

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**

WASHINGTON, D.C. 20549

**FORM 8-K**

**CURRENT REPORT  
PURSUANT TO SECTION 13 OR 15(d) OF THE  
SECURITIES EXCHANGE ACT OF 1934**

Date of Report (Date of earliest event reported): May 11, 2023

**VIRIOS THERAPEUTICS, INC.**

(Exact Name of Registrant as Specified in Charter)

**Delaware**  
(State or other jurisdiction  
of incorporation)

**001-39811**  
(Commission  
File Number)

**85-4314201**  
(IRS Employer  
Identification No.)

**44 Milton Avenue**  
**Alpharetta, GA**  
(Address of principal executive offices)

**30009**  
(Zip Code)

Registrant's telephone number, including area code: **(866) 620-8655**

(Former name or former address, if changed since last report): Not Applicable

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value \$0.0001	VIRI	Nasdaq Capital Market

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

**Item 2.02 Results of Operations and Financial Condition.**

On May 11, 2023, Virios Therapeutics, Inc. (the “Company”) issued a press release announcing the results of operations for the first quarter ended March 31, 2023. A copy of the press release is included as Exhibit 99.1 to this Current Report on Form 8-K and is hereby incorporated by reference into this Item 2.02.

The information provided pursuant to this Item 2.02, including Exhibit 99.1, is being furnished and shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934 (the “Exchange Act”) or otherwise subject to the liabilities under that Section and shall not be deemed to be incorporated by reference into any filing of the Company under the Securities Act of 1933 or the Exchange Act.

**Item 9.01 Financial Statements and Exhibits.**

(d) Exhibits.

<b>Exhibit Number</b>	<b>Description</b>
99.1	<a href="#">Press Release of the Company, dated May 11, 2023 (furnished herewith).</a>
104	Cover Page Interactive Data File (formatted in Inline XBRL and contained in Exhibit 101)

**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

**VIRIOS THERAPEUTICS, INC.**

By: /s/ Angela Walsh  
Name: Angela Walsh  
Title: Senior Vice President of Finance and Corporate Secretary and  
Treasurer

May 11, 2023



**Exhibit 99.1**

## **Virios Therapeutics Announces First Quarter 2023 Financial Results**

ATLANTA, Ga., May 11, 2023 --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](http://www.virios.com).

### **Follow Virios Therapeutics**

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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.

### **Contact:**

IR@Virios.com

-Financial Tables Follow-



**VIRIOS THERAPEUTICS**  
**Selected Financial Data**  
(unaudited)

**Condensed Statements of  
Operations Data**

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

**Condensed Balance Sheet Data**

	<b>March 31,</b>	<b>December 31,</b>
	<b>2023</b>	<b>2022</b>
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.