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 2022

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 February 2, 2022, Endpoints News published a news article regarding BioNTech SE's receipt of a priority review voucher from the U.S. FDA. The new article 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: February 3, 2022

EXHIBIT INDEX

Exhibit	Description of Exhibit
99.1	The curious case of the BioNTech priority review voucher

The curious case of the BioNTech priority review voucher
Zachary Brennan

February 2, 2022

Earlier this week, the FDA fully approved Moderna's Covid-19 vaccine, and with that approval, the company was awarded what is almost certainly a lucrative priority review voucher.

The vouchers can be used for a priority review of a new drug, offering a short cut to an FDA decision, or can be sold on the open market — for upwards of $100 million.

The PRV for Moderna was issued by the FDA under its material threat medical countermeasure PRV program, and that program has allowed FDA to provide a PRV for all fully approved products used to treat or prevent Covid-19.

But the only other two Covid-related products that have been fully approved are the Pfizer-BioNTech vaccine and Gilead's Veklury.

Indeed, the FDA's updated list now includes both Moderna's Covid vaccine and Gilead's Veklury.

But curiously, Pfizer's vaccine is not listed by the FDA under its MCM PRVs, and the approval letter for the vaccine did not include any mention of the PRV (even though Moderna's approval letter does mention the PRV).

A Pfizer spokesperson told Endpoints News that BioNTech is the marketing authorization holder for the vaccine, and a BioNTech spokesperson told us that the company did receive the voucher, but did not issue a press release on it.

So why the lack of transparency from the FDA? Why not mention the PRV in the Pfizer vaccine approval letter? An FDA spokesperson did not respond to a request for comment.

As the agency's voucher program has aged, and added different types of vouchers like the MCM PRVs, more and more companies have gone silent on what they're doing with the PRVs, how many are being used internally, and how many are being sold, and at what price.

While details eventually do emerge, as with BioNTech, the companies have no incentive to be clear on what's going on, particularly when a company is big enough that $100 million might not be noteworthy.