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 9, 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 9, 2023, Phathom Pharmaceuticals, Inc. (Phathom or the Company) announced positive topline results from PHALCON-NERD-301, a Phase 3 study evaluating the efficacy and safety of vonoprazan for the daily treatment of adults in symptomatic non-erosive gastroesophageal reflux disease (sGERD or NERD). Vonoprazan is an investigational potassium-competitive acid blocker (PCAB), a novel class of medicines that block acid secretion in the stomach. Full results from the study are expected later this year.

The topline results from the four-week, double-blind, placebo-controlled period showed both doses of vonoprazan 20 mg and 10 mg met the primary endpoint and demonstrated a significantly greater percentage of 24-hour heartburn-free days versus placebo (mean 46.4% vonoprazan 10 mg, 46.0% vonoprazan 20 mg, compared to 27.5% for placebo; $p<0.0001$ for both vonoprazan 10 mg and 20 mg versus placebo). The median percentage of 24-hour heartburn-free days was 48.3%, 46.7% and 17.0% for vonoprazan 10 mg, vonoprazan 20 mg, and placebo, respectively.

The primary endpoint of the double-blind Phase 3 PHALCON-NERD-301 study evaluated the efficacy of vonoprazan 10 mg and 20 mg as a daily dosing (QD) treatment, as compared to placebo (QD), in the relief of heartburn over four weeks in participants with sGERD. The trial also includes a blinded 20-week long-term extension period, which is currently ongoing, to further evaluate the safety and efficacy of both doses of vonoprazan after six months of continuous use. A total of 776 patients with symptomatic NERD were enrolled and randomized in the multisite U.S. trial.

Vonoprazan was generally well tolerated in the initial four week double-blind, placebo-controlled phase of the trial. The overall adverse events for all vonoprazan arms were comparable to placebo and consistent with what was reported in previous studies. The most commonly reported adverse event was nausea (2.3% vonoprazan 10 mg, 3.1% vonoprazan 20 mg, 0.4% placebo) with no other events reported above 3.0% in either vonoprazan dose arm.

Phathom is currently in discussions with the FDA on the design of a separate Phase 3 trial to evaluate the novel dosing regimen for vonoprazan as an on-demand or “as needed” treatment for episodic heartburn relief in patients with NERD, a dosing treatment regimen not approved in the U.S. for PPIs.

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 the expected timing of full trial results from NERD-301, NERD-301 data providing the basis for submission of a marketing application to FDA and the potential of vonoprazan as a treatment for patients with symptomatic NERD. 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: reported top-line data is based on preliminary analysis of key efficacy and safety data, which is subject to completion of the NERD-301 trial and additional audit and verification procedures that could result in material changes in the final data; FDA actions related to Phathom’s EE NDA, or its approved *H. Pylori* NDAs may negatively affect or delay the symptomatic NERD program; the FDA may disagree that the existing safety and efficacy data are sufficient for an NDA submission for symptomatic NERD; 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 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 9, 2023

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