Phathom Pharmaceuticals Reports Third Quarter 2022 Financial Results and Provides Business Updates

November 8, 2022

- Patient enrollment completed for Phase 3 non-erosive gastroesophageal reflux disease (NERD) daily dosing trial with topline data for primary endpoint expected in Q1 2023
- Obtained commitment for up to an additional $40 million under revenue interest financing agreement; total financing potentially available increased to $300 million
- Commercial launches in *H. pylori,* and Erosive Esophagitis (EE), if approved, anticipated in Q1 2023

FLORHAM PARK, N.J., Nov. 08, 2022 (GLOBE NEWSWIRE) -- Phathom Pharmaceuticals, Inc. (Nasdaq: PHAT), a biopharmaceutical company focused on developing and commercializing novel treatments for gastrointestinal diseases, today reported financial results for the third quarter of 2022 and provided recent business updates.

“Phathom continued to make significant progress in the third quarter, including completing enrollment in our Phase 3 NERD daily dosing trial, and increasing the total amount potentially available under our royalty financing agreement to $300 million which will further fund our planned product launches and future vonoprazan development programs,” said Terrie Curran, President and Chief Executive Officer of Phathom. “Over the last several months we have developed and validated test methods for detecting the nitrosamine impurity discovered at trace levels in our drug product as reported in August and are in discussions with the FDA on our control limits in advance of bringing our novel products to market.” In addition, we are pleased with the progress our commercial and market access teams have made over the last quarter preparing for the anticipated first quarter 2023 launches of VOQUEZNA™ TRIPLE PAK™ and VOQUEZNA™ DUAL PAK™ as well as, if approve VOQUEZNA™ tablets for EE.”

Third Quarter and Recent Business Updates:

- On November 1, 2022, Phathom announced the placement of the remaining $40 million in non-dilutive capital under its up to $300 million revenue interest financing agreement. This commitment provides an additional $15 million upon FDA approval of vonoprazan for treatment of EE and $25 million for achievement of a sales milestone.
- On October 24, 2022, the Company announced it had completed enrollment in its PHALCON-NERD Daily Dosing Phase 3 trial of vonoprazan in non-erosive gastroesophageal reflux disease (NERD). The trial enrolled a total of 776 patients with NERD at study sites across the United States. Topline data for the primary endpoint is expected in the first quarter of 2023 with full trial results available in late 2023. If successful, the Company believes that the trial will form the basis of a supplemental New Drug Application (sNDA) for vonoprazan as once daily therapy for the treatment of symptomatic NERD in adults with a planned submission in 2023.
- During the American College of Gastroenterology (ACG) 2022 Annual Scientific Meeting, held October 21-26, 2022, in Charlotte, NC, Phathom presented new data on vonoprazan for the treatment of gastric acid-related disorders, including the results of an exploratory endpoint in the Phase 2 PHALCON-NERD trial evaluating vonoprazan as an investigational on-demand treatment. These results demonstrated higher rates of complete and sustained relief of episodic heartburn for all vonoprazan doses versus placebo within one hour, and maintained for 24 hours, after taking study drug. Additional findings from a study examining the pharmacodynamic and pharmacokinetic effects of vonoprazan on intragastric acidity were also presented and demonstrated vonoprazan provided consistent, dose-dependent acid suppression.
- On October 10, 2022, Phathom announced it entered into a long-term commercial supply agreement with Evonik to produce vonoprazan at its FDA-inspected manufacturing sites in Tippecanoe, Indiana, and Dossenheim, Germany.
- Phathom announced the strengthening of its company leadership with the appointment of James Topper, M.D., Ph.D., to its Board of Directors. Dr. Topper currently serves as a Managing Partner at Frazier Life Sciences and is also the Chairman and Chief Executive

Officer of Frazier Lifesciences Acquisition Corporation. Dr. Topper has rejoined Phathom's Board having served as a Phathom Board member from its creation in January 2018 until May 2021.

Third Quarter 2022 Financial Results:

- Net loss for the third quarter ended September 30, 2022, was $51.1 million, compared to $36.7 million for third quarter 2021. Third quarter 2022 net loss included a non-cash charge related to stock-based compensation of $5.8 million compared to the third quarter of 2021 non-cash charge related to stock-based compensation of $4.4 million.
- Research and development expenses for the third quarter were $19.0 million, an increase of $2.4 million compared to $16.6 million for third quarter 2021. The increase was a result of increased clinical trial costs related to the development of vonoprazan including activity relating to the ongoing Phase 3 NERD daily dosing trial.
- General and administrative expenses for the third quarter were $23.5 million, an increase of $7.0 million compared to $16.5 million for third quarter 2021 primarily due to the ongoing buildout of commercial infrastructure in support of the planned first quarter 2023 U.S. launch of VOQUEZNA TRIPLE PAK and DUAL PAK, and, if approved, VOQUEZNA tablets for EE.
- As of September 30, 2022, cash and cash equivalents were $196.8 million plus an additional $100 million available under the Company's term loan with Hercules Capital.
- Based on its current operating plan, including the anticipated funds available under its existing term loan and royalty interest financing, the Company believes it has sufficient capital to fund operations through 2024.

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 first-in-class potassium-competitive acid blocker (PCAB). Vonoprazan-based regimens are approved in the U.S. as part of a co-packaged product in combination with antibiotics for the treatment of *H. pylori* infection in adults, marketed as VOQUEZNA™ TRIPLE PAK™ (vonoprazan, amoxicillin, clarithromycin) and VOQUEZNA™ DUAL PAK™ (vonoprazan, amoxicillin). Phathc has a New Drug Application under review by the FDA for vonoprazan in erosive esophagitis (EE) and is studying the use of vonoprazan for the treatment of non-erosive reflux disease (NERD). 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

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 PDUFA target action date and potential approval of our EE NDA; our plans to launch vonoprazan for our *H. pylori* and EE indications and the timing thereof; the expected timing of topline data for the NERD daily dosing Phase 3 trial; and our plans to address the trace levels of a nitrosamine impurity observed in vonoprazan drug product for VOQUEZNA DUAL PAK and TRIPLE PAK and to obtain FDA approval to enable commercial launch of these products as well as VOQUEZNA, if approved, for EE. 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 FDA may disagree that the existing safety and efficacy data is sufficient to approve the EE NDA, including as a result of the trace levels of a nitrosamine impurity observed in commercial batches of vonoprazan drug product for VOQUEZNA DUAL PAK and TRIPLE PAK; the potential for the FDA to delay the PDUFA target action date related to the EE NDA due to the FDA's internal resource constraints or other reasons; the inherent risks of clinical development of vonoprazan; Phathom's dependence on third parties in connection with product manufacturing, research and preclinical and clinical testing; Phathom's ability to successfully address the formation of nitrosamine impurities in commercial batches of vonoprazan drug product and gaining FDA approval of any such resolution including the applicable acceptable daily intake limit; 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; Phathom's ability to access additional capital under its term loan facility and royalty interest finance agreements is subject to certain conditions; 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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Selected Condensed Balance Sheets
(Unaudited)
(in thousands)

	September 30, 2022	December 31, 2021
Assets		
Cash and cash equivalents	$ 196,838	$ 183,259
Total assets	$ 201,931	$ 189,431
Total liabilities	$ 228,354	$ 117,275
Total stockholders' equity (deficit)	$ (26,423)	$ 72,156

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,	
	2022	2021	2022	2021
Operating expenses:				
Research and development (includes related party amounts of $77, $849, $1,800, and $2,695, respectively)	$ 19,020	$ 16,608	$ 55,495	$ 58,786
General and administrative (includes related party amounts of $0, $0, $0, and $16, respectively)	23,509	16,529	70,303	43,254
Total operating expenses	42,529	33,137	125,798	102,040
Loss from operations	(42,529)	(33,137)	(125,798)	(102,040)
Other income (expense):				
Interest income	726	8	845	35
Interest expense	(9,277)	(1,485)	(17,703)	(4,013)
Other expense	(11)	(2,048)	(20)	(2,039)
Total other expense	(8,562)	(3,525)	(16,878)	(6,017)
Net loss and comprehensive loss	$ (51,091)	$ (36,662)	$ (142,676)	$ (108,057)
Net loss per share, basic and diluted	$ (1.32)	$ (0.98)	$ (3.72)	$ (2.94)
Weighted-average shares of common stock outstanding, basic and diluted	38,820,266	37,299,351	38,379,292	36,748,492