

Virios Therapeutics Announces Fourth Quarter and Full Year 2022 Financial Results

ATLANTA, March 14, 2023 (GLOBE NEWSWIRE) -- <u>Virios Therapeutics, Inc.</u> (Nasdaq: VIRI) (the "Company"), a development-stage biotechnology company focused on advancing novel antiviral therapies to treat debilitating chronic diseases, including <u>fibromyalgia</u> ("FM"), today announced financial results for the fourth guarter and full year ended December 31, 2022.

Key Highlights

- Based on extensive analysis of the data generated from the recently completed FORTRESS Phase 2b trial, the Company believes targeting community-based FM patients, who have not participated in prior FM trials, is the optimal approach to advancing IMC-1's continued development.
- The Company has an End-of-Phase 2 Meeting scheduled with the U.S. Food & Drug Administration in March to discuss the progression of IMC-1 into Phase 3 development.
- Patient enrollment for the exploratory Long-COVID treatment study is complete, with top-line results from this exploratory trial expected in mid-2023.

Fourth Quarter 2022 Financial Results

Research and development expenses for the fourth quarter ended December 31, 2022 were \$1.3 million, compared to \$2.9 million for the fourth quarter ended December 31, 2021. The \$1.6 million decrease was primarily due to a reduction in clinical trial expenses for the FORTRESS study of \$1.8 million, offset by an increase in expenses related to the chronic toxicology program of \$0.1 million and an increase in salaries and related personnel costs of \$0.1 million.

General and administrative expenses for the fourth quarter ended December 31, 2022 were \$0.8 million, compared to \$1.3 million for the fourth quarter ended December 31, 2021. The \$0.5 million decrease was primarily due to a reduction in salaries and related personnel costs of \$0.2 million, legal and accounting fees of \$0.1 million and costs associated with being a public company of \$0.2 million.

Net loss for the fourth quarter ended December 31, 2022 was \$2.0 million, or \$0.11 basic and diluted net loss per share, compared to a net loss of \$4.5 million, or \$0.54 basic and diluted net loss per share, for the fourth quarter ended December 31, 2021.

Full Year 2022 Financial Results

Research and development expenses for the year ended December 31, 2022 were \$8.1 million, compared to \$10.8 million for the year ended December 31, 2021. The \$2.7 million decrease was primarily attributable to a reduction in clinical trial expenses for the FORTRESS study of \$1.5 million, a decrease in expenses related to the chronic toxicology program of \$1.1 million and a decrease in drug development and manufacturing costs of \$0.4 million, offset by an increase in salaries and related personnel costs of \$0.2 million and amortization of the Bateman Horne Center ("BHC") research grant of \$0.1 million.

General and administrative expenses for the year ended December 31, 2022 were \$4.2 million, compared to \$4.8 million for the year ended December 31, 2021. The \$0.6 million decrease was primarily due to a reduction in expenses for salary and related personnel costs of \$0.2 million, a decrease in accounting and legal fees of \$0.2 million and a decrease in costs associated with being a public company of \$0.2 million.

Net loss for the year ended December 31, 2022 was \$12.2 million, or \$1.11 basic and diluted net loss per share, compared to a net loss of \$16.0 million, or \$1.92 basic and diluted net loss per share, for the year ended December 31, 2021.

As of December 31, 2022, Virios Therapeutics' cash totaled \$7.0 million. The Company believes it will have sufficient resources to support the Long-COVID exploratory program and fund its current planned operations through mid-2024, provided that future IMC-1 FM research or clinical trials will require additional funding.

About Virios Therapeutics

Virios Therapeutics (Nasdaq: VIRI) is a development-stage biotechnology company focused on advancing novel antiviral therapies to treat debilitating chronic diseases, such as fibromyalgia ("FM"). Immune responses related to the activation of tissue resident herpes have been postulated as a potential root cause triggering and/or sustaining chronic illnesses such as FM, irritable bowel disease, chronic fatigue syndrome and other functional somatic syndromes, all of which are characterized by waxing and waning symptoms with no obvious etiology. Our lead development candidate ("IMC-1") is a novel, proprietary, fixed dose combination of famciclovir and celecoxib designed to synergistically suppress herpes virus replication, with the end goal of reducing virally promoted disease symptoms. IMC-1 has been granted fast track designation by the FDA.

The Company is pursuing a second development candidate, IMC-2 (valacyclovir and celecoxib), as a potential treatment for managing the fatigue, sleep, attention, pain, autonomic function and anxiety associated with Long-COVID, otherwise known as Post-Acute Sequelae of COVID-19 (PASC). The Company has provided BHC with an unrestricted investigational grant to conduct this study. BHC is a non-profit, interdisciplinary Center of Excellence advancing the diagnosis and treatment of chronic fatigue disorders, FM, post-viral syndromes, and related comorbidities.

For more information, please visit www.virios.com

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Forward-Looking Statements

Statements in this press release contain "forward-looking statements," within the meaning of the U.S. Private Securities Litigation Reform Act of 1995, that are subject to substantial risks and uncertainties. All statements, other than statements of historical fact, contained in this press release are forward-looking statements. Forward-looking statements contained in this press release may be identified by the use of words such as "anticipate," "believe," "contemplate," "could," "estimate," "expect," "intend," "seek," "may," "might," "plan," "potential," "predict," "project," "suggest," "target," "aim," "should," "will," "would," or the negative of these words or other similar expressions, although not all forward-looking statements contain these words. Forward-looking statements are based on Virios Therapeutics' current expectations and are subject to inherent uncertainties, risks and assumptions that are difficult to predict, including risks related to the completion, timing and results of current and future clinical studies relating to Virios Therapeutics' product candidates. Further, certain forward-looking statements are based on assumptions as to future events that may not prove to be accurate. These and other risks and uncertainties are described more fully in the section titled "Risk Factors" in the Annual Report on Form 10-K for the year ended December 31, 2022, filed with the Securities and Exchange Commission. Forward-looking statements contained in this announcement are made as of this date, and Virios Therapeutics, Inc. undertakes no duty to update such information except as required under applicable law.

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-Financial Tables Follow-

VIRIOS THERAPEUTICS Selected Financial Data (unaudited)

Condensed Statements of Operations Data	Three Months Ended December 31,			Twelve Months Ended December 31,				
		2022		2021		2022		2021
Revenue	\$	_	\$	_	\$	_	\$	_
Operating expenses:								
Research and development		1,271,714		2,918,407		8,069,628		10,795,688
General and administrative		818,002		1,269,151		4,245,681		4,845,252
Total operating expenses		2,089,716		4,187,558		12,315,309		15,640,940
Loss from operations		(2,089,716)		(4,187,558)		(12,315,309)		(15,640,940)
Other income (expense)		45,160		(323,733)		67,475		(319,328)
Net loss	\$	(2,044,556)	\$	(4,511,291)	\$	(12,247,834)	\$	(15,960,268)
Net loss per share of common stock — basic and diluted	•	(0.11	•	(0.54	•	, , , , , , , , , , , , , , , , , , ,	_	, (4.00
	\$	(0.11)	\$	(0.54)	\$	(1.11)	\$	(1.92)
Weighted average shares outstanding — basic and diluted		18,330,390		8,330,390		11,070,116		8,329,310

Condensed Balance Sheet Data	December 31, 2022			December 31, 2021		
Cash	\$	7,030,992	\$	14,008,184		
Total assets		8,369,756		15,776,687		
Total liabilities		1,043,262		1,275,623		
Total stockholders' equity		7,326,494		14,501,064		

Source: Virios Therapeutics, Inc.



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