

Phathom[®]

PHARMACEUTICALS

Phathom Pharmaceuticals Reports Third Quarter 2020 Results and Provides Update on Phase 3 Trials

November 10, 2020

- Pivotal Phase 3 PHALCON-EE trial enrollment expected to complete before year-end 2020; top-line results expected in the second half of 2021
- Pivotal Phase 3 PHALCON-HP trial enrollment expected to complete in Q1 2021; top-line results expected in Q2 2021

FLORHAM PARK, N.J., Nov. 10, 2020 (GLOBE NEWSWIRE) -- 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 third quarter of 2020 and provided an update of its ongoing pivotal Phase 3 trials for vonoprazan.

"We are very pleased with the progress made in the third quarter, especially the robust activity across our trial sites. We expect to complete patient enrollment in both of our Phase 3 trials in the coming months despite the ongoing COVID-19 pandemic," said Terrie Curran, President and Chief Executive Officer of Phathom Pharmaceuticals. "We continue to build an impressive commercial and medical organization to lay the foundation for the potential launch of vonoprazan. With topline data for both the PHALCON-EE and PHALCON-HP pivotal Phase 3 studies expected in 2021, our teams are executing on our key strategic imperatives to advance the treatment of acid-related disorders."

PHALCON-EE and PHALCON-HP Clinical Trial Updates:

- During the third quarter of 2020, patient enrollment across Phathom's U.S. and European clinical trial sites accelerated. Based on the current enrollment rates, the Company believes full enrollment in the PHALCON-EE Phase 3 trial will be achieved before year-end. Additionally, based on current enrollment rates, Phathom expects to achieve full enrollment in the PHALCON-HP Phase 3 trial in the first quarter of 2021.
- Phathom believes top-line results from PHALCON-HP, studying vonoprazan in *H. pylori*, will be available in the second quarter of 2021. Top-line results from PHALCON-EE, studying patients with erosive esophagitis, are expected in the second half of 2021.

Third Quarter 2020 Financial Results:

- Third quarter 2020 net loss was \$34.1 million compared to \$68.1 million for third quarter 2019.
- Third quarter 2020 net loss included a non-cash charge related to stock-based compensation of \$2.1 million compared to the third quarter 2019 non-cash charges of \$60.3 million. Third quarter 2019 non-cash charges were related to the change in fair value of warrant liabilities of \$57.8 million and change in fair value of convertible promissory notes of \$2.5 million.
- Third quarter 2020 research and development expenses increased to \$25.8 million compared to \$4.5 million for third quarter 2019 as a result of higher clinical trial costs and personnel-related expenses following the in-licensing of vonoprazan in the second quarter of 2019 as well as the acceleration in patient enrollment in the current quarter.
- Third quarter 2020 general and administrative expenses increased to \$7.1 million compared to \$1.8 million for third quarter 2019 due to the ongoing buildout of administrative and commercial functions.
- As of September 30, 2020, cash and cash equivalents were \$226.4 million.

Recent Business Updates:

- During the past month Phathom continued to add experienced biopharmaceutical leaders to its commercial and medical functions. Mark Devlin joined as Vice President, Head of Market Access; Joe Jones joined as Vice President, Head of Sales; and Dr. Philippe Brudi joined as Vice President, Head of Medical Affairs. Messrs. Devlin and Jones and Dr. Brudi each bring more than 20 years of industry experience with them to Phathom.

- Mr. Devlin most recently served as Senior Vice President of Market Access at Allergan, where he led pricing and market access strategies for Allergan's \$12 billion dollar U.S. pharmaceutical portfolio, including its gastrointestinal franchise.
- Mr. Jones joined Phathom from Ironwood Pharmaceuticals where he was most recently U.S. Commercial Brand Lead with responsibility for the marketing and market access efforts for LINZESS®. Mr. Jones joined Ironwood prior to the launch of LINZESS® and helped build the sales organization and developed strategies for multiple launches as both Regional Sales Manager and Area Vice President of Sales.
- Dr. Brudi has held positions of increasing responsibility in Clinical Development and Medical Affairs at ICI/Zeneca Pharma, Bristol-Myers Squibb, Novartis, Merck and, most recently, Liquidia Technologies, where he served as Head of Medical Affairs. Dr. Brudi led the build out of Liquidia's medical affairs organization in preparation for its first product launch.

Planned Virtual Phathom Investor Day:

Phathom will host a virtual Investor Day on December 14, 2020 from 1 pm to 3:30 pm Eastern Time. Members of Phathom's management team and gastroenterology key opinion leaders will provide updates on the company's pipeline and commercial strategy.

A subsequent press release with detailed event information will be shared in the coming weeks and will also be posted on the News & Events section of the Phathom website at www.investors.phathompharma.com. A replay of the webcast will also be available and archived on the site.

About Vonoprazan

Vonoprazan is an 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 U.S. Food and Drug Administration (FDA) has designated as a qualified infectious disease product (QIDP) and awarded Fast Track status to vonoprazan for the treatment of *H. pylori* infection in combination with both amoxicillin and clarithromycin and with amoxicillin alone. 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 13 countries in Asia and Latin America.

About PHALCON-EE

PHALCON-EE is a randomized, double-blind, two-phase, multicenter Phase 3 trial that is planned to enroll approximately 1,000 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-HP

PHALCON-HP is a randomized, multicenter, Phase 3 trial that is planned to enroll approximately 975 patients with *H. pylori* infection in the U.S. and Europe. Participants are being randomized 1:1:1 to one of three arms: vonoprazan 20 mg administered twice a day (BID) and amoxicillin 1g administered three times a day (TID); vonoprazan 20 mg BID, amoxicillin 1 g BID and clarithromycin 500 mg BID; and lansoprazole 30 mg BID, amoxicillin 1 g BID and clarithromycin 500 mg BID. Each treatment regimen is being administered for 14 days. PHALCON-HP is evaluating the percentage of patients with successful eradication of *H. pylori* infection.

About Phathom

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 LinkedIn at www.linkedin.com/company/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 when the company expects to complete enrollment of patients in its PHALCON-EE and PHALCON-HP Phase 3 clinical trials; the expected availability of topline results from the PHALCON-EE and PHALCON-HP Phase 3 clinical trials; the company's expected cash runway; and the potential to receive regulatory and exclusivity benefits as a result of QIDP and Fast Track designations. 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: the rate of patient enrollment in PHALCON-EE and PHALCON-HP due to the COVID-19 pandemic is highly uncertain due to factors outside our control; potential additional delays in the commencement, enrollment and completion of clinical trials; patients already enrolled in PHALCON-EE and PHALCON-HP may not complete the clinical trials or public health conditions and governmental restrictions may lead us to stopping such trials all together, which may adversely impact our trial results and development plans; our 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 not actually lead to a faster development or regulatory review or extended exclusivity, and would not assure FDA approval of vonoprazan; our ability to obtain and maintain intellectual property protection for vonoprazan; our ability to comply with our license agreement with Takeda; our ability to maintain uninterrupted business operations due to the ongoing spread of the COVID-19 coronavirus, including delaying or otherwise disrupting our 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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(in thousands, except share and per share amounts)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Operating expenses:				
Research and development (includes related party amounts of \$1,023, \$207, \$1,676, and \$207 respectively)	\$ 25,770	\$ 4,469	\$ 56,494	\$ 7,670
In-process research and development	—	—	—	78,897
General and administrative (includes related party amounts of \$62, \$156, \$139, and \$174, respectively)	7,060	1,813	16,732	3,955
Total operating expenses	32,830	6,282	73,226	90,522
Loss from operations	(32,830)	(6,282)	(73,226)	(90,522)
Other income (expense):				
Interest income	15	429	1,075	530
Interest expense (includes related party amounts of \$0, \$(302), \$0 and \$(498), respectively)	(1,286)	(1,990)	(3,286)	(3,138)
Change in fair value of warrant liabilities (includes related party amounts of \$0, \$(57,754), \$0 and \$(59,031), respectively)	—	(57,776)	95	(59,060)
Change in fair value of convertible promissory notes (includes related party amounts of \$0, \$(732), \$0, and \$(1,053), respectively)	—	(2,486)	—	(4,928)
Other income (expense)	(4)	(7)	(5)	(7)
Total other income (expense)	(1,275)	(61,830)	(2,121)	(66,603)
Net loss	\$ (34,105)	\$ (68,112)	\$ (75,347)	\$ (157,125)
Net loss per share, basic and diluted	\$ (1.02)	\$ (9.30)	\$ (2.29)	\$ (22.87)
Weighted-average shares of common stock outstanding, basic and diluted	33,366,237	7,326,090	32,946,128	6,871,471

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

	September 30, 2020	December 31, 2019
Assets		
Current assets:		
Cash and cash equivalents	\$ 226,361	\$ 243,765
Prepaid expenses and other current assets	800	11,836
Total current assets	227,161	255,601
Property, plant and equipment, net	862	463
Operating lease right-of-use assets	2,485	933
Other long-term assets	381	181
Total assets	\$ 230,889	\$ 257,178
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable (including related party amounts of \$331 and \$200, respectively)	\$ 4,788	\$ 699
Accrued expenses (including related party amounts of \$415 and \$308, respectively)	16,593	2,319
Accrued interest	302	156
Current portion of long-term debt	5,556	—
Operating lease liabilities, current	431	161
Warrant liabilities	—	413
Total current liabilities	27,670	3,748
Long-term debt, net of discount	41,062	22,777
Operating lease liabilities	1,644	635
Other long-term liabilities	4,125	2,063
Total liabilities	74,501	29,223

Commitments and contingencies

Stockholders' equity:

Common stock, \$0.0001 par value; authorized shares — 400,000,000; issued shares — 28,964,506; outstanding shares — 25,916,093 at September 30, 2020 and 24,728,258 at December 31, 2019, respectively

Additional paid-in capital	488,151	484,372
Accumulated deficit	<u>(331,766)</u>	<u>(256,419)</u>
Total stockholders' equity	<u>156,388</u>	<u>227,955</u>
Total liabilities and stockholders' equity	<u>\$ 230,889</u>	<u>\$ 257,178</u>