# 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): August 21, 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 August 21, 2023, Phathom Pharmaceuticals, Inc. ("Phathom" or the "Company") announced that it has submitted to the U.S. Food and Drug Administration ("FDA") six-month stability data from its long-term and accelerated stability program for its reformulated vonoprazan tablets. The additional stability was required for the FDA to complete its New Drug Application ("NDA") review for vonoprazan, the Company's potassium-competitive acid blocker (PCAB), for the treatment of Erosive GERD (gastroesophageal reflux disease), also referred to as erosive esophagitis.

With the submission of this data, Phathom believes it has satisfied the FDA's request for additional data in response to the Complete Response Letter (CRL) issued in February 2023 relating to specifications and controls for a nitrosamine drug substance related impurity, N-nitroso-vonoprazan (NVP). Phathom resubmitted the NDA for vonoprazan for Erosive GERD in May 2023 on the basis of three months of stability data, and the resubmission was assigned a PDUFA goal date of November 17, 2023.

The long-term and accelerated six-month data from Phathom's stability program has demonstrated that the minor drug product tablet reformulation is controlling NVP growth through six months and keeping levels greater than 10 fold below the acceptable daily intake limit of 96 ng/day or 2.4 ppm based on the maximum approved daily dose of 40 mg/day.

The NDA seeks regulatory approval for vonoprazan as a treatment for the healing and maintenance of healing of Erosive GERD, and relief of associated heartburn symptoms, and was previously classified as a Class 2 resubmission with a six-month review period. If approved, a combined U.S. commercial launch for Erosive GERD and H. pylori is planned for the fourth quarter of 2023.

**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 about the potential of vonoprazan as a treatment for Erosive GERD and H. pylori; Phathom's expectations that the stability data will support the requested shelf life of 24 months; the timing of potential approval of the Erosive GERD NDA; and the timing of a U.S. commercial launch for Erosive GERD and H. pylori indications. 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: the FDA may determine that the NDA resubmission does not adequately address the deficiencies raised in the CRL; future data generated from our stability program may be different from the data generated to date and may not demonstrate that our mitigation efforts will meet the acceptable intake (AI) of the nitrosamine impurity, or reduce the impurity to an acceptable level throughout the six-month period required by FDA or the shelf life of the product, to obtain approval for its Erosive GERD NDA or to bring vonoprazan to market for patients with Erosive GERD, if approved, or for patients with H. pylori, if the pending prior approval supplements to the convenience pack NDAs are approved; risks associated with product manufacturing or formulation changes required to be made in connection with achieving the AI; the FDA may disagree that the existing safety and efficacy data, together with additional data, is sufficient to approve the Erosive GERD NDA or supplements to the H. pylori NDAs; 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; 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: August 21, 2023

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