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 18, 2021

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 2.02 Results of Operations and Financial Condition.

As described in Item 8.01 below, on October 18, 2021, Phathom Pharmaceuticals, Inc. (the "Company") issued a press release announcing the topline data from the Company's Phase 3 clinical trial of vonoprazan for the healing of all grades of erosive esophagitis ("EE") and relief of heartburn, and maintenance of healing of all grades of EE and relief of heartburn. In this press release, the Company disclosed that as of September 30, 2021, Phathom had approximately $225 million in cash and cash equivalents. The Company's cash and cash equivalents as of September 30, 2021, reflects the Company's drawdown of $100 million pursuant to its previously announced Loan and Security Agreement (the "Loan Agreement") with Hercules Capital, Inc. and the payment of approximately $54 million to satisfy in full and retire the indebtedness under the Company's previous credit facility with Silicon Valley Bank. The announcement of the positive PHALCON-EE data, as described in Item 8.01 below, provides the Company with access to an additional $50 million from the Loan Agreement.

The Company's estimated cash and cash equivalents at September 30, 2021, is preliminary, has not been audited and is subject to change upon completion of the preparation of the Company's financial statements as of and for the three and nine months ended September 30, 2021. In addition, the Company's independent registered public accounting firm has not audited, reviewed, compiled or performed any procedures with respect to this unaudited preliminary financial information and does not express an opinion or any other form of assurance with respect thereto. These results could change as a result of further review. Additional information and disclosures would be required for a more complete understanding of the Company's financial condition, liquidity and results of operations as of and for the three and nine months ended September 30, 2021.

Accordingly, undue reliance should not be placed on such preliminary estimates. The information contained in this Item 2.02 shall not be incorporated by reference into any filing of the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing, unless expressly incorporated by specific reference to such filing. The information in this Item 2.02 shall not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that section or Sections 11 and 12(a)(2) of the Securities Act of 1933, as amended.

Item 8.01 Other Events.

On October 18, 2021, the Company announced that vonoprazan successfully met its primary endpoints and key secondary superiority endpoints in PHALCON-EE, a pivotal Phase 3 trial evaluating vonoprazan versus lansoprazole for the treatment of EE. Based on the positive PHALCON-EE data, the Company plans to submit a new drug application ("NDA") in the first half of 2022 to the U.S. Food and Drug Administration (the "FDA") seeking the following indications: healing of all grades of EE and relief of heartburn, and maintenance of healing of all grades of EE and relief of heartburn. We expect a decision on the NDA in 2023 and, if approved, we expect a commercial launch of vonoprazan for the treatment of EE in 2023.

Study Design

PHALCON-EE was a trial with two phases. In the first phase, vonoprazan 20 mg was compared to lansoprazole 30 mg in the healing of EE after up to 8 weeks of treatment ("Healing Phase"). In the Healing Phase, patients were assessed via endoscopy to determine complete healing following 2 weeks of treatment and, if complete healing was not achieved, a second endoscopy occurred at 8 weeks of treatment. Patients who achieved complete healing were re-randomized into the second phase of the trial, where vonoprazan 10 mg and 20 mg were compared to lansoprazole 15 mg to assess maintenance of healing via endoscopy following 24 weeks of treatment ("Maintenance Phase"). Heartburn symptom relief was assessed via secondary endpoints in both the Healing and Maintenance Phases of the study based on twice daily e-diary data collection.

Study Results

Healing Phase

The primary endpoint of the Healing Phase was non-inferiority of vonoprazan 20 mg compared to lansoprazole 30 mg in the percentage of all patients who have complete healing of EE by Week 8. Vonoprazan met the Healing Phase primary endpoint with a healing rate of 93% compared to 85% for lansoprazole ($p<0.0001$). In a preplanned exploratory superiority test, the difference between vonoprazan and lansoprazole was also significant ($p<0.0001$).[1]

1 Exploratory superiority comparison, nominal p value presented.

Vonoprazan met the secondary superiority endpoint of healing in patients with moderate-to-severe disease[2] at Week 2, demonstrating significantly faster healing than lansoprazole (70% for vonoprazan 20 mg and 53% for lansoprazole 30 mg) (p=0.0004). Vonoprazan 20 mg was also compared to lansoprazole 30 mg in a superiority test for onset of sustained resolution of heartburn by day 3 but did not achieve statistical significance (p=0.2196). In additional secondary endpoint superiority comparisons, vonoprazan 20 mg healing rates were numerically greater than lansoprazole 30 mg in all patients at Week 2 (p=0.0174)[3] and in moderate-to-severe patients[2] by Week 8 (p<0.0001)[3] although deemed nominally significant due to the sequential testing method.

Vonoprazan also met the secondary endpoint of showing non-inferiority to lansoprazole 30 mg in the mean percentage of 24-hour heartburn free days over the healing period.

Maintenance Phase

Vonoprazan met the primary and all secondary endpoints in the Maintenance Phase. The primary endpoint of the Maintenance Phase was non-inferiority of vonoprazan 10 mg and 20 mg compared to lansoprazole 15 mg in the percentage of all patients who maintained healing of EE through Week 24.

Both vonoprazan doses met the Maintenance Phase primary endpoint of non-inferiority while also meeting the secondary comparison demonstrating superiority of maintenance of healing versus lansoprazole (79% for vonoprazan 10 mg, 81% for vonoprazan 20 mg compared to 72% for lansoprazole 15 mg) (p<0.0001 for both non-inferiority comparisons; p=0.0218 for vonoprazan 10 mg superiority comparison; p=0.0068 for vonoprazan 20 mg superiority comparison).

Both vonoprazan doses also met the secondary endpoint of demonstrating superiority of the percentage of patients with moderate-to-severe disease[2] who maintained healing of EE through Week 24 (75% vonoprazan 10 mg, 77% vonoprazan 20 mg v. 61% lansoprazole 15 mg) (p=0.0245 for vonoprazan 10 mg superiority comparison; p=0.0098 for vonoprazan 20 mg superiority comparison). Additionally, both vonoprazan doses also met the secondary endpoint of showing non-inferiority to lansoprazole 15 mg in the mean percentage of 24-hour heartburn free days over the maintenance period.

Safety profile

Overall, the safety results for vonoprazan observed in PHALCON-EE were consistent with the results observed in prior clinical studies.

The most common reported adverse event in the Healing Phase was diarrhea (2.1% for vonoprazan 20 mg and 2.5% for lansoprazole 30 mg). The most commonly reported adverse events in the Maintenance Phase (>5%) were COVID-19 infection (10.1% vonoprazan 20 mg, 6.1% vonoprazan 10 mg, 6.7% lansoprazole 15 mg), gastritis (2.7% vonoprazan 20 mg, 6.4% vonoprazan 10 mg, 2.7% lansoprazole 15 mg), and abdominal pain (5.4% vonoprazan 20 mg, 4.1% vonoprazan 10 mg, 2.4% lansoprazole 15 mg).

Frequency of serious adverse events (“SAEs”) in the Healing Phase were the same between vonoprazan 20 mg and lansoprazole 30 mg at 0.6%. In the Maintenance Phase, SAEs were reported in 4.7% of patients for vonoprazan 20 mg, 3.4% for vonoprazan 10 mg and 2.4% for lansoprazole 15 mg. COVID-19 infection was the only SAE reported in more than one patient per group. There were seven COVID-19 SAEs across both phases of the study (5 on vonoprazan 20 mg and 2 on vonoprazan 10 mg). Two deaths occurred among the reported COVID-19 SAE cases.

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2 Patients with moderate-to-severe disease relates to patients with esophageal erosions classified as Grades C or D by the Los Angeles (LA) Classification System

3 Superiority comparison, not tested due to the pre-specified testing hierarchy, nominal p value presented

None of the COVID-19 SAEs were deemed related to the study drug by the investigator.

The Company plans to present the full results from the PHALCON-EE study at a medical meeting next year and submit them for publication in a peer-reviewed journal.

Detailed PHALCON-EE Topline Data

PHALCON-EE Topline Data

Endpoints (Healing Phase) (n=1024*)	Vonoprazan 20 mg (n=514)	Lansoprazole 30 mg (n=510)	P-Value (95%CI)
A **% of all patients healed by Week 8**	93%	85%	p<0.0001[1] [p<0.0001][2]
Mean % of 24-hour heartburn free days over the healing period	67%	64%	-1.60, 7.03[5]
% of Grades C/D patients healed at Week 2	70%	53%	p=0.0004[3]
% of all patients with onset of sustained resolution of heartburn by Day 3	34%	32%	p=0.2196[3]
% of Grades C/D patients healed by Week 8	92%	72%	[p<0.0001][4]
% of all patients healed at Week 2	74%	68%	[p=0.0174][4]

Endpoints (Maintenance of Healing)	Vonoprazan 20 mg (n=291)	Vonoprazan 10 mg (n=293)	Lansoprazole 15 mg (n=294)	P-Value (95%CI) vono 20mg v. lanso 15mg	P-Value (95%CI) vono 10mg v. lanso 15mg
A **% of all patients maintained through Week 24**	81%	79%	72%	p<0.0001[1] p=0.0068[3]	p<0.0001[1] p=0.0218[3]
% of Grades C/D patients maintained through Week 24	77%	75%	61%	p=0.0098[3]	p=0.0245[3]
Mean % of 24-hour heartburn free days through Week 24[1]	81%	81%	79%	-2.63, 6.72[5]	-2.27, 6.84[5]

A primary endpoint
1 non-inferiority comparison for primary endpoints
2 exploratory superiority comparison, nominal p value presented
3 superiority comparison
4 superiority comparison, not significant based on pre-specified testing hierarchy, nominal p value presented
5 non-inferiority comparison, non-inferiority margin 15%
***** 34.3% of the 1024 patients were classified as having LA Grades C/D erosions

Forward Looking Statements

The Company 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 regarding the expected submission of an NDA

for the healing of all grades of EE and relief of heartburn, and maintenance of healing of all grades of EE and relief of heartburn and the Company's ability to access additional capital under the Loan Agreement. The inclusion of forward-looking statements should not be regarded as a representation by the Company 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 the Company's business, including, without limitation: reported top-line data is based on preliminary analysis of key efficacy and safety data is subject to more audit and verification procedures that could result in material changes in the final data; the Company may experience delays submitting the NDAs including in the event that the FDA does not agree with the Company's interpretation of the data or feedback from the FDA that may be inconsistent with feedback received at prior meetings with the FDA; Phathom' ability to access additional capital under the Loan Agreement is subject to certain conditions including verification by the lender that the clinical milestone has been met; the Company'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; the Company's pending qualified infectious disease product ("QIDP") requests may not be granted and previously granted QIDP and Fast Track designations may be withdrawn or not actually lead to a faster development or regulatory review or extended exclusivity, and would not assure FDA approval of vonoprazan; the Company's ability to obtain and maintain intellectual property protection for vonoprazan; the Company's ability to comply with its license agreement with Takeda; the Company's ability to maintain undisrupted business operations due to the ongoing spread of the COVID-19 coronavirus, including delaying or otherwise disrupting its clinical trials, manufacturing and supply chain, 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 the Company 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 18, 2021

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