# 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): April 29, 2021**

# 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 April 29, 2021, Phathom Pharmaceuticals, Inc. (the "Company"), announced that in PHALCON-HP, its pivotal Phase 3 clinical trial for the eradication of Helicobacter pylori ("*H. pylori*") infection, both vonoprazan-based regimens successfully met their primary endpoints and met all secondary endpoints. The trial studied vonoprazan in combination with amoxicillin and clarithromycin ("vonoprazan triple therapy") and vonoprazan in combination with amoxicillin ("vonoprazan dual therapy") compared to lansoprazole in combination with amoxicillin and clarithromycin ("lansoprazole triple therapy").

PHALCON-HP is the largest Phase 3 registration trial ever conducted in *H. pylori* infection, randomizing 992 patients with confirmed *H. pylori* infection.

The primary endpoints in the PHALCON-HP study were non-inferiority of the *H. pylori* eradication rate for each of vonoprazan triple and dual therapy compared to lansoprazole triple therapy. Based on U.S. Food and Drug Administration ("FDA") feedback, the primary endpoint excluded patients with amoxicillin or clarithromycin resistant strains of *H. pylori*.

Both vonoprazan-based regimens successfully met their primary endpoints in the modified intent-to-treat ("mITT") population *H. pylori* eradication rates were 84.7% with vonoprazan triple therapy and 78.5% for vonoprazan dual therapy compared with 78.8% for lansoprazole triple therapy ($p<0.0001$ and $p=0.0037$, respectively, for non-inferiority).

Additional efficacy analyses were conducted using the pre-specified per protocol population, a subset of the mITT population comprised of patients who were protocol compliant as defined by FDA draft Guidance for Industry. In the per protocol population, *H. pylori* eradication rates were 90.4% with vonoprazan triple therapy and 81.2% with vonoprazan dual therapy compared to 82.1% with lansoprazole triple therapy ($p<0.0001$ and $p=0.0077$, respectively, for non-inferiority).

Vonoprazan triple therapy and vonoprazan dual therapy also met all secondary endpoints, demonstrating superior eradication rates versus lansoprazole triple therapy in all patients and patients with clarithromycin-resistant strains of *H. pylori*. Patients with clarithromycin resistant strains comprised 20.3% of the study population.

The *H. pylori* eradication rate of vonoprazan triple therapy was superior to that of lansoprazole triple therapy among all patients in both the mITT population (80.8% vs. 68.5%; $p=0.0001$) and the per protocol population (85.7% vs. 70.0%; $p<0.0001$).

The *H. pylori* eradication rate with vonoprazan triple therapy was superior to that of lansoprazole triple therapy in the subset of patients with *H. pylori* strains resistant to clarithromycin in both the mITT population (65.8% vs. 31.9%; $p<0.0001$) and the per protocol population (67.2% vs. 29.0%; $p<0.0001$).

The *H. pylori* eradication rate of vonoprazan dual therapy was superior to that of lansoprazole triple therapy among all patients in both the mITT population (77.2% vs. 68.5%; $p=0.0063$) and the per protocol population (81.1% vs. 70.0%; $p=0.0013$).

The *H. pylori* eradication rate of vonoprazan dual therapy was superior to that of lansoprazole triple therapy in the subset of patients with *H. pylori* strains resistant to clarithromycin in both the mITT population (69.6% vs. 31.9%; $p<0.0001$) and the per protocol population (79.5% vs. 29.0%; $p<0.0001$).

Both vonoprazan-based regimens were generally well tolerated with a safety profile comparable to lansoprazole triple therapy. The most common adverse events (>2.0%) reported in the vonoprazan triple therapy, vonoprazan dual therapy, and lansoprazole triple therapy arms, respectively, were diarrhea (4.0%, 5.2%, and 9.6%), dysgeusia (4.3%, 0.6%, and 6.1%), nausea (1.7%, 1.7% and 2.6%), headache (2.6%, 1.4%, 1.4%) and vaginal infections (2.3%, 0.9%, 0.3%). Overall rates of discontinuation due to adverse events were 2.3% percent for vonoprazan triple therapy-treated patients, 0.9% percent for vonoprazan dual therapy-treated patients, and 1.4% percent for lansoprazole triple therapy-treated patients.

Full results from the PHALCON-HP study will be presented at a future medical meeting and submitted for publication in a peer-reviewed journal.

The Company plans to submit new drug applications ("NDAs") with the FDA for vonoprazan triple therapy and vonoprazan dual therapy in *H. pylori* in the fourth quarter of 2021. The Company also expects to report top-line data from PHALCON-EE, the ongoing pivotal Phase 3 clinical trial of vonoprazan for the treatment of erosive gastroesophageal reflux disease, in the fourth quarter of 2021. In addition, in April 2021, the Company commenced enrollment of patients in its Phase 2 trial evaluating various doses of vonoprazan as an on-demand therapy for non-erosive reflux disease.

**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 submission of NDAs for the eradication of *H. pylori* infection; and the timing of top-line data from the PHALCON-EE clinical trial. 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; we may experience delays submitting the NDAs including in the event that the FDA does not agree with the Company's interpretation of the data or feedback from the FDA that may be inconsistent with feedback received at prior meetings with the FDA; 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 pending qualified infectious disease product ("QIDP") requests may not be granted and previously granted QIDP 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: April 29, 2021

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