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): May 11, 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.

On May 11, 2021, Phathom Pharmaceuticals, Inc. (the "Company") issued a press release announcing its financial results for the quarter ended March 31, 2021. A copy of the press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

In accordance with General Instruction B.2 of Form 8-K, the information in this Current Report on Form 8-K, including Exhibit 99.1, shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, whether made before or after the date hereof, except as expressly set forth by specific reference in such filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release issued on May 11, 2021

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: May 11, 2021

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

Exhibit 99.1

Phathom Pharmaceuticals Reports First Quarter 2021 Results and Provides Recent Business Updates

- Positive Phase 3 trial of vonoprazan in Helicobacter pylori (*H. pylori*) infection; New Drug Applications (NDAs) targeted for the fourth quarter of 2021
- U.S. Food and Drug Administration (FDA) grants additional qualified infectious disease product (QIDP) designations to vonoprazan-based regimens with amoxicillin capsules; FDA had previously designated vonoprazan-based regimens with amoxicillin tablets as QIDP
- Initiated Phase 2 trial evaluating vonoprazan on-demand in non-erosive reflux disease (NERD) – disease with large unmet need impacting an estimated more than 40 million people in the U.S.
- Pivotal Phase 3 PHALCON-EE trial topline results expected in the fourth quarter of 2021

Florham Park, N.J., May 11, 2021 – Phathom Pharmaceuticals, Inc. (Nasdaq: PHAT), a late clinical-stage biopharmaceutical company focused on developing and commercializing novel treatments for gastrointestinal diseases, today reported financial results for the first quarter of 2021 and provided an update on its recent clinical and organizational progress.

“With both the impressive results from our pivotal Phase 3 PHALCON-HP trial and the initiation of our NERD development program, Phathom marks a strong start to 2021 having accomplished two of our key strategic imperatives for the year,” said Terrie Curran, Phathom’s President and Chief Executive Officer. “We are well-positioned to further build on this positive momentum as we anticipate several other significant catalysts in 2021 – including the expected readout from our pivotal Phase 3 trial in erosive esophagitis and the planned NDA submissions for vonoprazan-based regimens in the treatment of *H. pylori* infection.”

PHALCON-HP Clinical Development and Regulatory Updates:

- On April 29, 2021, the company announced PHALCON-HP, a pivotal Phase 3 trial of vonoprazan in *H. pylori* infection, met all primary and secondary endpoints.
- The PHALCON-HP study met the FDA required primary endpoints of noninferiority for vonoprazan in combination with amoxicillin and clarithromycin (“vonoprazan triple therapy”) and vonoprazan in combination with amoxicillin (“vonoprazan dual therapy”) compared to lansoprazole in combination with amoxicillin and clarithromycin (“lansoprazole triple therapy”) in clarithromycin sensitive patient population.
- The PHALCON-HP study also demonstrated vonoprazan triple therapy and vonoprazan dual therapy were superior in the eradication of *H. pylori* compared to lansoprazole triple therapy in all patients and patients with clarithromycin resistant strains of *H. pylori*.
- Based on these positive results, Phathom remains on track to submit NDAs for both vonoprazan-based regimens in the fourth quarter of 2021.
- In May 2021, the FDA granted additional QIDP designations to vonoprazan triple therapy and vonoprazan dual therapy, each containing amoxicillin capsules, for the treatment of *H. pylori* infection. The FDA had previously granted QIDP designations to vonoprazan-based *H. pylori* regimens containing amoxicillin tablets.

Other Clinical and Business Updates:

- In April 2021, the company commenced its NERD program by initiating PHALCON-NERD on-demand, a Phase 2 trial evaluating various doses of vonoprazan as an on-demand therapy for patients with NERD. The company expects to complete patient enrollment in the fourth quarter of 2021 and share topline results in the first half of 2022. NERD is a major subcategory of gastroesophageal reflux disease (GERD) and is characterized by reflux-related symptoms in the absence of esophageal erosions. There are estimated to be over 40 million people with NERD in the U.S.

- The PHALCON-EE pivotal Phase 3 trial evaluating vonoprazan for both the healing and maintenance of healing of erosive esophagitis, as well as the relief of heartburn, remains on-track with topline results expected in the fourth quarter of 2021.
- Phathom will have a significant presence at the Digestive Disease Week® (DDW) Virtual Meeting scheduled for May 21-23, 2021. A vonoprazan-focused poster presentation, *The Effect of Food on the Pharmacokinetics of the Potassium-competitive Acid Blocker Vonoprazan*, has received recognition as a of a poster of distinction and will be presented in a virtual session. The poster will be presented live by Prof. Colin W. Howden, MD, FRCP, FACP, AGAF, FACG, on May 22, 2021 at 12:15 pm ET. More information about Phathom's DDW abstracts will be made available on www.phathompharma.com following the conference.

First Quarter 2021 Financial Results:

- First quarter 2021 net loss was $34.8 million compared to $20.1 million for the first quarter of 2020.
- First quarter 2021 net loss included a non-cash charge related to stock-based compensation of $3.8 million compared to the first quarter of 2020 non-cash charges related to stock-based compensation of $0.6 million and change in fair value of warrant liabilities of ($0.1) million.
- First quarter 2021 research and development expenses increased to $20.6 million compared to $15.9 million for the first quarter 2020 as a result of higher chemistry, manufacturing, and controls (CMC) costs, clinical trial costs, and personnel-related expenses. Compared to the fourth quarter of 2020, research and development expenses decreased by $21.0 million following the acceleration of patient enrollment in our Phase 3 trials during late 2020.
- First quarter 2021 general and administrative expenses increased to $13.0 million compared to $4.5 million for the first quarter of 2020 due to the ongoing buildout of administrative and commercial functions.
- As of March 31, 2021, cash and cash equivalents were $238.0 million. Cash and cash equivalents are expected to be sufficient to meet anticipated cash requirements into the fourth quarter of 2022.

About Vonoprazan

Vonoprazan is an investigational, oral small molecule potassium-competitive acid blocker (P-CAB). P-CABs are a novel class of medicines that block acid secretion in the stomach. Vonoprazan has shown the potential to have rapid, potent, and durable anti-secretory effects as a single agent in the treatment of gastroesophageal reflux disease (GERD) and in combination with antibiotics for the treatment of Helicobacter pylori (*H. pylori)* infection. The FDA has designated vonoprazan in combination with both amoxicillin and clarithromycin and with amoxicillin alone as qualified infectious disease products (QIDP) and awarded them Fast Track status for the treatment of *H. pylori* infection. Phathom in-licensed the U.S., European, and Canadian rights to vonoprazan from Takeda, which completed 19 Phase 3 trials for vonoprazan and received marketing approval in Japan and numerous other countries in Asia and Latin America.

About PHALCON-HP

PHALCON-HP was a randomized, multicenter, Phase 3 trial that enrolled 1046 patients of which 992 patients with a confirmed *H. pylori* infection were randomized to one of three arms: vonoprazan 20 mg administered twice a day (BID) and amoxicillin 1g administered three times a day (TID) (n=324); vonoprazan 20 mg BID, amoxicillin 1g BID and clarithromycin 500 mg BID (n=338); and lansoprazole 30 mg BID, amoxicillin 1g BID and clarithromycin 500 mg BID (n=330). Each treatment regimen was administered for 14 days. Diagnoses of infection and test of cure were confirmed by 13C-urea breath test. Additional efficacy analyses were conducted using the pre-specified per protocol population (n=822), a subset of the mITT population comprised of patients who were protocol compliant.

About PHALCON-EE

PHALCON-EE is a randomized, double-blind, two-phase, multicenter Phase 3 trial that has completed enrollment of patients with erosive esophagitis (EE) in the U.S. and Europe. The first phase of the trial is evaluating the efficacy and safety of vonoprazan 20 mg administered once-daily (QD) compared to lansoprazole 30 mg QD for the healing of EE for up to eight weeks. The second phase of the trial is evaluating the efficacy and safety of vonoprazan 10 mg QD and 20 mg QD compared to lansoprazole 15 mg QD for the maintenance of healing of EE for 24 weeks. Both phases are also evaluating heartburn symptoms.

About PHALCON-NERD on-demand

PHALCON-NERD on-demand is a randomized, double-blind, multicenter Phase 2 study evaluating the efficacy and safety of various doses of vonoprazan compared to placebo for relief of episodic heartburn in subjects with symptomatic non-erosive gastroesophageal reflux disease or NERD. The first phase of the trial is a four-week, open-label run-in period with daily dosing of vonoprazan 20 mg. Following the run-in period, responders will be evenly randomized to one of three doses of vonoprazan (10 mg, 20 mg, and 40 mg) or placebo and treated on-demand for six weeks. The primary endpoint is evaluating the proportion of heartburn episodes with complete and durable relief. Secondary endpoints will also assess different aspects of the speed of onset of symptom relief and durability of relief, as well as number of doses of study drug and use of rescue antacids.

About Phathom Pharmaceuticals, Inc.

Phathom Pharmaceuticals is a biopharmaceutical company focused on the development and commercialization of novel treatments for gastrointestinal diseases and disorders. Phathom has in-licensed the exclusive rights in the United States, Europe, and Canada to vonoprazan, a novel potassium competitive acid blocker (P-CAB) in late-stage development for the treatment of acid-related disorders. For more information about Phathom, visit the Company's website at www.phathompharma.com or follow the Company on social media: LinkedIn at www.linkedin.com/company/phathompharma and Twitter @PhathomPharma.

Forward Looking Statements

Phathom cautions you that statements contained in this press release 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 availability of topline results from the PHALCON-EE Phase 3 clinical trial; the expected submission of New Drug Applications for the eradication of *H. pylori* infection; the expected completion of enrollment in the Phase 2 NERD study; and Phathom's belief that vonoprazan could represent an important treatment option for acid-related diseases, if approved. 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 press release due to the risks and uncertainties inherent in Phathom's business, including, without limitation: potential additional delays in the commencement, enrollment and completion of clinical trials due to the COVID-19 pandemic and other factors outside of Phathom's control; patients already enrolled in PHALCON-EE and the Phase 2 NERD study may not complete the clinical trials or public health conditions and governmental restrictions may lead Phathom to stop such trial all together, which may adversely impact its trial results and development plans; 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; 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; Phathom's ability to obtain and maintain intellectual property protection for vonoprazan; Phathom's ability to comply with its license agreement with Takeda; Phathom'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 press releases and 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.

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PHATHOM PHARMACEUTICALS, INC.
Balance Sheets
(Unaudited)
(in thousands, except share and par value amounts)

	March 31, 2021	December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	$ 237,974	$ 287,496
Prepaid expenses and other current assets (including related party amounts of $0 and $82, respectively)	4,836	3,872
Total current assets	242,810	291,368
Property, plant and equipment, net	907	986
Operating lease right-of-use assets	2,261	2,373
Other long-term assets	385	384
Total assets	$ 246,363	$ 295,111
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable (including related party amounts of $335 and $173, respectively)	$ 10,857	16,782
Accrued clinical trial expenses	10,868	19,997
Accrued expenses (including related party amounts of $1,000 and $734, respectively)	6,566	10,606
Accrued interest	312	312
Current portion of long-term debt	11,765	7,353
Operating lease liabilities, current	477	474
Total current liabilities	40,845	55,524
Long-term debt, net of discount	35,587	39,634
Operating lease liabilities	1,467	1,557
Other long-term liabilities	4,125	4,125
Total liabilities	82,024	100,840
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, $0.0001 par value; authorized shares — 40,000,000 at March 31, 2021 and December 31, 2020; no shares issued and outstanding at March 31, 2021 and December 31, 2020	—	—
Common stock, $0.0001 par value; authorized shares — 400,000,000; issued shares — 31,321,613 and 31,262,769 at March 31, 2021 and December 31, 2020, respectively; outstanding shares — 28,876,510 and 28,516,010 at March 31, 2021 and December 31, 2020, respectively	3	3
Additional paid-in capital	584,666	579,755
Accumulated deficit	(420,330)	(385,487)
Total stockholders' equity	164,339	194,271
Total liabilities and stockholders' equity	$ 246,363	$ 295,111

PHATHOM PHARMACEUTICALS, INC.
Statements of Operations and Comprehensive Loss
(Unaudited)
(in thousands, except share and per share amounts)

	Three Months Ended March 31,	
	2021	**2020**
Operating expenses:		
Research and development (includes related party amounts of $939 and $404 respectively)	$ 20,580	$ 15,865
General and administrative (includes related party amounts of $16 and $43, respectively)	13,004	4,510
Total operating expenses	33,584	20,375
Loss from operations	(33,584)	(20,375)
Other income (expense):		
Interest income	14	878
Interest expense	(1,272)	(738)
Change in fair value of warrant liabilities	—	95
Other income (expense)	(1)	(1)
Total other income (expense)	(1,259)	234
Net loss and comprehensive loss	$ (34,843)	$ (20,141)
Net loss per share, basic and diluted	$ (0.96)	$ (0.62)
Weighted-average shares of common stock outstanding, basic and diluted	36,298,968	32,470,402