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): December 11, 2024

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 December 11, 2024, Phathom Pharmaceuticals, Inc. ("Phathom" or the "Company"), announced that it has submitted a Citizen Petition ("CP") with the U.S. Food and Drug Administration ("FDA"). The petition formally requests correction of the Orange Book listings for VOQUEZNA (vonoprazan) 10 mg and 20 mg tablets to accurately reflect the full 10-year New Chemical Entity ("NCE") exclusivity period until May 3, 2032.

The update would align the VOQUEZNA tablets Orange Book listings to reflect the same period of NCE exclusivity that was granted upon approval of vonoprazan-based VOQUEZNA TRIPLE PAK® and VOQUEZNA DUAL PAK® in May 2022. The statutory 10-year exclusivity period encompasses the five-year standard exclusivity period for NCEs as extended by the additional five years by operation of the Generating Antibiotic Incentives Now ("GAIN") Act. As VOQUEZNA tablet products contain the same drug substance with the active moiety, vonoprazan, they should be entitled to the same protection.

The main points addressed in Phathom's Citizen Petition include:

- **New Chemical Entity Exclusivity Provisions:** The approval of VOQUEZNA TRIPLE PAK and VOQUEZNA DUAL PAK in May 2022 triggered a 10-year NCE exclusivity period by operation of the GAIN Act, tied to the drug substance containing vonoprazan, which had never previously been approved. This exclusivity period expires in May 2032. Under the law and FDA's longstanding interpretations of it, NCE exclusivity precludes the submission of any Abbreviated New Drug Application ("ANDA") or 505(b)(2) New Drug Application ("NDA") referencing any drug containing vonoprazan for the NCE exclusivity period, including VOQUEZNA tablets.
- **The GAIN Act:** The NCE exclusivity period awarded upon approval of VOQUEZNA DUAL PAK and VOQUEZNA TRIPLE PAK is 10 years. This is because the GAIN Act's application to the approval of VOQUEZNA DUAL PAK and VOQUEZNA TRIPLE PAK was to extend, by five years, the underlying NCE exclusivity tied to the drug substance containing vonoprazan. While the GAIN Act includes certain limitations on the application of the extension, none of these exceptions have any effect on the 10-year NCE exclusivity period already awarded and honored by the FDA, and such 10-year NCE exclusivity period equally benefits any vonoprazan-containing products, including VOQUEZNA tablets.
- **Established and Sound Public Policy:** As mandated by the plain language of the applicable statutes and the FDA's longstanding interpretations, Phathom requests that the FDA promptly correct the Orange Book to accurately reflect the statutorily-required 10-year period of NCE exclusivity for vonoprazan in the Orange Book listings for the VOQUEZNA tablet products, identifying the correct expiry date of May 3, 2032.

Phathom expects the CP and related docket information to be made available on the www.regulations.gov website in the coming days. The FDA must provide a response to the petition within 180 days from the date of submission. The response will either approve the petition, deny or dismiss the petition, or provide a tentative response indicating why the agency hasn't been able to reach a decision. The Company believes that a CP affords the FDA the ability to analyze the request under an established framework, and ultimately formalize its decision in accordance with its procedural regulations.

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 ultimate decision by the FDA on the action requested in the CP and the timing any FDA action regarding the CP; the possible extension of NCE exclusivity to VOQUEZNA tablets; and the expected duration of patent term extension for VOQUEZNA. 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 reject Phathom's request to correct the Orange Book listings identifying the expiration date for the NCE exclusivity period on the VOQUEZNA tablets Orange Book listings; the FDA may take longer than the Company expects to act on its CP, if at all; members of the public may comment on the Company's CP which may influence the FDA's decision; Phathom's ability to obtain and maintain intellectual property protection, including patent term extensions, and non-patent regulatory exclusivity for vonoprazan; Phathom may face competition earlier than expected if it loses or fails to obtain any of its patent protection or non-patent regulatory exclusivity for VOQUEZNA tablets; 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 most recent 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: December 11, 2024

By: /s/ Molly Henderson
Molly Henderson
Chief Financial and Business Officer