

**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): **February 29, 2024**

**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 February 29, 2024, Virios Therapeutics, Inc. (the “Company”) issued a press release announcing the results of operations for the fourth quarter and full year ended December 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 February 29, 2024 (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, Corporate Secretary and  
Treasurer

February 29, 2024



Exhibit 99.1

## Virios Therapeutics Announces Fourth Quarter and Full Year 2023 Financial Results

ATLANTA, Ga., February 29, 2024 -- 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](http://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](mailto:IR@Virios.com)

-Financial Tables Follow-



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

**Condensed Statements of Operations Data**

	<b>Three Months Ended December 31,</b>		<b>Year Ended December 31,</b>	
	<b>2023</b>	<b>2022</b>	<b>2023</b>	<b>2022</b>
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	<u>1,138,126</u>	<u>2,089,716</u>	<u>5,446,919</u>	<u>12,315,309</u>
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	<u>\$ (1,103,173)</u>	<u>\$ (2,044,556)</u>	<u>\$ (5,296,015)</u>	<u>\$ (12,247,834)</u>
Net loss per share of common stock — basic and diluted	<u>\$ (0.06)</u>	<u>\$ (0.11)</u>	<u>\$ (0.28)</u>	<u>\$ (1.11)</u>
Weighted average shares outstanding — basic and diluted	<u>19,257,937</u>	<u>18,330,390</u>	<u>18,776,790</u>	<u>11,070,116</u>

**Condensed Balance Sheet Data**

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