

February 29, 2024



Virios Therapeutics Announces Fourth Quarter and Full Year 2023 Financial Results

ATLANTA, Feb. 29, 2024 (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") and [Long-COVID](#) ("LC"), today announced financial results for the fourth quarter and full year ended December 31, 2023.

Key Highlights and Upcoming Milestones

- Virios received written communication from the Food and Drug Administration ("FDA") on the development requirements and key endpoints associated with advancing IMC-2 into Phase 2 for treatment of LC symptoms.
- The FDA agreed that for its planned Phase 2 study, Virios can use fatigue as the primary endpoint and orthostatic intolerance as a key secondary endpoint to assess the effectiveness of IMC-2 in treating LC.
- New placebo-controlled 12-week clinical data assessing valacyclovir/celecoxib to treat Long-COVID, from an ongoing study conducted by the Bateman Horne Center via an unrestricted investigational grant provided by the Company, expected this summer.
- Initiation of a Phase 2 program in LC is targeted in the second half of 2024, contingent on securing funding for the program.
- Discussions are ongoing with potential partners to fund the advancement of IMC-1 into Phase 3 development for the treatment of FM.

"We are pleased to have recently reached alignment with FDA on using fatigue response as the primary end point for evaluating IMC-2 as a treatment for Long-COVID symptoms," said Greg Duncan, Chairman and CEO of Virios Therapeutics, Inc. "This is particularly encouraging given that our unique combination antiviral agents have demonstrated clinically and statistically significant improvement in patient fatigue in several studies, including for IMC-2 treated Long-COVID patients."

Fourth Quarter 2023 Financial Results

Research and development expenses for the fourth quarter of 2023 were \$0.3 million, compared to \$1.3 million for the fourth quarter of 2022. The decrease quarter over quarter was due to decreases in expenses for clinical trials of \$0.6 million, toxicology studies of \$0.3

million and salaries and related personnel costs of \$0.1 million.

General and administrative expenses for the fourth quarter of 2023 remained level with the fourth quarter of 2022 at \$0.8 million.

Net loss for the fourth quarter of 2023 was \$1.1 million, or \$0.06 basic and diluted net loss per share, compared to a net loss of \$2.0 million, or \$0.11 basic and diluted net loss per share, for the fourth quarter of 2022.

Full Year 2023 Financial Results

Research and development expenses for the year ended December 31, 2023 were \$1.7 million, compared to \$8.1 million for the year ended December 31, 2022. The \$6.4 million decrease was primarily due to decreases in expenses for clinical trials of \$5.5 million, toxicology studies of \$0.6 million, drug development and manufacturing costs of \$0.1 million, and salaries and related personnel costs of \$0.3 million partially offset by an increase in regulatory consulting of \$0.1 million.

General and administrative expenses for the year ended December 31, 2023 were \$3.7 million, compared to \$4.2 million for the year ended December 31, 2022. The \$0.5 million decrease was primarily due to a decrease in costs associated with being a public company.

Net loss for the year ended December 31, 2023 was \$5.3 million, or \$0.28 basic and diluted net loss per share, compared to a net loss of \$12.2 million, or \$1.11 basic and diluted net loss per share, for the year ended December 31, 2022.

As of December 31, 2023, Virios Therapeutics' cash totaled \$3.3 million. The Company believes it has sufficient resources to fund operations into the fourth quarter of 2024.

About Virios Therapeutics

Virios Therapeutics (Nasdaq: VIRI) is a development-stage biotechnology company focused on advancing novel antiviral therapies to treat diseases associated with a viral triggered abnormal immune response such as fibromyalgia ("FM") and Long-COVID ("LC"). Overactive immune response related to activation of tissue resident herpesvirus has been postulated to be a potential root cause of chronic illnesses such as FM, irritable bowel syndrome, LC, chronic fatigue syndrome and functional somatic syndromes, all of which are characterized by a waxing and waning manifestation of disease, often triggered by events which compromise the immune system. Our lead development candidates are novel, proprietary, fixed dose combinations of an antiviral compound and celecoxib designed to synergistically suppress herpesvirus replication, with the end goal of reducing virally promoted disease symptoms. IMC-1 (fixed dose combination of famciclovir and celecoxib) has been granted fast track designation by the FDA.

For more information, please visit www.virios.com.

Follow Virios Therapeutics

Email Alerts: <https://ir.virios.com/resources/email-alerts>

LinkedIn: <https://www.linkedin.com/company/viriosbiotech/>

Twitter: <https://twitter.com/ViriosBiotech>

Facebook: <https://www.facebook.com/ViriosBiotech/>

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, potential future partnerships or other material transactions, and the requirements of or feedback from Nasdaq regarding the continued listing of our common stock. 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.

Contact:

IR@Virios.com

VIRIOS THERAPEUTICS Selected Financial Data (unaudited)

Condensed Statements of Operations Data	Three Months Ended December 31,		Year Ended December 31,	
	2023	2022	2023	2022
Revenue	\$ —	\$ —	\$ —	\$ —
Operating expenses:				
Research and development	298,320	1,271,714	1,728,078	8,069,628
General and administrative	839,806	818,002	3,718,841	4,245,681
Total operating expenses	1,138,126	2,089,716	5,446,919	12,315,309
Loss from operations	(1,138,126)	(2,089,716)	(5,446,919)	(12,315,309)
Other income	34,953	45,160	150,904	67,475
Net loss	\$ (1,103,173)	\$ (2,044,556)	\$ (5,296,015)	\$ (12,247,834)
Net loss per share of common stock — basic and diluted	\$ (0.06)	\$ (0.11)	\$ (0.28)	\$ (1.11)

Weighted average shares outstanding — basic and diluted

19,257,937

18,330,390

18,776,790

11,070,116

Condensed Balance Sheet Data

	December 31, 2023	December 31, 2022
Cash	\$ 3,316,946	\$ 7,030,992
Total assets	4,165,442	8,369,756
Total liabilities	358,548	1,043,262
Total stockholders' equity	3,806,894	7,326,494



Source: Virios Therapeutics