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 MARCH 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 March 26, 2021, BioNTech SE (the "Company") announced that the European Medicines Agency (EMA) approved the manufacturing of the COVID-19 vaccine drug product at the facility in Marburg. EMA has validated the production of the drug substance, the mRNA, this week as well. 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: March 26, 2021

EXHIBIT INDEX

Exhibit	Description of Exhibit
99.1	Update on COVID-19 vaccine production at BioNTech’s manufacturing site in Marburg.

Exhibit 99.1

BioNTech provides Update on Vaccine Production Status at Marburg Manufacturing Site

MAINZ, GERMANY, March 26, 2021 (GLOBE NEWSWIRE) — BioNTech today announced that the European Medicines Agency (EMA) approved the manufacturing of the COVID-19 vaccine drug product at the facility in Marburg. As part of the process, the EMA has approved the production of the drug substance, the mRNA, at the Marburg site over the course of this week. The approvals make BioNTech's Marburg manufacturing site one of the largest mRNA vaccine manufacturing sites in Europe as well as worldwide with an annual production capacity of up to one billion doses of our COVID-19 vaccine, once fully operational. Due to optimized operational efficiencies which were initiated last year, BioNTech has been able to increase the expected annual manufacturing capacity by 250 million doses.

A single mRNA batch of the current scale is sufficient to produce around eight million vaccine doses. Currently, 400 BioNTech employees work in Marburg, 200 of them in 24/7 shifts in order to maximize the production's output. Based on the approval by the EMA, first drug product batches of the vaccine can now be delivered to partner sites for sterile fill and finish, before distribution to the European Union and countries worldwide. The first batches of vaccines manufactured at the Marburg site are expected to be delivered in the second half of April.

In total, 50,000 steps are required from manufacturing the mRNA to the bulk drug substance which then can be handed over for fill and finish. Materials and components for production arrive from a global supply chain that has been dramatically expanded in the last 12 months.

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.

Together with our partner Pfizer, we are working continuously on multiple initiatives to respond to global demand. A key factor in the expansion of our manufacturing network has been the set-up of this new manufacturing site in Marburg, Germany. 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.

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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