## 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 27, 2021

# 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)

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)
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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:

Trading Symbol(s)

Common Stock, par value \$0.0001 per share

Trading Symbol(s)

Symbol(s)

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 ⊠

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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.  $\boxtimes$ 

#### Item 8.01 Other Events.

On September 27, 2021, Phathom Pharmaceuticals, Inc. (the "Company"), announced the results from VONO-103, a Phase 1, open-label, randomized, crossover study evaluating the pharmacokinetics, pharmacodynamics, and safety of vonoprazan (20 mg) once daily ("QD") and lansoprazole (30 mg) QD in healthy subjects in the US. In the study, vonoprazan demonstrated significantly greater acid inhibition as compared to lansoprazole. The study treatments were generally well tolerated with no reported serious adverse events.

The primary pharmacodynamic endpoints of VONO-103 were mean gastric pH over twenty four hours ("mean 24-hour pH value") and the percentage of time with gastric pH above 4 ("pH>4 holding time ratio" or "pH>4 HTR") on Days 1 and 7. Gastric pH levels are measured on a logarithmic scale from 0.0 to 14.0, in which each point represents a 10-fold change in acidity and higher pH values represent lower acidity.

Following the first dose, the mean 24-hour gastric pH value on Day 1 for vonoprazan was 4.6 as compared to 2.8 for lansoprazole (p<0.0001). The least squares mean pH>4 HTR on Day 1 for vonoprazan was 62.2% as compared to 23.2% for lansoprazole. Following seven days of once daily dosing, the mean 24-hour pH value on Day 7 for vonoprazan was 5.9 as compared to 3.8 for lansoprazole (p<0.0001). The least squares mean pH>4 HTR on Day 7 was 86.8% for vonoprazan as compared to 42.1% for lansoprazole. The least squares mean difference in pH>4 HTR on Days 1 and 7 for vonoprazan vs. lansoprazole was 39.0% [95% confidence interval (CI): 31.9-46.0; p<0.0001] and 44.6% [95% CI: 37.6-51.7; p<0.0001], respectively.

VONO-103 is the first pharmacokinetic and pharmacodynamic (PK/PD) and safety study comparing vonoprazan 20 mg QD and lansoprazole 30 mg QD. Phathom is also currently conducting PHALCON-EE, a Phase 3 study in patients with erosive esophagitis, comparing vonoprazan and lansoprazole in both healing and maintenance of healing of erosions, as well as the relief of heartburn. Topline results of PHALCON-EE are expected in October 2021.

#### **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 topline results from the PHALCON-EE Phase 3 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: September 27, 2021

: /s/ Larry Miller

Larry Miller

General Counsel and Secretary