Phathom Pharmaceuticals Reports Fourth Quarter and Full Year 2022 Financial Results and Provides Business Update

February 28, 2023

- Meeting scheduled in March 2023 with the U.S. Food and Drug Administration (FDA) to discuss stability data and resubmission requirements for erosive GERD and *H. pylori* New Drug Applications

FLORHAM PARK, N.J., Feb. 28, 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 fourth quarter and full year ended December 31, 2022, and provided a business update.

“Over the past year, our teams made significant progress to advance the development and commercial potential of vonoprazan. We obtained FDA approval of our first products, aligned with the FDA on a near final label for erosive GERD, and delivered our third positive Phase 3 trial for vonoprazan in a third potential indication,” said Terrie Curran, President and Chief Executive Officer of Phathom. “While our anticipated commercial launch is on hold pending resolution of the previously announced nitrosamine impurity issue, we are confident in the progress we have made in generating additional stability data, and based on initial testing results, we believe the mitigation measures put in place are achieving their intended effects. We have a meeting scheduled with the FDA in March to discuss our proposed resubmission plan and align on potential review timelines to help make vonoprazan available to patients as soon as possible. We look forward to meeting with the FDA and expect to share more details about our progress once we have obtained additional clarity.”

Full Year 2022 and Recent Business Highlights:

- Phathom delivered positive topline results for the primary endpoint from its third Phase 3 trial, PHALCON-NERD-301, evaluating the daily dosing of vonoprazan for the treatment of non-erosive gastroesophageal reflux disease (GERD) in adults. In the four-week placebo-controlled period of the study, both vonoprazan doses (10 mg and 20 mg) met the primary endpoint by showing a 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 currently ongoing to further evaluate the safety and efficacy of both doses of vonoprazan after six months of continuous daily use. Full results from the trial are anticipated in the second half of 2023 and are expected to form the basis for Phathom’s regulatory submission for vonoprazan as a daily treatment for patients with non-erosive GERD.
- Phathom reported positive topline results from a Phase 2 proof-of-concept trial for vonoprazan dosed as needed (on-demand) for non-erosive GERD, demonstrating statistical significance for all doses of vonoprazan (10 mg, 20 mg, 40 mg) when compared to placebo ($p<0.0001$). Significant differences in complete and sustained relief occurred as early as one hour after dosing and these differences were maintained over 24 hours. Phathom believes these results support the potential of vonoprazan to provide patients with a rapid relief agent to treat non-erosive GERD on an as needed basis, a dosing regimen for which proton pump inhibitors (PPIs) are not approved in the U.S.
- On May 3, 2022, Phathom announced the FDA approval of VOQUEZNA™ TRIPLE PAK™ (vonoprazan, amoxicillin, clarithromycin) and VOQUEZNA DUAL PAK™ (vonoprazan, amoxicillin) for the treatment of *Helicobacter pylori* (*H. pylori)* infection in adults. These products contain antibiotics conveniently packaged with vonoprazan, a novel potassium-competitive acid blocker (PCAB) and the first innovative acid suppressant from a new drug class approved in the U.S. in over 30 years.
- Phathom secured up to $300 million in non-dilutive capital under the terms of its revenue interest financing agreement. The agreement provided an upfront $100 million cash payment and has the potential to provide an additional $175 million upon FDA approval of vonoprazan for erosive GERD, and $25 million upon achievement of a sales milestone, with total royalty payments capped at 2.0x invested capital.
- Upon approval and in advance of the planned commercial launches of VOQUEZNA TRIPLE PAK and VOQUEZNA DUAL PAK, Phathom secured coverage for 51% of commercial lives to date.

Fourth Quarter and Full Year 2022 Financial Results:

- Net loss for the fourth quarter ended December 31, 2022 was $55.0 million, compared to $35.8 million for fourth quarter 2021. Fourth quarter 2022 net loss included a non-cash charge related to stock-based compensation of $6.7 million compared to $4.3 million for fourth quarter 2021. Net loss for the year ended December 31, 2022 was $197.7 million, compared to $143.9 million for the full year ended December 31, 2021. Full year 2022 net loss included a non-cash charge related to stock-based compensation of $24.1 million, compared to $16.8 million in 2021.
- Research and development expenses for the fourth quarter 2022 were $15.9 million, an increase of $2.3 million compared to $13.6 million for fourth quarter 2021. The increase was a result of increased clinical trial costs related to the development of vonoprazan, including activity related to the ongoing Phase 3 PHALCON-NERD-301 daily dosing trial. Research and development expenses for the full year 2022 were $71.4 million, a decrease of $0.9 million compared to $72.3 million in 2021. The decrease was a result of decreased regulatory costs partially offset by increased clinical trial costs related to the development of vonoprazan.
- General and administrative expenses for the fourth quarter 2022 were $30.7 million, an increase of $11.2 million compared to $19.5 million for fourth quarter 2021. The increase was primarily due to the ongoing buildout of commercial infrastructure in support of the planned U.S. launch of VOQUEZNA TRIPLE PAK and DUAL PAK for *H. pylori* infection, and, if approved, VOQUEZNA for erosive GERD. General and administrative expenses for the full year 2022 were $101.0 million, an increase of $38.3 million compared to $62.7 million in 2021. The increase was primarily due to the ongoing buildout of commercial infrastructure in support of the planned U.S. launch of VOQUEZNA TRIPLE PAK and DUAL PAK for *H. pylori* infection, and, if approved, VOQUEZNA for erosive GERD.
- As of December 31, 2022, cash and cash equivalents were $155.4 million. An additional $100 million is available under Phathom's term loan with Hercules Capital.
- Based on its current operating plan, including the funds currently available under its existing term loan and following approval of vonoprazan for erosive GERD, available under its royalty interest financing agreement, Phathom believes it will have 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. 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 and the potential approval of its erosive esophagitis NDA and post approval supplements for its *H. pylori* NDAs, and anticipated product launches in H. pylori and erosive esophagitis; the expected timing of topline data from the Phase 3 trial of vonoprazan as a daily treatment for patients with non-erosive GERD; the potential of vonoprazan to provide patients with a rapid relief agent to treat non-erosive GERD; and that Phathom will have sufficient capital to fund operations through 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 esophagitis NDA or to bring vonoprazan to market for patients with erosive esophagitis, if approved, or for patients with *H. Pylori*; 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
(in thousands)

	December 31, 2022	December 31, 2021
Assets		
Cash and cash equivalents	$ 155,385	$ 183,259
Total assets	$ 164,810	$ 189,431

Total liabilities	$ 239,624	$ 117,275
Total stockholders' equity (deficit)	$ (74,814)	$ 72,156

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

	Three Months Ended December 31,		Years Ended December 31,	
	2022	2021	2022	2021
Operating expenses:				
Research and development	$ 15,946	$ 13,553	$ 71,441	$ 72,338
General and administrative	30,695	19,487	100,999	62,742
Total operating expenses	46,641	33,040	172,440	135,080
Loss from operations	(46,641)	(33,040)	(172,440)	(135,080)
Other income (expense):				
Interest income	1,286	6	2,132	41
Interest expense	(9,603)	(2,775)	(27,305)	(6,788)
Other expense	(89)	(17)	(110)	(2,056)
Total other expense	(8,406)	(2,786)	(25,283)	(8,803)
Net loss and comprehensive loss	$ (55,047)	$ (35,826)	$ (197,723)	$ (143,883)
Net loss per share, basic and diluted	$ (1.33)	$ (0.95)	$ (5.05)	$ (3.89)
Weighted-average shares of common stock outstanding, basic and diluted	41,310,887	37,758,061	39,118,215	37,002,959