

May 11, 2023



Virios Therapeutics Announces First Quarter 2023 Financial Results

ATLANTA, May 11, 2023 (GLOBE NEWSWIRE) -- [Virios Therapeutics, Inc.](#) (Nasdaq: VIRI) (the "Company"), a development-stage biotechnology company focused on advancing novel antiviral therapies to treat debilitating chronic diseases, including [fibromyalgia](#) ("FM"), today announced financial results for the first quarter ended March 31, 2023.

Key Highlights

- The Company proposed a Phase 3 program for its lead development candidate IMC-1 to the U.S. Food & Drug Administration ("FDA") as a treatment for FM consisting of four primary components: two adequate and well-controlled clinical studies, one of which would be a full factorial design with each of the individual components of IMC-1 (famciclovir and celecoxib) as separate comparator arms, a long-term safety trial, and a preceding pharmacokinetic/food effect study.
- Based on data from its recently completed FORTRESS Phase 2b trial, the Company proposed a Phase 3 development program targeting community-based FM patients, who have not participated in prior FM trials.
- Initial FDA feedback was that the agency is amenable to the Company's Phase 3 proposal, subject to review of the final results from its recently completed chronic toxicology program. The Company submitted final toxicology reports as per FDA's request as part of their overall review of the Phase 3 proposal in May 2023.
- An updated IMC-1 Phase 3 program proposal, responsive to FDA guidance, will also be provided once FDA completes its review of the chronic toxicology reports.
- Top line results from the exploratory Long-COVID study, featuring the combination of valacyclovir and celecoxib to treat Long-COVID sequelae, are expected in June 2023.

"Our initial discussions with the FDA regarding our [fibromyalgia](#) program were constructive and we look forward to further FDA feedback on our proposal to advance IMC-1 to Phase 3 development," said Greg Duncan, Chairman and CEO of Virios Therapeutics.

First Quarter 2023 Financial Results

Research and development expenses for the first quarter of 2023 were \$0.5 million, compared to \$2.8 million for the first quarter of 2022. The quarter over quarter change was due to decreases in expenses for clinical trials of \$2.2 million, toxicology studies of \$0.1 million and salaries and related costs of \$0.1 million, offset by an increase in regulatory consulting costs of \$0.1 million.

General and administrative expenses for the first quarter of 2023 were \$1.1 million, compared to \$1.2 million for the first quarter of 2022. The quarter over quarter change was primarily due to a decrease in salaries and related costs.

Net loss for the first quarter of 2023 was \$1.5 million, or \$0.08 basic and diluted net loss per share, compared to a net loss of \$4.0 million, or \$0.48 basic and diluted net loss per share, for the first quarter of 2022.

As of March 31, 2023, Virios Therapeutics' cash totaled \$5.3 million. The Company believes it will have sufficient resources to support general research and development and administrative operations into the second quarter of 2024. Future IMC-1 FM research or clinical trials will require additional funding, licensing or partnership collaboration.

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, a combination of 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 the Bateman Horne Center ("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 March 31,	
	2023	2022
Revenue	\$ —	\$ —
Operating expenses:		
Research and development	497,714	2,769,102
General and administrative	1,059,573	1,192,112
Total operating expenses	1,557,287	3,961,214
Loss from operations	(1,557,287)	(3,961,214)
Other income	40,423	906
Net loss	\$ (1,516,864)	\$ (3,960,308)
Net loss per share of common stock — basic and diluted	\$ (0.08)	\$ (0.48)
Weighted average shares outstanding — basic and diluted	18,330,390	8,330,390

Condensed Balance Sheet Data

	March 31, 2023	December 31, 2022
Cash	\$ 5,332,542	\$ 7,030,992
Total assets	6,520,617	8,369,756
Total liabilities	549,290	1,043,262
Total stockholders’ equity	5,971,327	7,326,494

Source: Virios Therapeutics, Inc.



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