

**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 28, 2023

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)
- 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:

<u>Title of each class</u>	<u>Trading Symbol(s)</u>	<u>Name of each exchange on which registered</u>
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 28, 2023, Phathom Pharmaceuticals, Inc. (“Phathom” or the “Company”) announced the U.S. commercial launch and availability of 30-count bottles of VOQUEZNA® (vonoprazan) tablets for the treatment of adults with Erosive Esophagitis, also known as Erosive GERD (gastroesophageal reflux disease), and the relief of associated heartburn.

The U.S. Food and Drug Administration (FDA) recently approved VOQUEZNA for the healing of all severities (grades) of Erosive GERD, maintenance of healing of all severities of Erosive GERD, and relief of heartburn associated with Erosive GERD in adults. Its novel mechanism of action (MOA) provides rapid, potent, and durable acid suppression in a way that is distinct from other prescription and over-the-counter medications. Additionally, VOQUEZNA does not have the burden of mealtime dosing, whereas most PPIs must always be taken with food.

In a Phase 3, randomized clinical study, VOQUEZNA 20 mg met the primary endpoint of non-inferiority for complete healing by Week 8 in patients with all severities of Erosive GERD, demonstrating a strong 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 at Week 2 compared to lansoprazole (70% for VOQUEZNA 20 mg and 53% for lansoprazole 30 mg). In the maintenance phase of the study, 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).

The most common side effects of VOQUEZNA for the treatment of Erosive GERD include stomach inflammation, diarrhea, stomach bloating, stomach pain, nausea, indigestion, high blood pressure, and urinary tract infection.

Prescriptions for VOQUEZNA may be filled at major retail pharmacies and also through BlinkRx, an end-to-end digital fulfillment channel. Phathom is offering programs for eligible patients who face coverage or affordability issues, including co-pay assistance for patients with commercial insurance.

In addition, VOQUEZNA TRIPLE PAK® (vonoprazan tablets, amoxicillin capsules, clarithromycin tablets) and VOQUEZNA DUAL PAK® (vonoprazan tablets, amoxicillin capsules), two treatment regimens for adults with *H. pylori* infection, are expected to be commercially available in mid-December 2023. VOQUEZNA TRIPLE PAK and VOQUEZNA DUAL PAK each contain 14-days of VOQUEZNA-based treatment co-packaged with antibiotics in convenient blister packs.

VOQUEZNA is marketed exclusively by Phathom Pharmaceuticals, Inc.

Forward Looking Statements

This report contains forward-looking statements, including statements regarding the commercial availability of VOQUEZNA TRIPLE PAK and VOQUEZNA DUAL PAK. Investors are cautioned not to place undue reliance on these forward-looking statements. 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; 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 28, 2023

By: /s/ Larry Miller

Larry Miller

General Counsel and Secretary