made by BioNTech with the SEC, which are available on the SEC's website at www.sec.gov. These forward-looking statements speak only as of the date hereof. 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.

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[1] Disease Burden of Flu. Centers for Disease Control & Prevention. Available at https://www.cdc.gov/flu/about/burden/index.html

[2] Putri et al, Vaccine. 2018 Jun 22;36(27):3960-3966. doi: 10.1016/j.vaccine.2018.05.057

[3] Flu & People 65 Years and Older. Centers for Disease Control and Prevention. Available at: Flu & People 65 Years and Older | CDC

[4] Vaccine Effectiveness: How Well do the Flu Vaccines Work? Centers for Disease Control & Prevention. Available at https://www.cdc.gov/flu/vaccines-work/vaccineeffect.htm.

[5] Flu Disparities Among Racial and Ethnic Minority Groups CDC. Available at https://www.cdc.gov/flu/highrisk/disparities-racial-ethnic-minority-groups.html.