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

August 2, 2022

- Erosive Esophagitis (EE) New Drug Application (NDA) accepted by U.S. Food and Drug Administration (FDA) with Prescription Drug User Fee Act (PDUFA) action date of January 11, 2023; if approved, targeting U.S. launch in Q1 2023
- VOQUEZNA DUAL and TRIPLE PAK approved by FDA for treatment of *H. pylori* infection on May 3, 2022
- Initial testing for nitrosamines revealed trace levels in vonoprazan commercial drug product; working with FDA to make VOQUEZNA DUAL and TRIPLE PAK available to patients as soon as possible; *H. pylori* full commercial launch planned to coincide with expected EE launch in Q1 2023
- Topline data for primary endpoint in Phase 3 non-erosive reflux disease (NERD) daily dosing trial expected in Q1 2023

FLORHAM PARK, N.J., Aug. 02, 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 second quarter of 2022 and provided recent business updates.

“The second quarter of 2022 was pivotal for Phathom as our teams continued to achieve major milestones, including the approval of our first products, the receipt of an earlier than expected PDUFA date for our EE NDA, and key progress in enrollment in our Phase 3 NERD trial,” said Terrie Curran, President and Chief Executive Officer of Phathom. “As the pharmaceutical industry and global regulatory agencies continue to develop standards to help detect and control levels of nitrosamines, an impurity commonly found in water, meats, and vegetables, we detected trace levels of a nitrosamine in vonoprazan drug product in our post-approval testing as we prepared for commercial launch. We will be discussing with the FDA a new test method and controls, and confirming our assessment that our drug product is within acceptable intake levels. Our goal is to make our product available to *H. pylori* patients as soon as possible, however, we are now planning for a combined full commercial launch of both *H. pylori* and EE in the first quarter of 2023. We believe a combined launch will bring significant operational and financial benefits.”

Second Quarter and Recent Business Updates:

- On May 3, 2022, the Company announced the FDA approval of VOQUEZNA DUAL PAK (vonoprazan, amoxicillin) and VOQUEZNA TRIPLE PAK (vonoprazan, amoxicillin, clarithromycin) 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.
- On May 4, 2022, Phathom announced the signing of a revenue interest financing agreement for up to $260 million of non-dilutive financing. Phathom received an upfront $100 million cash payment upon closing and is eligible for an additional $160 million cash payment upon FDA approval of the NDA for vonoprazan in erosive esophagitis (EE).
- On May 25, 2022, the Company announced that the FDA had accepted the company’s NDA for vonoprazan as a treatment for adults for the healing of all grades of EE and relief of heartburn and for the maintenance of healing of all grades of EE and relief of heartburn. The FDA has assigned the application a PDUFA target action date of January 11, 2023.
- Consistent with current FDA recommendations for all chemically synthesized drug compounds such as vonoprazan, the Company initiated testing to determine whether nitrosamines were present in vonoprazan drug product. These tests revealed trace levels of a nitrosamine impurity that is not described within the FDA guidance document entitled “Control of Nitrosamine Impurities in Human Drugs – Guidance for Industry.” The Company is working with the FDA and plans to obtain approval of and implement an additional test method, specification, including a proposed acceptable intake limit, and additional controls to address this impurity prior to releasing our first vonoprazan-based products to the market. These additional activities will result in a delay of the planned VOQUEZNA DUAL PAK and VOQUEZNA TRIPLE PAK product launches. The Company currently expects the full commercial launch of these products, as well as, if approved VOQUEZNA tablets for EE, in the first quarter of 2023.
- Phase 3 NERD daily dosing trial continues to enroll, and the Company now expects topline results for the primary endpoint in the first quarter of 2023. Topline results for the full trial are expected later in 2023.

Second Quarter 2022 Financial Results:

- Net loss for the second quarter ended June 30, 2022 was $50.9 million, compared to $36.6 million for second quarter 2021. Second quarter 2022 net loss included a non-cash charge related to stock-based compensation of $5.9 million

compared to the second quarter of 2021 non-cash charge related to stock-based compensation of $4.2 million.

- Research and development expenses for the second quarter ended June 30, 2022 were $18.8 million, a decrease of $2.8 million compared to $21.6 million for second quarter 2021 as a result of lower clinical trial costs related to the development of vonoprazan. The second quarter of 2021 included activity relating to two pivotal Phase 3 trials.
- General and administrative expenses for the second quarter ended June 30, 2022 were $26.5 million, an increase of $12.8 million compared to $13.7 million for second quarter 2021 primarily due to the ongoing buildout of commercial infrastructure in support of the planned U.S. launch of VOQUEZNA DUAL and TRIPLE PAKs.
- As of June 30, 2022, cash and cash equivalents were $207.4 million plus an additional $100 million in liquidity available under its term loan with Hercules Capital.
- Based on its current operating plan, and the anticipated funds available under the existing term loan and royalty interest finance agreements, the Company believes it has sufficient capital to fund operations through 2024.

[Tables follow]

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). Phathom has submitted a New Drug Application to 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 Phase 3 trial; and our plans to address the trace levels of a nitrosamine impurity observed in vonoprazan drug product for VOQUEZNA DUAL and TRIPLE PAK and to obtain FDA approval to enable commercial launch of these products. 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 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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PHATHOM PHARMACEUTICALS, INC.
Selected Condensed Balance Sheets
(Unaudited)
(in thousands)

	June 30, 2022	December 31, 2021

Assets				
Cash and cash equivalents	$	207,392	$	183,259
Total assets	$	213,502	$	189,431
Total liabilities	$	220,502	$	117,275
Total stockholders' equity (deficit)	$	(7,000)	$	72,156

PHATHOM PHARMACEUTICALS, INC.
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,	
	2022	**2021**	**2022**	**2021**
Operating expenses:				
Research and development (includes related party amounts of $370, $905, $1,800, and $1,846, respectively)	$18,815	$21,597	$36,475	$42,178
General and administrative (includes related party amounts of $0, $0, $0, and $16, respectively)	26,548	13,722	46,794	26,725
Total operating expenses	45,363	35,319	83,269	68,903
Loss from operations	(45,363)	(35,319)	(83,269)	(68,903)
Other income (expense):				
Interest income	112	13	119	27
Interest expense	(5,667)	(1,256)	(8,426)	(2,528)
Other (expense)	(2)	10	(9)	9
Total other (expense)	(5,557)	(1,233)	(8,316)	(2,492)
Net loss and comprehensive loss	$(50,920)	$(36,552)	$(91,585)	$(71,395)
Net loss per share, basic and diluted	$(1.33)	$(1.00)	$(2.40)	$(1.96)
Weighted-average shares of common stock outstanding, basic and diluted	38,272,044	36,636,164	38,155,151	36,468,498