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, 2022

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 February 9, 2022, Phathom Pharmaceuticals, Inc. (the "Company") announced positive topline results from PHALCON-NERD, a Phase 2 study evaluating three dose levels of vonoprazan (10 mg, 20 mg, and 40 mg) as an on-demand therapy for relief of episodic heartburn in subjects with non-erosive gastroesophageal reflux disease ("NERD"). In this double-blind, placebo-controlled study, all three vonoprazan dose levels successfully met the primary endpoint and were statistically significant ($p<0.0001$) when compared to placebo. The primary endpoint evaluated the percentage of heartburn episodes completely relieved within three hours ("complete relief") with relief sustained for over 24 hours ("sustained relief"). Within three hours, vonoprazan 10 mg, 20 mg, and 40 mg achieved complete and sustained relief in 56.0%, 60.6% and 70.0% of evaluable heartburn episodes, respectively, as compared to 27.3% of episodes for placebo. Evaluable heartburn episode is a heartburn episode for which the participant completes a minimum of one timed assessment after taking study medication.

The PHALCON-NERD trial also included an open-label daily dosing run-in phase where all participants enrolled received vonoprazan 20 mg once daily ("QD") for four weeks. Over this period the mean percentage of 24-hour heartburn free days observed was 65.4% (median 76.0%).

Vonoprazan was generally well tolerated in the trial. In both phases of the trial, no adverse event was reported in more than three percent of the participants in a treatment group. There were total of four serious adverse events ("SAEs") in the daily dosing phase and none in the on-demand phase. The safety data for all vonoprazan arms were comparable to placebo and consistent with what was reported in previous studies.

In addition to reporting the positive topline on-demand results, the Company also announced that it has initiated NERD-301, a Phase 3 study evaluating vonoprazan 10 mg and 20 mg QD for the treatment of NERD. The Company expects to report topline results from NERD-301 in 2023. In addition, based on the positive Phase 2 on-demand data, the Company also plans to discuss with the U.S. Food and Drug Administration ("FDA") a Phase 3 trial design to support the novel dosing regimen for vonoprazan as an on-demand treatment for episodic heartburn relief in patients with NERD, a dosing treatment regimen not approved in the U.S. for proton pump inhibitors.

Phathom plans to present the full results from this Phase 2 study at a future medical meeting.

PHALCON-NERD-201 study design

In this Phase 2 multi-site study conducted in the U.S., there were two separate phases. The daily dosing phase consisted of a four-week open-label run-in period where 458 participants with symptomatic NERD received vonoprazan 20 mg QD for up to four weeks. Participants recorded their heartburn symptoms during the run-in period using a twice daily electronic diary. Participants who had no heartburn on the last seven days of the run-in period and had complied with study drug and diary completion compliance requirements were randomized 1:1:1:1 to the on-demand phase of the trial.

The six-week on-demand phase consisted of four blinded study arms (n=207): vonoprazan 10 mg, vonoprazan 20 mg, vonoprazan 40 mg, and placebo comparator. Participants in the on-demand phase were instructed to take test medication at the onset of a heartburn episode and record their symptoms in an electronic diary over the following three hours. Participants were advised to refrain from taking rescue medication during the first three hours. Any additional heartburn episodes occurring up to 24 hours after study drug administration were also captured.

Data Table

Primary Endpoint – Complete and sustained relief within three hours

Dose	Number of evaluable heartburn episodes	% with complete and sustained heartburn relief within three hours	P-value
Placebo	370	27.3%	NA
Vonoprazan 10 mg	359	56.0%	p<0.0001
Vonoprazan 20 mg	327	60.6%	p<0.0001
Vonoprazan 40 mg	323	70.0%	p<0.0001

Forward Looking Statements

The Company 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 date of topline data from the Company's Phase 3 trial evaluating vonoprazan as daily dosing therapy for the treatment of NERD. The inclusion of forward-looking statements should not be regarded as a representation by the Company 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 the Company's business, including, without limitation: reported top-line data is based on preliminary analysis of key efficacy and safety data is subject to more audit and verification procedures that could result in material changes in the final data; the Company may experience delays in designing and initiating a Phase 3 study in NERD including in the event that the FDA does not agree with the Company's interpretation of the data; the Company'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; the Company's qualified infectious disease product and Fast Track designations may be withdrawn or not actually lead to a faster development or regulatory review or extended exclusivity, and would not assure FDA approval of vonoprazan; the Company's ability to obtain and maintain intellectual property protection for vonoprazan; the Company's ability to comply with its license agreement with Takeda; the Company'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 the Company 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, 2022

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