

**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 2025

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):

INFORMATION INCLUDED AS PART OF THIS FORM 6-K

The U.S. Food and Drug Administration (“FDA”) has informed BioNTech SE (“BioNTech”) that it has placed a clinical hold on BioNTech’s Investigational New Drug application (“IND”) and the related Phase I/IIa clinical trial (NCT06069544) evaluating the safety, tolerability, immunogenicity and efficacy of an investigational RNA-based vaccine (BNT165e) for prevention of *P. falciparum* malaria in healthy malaria-naive adults.

BioNTech has complied with the hold by the FDA and, in accordance with the clinical trial protocol, had proactively paused the study. BioNTech is taking actions to address the FDA’s requests and will work with the FDA to assess next steps.

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
Name: Jens Holstein
Title: Chief Financial Officer

By: /s/ Dr. Sierk Poetting
Name: Dr. Sierk Poetting
Title: Chief Operating Officer

Date: March 4, 2025