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): May 23, 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 May 23, 2023, Phathom Pharmaceuticals, Inc. ("Phathom" or the "Company") announced that it has resubmitted its New Drug Application ("NDA") for vonoprazan, a novel first-in-class potassium-competitive acid blocker ("PCAB"), for the treatment of erosive gastroesophageal reflux disease ("Erosive GERD") to the U.S. Food and Drug Administration (the "FDA").

This resubmission responds to the Complete Response Letter ("CRL") issued by the FDA in February 2023 relating to specifications and controls for a nitrosamine drug substance related impurity, N-nitroso-vonoprazan ("NVP"). As previously reported, Phathom implemented mitigation measures, including a minor drug product tablet reformulation, to inhibit the growth of NVP, and has been conducting a stability program to demonstrate these measures are effective and support the commercial shelf life.

The NDA resubmission contains three months of stability data for six batches of the reformulated vonoprazan tablets. The three-month data demonstrate that Phathom's mitigation measures are controlling NVP growth through three months and keeping levels well below the acceptable daily intake limit of 96 ng/day or 2.4 ppm (parts per million) based on the maximum approved daily dose of 40 mg/day. All of the reformulated batches have demonstrated control of NVP under long-term stability conditions with NVP levels that are more than tenfold below the acceptable intake limit through three months, which results Phathom believes comfortably support the requested shelf life of 24 months based on its statistical modeling. In addition, the NDA is supported by extensive clinical data including efficacy and safety data from Phathom's pivotal Phase 3 PHALCON-EE trial, a randomized, double-blind, multicenter trial that enrolled 1,024 patients with Erosive GERD in the U.S. and Europe and compared vonoprazan to lansoprazole, a proton pump inhibitor ("PPI"), in the healing and maintenance of healing of Erosive GERD, and relief of associated heartburn symptoms.

Phathom expects the NDA to be classified as a Class 2 resubmission with a six-month review period and plans to provide the FDA with six-month stability data from its ongoing stability program during the regulatory review process. If the NDA is approved, a combined U.S. commercial launch for the Erosive GERD and *H. pylori* indications is planned for the fourth 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 about the potential of vonoprazan as a treatment for Erosive GERD and *H. pylori*; Phathom's expectations that the stability data will comfortably support the requested shelf life of 24 months; the timing of potential approval of the NDA; and the timing of a U.S. commercial launch for Erosive GERD and *H. pylori* indications. 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: the FDA may refuse to accept our NDA resubmission prior to full review; future data generated from our stability program may be different from the data generated to date and may not demonstrate that our mitigation efforts will meet the acceptable intake (AI) of the nitrosamine impurity, or reduce the impurity to an acceptable level throughout the six-month period required by FDA or the shelf life of the product, to obtain approval for its Erosive GERD NDA or to bring vonoprazan to market for patients with Erosive GERD, if approved, or for patients with *H. pylori*, if our anticipated supplements to NDAs are approved; prior to commercial launch of the *H. pylori* convenience packs, Phathom must submit post approval supplements to the relevant NDAs and Phathom may not submit such supplements on the timeframe it expects and the FDA may not approve such supplements to the *H. pylori* convenience pack NDAs; risks associated with product manufacturing or formulation changes required to be made in connection with achieving the AI; the FDA may disagree that the existing safety and efficacy data, together with additional data, is sufficient to approve the Erosive GERD NDA or supplements to the *H. pylori* convenience pack 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; 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: May 23, 2023

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