

August 10, 2023



Virios Therapeutics Announces Second Quarter 2023 Financial Results and Provides Corporate Update

*- Continued Progress in Expanding and Advancing Clinical Pipeline -
- Conference Call Today at 8:30 a.m. ET -*

ATLANTA, Aug. 10, 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") and Long-COVID, today announced financial results for the second quarter ended June 30, 2023 and provided a corporate update.

Key Highlights and Upcoming Milestones

- The Company announced that the Food & Drug Administration ("FDA") communicated that, following their initial review of the Company's chronic toxicology program, the program's studies appear adequate to support the safety of IMC-1 at the dose proposed by the Company for chronic use treating fibromyalgia.
- The Company plans to initiate its proposed pharmacokinetic and food effect study ("pK") this year, while concurrently submitting a final Phase 3 program outline and associated Phase 3 study protocols for FDA review.
- Following completion of the pK study, the goal will be to begin enrollment in the first fibromyalgia Phase 3 safety and efficacy study in mid-2024.
- With the recent completion of the IMC-2 (fixed combination of valacyclovir and celecoxib) exploratory, open-label, Long-COVID proof of concept study conducted by the Bateman Horne Center, we are planning to sponsor a second investigator-initiated study with the Bateman Horne Center this fall. This follow up study will be a double-blinded placebo-controlled study otherwise very similar to the initial proof of concept study.
- The Company plans to meet with the FDA in the second half of 2023 to discuss a proposal to advance its IMC-2 into Phase 2 development as a potential treatment for the symptoms associated with Long-COVID illness.

"We are encouraged about the potential to expand our pipeline and progress IMC-1 into Phase 3 development as a treatment for FM and IMC-2 into Phase 2 development as a treatment for Long-COVID. Our team is working closely with the FDA to determine next steps in advancing these promising programs," said Greg Duncan, Chairman and CEO of

Virios Therapeutics.

Second Quarter 2023 Financial Results

Research and development expenses for the second quarter of 2023 were \$0.6 million, compared to \$2.4 million for the second quarter of 2022. The decrease quarter over quarter was due decreases in expenses related to human clinical trials of \$1.7 million and animal toxicology studies of \$0.2 million, offset by an increase in drug development and manufacturing costs of \$0.1 million.

General and administrative expenses for the second quarter of 2023 were \$0.9 million, compared to \$1.3 million for the second quarter of 2022. The decrease quarter over quarter was due to decreases in expenses associated with being a public company of \$0.2 million, legal and accounting fees of \$0.1 million and salaries and related costs of \$0.1 million.

Net loss for the second quarter of 2023 was \$1.4 million, or \$0.08 basic and diluted net loss per share, compared to a net loss of \$3.7 million, or \$0.44 basic and diluted net loss per share, for the second quarter of 2022.

As of June 30, 2023, Virios Therapeutics' cash totaled \$4.6 million. As previously disclosed, in July 2023, the Company entered into a Credit on DemandTM Sales Agreement ("Sales Agreement") with JonesTrading Institutional Services LLC. The Company believes that the Company's cash balance at June 30, 2023, together with the additional \$1.4 million raised using the Sales Agreement subsequent to June 30, 2023, is sufficient to fund operating expenses and capital requirements for at least the next 12 months.

Conference Call & Webcast Details

Virios Therapeutics management will host a webcast and conference call on August 10, 2023, at 8:30 a.m. ET to discuss the Company's financial results and provide a corporate update. The live and archived webcast of the call may be accessed on the Virios Therapeutics website under the Investors section: [Events and Presentations](#). The live call can be accessed by dialing 888-506-0062 (domestic) or 973-528-0011 (international) and asking to be connected to the "Virios Therapeutics Conference Call" using the access code: 133321.

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. 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, Long-COVID, 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. The Company plans to engage the FDA

in the latter half of 2023 with the goal of filing an investigational new drug application to formally assess IMC-2 (fixed combination of valacyclovir and celecoxib) as a potential treatment for Long-COVID sequelae.

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 June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Revenue	\$ —	\$ —	\$ —	\$ —
Operating expenses:				
Research and development	557,843	2,406,438	1,055,557	5,175,540
General and administrative	919,374	1,265,621	1,978,947	2,457,733
Total operating expenses	1,477,217	3,672,059	3,034,504	7,633,273
Loss from operations	(1,477,217)	(3,672,059)	(3,034,504)	(7,633,273)
Other income	36,313	4,804	76,736	5,710
Net loss	\$ (1,440,904)	\$ (3,667,255)	\$ (2,957,768)	\$ (7,627,563)
Net loss per share of common stock — basic and diluted	\$ (0.08)	\$ (0.44)	\$ (0.16)	\$ (0.92)
Weighted average shares outstanding — basic and diluted	18,411,399	8,330,390	18,371,118	8,330,390

Condensed Balance Sheet Data

	June 30, 2023	December 31, 2022
Cash	\$ 4,590,128	\$ 7,030,992
Total assets	5,212,119	8,369,756
Total liabilities	520,032	1,043,262
Total stockholders' equity	4,692,087	7,326,494

Source: Virios Therapeutics, Inc.



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