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 OCTOBER 2020

COMMISSION FILE NUMBER 001-39081

BioNTech SE

(Translation of registrant's name into English)

An der Goldgrube 12 D-
55131 Mainz 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 October 16, 2020, Pfizer Inc., which has partnered with BioNTech SE in the development of BNT162, the companies' vaccine development program against COVID-19, published a letter that provided guidance on the clinical trial timeline of BNT162. The letter is attached hereto as Exhibit 99.1.

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, 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: October 16, 2020

EXHIBIT INDEX

Exhibit	Description of Exhibit
99.1	Letter from Pfizer Inc. dated October 16, 2020 – A Letter from Pfizer Inc. Chairman and CEO Albert Bourla.

An Open Letter from Pfizer Chairman and CEO Albert Bourla

As we get closer to an important data readout from our COVID-19 vaccine program, I wanted to speak directly to the billions of people, millions of businesses and hundreds of governments around the world that are investing their hopes in a safe and effective COVID-19 vaccine to overcome this pandemic. I know there is a great deal of confusion regarding exactly what it will take to ensure its development and approval, and given the critical public health considerations and the importance of transparency, I would like to provide greater clarity around the development timelines for Pfizer's and our partner BioNTech's COVID-19 vaccine.

There are three key areas where, as with all vaccines, we must demonstrate success in order to seek approval for public use. First, the vaccine must be proven effective, meaning it can help prevent COVID-19 disease in at least a majority of vaccinated patients. Second and equally important, the vaccine must be proven safe, with robust safety data generated from thousands of patients. And finally, we must demonstrate that the vaccine can be consistently manufactured at the highest quality standards.

To ensure public trust and clear up a great deal of confusion, I believe it is essential for the public to understand our estimated timelines for each of these three areas.

As I've said before, we are operating at the speed of science. This means we may know whether or not our vaccine is effective by the end of October. To do so, we must accumulate a certain number of COVID-19 cases in our trial to compare the effectiveness of the vaccine in vaccinated individuals to those who received a placebo. Since we must wait for a certain number of cases to occur, this data may come earlier or later based on changes in the infection rates. As Pfizer is blinded to who received the vaccine versus the placebo, a committee of independent scientists will review the complete data and they will inform us if the vaccine is effective or not based on predetermined criteria at key interim analysis points throughout the trial. Pfizer will continue running the trial through its final analysis point even if it is declared effective at an earlier stage. In the spirit of candor, we will share any conclusive readout (positive or negative) with the public as soon as practical, usually a few days after the independent scientists notify us.

A key point that I'd like to make clear is that effectiveness would satisfy only one of the three requirements and, alone, would not be enough for us to apply for approval for public use.

The second requirement is to prove that the vaccine is safe. Our internal standards for vaccine safety and those required by regulators are set high. In the instance of Emergency Use Authorization in the U.S. for a potential COVID-19 vaccine, FDA is requiring that companies provide two months of safety data on half of the trial participants following the final dose of the vaccine. Based on our current trial enrollment and dosing pace, we estimate we will reach this milestone in the third week of November. Safety is, and will remain, our number one priority, and we will continue monitoring and reporting safety data for all trial participants for two years.

And finally, if we achieve a positive efficacy readout and a robust safety profile, the last requirement will be the submission of manufacturing data that demonstrates the quality and consistency of the vaccine that will be produced. Pfizer has been investing at risk since the early days of the pandemic to perfect our manufacturing processes and rapidly build up capacity. We expect to have our manufacturing data ready for submission before the safety milestone is reached.

So let me be clear, assuming positive data, Pfizer will apply for Emergency Authorization Use in the U.S. soon after the safety milestone is achieved in the third week of November. All the data contained in our U.S. application would be reviewed not only by the FDA's own scientists but also by an external panel of independent experts at a publicly held meeting convened by the agency.
The timelines above reflect our best estimates of when these important milestones could be achieved. For 171 years Pfizer has been known for our high-quality standards. Our purpose is to discover breakthroughs that change patients' lives. I cannot think of a breakthrough that would be more meaningful to a greater number of people than an effective and safe COVID-19 vaccine.

In the meantime, I hope you and your loved ones are staying safe and well.

s/Albert Bourla

BioNTech Forward-looking Statements

This report and the accompanying exhibit contain "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 to develop a potential COVID-19 vaccine; our expectations regarding the potential characteristics of BNT162b2 in our Phase 2/3 trial and/or in commercial use based on data observations to date; the expected timing of any readout on efficacy and safety data of BNT162b2 in our Phase 2/3 trial; the timing for any potential emergency use authorizations or approvals; the nature of the clinical data, which is subject to ongoing peer review, regulatory review and market interpretation; and the ability of BioNTech and Pfizer to supply the quantities of BNT162 to support clinical development and, if approved, market demand, including BioNTech and Pfizer's production estimates for 2020 and 2021. Any forward-looking statements in this report and the accompanying exhibit 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 infection rate observed in our Phase 2/3 trial of BNT162b2; competition to create a vaccine for COVID-19; the ability to produce comparable clinical results in larger and more diverse clinical trials; 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 Annual Report on Form 20-F filed with the SEC on March 31, 2020, which is available on the SEC's website at www.sec.gov. All information in this report and the accompanying exhibit is as of the date of the report, and BioNTech undertakes no duty to update this information unless required by law.