Phathom Pharmaceuticals Reports Third Quarter 2021 Results and Provides Key Clinical, Regulatory, and Business Updates

November 8, 2021

- Two New Drug Applications (NDAs) for vonoprazan-based treatment regimens for *H. pylori* infection were accepted for filing by FDA with six-month Priority Review granted; PDUFA target action date of May 3, 2022
- U.S. launch for both vonoprazan-based treatment regimens for *H. pylori* anticipated in the second half of 2022, if approved
- Positive Phase 3 trial results for vonoprazan in erosive esophagitis (EE) reported in October 2021; NDA submission targeted for the first quarter of 2022

FLORHAM PARK, N.J., Nov. 08, 2021 (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 2021 and provided updates regarding recent clinical, regulatory, and business progress.

“Phathom continued its strong execution through the third quarter of 2021, delivering impressive topline results from our pivotal Phase 3 PHALCON-EE study. The PHALCON-EE data adds to our excitement about vonoprazan’s potential to satisfy large unmet patient needs in the U.S. and European erosive esophagitis market,” said Terrie Curran, Phathom’s President and Chief Executive Officer. “With the recent acceptance of both NDAs for vonoprazan-based treatments in *H. pylori,* and the planned submission of an NDA for vonoprazan in EE in the first quarter of 2022, we are enthusiastic about vonoprazan’s potential to offer a novel treatment option to address the significant unmet needs that exist for so many patients across these prevalent acid-related disorders.”

Clinical and Regulatory Updates:

- The U.S. Food and Drug Administration (FDA) accepted NDAs for two convenience packs containing vonoprazan-based treatment regimens for adults with *H. pylori* infection: vonoprazan in combination with amoxicillin and clarithromycin (“vonoprazan triple therapy”) and vonoprazan in combination with amoxicillin (“vonoprazan dual therapy”). The NDAs were granted Priority Review designation with a Prescription Drug User Fee Act (PDUFA) target action date of May 3, 2022. Phathom submitted the NDAs to the FDA on September 3, 2021. The FDA previously designated vonoprazan dual and triple therapy as qualified infectious disease products (QIDPs) which, if approved, will provide vonoprazan five additional years of regulatory exclusivity.
- If approved, the U.S. commercial launch for vonoprazan dual and triple therapy is anticipated in the second half of 2022.
- Vonoprazan successfully met its primary endpoints and key secondary superiority endpoints in PHALCON-EE, a pivotal Phase 3 trial evaluating vonoprazan for the healing and maintenance of healing of erosive esophagitis. Based on these results, Phathom expects to submit an NDA in the first quarter of 2022 seeking the following indications for vonoprazan: healing of all grades of EE and relief of heartburn, and maintenance of healing of all grades of EE and relief of heartburn.
- Topline results from the Phase 2 PHALCON-NERD on-demand trial evaluating various doses of vonoprazan as an on-demand therapy for patients with non-erosive reflux disease are expected in the first quarter of 2022.

Recent Business and Financial Updates:

- On September 17, 2021, Phathom secured an up to $200 million term loan facility from Hercules Capital (Loan Agreement). One-hundred million dollars were drawn at closing and an additional $50 million became available upon the receipt of positive topline results in PHALCON-EE. The final $50 million tranche will become available upon the occurrence of both FDA approval of a vonoprazan-based regimen for the treatment of *H. pylori*, and FDA acceptance of filing of an NDA for vonoprazan for the treatment of erosive esophagitis.

Third Quarter 2021 Financial Results:

- Third quarter 2021 net loss was $36.7 million compared to $34.1 million for the third quarter of 2020.
- Third quarter 2021 net loss included a non-cash charge related to stock-based compensation of $4.4 million compared to the third quarter of 2020 non-cash charge related to stock-based compensation of $2.1 million.
- Third quarter 2021 research and development expenses decreased to $16.6 million compared to $25.8 million for the third

quarter 2020 due to lower clinical trial costs, partially offset by higher regulatory and personnel-related expenses.

- Third quarter 2021 general and administrative expenses increased to $16.5 million compared to $7.1 million for the third quarter of 2020 due to the ongoing buildout of administrative and commercial functions.
- Third quarter 2021 other expenses increased by $2.3 million compared to the third quarter of 2020 due to a $2.0 million charge related to the early extinguishment of Phathom's previous debt facility replaced by the Loan Agreement.
- As of September 30, 2021, cash and cash equivalents were $224.6 million. Cash and cash equivalents combined with the future drawdown of the remaining $100 million under the Loan Agreement are expected to be sufficient to meet anticipated cash requirements into mid-2023 based on current operating plans.

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 U.S. FDA has awarded qualified infection disease product (QIDP) status and granted Fast Track designation to vonoprazan in combination with both amoxicillin and clarithromycin and with amoxicillin alone for the treatment of *H. pylori* infection. In November 2021, the FDA accepted for filing two new drug applications for vonoprazan-based regimens 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, Russia, and numerous other countries in Asia and Latin America.

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 and follow the Company on LinkedIn and Twitter.

Forward Looking Statements
The Company 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-NERD on demand clinical trial, 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, the expected approval of NDAs for vonoprazan-based treatments for the treatment of *H. pylori* infection, 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 press release 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 an NDA 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's 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; 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 presence 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.

CONTACTS

Media Contact:
Nick Benedetto
1-877-742-8466
media@phathompharma.com

Investor Contact:
Joe Hand
1-877-742-8466
ir@phathompharma.com

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

	September 30, 2021	December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	$ 224,618	$ 287,496
Prepaid expenses and other current assets (including related party amounts of $0 and $82, respectively)	695	3,872
Total current assets	225,313	291,368
Property, plant and equipment, net	692	986
Operating lease right-of-use assets	2,031	2,373
Other long-term assets	341	384
Total assets	$ 228,377	$ 295,111
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable (including related party amounts of $311 and $173, respectively)	$ 5,582	$ 16,782
Accrued clinical trial expenses	10,491	19,997
Accrued expenses (including related party amounts of $1,847 and $734, respectively)	11,040	10,606
Accrued interest	214	312
Current portion of long-term debt	—	7,353
Operating lease liabilities, current	484	474
Total current liabilities	27,811	55,524
Long-term debt, net of discount	88,305	39,634
Operating lease liabilities	1,280	1,557
Other long-term liabilities	7,500	4,125
Total liabilities	124,896	100,840
Stockholders' equity:		
Preferred stock, $0.0001 par value; authorized shares - 40,000,000 at September 30, 2021 and December 31, 2020 ; no shares issued and outstanding at September 30, 2021 and December 31, 2020	-	-
Common stock, $0.0001 par value; authorized shares — 400,000,000; issued shares — 31,414,827 and 31,262,769 at September 30, 2021 and December 31, 2020, respectively; outstanding shares — 30,047,428 and 28,516,010 at September 30, 2021 and December 31, 2020, respectively	3	3
Additional paid-in capital	597,022	579,755
Accumulated deficit	(493,544)	(385,487)
Total stockholders' equity	103,481	194,271
Total liabilities and stockholders' equity	$ 228,377	$ 295,111

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Operating expenses:				
Research and development (includes related party amounts of $849, $1,023, $2,695, and $1,676, respectively)	$ 16,608	$ 25,770	$ 58,786	$ 56,494
General and administrative (includes related party amounts of $0, $62, $16, and $139, respectively)	16,529	7,060	43,254	16,732
Total operating expenses	33,137	32,830	102,040	73,226
Loss from operations	(33,137)	(32,830)	(102,040)	(73,226)
Other income (expense):				
Interest income	8	15	35	1,075
Interest expense	(1,485)	(1,286)	(4,013)	(3,286)

Change in fair value of warrant liabilities	—	—	—	95
Other income (expense)	(2,048)	(4)	(2,039)	(5)
Total other income (expense)	(3,525)	(1,275)	(6,017)	(2,121)
Net loss and comprehensive loss	$ (36,662)	$ (34,105)	$ (108,057)	$ (75,347)
Net loss per share, basic and diluted	$ (0.98)	$ (1.02)	$ (2.94)	$ (2.29)
Weighted-average shares of common stock outstanding, basic and diluted	37,299,351	33,366,237	36,748,492	32,946,128