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): September 26, 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 September 26, 2023, Phathom Pharmaceuticals, Inc. ("Phathom" or the "Company") announced the submission of a New Drug Application ("NDA") to the U.S. Food and Drug Administration ("FDA") for vonoprazan as a daily treatment for Non-Erosive gastroesophageal reflux disease ("GERD") in adults. The regulatory submission is supported by the positive data from the PHALCON-NERD-301 study, a Phase 3 study evaluating the efficacy and safety of vonoprazan for the daily treatment of adults with Non-Erosive GERD. Vonoprazan is an investigational first-in-class potassium-competitive acid blocker from a novel class of medicines that block acid secretion in the stomach.

The effectiveness and safety of vonoprazan 10 mg and 20 mg given once daily in Non-Erosive GERD was evaluated in a randomized, placebo-controlled, double-blind, 4-week trial with a 20-week blinded extension conducted in the United States in 772 adult patients. As previously reported, both vonoprazan doses met the primary endpoint for the mean percentage of heartburn free days over the 4-week placebo-controlled period at 45%, 44%, and 28% for vonoprazan 10 mg, vonoprazan 20 mg and placebo, respectively ($p<0.0001$ for both doses).

Patients randomized to vonoprazan 10 mg and 20 mg during the initial 4-week period remained on their blinded treatment assignment for the 20-week extension period. The mean percentage of heartburn free days reported over the 20-week extension period for these patients was 63% for vonoprazan 10 mg and 61% for vonoprazan 20 mg.

Additionally, patients who were randomized to placebo during the initial 4-week period were re-randomized to either vonoprazan 10 mg or 20 mg for the 20-week extension period. For these patients, the mean percentage of heartburn free days reported over the 20-week extension period was 62% for vonoprazan 10 mg and 63% for vonoprazan 20 mg.

As previously reported, the overall adverse events were comparable between vonoprazan and placebo during the 4-week placebo-controlled period of which the most common events were nausea, abdominal pain, constipation, and diarrhea, reported at or below 3% for either vonoprazan 10 mg or 20 mg doses. The most common adverse events reported for the two vonoprazan doses during the 20-week extension period were upper respiratory tract infection, sinusitis, influenza, urinary tract infection, nasopharyngitis, nausea, and gastroenteritis, reported at or below 5%.

Phathom expects a 10-month regulatory review and if approved, anticipates a third quarter 2024 U.S. launch for vonoprazan as a daily treatment for Non-Erosive GERD.

Phathom also plans to initiate an additional Phase 3 study to evaluate vonoprazan as an As Needed treatment for episodic heartburn relief in adults with Non-Erosive GERD, a novel dosing treatment regimen.

Vonoprazan is under active review by the FDA as a treatment of Erosive GERD and relief of heartburn associated with Erosive GERD in adults, with a Prescription Drug User Fee Act ("PDUFA") goal date of November 17, 2023. If approved, a commercial launch 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 Non-Erosive GERD; the timing of potential approval of the Non-Erosive GERD NDA; the timing of initiating the additional Phase 3 clinical trial to evaluate vonoprazan as an as-needed treatment for episodic heartburn relief in patients with Non-Erosive GERD, and statements regarding the PDUFA goal date and the timing of a U.S. commercial launch for the 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 file the NDA for Non-Erosive GERD; Phathom may delay or choose not to initiate the planned Phase 3 trial to evaluate vonoprazan as an as-needed treatment for Non-Erosive GERD; future data generated from Phathom's stability program may be different from the data submitted to the FDA to date and may not demonstrate that Phathom's mitigation efforts will continue to maintain the level of the nitrosamine impurity below the acceptable intake ("AI") level throughout the shelf life of the products, if approved, which could result in market action or shelf life reduction; 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 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: September 26, 2023

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