

**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): October 24, 2022

PHATHOM PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

001-39094
(Commission
File Number)

82-4151574
(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)

(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 October 24, 2022, Phathom Pharmaceuticals, Inc. (the “Company”) announced that it has completed patient enrollment in its PHALCON-NERD Daily Dosing Phase 3 trial of vonoprazan in non-erosive gastroesophageal reflux disease (“NERD”). The Company enrolled 776 patients. The Company expects to report topline data in the first quarter of 2023 and full results from the study in late 2023.

If successful, the Company believes that the trial will form the basis of a supplemental New Drug Application (“sNDA”) for vonoprazan as once daily therapy for the treatment of symptomatic NERD in adults in 2023.

NERD is the largest subcategory of gastroesophageal reflux disease (“GERD”) and is characterized by reflux-related symptoms in the absence of esophageal mucosal erosions. There are estimated to be over 65 million individuals with GERD in the U.S., and it is estimated that up to seventy percent (70%) of this population have NERD.

The primary endpoint of the double-blind Phase 3 PHALCON-NERD-301 study is evaluating 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 symptomatic NERD. The trial also includes a unique blinded 20-week long-term extension period to further evaluate the safety and efficacy of both doses of vonoprazan after six months

The Company is also currently in discussions with the U.S. Food and Drug Administration (“FDA”) on a second Phase 3 trial design to support 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 proton pump inhibitors.

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 availability of results from the PHALCON-NERD-301 trial, whether such trial will form the basis for an sNDA for vonoprazan as a once-daily treatment for NERD, and the timing for the submission of such sNDA with the FDA. 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: inherent risks of clinical development of vonoprazan; 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; the Company’s ability to successfully launch and commercialize vonoprazan; 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 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 uninterrupted business operations due to the ongoing impact of the COVID-19 coronavirus, including delaying or otherwise disrupting its clinical trials, manufacturing and supply chain and launch and commercialization efforts; the Company’s ability to achieve and maintain adequate levels of coverage and reimbursement for vonoprazan; the Company’s ability to access additional capital under each of its term loan facility and its revenue interest financing agreement which are subject to certain conditions; 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: October 24, 2022

By: /s/ Larry Miller

Larry Miller

General Counsel and Secretary