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): June 12, 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 June 12, 2023, Phathom Pharmaceuticals, Inc. ("Phathom" or the "Company"), a biopharmaceutical company focused on developing and commercializing novel treatments for gastrointestinal diseases, announced that the U.S. Food and Drug Administration ("FDA") has acknowledged that its New Drug Application (NDA) resubmission for vonoprazan, a novel first-in-class potassium-competitive acid blocker (PCAB), for the treatment of Erosive GERD (gastroesophageal reflux disease) constitutes a complete response to the February 2023 complete response letter. The FDA has classified this as a Class 2 resubmission and assigned a Prescription Drug User Fee Act (PDUFA) goal date of November 17, 2023.

The NDA resubmission, which was submitted in response to the complete response letter (CRL) issued by the FDA in February 2023, contained three months of stability data of reformulated vonoprazan tablets to support the commercial shelf life of vonoprazan. Phathom announced that it will continue to provide additional stability data during the regulatory review as previously agreed with FDA as part of the resubmission.

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. 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 our anticipated supplements to NDAs are approved; prior to commercial launch of the *H. pylori* convenience packs, Phathom must submit post approval supplements to the relevant NDAs and Phathom may not submit such supplements on the timeframe it expects and the FDA may not approve such supplements to the *H. pylori* convenience pack NDAs; 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* convenience pack 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: June 12, 2023

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