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 30, 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 October 30, 2023, Phathom Pharmaceuticals, Inc. ("Phathom" or the "Company"), announced that the U.S. Food and Drug Administration ("FDA") approved prior approval supplements covering reformulated vonoprazan tablets in both VOQUEZNA® TRIPLE PAK® (vonoprazan tablets, amoxicillin capsules, clarithromycin tablets) and VOQUEZNA® DUAL PAK® (vonoprazan tablets, amoxicillin capsules), for the treatment of *Helicobacter pylori* ("*H. pylori*") infection in adults. VOQUEZNA treatment regimens contain antibiotics conveniently packaged with vonoprazan, a novel potassium-competitive acid blocker and the first innovative acid suppressant from a new drug class approved in the U.S. in over 30 years.

VOQUEZNA TRIPLE PAK and VOQUEZNA DUAL PAK are expected to be available in the U.S. in December 2023 and marketed exclusively by the Company. Phathom is planning for a combined U.S. commercial launch of VOQUEZNA TRIPLE PAK and VOQUEZNA DUAL PAK, together with vonoprazan for Erosive GERD, if approved.

H. pylori is a bacterial pathogen that is estimated to infect nearly 115 million individuals in the United States. If left untreated, *H. pylori* infection can lead to serious complications, such as peptic ulcer disease and non-cardia gastric cancer. Approximately 50% of the world and 36% of the U.S. population is estimated to be infected with the bacterium. As a result of the chronic inflammation induced by *H. pylori* infection, infected patients may develop a range of pathologies including dyspepsia, peptic ulcer disease, non-cardia gastric cancer, and mucosa-associated lymphoid tissue (MALT) lymphoma. Studies have found that roughly 1 in 4 patients treated for *H. pylori* will fail first-line therapy when using PPI-based clarithromycin triple therapy.

Forward Looking Statements

This report contains forward-looking statements. Investors are cautioned not to place undue reliance on these forward-looking statements, including statements about the timing of the commercial launch of convenience packs containing vonoprazan for *H. pylori* infection, the potential of vonoprazan-based therapies to address declining *H. pylori* eradication rates in the U.S., and statements regarding the PDUFA goal date and the timing of a U.S. commercial launch for vonoprazan 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: future data generated from our stability program may be different from the data submitted to the FDA to date and may not demonstrate that our mitigation efforts will continue to maintain the level of the nitrosamine impurity below the acceptable intake (AI) level throughout the shelf life of products containing vonoprazan, which could result in market action or shelf life reduction; 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; 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 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 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: October 30, 2023

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