Phathom Pharmaceuticals Reports Second Quarter 2021 Results and Provides Update Regarding Key Clinical and Regulatory Milestones

August 10, 2021

- Pivotal Phase 3 PHALCON-EE trial topline data for vonoprazan in erosive esophagitis expected in October 2021
- Phase 2 PHALCON-NERD on-demand trial for vonoprazan in non-erosive reflux disease enrolling ahead of schedule with topline data now expected in the first quarter of 2022

FLORHAM PARK, N.J., Aug. 10, 2021 (GLOBE NEWSWIRE) -- Phathom Pharmaceuticals, Inc. (Nasdaq: PHAT), a late clinical-stage biopharmaceutical company focused on developing and commercializing novel treatments for gastrointestinal diseases, today reported financial results for the second quarter of 2021 and provided an update on expected clinical and regulatory milestones.

"Our execution against key priorities through the second quarter has advanced several critical catalysts which we expect will lay the foundation for Phathom's long-term success," said Terrie Curran, Phathom's President and Chief Executive Officer. "We continue to progress our GERD development programs, which have the potential to address the unmet needs in a population of approximately 65 million people in the U.S. We are expecting topline data from our pivotal Phase 3 PHALCON-EE trial evaluating vonoprazan for erosive esophagitis (EE) in October 2021 and are now expecting topline data from our Phase 2 PHALCON-NERD trial evaluating vonoprazan as an on-demand treatment for non-erosive reflux disease (NERD) in Q1 2022. Additionally, we are nearing the submission of new drug applications (NDAs) to the FDA for both the dual and triple vonoprazan-based regimens for the treatment of *H. pylori* infection, now expected in September 2021. The anticipated progress over the next several months will be key to advancing our mission of changing the landscape in gastrointestinal diseases."

Clinical Development and Regulatory Timing Updates:

- Phathom has accelerated its work on the NDAs for dual and triple vonoprazan-based regimens for the treatment of *H. pylori* infection and now expects to submit both NDAs in September 2021 instead of in the fourth quarter of 2021.
- Topline results from PHALCON-EE, a pivotal Phase 3 trial evaluating vonoprazan for the healing and maintenance of erosive esophagitis, are expected in October 2021.
- Topline results from the PHALCON-NERD on-demand Phase 2 trial evaluating various doses of vonoprazan as an on-demand therapy for patients with non-erosive reflux disease are expected in the first quarter of 2022.

Second Quarter 2021 Financial Results:

- Second quarter 2021 net loss was $36.6 million compared to $21.1 million for the second quarter of 2020.
- Second quarter 2021 net loss included a non-cash charge related to stock-based compensation of $4.2 million compared to the second quarter of 2020 non-cash charge related to stock-based compensation of $0.8 million.
- Second quarter 2021 research and development expenses increased to $21.6 million compared to $14.9 million for the second quarter 2020 as a result of higher clinical trial costs, higher chemistry, manufacturing, and controls (CMC) costs, and higher personnel-related expenses.
- Second quarter 2021 general and administrative expenses increased to $13.7 million compared to $5.2 million for the second quarter of 2020 due to the ongoing buildout of administrative and commercial functions.
- As of June 30, 2021, cash and cash equivalents were $209.7 million. Cash and cash equivalents are expected to be sufficient to meet anticipated cash requirements into the fourth quarter of 2022.

About Vonoprazan
Vonoprazan is an investigational, oral small molecule potassium-competitive acid blocker (P-CAB). P-CABs are a novel class of medicines that block acid secretion in the stomach. Vonoprazan has shown the potential to have rapid, potent, and durable anti-secretory effects as a single agent in the treatment of gastroesophageal reflux disease (GERD) and in combination with antibiotics for the treatment of Helicobacter pylori (*H. pylori)* infection. The FDA has designated vonoprazan in combination with both amoxicillin and clarithromycin and with amoxicillin alone as qualified infectious disease products (QIDP) and awarded them Fast Track status for the treatment of *H. pylori* infection. 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.

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 novel potassium competitive acid blocker (P-CAB) in late-stage development for the treatment of acid-related disorders. For more information about Phathom, visit the Company's website at www.phathompharma.com or follow the Company on social media: LinkedIn at www.linkedin.com/company/phathompharma and Twitter @PhathomPharma.

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 availability of topline results from the PHALCON-EE Phase 3 and the Phase 2 NERD on demand clinical trials; and the expected submission of New Drug Applications for vonoprazan-based therapies for the eradication of *H. pylori* infection. 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: potential additional delays in the commencement, enrollment and completion of clinical trials due to the COVID-19 pandemic and other factors outside of Phathom's control; patients already enrolled in the Phase 2 NERD study may not complete the clinical trial or public health conditions and governmental restrictions may lead Phathom to stop such trial all together, which may adversely impact its trial results and development plans; 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; QIDP and Fast Track designations may be withdrawn or not actually lead to a faster development or regulatory review or extended exclusivity, and would not assure FDA approval of vonoprazan; 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.
Balance Sheets
(Unaudited)
(in thousands, except share and par value amounts)

	June 30, 2021	December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	$ 209,669	$ 287,496
Prepaid expenses and other current assets (including related party amounts of $0 and $82, respectively)	1,669	3,872
Total current assets	211,338	291,368
Property, plant and equipment, net	803	986
Operating lease right-of-use assets	2,147	2,373
Other long-term assets	291	384
Total assets	$ 214,579	$ 295,111
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable (including related party amounts of $124 and $173, respectively)	$ 5,401	$ 16,782
Accrued clinical trial expenses	14,238	19,997
Accrued expenses (including related party amounts of $1,505 and $734, respectively)	8,845	10,606
Accrued interest	302	312
Current portion of long-term debt	10,345	7,353
Operating lease liabilities, current	480	474
Total current liabilities	39,611	55,524
Long-term debt, net of discount	37,340	39,634
Operating lease liabilities	1,375	1,557
Other long-term liabilities	4,125	4,125
Total liabilities	82,451	100,840

Commitments and contingencies		
Stockholders' equity:		
Preferred stock, $0.0001 par value; authorized shares — 40,000,000 at June 30, 2021 and December 31, 2020 ; no shares issued and outstanding at June 30, 2021 and December 31, 2020	-	-
Common stock, $0.0001 par value; authorized shares — 400,000,000; issued shares — 31,329,613 and 31,262,769 at June 30, 2021 and December 31, 2020, respectively; outstanding shares — 29,186,169 and 28,516,010 at June 30, 2021 and December 31, 2020, respectively	3	3
Additional paid-in capital	589,007	579,755
Accumulated deficit	(456,882)	(385,487)
Total stockholders' equity	132,128	194,271
Total liabilities and stockholders' equity	$ 214,579	$ 295,111

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,	
	2021	**2020**	**2021**	**2020**
Operating expenses:				
Research and development (includes related party amounts of $905, $249, $1846, and $653, respectively)	$ 21,597	$ 14,859	$ 42,178	$ 30,724
General and administrative (includes related party amounts of $0, $34, $16, and $77, respectively)	13,722	5,162	26,725	9,672
Total operating expenses	35,319	20,021	68,903	40,396
Loss from operations	(35,319)	(20,021)	(68,903)	(40,396)
Other income (expense):				
Interest income	13	182	27	1,060
Interest expense	(1,256)	(1,262)	(2,528)	(2,000)
Change in fair value of warrant liabilities	—	—	—	95
Other income (expense)	10	—	9	(1)
Total other income (expense)	(1,233)	(1,080)	(2,492)	(846)
Net loss and comprehensive loss	$ (36,552)	$ (21,101)	$ (71,395)	$ (41,242)
Net loss per share, basic and diluted	$ (1.00)	$ (0.64)	$ (1.96)	$ (1.26)
Weighted-average shares of common stock outstanding, basic and diluted	36,636,164	32,997,099	36,468,498	32,733,750