

Phathom[®]

PHARMACEUTICALS

Phathom Pharmaceuticals Reports First Quarter 2022 Results and Provides Recent Clinical, Regulatory, and Business Updates

May 10, 2022

- U.S. Food and Drug Administration (FDA) approval received for VOQUEZNA™ TRIPLE PAK™ (vonoprazan, amoxicillin, clarithromycin) and VOQUEZNA™ DUAL PAK™ (vonoprazan, amoxicillin) for treatment of *H. pylori* infection in adults
- Up to \$260 million revenue interest financing agreement strengthens balance sheet with non-dilutive financing

FLORHAM PARK, N.J., May 10, 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 first quarter of 2022 and provided updates on recent clinical, regulatory, and business progress.

"Phathom demonstrated strong execution on several key initiatives throughout the start of 2022, resulting in the accomplishment of important regulatory and financial milestones that we believe provide the basis to achieve success for years to come," said Terrie Curran, President and Chief Executive Officer of Phathom. "We were excited to receive the company's first FDA approval of VOQUEZNA TRIPLE and DUAL PAKs in *H. pylori* infection, and our teams are working diligently to prepare for the planned launch of these innovative products in the third quarter of this year. Additionally, the strengthening of our financial position with the recent signing of a royalty financing agreement provides us with a strong foundation to become the leading gastrointestinal-focused commercial pharmaceutical company."

Clinical and Regulatory Updates:

- 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 VOQUEZNA treatment regimens 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. The two New Drug Applications for these products were given priority review designation by the FDA and were previously designated as qualified infectious disease products (QIDP). A U.S. commercial launch is anticipated for the third quarter of 2022.
- Phathom [announced](#) positive topline results from a Phase 2 trial evaluating vonoprazan for non-erosive gastroesophageal reflux disease (NERD). The primary endpoint was met for all three dose levels (10 mg, 20 mg, 40 mg) taken on-demand in the trial, demonstrating faster and sustained relief of episodic heartburn as compared to placebo (p<0.0001).
- Based on input from the FDA, Phathom commenced a Phase 3 NERD development program in the first quarter of 2022 with the initiation of a pivotal Phase 3 vonoprazan daily dosing trial (NERD-301). The trial is actively recruiting across the U.S. with topline results expected in 2023.
- Phathom is currently designing a Phase 3 study to support the novel dosing regimen for vonoprazan as an on-demand treatment for episodic heartburn relief in patients with NERD, a dosing regimen not approved in the U.S. for proton pump inhibitors (PPIs). Pending FDA input, we expect to initiate the NERD Phase 3 on-demand trial (NERD-302) in 2023.

Recent Financial and Business Updates:

- Phathom announced the signing of a revenue interest financing agreement for up to \$260 million in non-dilutive financing on May 4, 2022. The agreement provides for an upfront \$100 million cash payment and an additional \$160 million cash payment upon FDA approval of vonoprazan for treatment of erosive esophagitis (EE). The company has an option, upon the same terms, to obtain an

additional \$15 million in funding upon EE approval and an additional cash payment up to \$25 million upon achievement of a sales milestone, which could bring the total financing to \$300 million. Under the agreement, the company will pay the investors a 10% royalty on net sales of products containing vonoprazan, which royalty rate is subject to a step-down on net sales exceeding annual thresholds if the company receives approval of vonoprazan for NERD. Based upon the company's current operating plan, the full amount of this non-dilutive funding, in combination with existing cash and a full drawdown of funds under the loan agreement with Hercules Capital and anticipated future sales of products containing vonoprazan, the company believes it will have sufficient capital to fund operations through 2024, which includes supporting the launch of vonoprazan in both *H. pylori* and EE (if approved) in addition to completing its daily dosing Phase 3 trial in NERD.

- During Digestive Disease Week® (DDW) 2022, to be held May 21-24 in San Diego, CA and virtually, Phathom will have a large presence including showcasing new data for vonoprazan. An analysis of *H. pylori* diagnosis and treatment patterns will be presented, among other important clinical developments. Several abstracts being presented during DDW have been recognized as "posters of distinction" by the American Gastroenterological Association (AGA) Institute.
- Phathom announced the strengthening of its company leadership with the appointments of Molly Henderson as Chief Financial and Business Officer and Frank Karbe to its Board of Directors. Ms. Henderson most recently served as Chief Financial Officer of UroGen Pharma (Nasdaq: URGN) and brings over two decades of global finance expertise and has extensive experience in financial planning and analysis, investor relations, and capital raising. Mr. Karbe, who most recently served as President and Chief Financial Officer of Myovant Sciences (NYSE: MYOV) brings over twenty-five years of financial and life-sciences expertise to Phathom.

First Quarter 2022 Financial Results:

- Research and development expenses for the first quarter ended March 31, 2022 decreased to \$17.7 million compared to \$20.6 million for first quarter 2021 as a result of lower clinical trial costs related to the development of vonoprazan. The first quarter of 2021 included activity relating to two pivotal Phase 3 trials which supported the recent approval of vonoprazan-based regimens in *H. pylori* infection and the NDA submission for vonoprazan in EE. Non-cash stock compensation expense included within research and development expenses for the first quarter ended 2022 and 2021 was \$1.1 million and \$0.9 million, respectively.
- General and administrative expenses for the first quarter ended March 31, 2022 increased to \$20.2 million compared to \$13.0 million for first quarter 2021 primarily due to the ongoing buildout of the commercial organization in support of the planned U.S. launch of VOQUEZNA TRIPLE and DUAL PAKs, the company's first FDA approved products in *H. pylori* infection. Non-cash stock compensation expense included within general and administrative expenses for the first quarter ended 2022 and 2021 was \$4.6 million and \$3.0 million, respectively.
- Net loss for the first quarter ended March 31, 2022 was \$40.7 million, compared to \$34.8 million for first quarter 2021.
- As of March 31, 2022, cash and cash equivalents were \$138.1 million plus an additional \$150 million in liquidity for which Phathom is eligible to receive, which includes \$100 million in proceeds from the revenue interest financing agreement announced on May 4, 2022 and \$50 million from its term loan with Hercules Capital.

[Tables follow]

About VOQUEZNA TRIPLE and DUAL PAKs

VOQUEZNA TRIPLE PAK (vonoprazan, amoxicillin, clarithromycin) and VOQUEZNA DUAL PAK (vonoprazan, amoxicillin) contain vonoprazan, an oral small molecule potassium-competitive acid blocker (PCAB) co-packaged with antibiotics. PCABs are a novel class of medicines that block acid secretion in the stomach. Vonoprazan has shown the potential to provide acid suppression that can achieve pH levels that are important in enhancing antibiotic effectiveness. Phathom in-licensed the U.S., European, and Canadian rights to vonoprazan from Takeda, which completed 19 Phase 3 trials for vonoprazan and received marketing approval in Japan and numerous other countries in Asia and Latin America.

Indication and Important Safety Information **INDICATIONS AND USAGE**

VOQUEZNA™ TRIPLE PAK™ is a co-packaged product containing vonoprazan, a potassium-competitive acid blocker (PCAB), amoxicillin, a penicillin-class antibacterial, and clarithromycin, a macrolide antimicrobial. VOQUEZNA™ DUAL PAK™ is a co-packaged product containing vonoprazan and amoxicillin. Both products are indicated for the treatment of *Helicobacter pylori* infection in adults.

To reduce the development of drug-resistant bacteria and maintain the effectiveness of VOQUEZNA TRIPLE PAK, VOQUEZNA DUAL PAK and other antibacterial drugs, both products should be used only to treat or prevent infections that are proven or strongly suspected of being caused by bacteria.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

VOQUEZNA TRIPLE PAK and VOQUEZNA DUAL PAK are contraindicated in patients with known hypersensitivity to vonoprazan or amoxicillin, any other components of the formulation, any other beta-lactams, or in patients receiving rilpivirine-containing products.

Due to the clarithromycin component, VOQUEZNA TRIPLE PAK is also contraindicated in patients with any known hypersensitivity to clarithromycin or any macrolide antibiotic, in patients receiving pimozide, lomitapide, lovastatin, simvastatin, ergotamine, dihydroergotamine, colchicine in patients with renal or hepatic impairment, or those with a history of cholestatic jaundice/hepatic dysfunction.

WARNINGS AND PRECAUTIONS

Hypersensitivity Reactions: Serious and occasionally fatal reactions (e.g., anaphylaxis) have been reported with components of VOQUEZNA TRIPLE PAK and VOQUEZNA DUAL PAK. If hypersensitivity reactions occur, discontinue use and institute immediate therapy (e.g., anaphylaxis management).

Severe Cutaneous Adverse Reactions (SCAR): Discontinue use of VOQUEZNA TRIPLE PAK or VOQUEZNA DUAL PAK at first signs or symptoms of SCAR or other signs of hypersensitivity and consider further evaluation. SCAR, including Stevens-Johnson syndrome (SJS) and toxic epidermal necrolysis (TEN) have been reported with the components of both products. In addition, drug reaction with eosinophilia and systemic symptoms (DRESS), and acute generalized exanthematous pustulosis (AGEP) have been reported with amoxicillin and clarithromycin.

Clostridioides difficile-associated diarrhea (CDAD): Evaluate if diarrhea occurs with VOQUEZNA TRIPLE PAK or VOQUEZNA DUAL PAK. CDAD has been reported with use of acid suppressing therapies and nearly all antibacterial agents, and may range in severity from mild diarrhea to fatal colitis. If CDAD is confirmed, discontinue therapy and treat appropriately.

VOQUEZNA TRIPLE PAK Warnings or Precautions Due to the Clarithromycin Component:

QT Prolongation: Avoid VOQUEZNA TRIPLE PAK in patients with known QT prolongation or receiving drugs known to prolong the QT interval, ventricular arrhythmia (*torsades de pointes*), hypokalemia/hypomagnesemia, significant bradycardia, or taking Class IA or III antiarrhythmics.

Hepatotoxicity: Discontinue use of VOQUEZNA TRIPLE PAK if signs and symptoms of hepatitis occur.

Serious adverse reactions due to concomitant use with other drugs: Serious adverse reactions can occur with VOQUEZNA TRIPLE PAK due to drug interactions of clarithromycin with colchicine, some lipid lowering agents, some calcium channel blockers, hypoglycemic agents including insulin, quetiapine, warfarin, benzodiazepines, and other drugs.

Embryo-Fetal Toxicity: VOQUEZNA TRIPLE PAK is not recommended for use in pregnancy as clarithromycin may cause fetal harm.

Myasthenia Gravis: Exacerbation of myasthenia gravis can occur with VOQUEZNA TRIPLE PAK since it has been reported in patients receiving clarithromycin tablets.

ADVERSE REACTIONS

The most common adverse reactions (≥2%) include diarrhea, dysgeusia, vulvovaginal candidiasis, abdominal pain, headache, hypertension, and nasopharyngitis.

DRUG INTERACTIONS

Components of VOQUEZNA TRIPLE PAK and VOQUEZNA DUAL PAK have the potential for clinically important drug interactions. See full Prescribing Information for important drug interactions.

USE IN SPECIFIC POPULATIONS

Lactation: Breastfeeding not recommended during treatment, but a lactating woman can pump and discard breast milk during treatment and for 2 days after VOQUEZNA TRIPLE PAK and VOQUEZNA DUAL PAK administration.

Geriatrics: VOQUEZNA TRIPLE PAK increased risk of *torsades de pointes* due to clarithromycin.

Renal and Hepatic Impairment: Avoid use in patients with severe renal impairment and avoid use in patients with moderate to severe hepatic impairment.

You are encouraged to report suspected adverse reactions by contacting Phathom Pharmaceuticals at 1-888-775-PHAT (7428) or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Please see full Prescribing Information for VOQUEZNA TRIPLE PAK and VOQUEZNA DUAL PAK.

About DDW

Digestive Disease Week® (DDW) is the largest international gathering of physicians, researchers and academics in the fields of gastroenterology, hepatology, endoscopy and gastrointestinal surgery. Jointly sponsored by the American Association for the Study of Liver Diseases (AASLD), the American Gastroenterological Association (AGA) Institute, the American Society for Gastrointestinal Endoscopy (ASGE) and the Society for Surgery of the Alimentary Tract (SSAT), DDW is an in-person and virtual meeting from May 21-24, 2022. The meeting showcases more than 5,000 abstracts and hundreds of lectures on the latest advances in GI research, medicine and technology. More information can be found at www.ddw.org.

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 our plans to launch vonoprazan-based therapies for the treatment of *H. pylori* infection in the third quarter of 2022, the timing of topline results from our Phase 3 daily dosing trial for NERD and initiation of a Phase 3 on-demand dosing trial for NERD, the availability of additional funds under our revenue interest financing agreement and loan agreement with Hercules Capital, and the sufficiency of our capital to fund the Company's operations. 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 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; Phathom's ability to successfully launch and commercialize vonoprazan; 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 QIDP designations may not actually lead to extended exclusivity; 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 uninterrupted 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 launch and commercialization efforts; Phathom's ability to achieve and maintain adequate levels of coverage and reimbursement for vonoprazan; Phathom's ability to access additional capital under the term loan facility is subject to certain conditions; 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.
Statements of Operations and Comprehensive Loss
(Unaudited)
(in thousands, except share and per share amounts)

	Three Months Ended	
	March 31,	
	2022	2021
Operating expenses:		
Research and development (includes related party amounts of \$1,430 and \$939 respectively)	\$ 17,660	\$ 20,580
General and administrative (includes related party amounts of \$0 and \$16, respectively)	20,246	13,004
Total operating expenses	37,906	33,584
Loss from operations	(37,906)	(33,584)
Other income (expense):		
Interest income	7	14
Interest expense	(2,759)	(1,272)
Other (expense)	(7)	(1)
Total other (expense)	(2,759)	(1,259)
Net loss and comprehensive loss	\$ (40,665)	\$ (34,843)
Net loss per share, basic and diluted	\$ (1.07)	\$ (0.96)
Weighted-average shares of common stock outstanding, basic and diluted	38,036,960	36,298,968

PHATHOM PHARMACEUTICALS, INC.
Selected Condensed Balance Sheets
(Unaudited)
(in thousands)

	March 31,	December 31,
	2022	2021
Assets		
Cash and cash equivalents	\$ 138,090	\$ 183,259
Total assets	\$ 149,049	\$ 189,431
Total liabilities	\$ 111,014	\$ 117,275
Total stockholders' equity	\$ 38,035	\$ 72,156