Pharmaceuticals

Phathom Pharmaceuticals Reports Fourth Quarter and Full Year 2021 Financial Results and Highlights Recent Pipeline and Business Progress

March 1, 2022

FLORHAM PARK, N.J., March 01, 2022 (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 fourth quarter and full year ended December 31, 2021 and provided highlights of pipeline and business progress.

"During 2021 our teams made great strides towards delivering on the clinical promise of vonoprazan and the potential to change gastrointestinal treatment paradigms, including the positive results from two pivotal Phase 3 programs," said Terrie Curran, President and Chief Executive Officer of Phathom. "As we move into 2022, we are excited about our planned NDA submission for erosive esophagitis later this month and preparing for the anticipated FDA approval and commercial launch of two vonoprazan-based therapies for the treatment of *H. pylori*, which would mark the first approval of an innovative gastric anti-secretory agent in the U.S. in over 30 years. These key near-term catalysts, coupled with the recent initiation of a NERD Phase 3 development program, are expected to enhance the potential of vonoprazan across acid-related disorders."

2022 Expected Milestones:

- New Drug Application (NDA) submission for erosive esophagitis (EE) in March 2022 targeting the following indications: healing of all grades of EE and relief of heartburn, and maintenance of healing of all grades of EE and relief of heartburn.
- U.S. Food and Drug Administration (FDA) approval of vonoprazan-based regimens for treatment of Helicobacter pylori (*H. pylori*) infection expected by May 3, 2022.
- U.S. launch of vonoprazan for treatment of *H. pylori* in second half of 2022.
- Enrollment completion of Phase 3 non-erosive reflux disease (NERD) daily dosing trial in the second half of 2022.

Full Year 2021 and Recent Business Highlights:

- Positive topline results in pivotal Phase 3 trial for vonoprazan-based therapies in treatment *H. pylori* infection (PHALCON-HP).
- Positive topline results in pivotal Phase 3 trial for vonoprazan in erosive esophagitis (PHALCON-EE).
- Two NDAs accepted for filing by FDA for vonoprazan-based regimens for the treatment of *H. pylori* infection.
- Positive topline results from proof-of-concept Phase 2 trial for vonoprazan as an on-demand dosing regimen in NERD.
- Initiation of a multi-site pivotal Phase 3 trial for vonoprazan as a daily dosing regimen in NERD.

Fourth Quarter and Full Year 2021 Financial Results:

- Fourth quarter net loss for 2021 was \$35.8 million, compared to \$53.7 million for fourth quarter 2020.
- Fourth quarter net loss for 2021 was driven by a net loss from operations of \$33.0 million, which included a non-cash charge related to stock-based compensation of \$4.3 million.
- Fourth quarter net loss for 2020 was driven by a net loss from operations of \$52.4 million, which included a non-cash charge related to stock-based compensation of \$2.3 million.
- Fourth quarter 2021 research and development expenses decreased to \$13.5 million compared to \$41.6 million for fourth quarter 2020 as a result of reduced clinical trial costs related to the development of vonoprazan, the fourth quarter 2020 included the activity relating to two pivotal Phase 3 trials versus 2021.
- Fourth quarter 2021 general and administrative expenses increased to \$19.5 million compared to \$10.8 million for fourth quarter 2020 primarily due to the ongoing buildout of the commercial function in 2021.
- Full year net loss for 2021 was \$143.9 million, compared to \$129.1 million in 2020.
- Full year net loss for 2021 was driven by a net loss from operations of \$135.1 million, which included a non-cash charge related to stock-based compensation of \$16.8 million.
- Full year net loss for 2020 was driven by a net loss from operations of \$125.7 million, which included a non-cash charge related to stock-based compensation of \$5.8 million.
- Full year research and development expenses for 2021 decreased to \$72.3 million compared to \$98.2 million in 2020 as a result of reduced clinical trial costs, 2020 included the majority of the activity in two pivotal Phase 3 trials versus 2021.
- Full year general and administrative expenses for 2021 increased to \$62.8 million from \$27.5 million in 2020 primarily due to the ongoing buildout of the commercial function in 2021.
- As of December 31, 2021, cash and cash equivalents were \$183.3 million. Cash and cash equivalents combined with the future drawdown of the remaining \$100 million under our loan agreement are expected to be sufficient to meet anticipated

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 awarded qualified infection disease product (QIDP) status and granted Fast Track designation to vonoprazan in combination with both amoxicillin and clarithromycin and with amoxicillin alone for the treatment of *H. pylori* infection. Phathom submitted new drug applications in September 2021 to the FDA for vonoprazan-based regimens 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

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

The Company 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 submission of an NDA for the healing of all grades of EE and relief of heartburn, and maintenance of healing of all grades of EE and relief of heartburn, the expected approval of NDAs for vonoprazan-based treatments for the treatment of H. pylori infection and subsequent potential U.S. commercial launch of vonoprazan for treatment of H. pvlori infection, and the Company's ability to complete enrollment of its Phase 3 NERD daily dosing trial. The inclusion of forward-looking statements should not be regarded as a representation by the Company 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 the Company's business, including, without limitation: we may not obtain regulatory approval of our NDAs for the treatment of H. pylori or the other indications in which we are developing vonoprazan; even if we receive regulatory approval, the Company may experience delays in its plans to commercially launch vonoprazan in particular as we currently have a limited marketing and no sales organization and have no experience as a company in commercializing products; the Company may experience delays in designing and initiating a Phase 3 on-demand study in NERD, including in the event that the FDA does not agree with the Company's study design or its interpretation of the data; the Company will require substantial additional financing to achieve its goals and may not be able to obtain such financing on acceptable terms, or at all; the Company'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; previously granted 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; the Company's ability to obtain and maintain intellectual property protection for vonoprazan; the Company's ability to comply with its license agreement with Takeda; the Company's ability to maintain undisrupted business operations due to the ongoing presence 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 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 the Company 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.

[Tables follow]

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PHATHOM PHARMACEUTICALS, INC. Balance Sheets

(in thousands, except share and par value amounts)

		ember 31, 2021	December 31, 2020		
Assets					
Current assets:					
Cash and cash equivalents	\$	183,259	\$	287,496	
Prepaid expenses and other current assets (including related party amounts					
of \$0 and \$82, respectively)		3,267		3,872	

Total current assets		186,526		291,368
Property, plant and equipment, net		650		986
Operating lease right-of-use assets		1,914		2,373
Other long-term assets		341		384
Total assets	\$	189,431	\$	295,111
Liabilities and Stockholders' Equity				
Current liabilities:				
Accounts payable (including related party amounts of \$1,343 and \$173,				
respectively)	\$	5,150	\$	16,782
Accrued clinical trial expenses		1,402		19,997
Accrued expenses (including related party amounts of \$2,330 and \$734,				
respectively)		11,405		10,606
Accrued interest		477		312
Current portion of long-term debt		_		7,353
Operating lease liabilities, current		487		474
Total current liabilities		18,921		55,524
Long-term debt, net of discount		89,671		39,634
Operating lease liabilities		1,183		1,557
Other long-term liabilities		7,500		4,125
Total liabilities		117,275		100,840
Commitments and contingencies				
Stockholders' equity:				
Preferred stock, \$0.0001 par value; authorized shares — 40,000,000 at December 31, 2021 and 2020; no shares issued and outstanding at				
December 31, 2021 and 2020		_		—
Common stock, \$0.0001 par value; authorized shares				
-400,000,000 at December 31, 2021 and 2020; issued shares-				
31,656,035 and 31,262,769 at December 31, 2021 and 2020, respectively; outstanding shares— 30,511,226 and 28,516,010				
at December 31, 2021 and 2020, respectively		3		3
Additional paid-in capital		601,523		579,755
Accumulated deficit		(529,370)		(385,487)
Total stockholders' equity		72,156		194,271
	\$	189,431	\$	295,111
Total liabilities and stockholders' equity	Ψ	100,401	Ψ	200,111

PHATHOM PHARMACEUTICALS, INC. Statements of Operations and Comprehensive Loss (in thousands, except share and per share amounts)

	Three Months Ended December 31,				Years Ended December 31,				
		2021 2020		2020	020 2021		2020		
Operating expenses:									
Research and development (includes related party amounts of \$2,238,									
\$1,136, \$4,933, and \$2,812, respectively)	\$	13,553	\$	41,654	\$	72,338	\$	98,148	
General and administrative (includes related party amounts of \$2, \$18, \$18, and \$157, respectively)		19,487		10,785		62,742		27,517	
Total operating expenses		33,040		52,439		135,080		125,665	
Loss from operations		(33,040)		(52,439)		(135,080)		(125,665)	
Other income (expense):									
Interest income		6		16		41		1,091	
Interest expense		(2,775)		(1,296)		(6,788)		(4,581)	
Change in fair value of warrant liabilities		_		_		_		95	
Other income (expense)		(17)		(2)		(2,056)		(8)	
Total other income (expense)		(2,786)		(1,282)		(8,803)		(3,403)	
Net loss and comprehensive loss	\$	(35,826)	\$	(53,721)	\$	(143,883)	\$	(129,068)	

Net loss per share, basic and diluted	\$	(0.95)	\$	(1.58)	\$ (3	8.89)	\$	(3.88)
Weighted-average shares of common stock outstanding, basic								
and diluted	37	,758,061	34,06	0,291	37,002,	959	33,2	228,158