Phathom Pharmaceuticals Reports First Quarter 2023 Results

May 10, 2023

FLORHAM PARK, N.J., May 10, 2023 (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 first quarter of 2023 and provided updates on recent regulatory progress.

"This quarter, we made remarkable progress advancing mission-critical priorities that position Phathom to potentially deliver vonoprazan to patients suffering from Erosive GERD and *H. pylori* infection before year end," said Terrie Curran, President and Chief Executive Officer of Phathom. "Our ongoing stability program for the minor drug product reformulation continues to demonstrate effective control of the *N-nitroso-vonoprazan* (NVP) impurity and confirms our confidence that our planned NDA resubmission will address the sole deficiency cited in the FDA's complete response letters. Building on this positive momentum, our commercial team continues to prepare for a planned fourth quarter commercial launch and we remain engaged with payers, healthcare providers, and key opinion leaders to capitalize on the blockbuster potential of our first-in-class therapy."

Clinical, Regulatory, and Business Updates:

- Phathom remains on track to resubmit its erosive esophagitis (Erosive GERD) NDA this quarter, with potential for FDA approval and a subsequent U.S. commercial launch for Erosive GERD and *H. pylori* infection anticipated in the fourth quarter of 2023. The Company's ongoing stability program for the minor reformulation of vonoprazan drug product continues to demonstrate that it is achieving the intended effects of limiting and controlling NVP formation. Based on FDA feedback from the March 2023 meeting, Phathom believes the data package it expects to include in the resubmission will address the NVP issue, the sole deficiency noted in the FDA's complete response letters (CRLs).

- In January 2023, Phathom shared positive topline results from the Phase 3 PHALCON-NERD-301 trial evaluating the daily dosing of vonoprazan for Non-Erosive GERD. Both vonoprazan 10 mg and 20 mg doses met the primary endpoint and showed highly statistically significant greater percentage of 24-hour heartburn free days as compared to placebo ($p<0.0001$). The blinded 20-week long-term extension period of the trial is proceeding as planned and a regulatory submission is expected for the second half of 2023 seeking approval of vonoprazan as a daily (QD) treatment for Non-Erosive GERD, the largest subcategory of GERD with an estimated U.S. patient population of over 45 million people.

- Phathom has currently secured coverage for 60% of commercial lives for first-in-class *H. pylori* infection treatments VOQUEZNA® TRIPLE PAK® and VOQUEZNA® DUAL PAK®.

- New data from two post-hoc analyses were presented in poster presentations during Digestive Disease Week® (DDW) 2023, held May 6-9 in person in Chicago, IL and virtually:

    - Higher eradication rates of *H. pylori* infection were demonstrated with vonoprazan-based regimens vs. lansoprazole triple therapy, regardless of different baseline demographics and clinical characteristics.

    - A meta-analysis showed that potassium-competitor acid blockers (PCABs), including vonoprazan, provide a longer duration of pH >4, higher predicted Erosive GERD healing rates, and lower probabilities of failure to achieve healing, as compared to histamine$_2$–receptor antagonists (H_2RAs) and proton pump inhibitors (PPIs).

First Quarter 2023 Financial Results:

- Net loss for the first quarter ended March 31, 2023 was $37.8 million, compared to $40.7 million for first quarter 2022. First quarter 2023 net loss included a non-cash charge related to stock-based compensation of $7.0 million compared to $5.8 million for first quarter 2022.

- Operating expenses for the first quarter 2023 were 36% lower than the preceding quarter, primarily due to cost control measures enacted as a result of the delayed commercial launch of VOQUEZNA TRIPLE PAK and DUAL PAK for *H. pylori* infection, and, if approved, VOQUEZNA for Erosive GERD.

- Research and development expenses for the first quarter 2023 were $11.5 million, a decrease of $6.2 million compared to $17.7 million for first quarter 2022. The decrease was a result of decreased clinical trial costs and chemistry, manufacturing and controls costs, partially offset by increased personnel costs.

- General and administrative expenses for the first quarter 2023 were $18.6 million, a decrease of $1.6 million compared to $20.2 million for first quarter 2022. The decrease was primarily due to a reduction in professional services partially offset by increased personnel costs.

- As of March 31, 2023, cash and cash equivalents were $129.6 million. An additional $100.0 million is available under Phathom's term loan with Hercules Capital and $175.0 million becomes available to Phathom upon FDA approval of VOQUEZNA for Erosive GERD under the terms of our revenue interest financing agreement.

- Based on its current operating plan, including the funds currently available under our existing term loan and cash available under our royalty interest financing agreement following approval of VOQUEZNA for Erosive GERD, Phathom believes it will have sufficient capital to fund operations through the end of 2024.

About Phathom Pharmaceuticals, Inc.

Phathom Pharmaceuticals is a biopharmaceutical company focused on the development and commercialization of novel treatments for gastrointestinal diseases. 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). 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 Phathom's expectations of generating stability data necessary to support the proposed shelf life of vonoprazan; the expected timing of resubmission of the Erosive GERD NDA; the potential approval of its Erosive GERD NDA and post approval supplements for its *H. pylori* NDAs, and anticipated product launches in *H. pylori* and Erosive GERD; and that Phathom will have sufficient capital to fund operations through the end of 2024. 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: Phathom may be unable to generate the required data to meet the acceptable intake of its nitrosamine impurity, or may be unable to reduce the impurity to an acceptable level throughout the shelf life of the product, to obtain approval its Erosive GERD NDA or to bring vonoprazan to market for patients with Erosive GERD, if approved, or for patients with *H. pylori*; future nitrosamine data may be inconsistent with data generated to date; the FDA may not accept for review the Erosive GERD NDA even after we have submitted the NDA; risks associated with product manufacturing or formulation changes required to be made in connection with achieving the acceptable daily intake limit of the nitrosamine detected in vonoprazan drug product; the FDA may disagree that the existing safety and efficacy data, together with additional data, is sufficient to approve the erosive esophagitis NDA or supplements to the *H. pylori* NDAs; 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; 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; 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)

	March 31, 2023	December 31, 2022
Assets		
Cash and cash equivalents	$ 129,574	$ 155,385
Total assets	$ 144,010	$ 164,810
Total liabilities	$ 234,205	$ 239,624
Total stockholders' deficit	$ (90,195)	$ (74,814)

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

	Three Months Ended March 31,	
	2023	**2022**
Operating expenses:		
Research and development	$ 11,479	$ 17,660
General and administrative	18,598	20,246
Total operating expenses	30,077	37,906
Loss from operations	(30,077)	(37,906)
Other income (expense):		
Interest income	1,460	7
Interest expense	(9,217)	(2,759)
Other expense	20	(7)
Total other expense	(7,737)	(2,759)
Net loss and comprehensive loss	$ (37,814)	$ (40,665)
Net loss per share, basic and diluted	$ (0.89)	$ (1.07)
Weighted-average shares of common stock outstanding, basic and diluted	42,354,520	38,036,960