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 FEBRUARY 2021

COMMISSION FILE NUMBER 001-39081

BioNTech SE

(Translation of registrant's name into English)

An der Goldgrube 12
D-55131 Mainz
Germany
+49 6131-9084-0
(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 February 10, 2021, BioNTech SE (the "Company") announced that the Company started the manufacturing process at the Marburg facility with the execution of the first step: the production of mRNA, which is the active pharmaceutical ingredient of the Pfizer-BioNTech COVID-19 vaccine. 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 Financial Officer

Date: February 10, 2021

EXHIBIT INDEX

Exhibit	Description of Exhibit
99.1	Update on vaccine production at BioNTech's manufacturing site in Marburg.

Update on vaccine production at BioNTech's manufacturing site in Marburg

MAINZ, GERMANY, February 10, 2021 (GLOBE NEWSWIRE) — We started the manufacturing process at the Marburg facility with the execution of the first step: the production of mRNA, which is the active pharmaceutical ingredient of the Pfizer-BioNTech COVID-19 vaccine. A single mRNA batch of the current scale is sufficient to produce around eight million vaccine doses. BioNTech plans to start the manufacturing of the drug substance based on the new manufacturing license granted from Darmstadt Regional Administrative Council for the amended facility in Marburg.

After initial production of the mRNA, it will be purified and concentrated. After completion of mRNA production, Lipid Nanoparticles (LNP) are formed by combining mRNA and a mixture of lipids. Following further purification, the newly created drug product will then be transported to a partner site for fill and finish under sterile conditions. In addition, a panel of quality tests will be performed to confirm the quality of the product prior to release. The quality of the final product is analyzed by two independent laboratories: BioNTech's quality control laboratory in Idar-Oberstein and the official medicinal batch laboratory (Paul-Ehrlich-Institute in Germany).

To allow for supply of drug product from the site in Marburg, the production processes of the new facility need to be approved based on reviewing a range of quality and validation data by the European Medicines Agency (EMA). Data from the first production batches including from process validation will be assessed via the centralized variation procedure coordinated by the EMA. This validation, as well as the submission of data and other required information, will take place in February and March. Based on approval by the EMA, first drug product batches of the vaccine can then be delivered to partner sites for sterile fill and finish, before distribution to vaccination sites in line with established agreements with governments.

BioNTech's manufacturing facility in Marburg is a GMP-certified manufacturing facility. Good manufacturing practice (GMP) is a system of regulatory standards for ensuring that products are consistently produced and controlled according to quality standards aiming for a high level of drug quality and patient safety. The GMP regulations have been developed over decades to minimize the risks involved in any pharmaceutical production, including the vaccine production that cannot be eliminated through testing the final product. The production of vaccines under GMP standards are a prerequisite for the validation of the manufacturing processes by the EMA.

With Pfizer, we are working continuously on multiple initiatives to respond to global demand. We have increased our manufacturing capacity to up to 2 billion doses of our COVID-19 vaccine for 2021, assuming continuous process improvements, expansion at current facilities and adding new suppliers and contract manufacturers, and the updated six-dose labeling. A key factor in the expansion of our manufacturing network has been the set-up of this new manufacturing site in Marburg, Germany. This new BioNTech site will become one of the largest mRNA manufacturing sites in Europe with an annual production capacity of up to 750 million doses of our COVID-19 vaccine, once fully operational. BioNTech plans to be able to produce up to 250 million doses of BNT162b2 in the first half of 2021. The first vaccines manufactured at the Marburg site are scheduled for distribution in early April.

The vaccine, which is based on BioNTech's proprietary mRNA technology, was developed by both BioNTech and Pfizer. BioNTech is the Marketing Authorization Holder in the European Union, and the holder of emergency use authorizations or equivalent in the United States, United Kingdom, Canada and other countries in advance of a planned application for full marketing authorizations in these countries.

Please find an infographic on our manufacturing process and footage of the first production step here: https://investors.biontech.de/media-materials

Please also note: We ask for your understanding that until further notice site visits by external persons are not possible to ensure the production of the vaccine.

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

BioNTech Forward-looking Statements
This statement 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 regarding a COVID-19 vaccine; our contemplated shipping and storage plan, including our estimated product shelf life at various temperatures; and the ability of BioNTech to supply the quantities of BNT162 to support clinical development and market demand, including our production estimate for 2021 as well as the timing and expectations of manufacturing capacities of the manufacturing network. Any forward-looking statements in this statement are based on BioNTech's 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: competition to create a vaccine for COVID-19; 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 for the Three and Nine Months Ended September 30, 2020, filed as Exhibit 99.2 to its Current Report on Form 6-K filed with the SEC on November 10, which is available on the SEC's website at www.sec.gov. All information in this statement 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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