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): November 1, 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 November 1, 2023, Phathom Pharmaceuticals, Inc. ("Phathom" or the "Company"), announced that the U.S. Food and Drug Administration ("FDA") approved VOQUEZNA® (vonoprazan) tablets 10 mg and 20 mg, a novel potassium-competitive acid blocker (PCAB), as a new treatment for adults for the healing of all grades of Erosive GERD (gastroesophageal reflux disease), maintenance of healing of all grades of Erosive GERD, and relief of heartburn associated with Erosive GERD.

Erosive GERD, also referred to as erosive esophagitis or erosive acid reflux, is a major type of GERD that affects approximately 20 million people in the United States. In addition to experiencing troubling heartburn symptoms, patients with inadequately treated Erosive GERD may develop more severe diseases including Barrett's esophagus, a condition in which esophageal tissue changes can progress to cancer.

This approval is based on positive results from the Phase 3 PHALCON-EE study (NCT04124926). The pivotal trial was a randomized, double-blind, multicenter study that enrolled 1,024 patients with Erosive GERD in the United States and Europe and compared VOQUEZNA to the PPI lansoprazole in the healing and maintenance of healing of Erosive GERD and associated heartburn symptom relief.

Results showed that VOQUEZNA 20 mg met the primary endpoint of non-inferiority ($p<0.0001$) for complete healing by Week 8 in patients with all grades of Erosive GERD with a healing rate of 93% compared to 85% for lansoprazole 30 mg, with superior rates of healing demonstrated in a secondary endpoint in patients with moderate-to-severe disease (LA Grade C/D) at Week 2 compared to lansoprazole (70% for VOQUEZNA 20 mg and 53% for lansoprazole 30 mg) ($p=0.0008$). VOQUEZNA 20 mg also demonstrated non-inferiority to lansoprazole 30 mg in the mean percentage of 24-hour heartburn free days over the healing period. In the maintenance phase of the trial, VOQUEZNA 10 mg was superior to lansoprazole 15 mg in maintaining healing at six months in all randomized patients (79% for VOQUEZNA 10 mg, compared to 72% for lansoprazole 15 mg) as well as in the subset of patients with moderate-to-severe Erosive GERD (75% for VOQUEZNA 10 mg, compared to 61% for lansoprazole 15 mg) ($p=0.0490$). In addition, VOQUEZNA 10 mg was evaluated as a secondary endpoint for relief of heartburn in Erosive GERD patients and demonstrated non-inferiority to lansoprazole 15 mg over six months.

Adverse event (AE) rates for VOQUEZNA were comparable to lansoprazole in the trial. The most common AEs in the healing phase (> 2% in the VOQUEZNA treatment arm) were gastritis (3.0% for VOQUEZNA 20 mg and 2.0% for lansoprazole 30 mg), diarrhea (2.0% for VOQUEZNA 20 mg and 3.0% for lansoprazole 30 mg), abdominal distension (2.0% for VOQUEZNA 20 mg and 1.0 % for lansoprazole 30 mg), abdominal pain (2.0% for VOQUEZNA 20 mg and 1.0% for lansoprazole 30 mg) and nausea (2.0% for VOQUEZNA 20 mg and 1.0% for lansoprazole 30 mg). The most common AEs in the maintenance phase (> 3% in the VOQUEZNA treatment arm) for VOQUEZNA 10 mg compared to lansoprazole 15 mg were gastritis (6.0% vs. 3.0%), abdominal pain (4.0% vs. 2.0%), dyspepsia (4.0% vs. 3.0%), hypertension (3.0% vs. 2.0%), and urinary tract infection (3.0% vs. 2.0%).

VOQUEZNA is expected to be available in the United States in December 2023 and will be marketed exclusively by Phathom.

Based on the terms of the Revenue Interest Financing Agreement, dated May 3, 2022 and amended October 31, 2022, the FDA approval of VOQUEZNA for Erosive GERD also entitles the Company to receive a $175.0 million payment. Phathom expects to use the proceeds from this non-dilutive capital to help fund the commercial launch of VOQUEZNA.

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 a U.S. commercial launch for vonoprazan for Erosive GERD, the timing of receiving and anticipated use of proceeds from the Revenue Interest Financing Agreement and the size of the Erosive GERD patient population. 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: we may not be able to successfully commercialize VOQUEZNA which will depend on a number of factors including coverage and reimbursement levels from governmental authorities and health insurers as well as market acceptance by healthcare providers; the Company has broad discretion in the use of proceeds from the Revenue Interest Financing Agreement; 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 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: November 1, 2023

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