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): January 3, 2023

PHATHOM PHARMACEUTICALS, INC.
(Exact name of registrant as specified in its charter)

Delaware	001-39094	82-4151574
(State or other jurisdiction of incorporation or organization)	(Commission File Number)	(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 January 3, 2023, Phathom Pharmaceuticals, Inc. ("Phathom" or the "Company") announced that the U.S. Food and Drug Administration (the "FDA") has advised the Company that the FDA will not be taking any action on or prior to the January 11, 2023, Prescription Drug User Fee Act ("PDUFA") target action date for the New Drug Application (the "NDA") for the use of vonoprazan as a treatment for adults for the healing of all grades of erosive esophagitis ("EE"), maintenance of healing of all grades of EE, and relief of heartburn associated with EE.

In addition, while an acceptable daily intake limit for the nitrosamine impurity, N-nitroso-vonoprazan ("NVP"), previously identified by the Company in commercial batches of vonoprazan has now been established by the FDA at 96 ng/day, the FDA has requested additional stability data demonstrating that levels of NVP remain below that limit throughout the proposed shelf life of the product. The Company is actively in the process of both generating additional stability data and discussing with the FDA the nature and extent of such requested data. As a result, Phathom no longer expects product launches for *H. pylori* or erosive esophagitis in the first quarter of 2023.

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 to generate additional data to support the launch and proposed shelf life of vonoprazan and the potential approval of our EE NDA and anticipated product launches in *H. pylori* and erosive esophagitis and the timing thereof. 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 limit of NVP, or may be unable to reduce the NVP intake levels to an acceptable level throughout the shelf life of the product, to obtain approval of its EE NDA or to bring the product to market for its EE NDA, if approved, or its approved *H. Pylori* NDAs; risks associated with product manufacturing or formulation changes required to be made in connection with the required intake limit; the FDA may disagree that the existing safety and efficacy data, together with additional data, is sufficient to approve the EE NDA; the potential for the FDA to delay taking action related to the EE NDA following the FDA's decision not to do so on or prior to the PDUFA target action date; 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 undisrupted 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 prior 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: January 3, 2023

By: /s/ Larry Miller
Larry Miller
General Counsel and Secretary