Phathom Pharmaceuticals Reports Third Quarter 2023 Results and Recent Business Updates

November 9, 2023

- VOQUEZNA® (vonoprazan) tablets approved by the U.S. Food and Drug Administration (FDA) for the treatment of Erosive GERD and relief of associated heartburn in adults, marking the first major innovation in the U.S. Erosive GERD market in over 30 years
- Commercial availability of VOQUEZNA for Erosive GERD and *H. pylori* expected December 2023
- New Drug Application (NDA) submitted to the FDA for vonoprazan as a once-daily treatment for Non-Erosive GERD, the largest subcategory of GERD

FLORHAM PARK, N.J., Nov. 09, 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 third quarter of 2023 and provided updates on recent regulatory and business progress.

“Our recent FDA approval of VOQUEZNA makes 2023 another significant year for Phathom and marks a pivotal moment in our journey to bring a new class of treatment options to millions of patients in the U.S. with acid related disorders,” said Terrie Curran, President and Chief Executive Officer of Phathom. “We are completing the buildout and onboarding of our sales team to execute our highly anticipated launch and have already begun branded promotion in advance of VOQUEZNA’s expected commercial availability in December. Our organization also continues to make important regulatory progress to maximize the full commercial potential of vonoprazan, evidenced by our September NDA submission seeking approval of vonoprazan as a daily treatment for Non-Erosive GERD, the largest subcategory of GERD. With an additional $175 million in cash provided under our non-dilutive revenue interest financing agreement this quarter, we believe we are well capitalized to support the blockbuster potential of VOQUEZNA.”

Recent Clinical, Regulatory, and Business Updates:

- In November 2023, Phathom announced the FDA approval of VOQUEZNA® (vonoprazan) tablets 10 mg and 20 mg, a novel potassium-competitive acid blocker (PCAB), as a treatment for adults for the healing of all grades of Erosive Esophagitis, also known as Erosive GERD (gastroesophageal reflux disease), maintenance of healing of all grades of Erosive GERD, and relief of heartburn associated with Erosive GERD. This approval provides healthcare providers with a first-in-class therapeutic option that has demonstrated superiority over a standard-of-care proton pump inhibitor (PPI) in the healing of patients with moderate-to-severe disease after two weeks, and in the maintenance of healing of all patients. Commercial availability of VOQUEZNA is expected in December 2023.

- In October 2023, the FDA approved Phathom’s prior approval supplements for reformulated vonoprazan tablets packaged in VOQUEZNA TRIPLE PAK (vonoprazan tablets, amoxicillin capsules, clarithromycin tablets) and VOQUEZNA DUAL PAK (vonoprazan tablets, amoxicillin capsules), for the treatment of *Helicobacter pylori* (*H. pylori*) infection in adults. VOQUEZNA-based treatment regimens contain antibiotics conveniently packaged with vonoprazan.

- In September 2023, Phathom announced the submission of an NDA to the FDA seeking approval for vonoprazan as a daily treatment for Non-Erosive GERD (NERD), the largest subcategory of GERD and is characterized by reflux-related symptoms in the absence of esophageal mucosal erosions. Phathom expects a 10-month regulatory review with FDA action expected in the third quarter of 2024. If approved, a U.S. commercial launch for the expanded indication is planned for the same quarter.

- Phathom shared the top-line results from the 20-week extension period of its positive Phase 3 PHALCON-NERD-301 trial which evaluated the efficacy and safety of vonoprazan for the daily treatment of adults with Non-Erosive GERD. In the trial, vonoprazan (10 mg and 20 mg) controlled heartburn symptoms through the entire 6 months of the study with a safety profile consistent with prior vonoprazan studies.

- Phathom plans to commence a separate Phase 3 Non-Erosive GERD trial in 2024 studying the As Needed dosing of vonoprazan for active heartburn episodes, a dosing regimen for which proton pump inhibitors (PPIs) are not approved in the U.S. The Company hopes to confirm the positive results from its previous Phase 2 As Needed study of vonoprazan in Non-Erosive GERD to support an application for regulatory approval of this novel dosing regimen.

- Phathom has completed the onboarding of its sales leadership team and is finalizing the hiring and onboarding of an experienced national salesforce to support its upcoming commercial launches.

Third Quarter 2023 Financial Results:

- Net loss for the third quarter ended September 30, 2023, was $43.2 million, compared to $51.1 million for third quarter 2022. Third quarter 2023 net loss included a non-cash charge related to stock-based compensation of $6.1 million compared to $5.8 million for third quarter 2022.

- Research and development expenses for the third quarter 2023 were $12.3 million, a decrease of $6.7 million compared to $19.0 million for third quarter 2022. The decrease was a result of decreased clinical trial costs, partially offset by increased chemistry, manufacturing and controls costs, and personnel costs.

- General and administrative expenses for the third quarter 2023 were $23.4 million, a decrease of $0.1 million compared to $23.5 million for third quarter 2022. The decrease was primarily due to a reduction in professional services, partially offset by increased personnel costs in anticipation of the planned commercial launches in December.

- As of September 30, 2023, cash and cash equivalents were $213.7 million. Following the FDA approval of VOQUEZNA for Erosive GERD, $175.0 million will be paid to Phathom under the terms of its revenue interest financing agreement. An additional $100.0 million is also available under Phathom's term loan with Hercules Capital, Inc. (Hercules).

- Phathom anticipates a $19.3 million non-cash charge in the fourth quarter 2023 related to the immediate vesting of performance share units (PSUs) related to the approval of VOQUEZNA for Erosive GERD.

- Based on its current operating plan, including expected product revenues, the funds available under its existing term loan with Hercules and cash to be paid under our royalty interest financing agreement based on the recent approval of VOQUEZNA for Erosive GERD, Phathom believes it will have sufficient capital to fund operations through the end of 2025.

About Phathom Pharmaceuticals

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

This press release contains forward-looking statements. Investors are cautioned not to place undue reliance on these forward-looking statements, including statements about the timing of a U.S. commercial launch for vonoprazan for Erosive GERD, the timing of regulatory review and commercial launch of vonoprazan as a daily treatment for Non-Erosive GERD, the timing of commencement of our Phase 3 Non-Erosive GERD trial, and our cash runway. 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: we may not be able to successfully commercialize VOQUEZNA which will depend on a number of factors including coverage and reimbursement levels from governmental authorities and health insurers as well as market acceptance by healthcare providers; future data generated from our stability program may be different from the data submitted to the FDA to date and may not demonstrate that our mitigation efforts will continue to maintain the level of the nitrosamine impurity below the acceptable intake (AI) level throughout the shelf life of products containing vonoprazan, which could result in market action or shelf life reduction; risks associated with product manufacturing or formulation changes required to be made in connection with achieving the AI; 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)

	September 30, 2023	December 31, 2022
Assets		
Cash and cash equivalents	$ 213,677	$ 155,385
Total assets	$ 236,992	$ 164,810
Total liabilities	$ 254,765	$ 239,624
Total stockholders' deficit	$ (17,773)	$ (74,814)

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,	
	2023	2022	2023	2022
Operating expenses:				
Research and development	$ 12,263	$ 19,020	$ 36,505	$ 55,495
General and administrative	23,396	23,509	60,932	70,303
Total operating expenses	35,659	42,529	97,437	125,798
Loss from operations	(35,659)	(42,529)	(97,437)	(125,798)
Other income (expense):				
Interest income	2,720	726	4,528	845
Interest expense	(10,107)	(9,277)	(28,939)	(17,703)
Other (expense), net	(197)	(11)	(174)	(20)
Total other expense	(7,584)	(8,562)	(24,585)	(16,878)
Net loss and comprehensive loss	$ (43,243)	$ (51,091)	$ (122,022)	$ (142,676)
Net loss per share, basic and diluted	$ (0.76)	$ (1.32)	$ (2.48)	$ (3.72)
Weighted-average shares of common stock outstanding, basic and diluted	56,782,379	38,820,266	49,265,321	38,379,292