



Phathom Pharmaceuticals Reports Second Quarter 2023 Results

August 10, 2023

- Prior Approval Supplement (PAS) for VOQUEZNA® TRIPLE PAK® and VOQUEZNA® DUAL PAK® assigned a Prescription Drug User Fee Act (PDUFA) goal date of October 30, 2023 by the U.S. Food and Drug Administration (FDA)
- U.S. commercial launch for *H. pylori* and Erosive GERD planned for Q4 2023
- Successfully completed Phase 3 PHALCON-NERD-301 trial for Non-Erosive GERD; regulatory submission on track to occur by year-end

FLORHAM PARK, N.J., Aug. 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 second quarter of 2023 and provided updates on recent regulatory and business progress.

"We made great progress advancing key regulatory, financial, and commercial priorities during the second quarter, highlighted by our regulatory submissions for both Erosive GERD and *H. pylori* convenience packs, the successful execution of a capital raise resulting in \$141.4 million in net proceeds, and commencement of our salesforce recruiting in anticipation of our product launches in the fourth quarter," said Terrie Curran, President and Chief Executive Officer of Phathom. "Our manufacturing and regulatory teams have worked diligently to address the impurity cited by the FDA in the complete response letters we received in February, and we are pleased that our regulatory applications have been assigned PDUFA action dates later this year. We remain focused on onboarding a high-performing field force and completing the final preparations for our anticipated commercial launches."

Clinical, Regulatory, and Business Updates:

- In June 2023, Phathom submitted a PAS to the FDA for both VOQUEZNA TRIPLE PAK (vonoprazan, amoxicillin, clarithromycin) and VOQUEZNA DUAL PAK (vonoprazan, amoxicillin). The submission of these supplements signifies a full response to the February 2023 complete response letter (CRL) and, subject to filing, the FDA has assigned a PDUFA goal date of October 30, 2023. The PAS contained three months of stability data supporting both VOQUEZNA-based convenience packs, which includes reformulated vonoprazan tablets, to support the commercial shelf life of vonoprazan. Phathom plans to provide six-month stability data during the regulatory review as previously agreed with the FDA.
- In June 2023, Phathom [announced](#) that the FDA acknowledged the New Drug Application (NDA) resubmission for vonoprazan for the treatment of Erosive GERD (gastroesophageal reflux disease) constitutes a complete response to the February 2023 CRL and assigned a PDUFA goal date of November 17, 2023.
- In May 2023, Phathom recorded \$141.4 million in net proceeds from the completed public offering of its common stock. The total gross proceeds to Phathom from the offering were approximately \$150.3 million, before deducting the underwriting discounts and commissions and other offering expenses. Phathom intends to use the net proceeds from the offering to fund the clinical development of vonoprazan, pre-commercial activities and commercialization expenses, and for working capital and general corporate purposes.
- In its Phase 3 PHALCON-NERD-301 trial for Non-Erosive GERD, Phathom successfully completed the 20-week blinded extension period where patients were administered vonoprazan 10 mg or 20 mg once-daily for further safety and efficacy evaluation. Topline results from the extension period are expected to be shared by the end of 2023. A regulatory submission remains on track 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. population of over 45 million people.
- Phathom has currently secured coverage for 65% of commercial lives for first-in-class PCAB-based *H. pylori* infection treatments, VOQUEZNA TRIPLE PAK and VOQUEZNA DUAL PAK.
- Phathom is in the process of recruiting and onboarding a national salesforce in advance of the planned fourth quarter 2023 commercial launches for *H. pylori* and Erosive GERD.

Second Quarter 2023 Financial Results:

- Net loss for the second quarter ended June 30, 2023, was \$41.0 million, compared to \$50.9 million for second quarter

2022. Second quarter 2023 net loss included a non-cash charge related to stock-based compensation of \$7.3 million compared to \$5.9 million for second quarter 2022.

- Research and development expenses for the second quarter 2023 were \$12.8 million, a decrease of \$6.0 million compared to \$18.8 million for second 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 second quarter 2023 were \$18.9 million, a decrease of \$7.6 million compared to \$26.5 million for second quarter 2022. The decrease was primarily due to a reduction in professional services, partially offset by increased personnel costs.
- As of June 30, 2023, cash and cash equivalents were \$248.8 million. An additional \$100.0 million is available under Phathom's term loan with Hercules Capital, Inc. (Hercules) on October 1, 2023, and \$175.0 million will be paid to Phathom upon FDA approval of VOQUEZNA for Erosive GERD under the terms of its revenue interest financing agreement.
- 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 following 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

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 and submitting to the FDA stability data necessary to support the proposed shelf life of vonoprazan; the potential approval of its Erosive GERD NDA and prior approval supplements for its *H. pylori* convenience pack NDAs, and anticipated product launches in *H. pylori* and Erosive GERD; a potential regulatory submission seeking approval of vonoprazan as a daily treatment for Non-Erosive GERD; and that Phathom will have sufficient capital to fund operations through the end of 2025. 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 for 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 *H. pylori* convenience pack supplements; 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 GERD 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)

	June 30, 2023	December 31, 2022
Assets		
Cash and cash equivalents	\$ 248,847	\$ 155,385
Total assets	\$ 265,039	\$ 164,810
Total liabilities	\$ 247,439	\$ 239,624
Total stockholders' equity (deficit)	\$ 17,600	\$ (74,814)

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Operating expenses:				
Research and development	\$ 12,764	\$ 18,815	\$ 24,242	\$ 36,475
General and administrative	18,937	26,548	37,536	46,795
Total operating expenses	<u>31,701</u>	<u>45,363</u>	<u>61,778</u>	<u>83,270</u>
Loss from operations	(31,701)	(45,363)	(61,778)	(83,270)
Other income (expense):				
Interest income	348	112	1,808	119
Interest expense	(9,615)	(5,667)	(18,832)	(8,426)
Other income (expense)	3	(2)	23	(8)
Total other expense	<u>(9,264)</u>	<u>(5,557)</u>	<u>(17,001)</u>	<u>(8,315)</u>
Net loss and comprehensive loss	<u>\$ (40,965)</u>	<u>\$ (50,920)</u>	<u>\$ (78,779)</u>	<u>\$ (91,585)</u>
Net loss per share, basic and diluted	<u>\$ (0.84)</u>	<u>\$ (1.33)</u>	<u>\$ (1.73)</u>	<u>\$ (2.40)</u>
Weighted-average shares of common stock outstanding, basic and diluted	<u>48,500,516</u>	<u>38,272,044</u>	<u>45,444,496</u>	<u>38,155,151</u>