

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**
Washington, D.C. 20549

FORM 8-K

**CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934**

Date of report (Date of earliest event reported): February 9, 2023

PHATHOM PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

001-39094
(Commission
File Number)

82-4151574
(I.R.S. Employer
Identification No.)

100 Campus Drive, Suite 102
Florham Park, New Jersey 07932
(Address of principal executive offices) (Zip Code)

(877) 742-8466
(Registrant's telephone number, include area code)

N/A
(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value \$0.0001 per share	PHAT	The Nasdaq Global Select Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 8.01 Other Events.

On February 9, 2023, Phathom Pharmaceuticals, Inc. (“Phathom” or the “Company”) announced that it received complete response letters from the U.S. Food and Drug Administration (“FDA”) relating to its erosive esophagitis new drug application (“NDA”) and *H. pylori* post approval supplement, both of which address specifications and controls for a nitrosamine drug substance-related impurity, *N*-nitroso-vonoprazan (“NVP”), that was detected in the initial commercial launch materials of VOQUEZNA™ TRIPLE PAK™ and VOQUEZNA™ DUAL PAK™. These letters formalize FDA’s request, announced by the Company in January 2023, that Phathom provide additional stability data to demonstrate that levels of the impurity previously found in vonoprazan commercial drug product will remain at or below the daily acceptable intake throughout the proposed shelf life of the product. No additional deficiencies were cited by the FDA in either letter.

Phathom has conducted extensive root cause investigations regarding the trace levels of the impurity since it was detected and has implemented mitigation measures to control the levels of NVP below the acceptable intake. Phathom expects to meet with the FDA in the first quarter of this year to discuss the resubmission plan and timeline that Phathom believes will lead to approval and launch of products containing vonoprazan.

Forward Looking Statements

Phathom cautions you that statements contained in this report regarding matters that are not historical facts are forward-looking statements. These statements are based on the Company’s current beliefs and expectations. Such forward-looking statements include, but are not limited to, statements regarding Phathom’s expectations of generating stability data necessary to support the proposed shelf life of vonoprazan and the potential approval of its erosive esophagitis NDA and post approval supplements for its *H. pylori* NDAs, and anticipated product launches in *H. pylori* and erosive esophagitis. The inclusion of forward-looking statements should not be regarded as a representation by Phathom that any of its plans will be achieved. Actual results may differ from those set forth in this report due to the risks and uncertainties inherent in Phathom’s business, including, without limitation: Phathom may be unable to generate the required data to meet the acceptable intake of its nitrosamine impurity, or may be unable to reduce the impurity to an acceptable level throughout the shelf life of the product, to obtain approval its erosive esophagitis NDA or to bring vonoprazan to market for patients with erosive esophagitis, if approved, or for patients with *H. Pylori*; risks associated with product manufacturing or formulation changes required to be made in connection with achieving the acceptable daily intake limit; the FDA may disagree that the existing safety and efficacy data, together with additional data, is sufficient to approve the erosive esophagitis NDA or supplements to the *H. pylori* NDAs; the inherent risks of clinical development of vonoprazan; Phathom’s dependence on third parties in connection with product manufacturing, research and preclinical and clinical testing; regulatory developments in the United States and foreign countries; unexpected adverse side effects or inadequate efficacy of vonoprazan that may limit its development, regulatory approval and/or commercialization, or may result in recalls or product liability claims; Phathom’s ability to access additional capital under its term loan facility and royalty interest finance agreements is subject to certain conditions; Phathom’s ability to obtain and maintain intellectual property protection for vonoprazan; Phathom’s ability to comply with its license agreement with Takeda; Phathom’s ability to maintain uninterrupted business operations due to the ongoing spread of the COVID-19 coronavirus, including delaying or otherwise disrupting its clinical trials, manufacturing and supply chain, and other risks described in the Company’s filings with the Securities and Exchange Commission (“SEC”), including under the heading “Risk Factors” in the Company’s Annual Report on Form 10-K and any subsequent filings with the SEC. You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof, and Phathom undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date hereof. All forward-looking statements are qualified in their entirety by this cautionary statement, which is made under the safe harbor provisions of the Private Securities Litigation Reform Act of 1995.

SIGNATURES

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 hereunto duly authorized.

PHATHOM PHARMACEUTICALS, INC.

Date: February 9, 2023

By: /s/ Larry Miller

Larry Miller

General Counsel and Secretary