

**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 9, 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).

Emerging growth company

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 9, 2024, Virios Therapeutics, Inc. (the “Company”) issued a press release announcing the results of operations for the first quarter ended March 31, 2024. 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.

Exhibit Number	Description
99.1	Press Release of the Company, dated May 9, 2024 (furnished herewith).
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

May 9, 2024



Exhibit 99.1

Virios Therapeutics Announces First Quarter 2024 Financial Results and Provides Corporate Update

- Top-line results from the ongoing investigator-initiated Bateman Horne Center Long-COVID phase 2 featuring valacyclovir and celecoxib (IMC-2) expected in the second-half of 2024 -

- Conference Call Today at 8:30 a.m. ET -

ATLANTA, Ga., May 9, 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 first quarter ended March 31, 2024 and provided a corporate update.

Key Highlights

- The BHC-202 3-arm study comparing two dose levels of the valacyclovir/celecoxib combination vs placebo over 12 weeks to treat symptoms of LC is being conducted by the Bateman Horne Center ("BHC") via an unrestricted investigational grant provided by the Company has surpassed the 50% enrollment level. Top line results are expected in the second-half of 2024.
- Preliminary safety analysis of the BHC-202 study indicates that the combination of valacyclovir and celecoxib ("IMC-2") has been very well tolerated to date with no Serious Adverse Events reported, and only a few transient treatment emergent adverse events being reported.
- Virios' global patent for IMC-2 covering antiviral treatment of LC and Alzheimer's disease has been published. This enables the Company to streamline the process for obtaining patent protection globally, representing a precursor to the national phase of patent examination by targeted countries across the globe.
- Discussions are ongoing as we seek a partner to advance IMC-1 (fixed dosage combination of famciclovir and celecoxib) into Phase 3 development for the treatment of FM.
- The Company continues to actively explore complementary opportunities that will build shareholder value through strategic partnerships, collaborations or other transactions.

"Every week new scientific research highlights the emergence of Long-COVID as a major unmet medical need, causing significant morbidity amongst children, teenagers and professionals who are unable to attend school or work as a consequence of their Long-COVID symptoms. We are excited to explore our antiviral approach in this crippling condition given the dearth of effective



Long-COVID treatment options presently available” said Greg Duncan, Chairman and CEO of Virios Therapeutics. “We believe IMC-2 has the potential to provide a needed treatment option for Long-COVID symptoms and look forward to sharing results from the ongoing BHC study with the research and investor communities later this year.”

First Quarter 2024 Financial Results

Research and development expenses for the first quarter of 2024 were \$0.3 million, compared to \$0.5 million for the first quarter of 2023. The quarter over quarter change was due to decreases in expenses for toxicology studies of \$0.1 million and regulatory consulting costs of \$0.1 million.

General and administrative expenses for the first quarter of 2024 were \$1.0 million, compared to \$1.1 million for the first quarter of 2023. The quarter over quarter change was primarily due to a decrease in insurance expenses associated with being a public company.

Net loss for the first quarter of 2024 was \$1.3 million, or \$0.07 basic and diluted net loss per share, compared to a net loss of \$1.5 million, or \$0.08 basic and diluted net loss per share, for the first quarter of 2023.

As of March 31, 2024, Virios Therapeutics’ cash totaled \$2.4 million. The Company believes it will have 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 dosage combination of famciclovir and celecoxib) has been granted fast track designation by the FDA.

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 Amended Annual Report on Form 10-K/A for the year ended December 31, 2023, filed with the Securities and Exchange Commission. In particular, there can be no assurance that any development partnership or other transaction involving Virios Therapeutics will be completed on favorable terms, or at all. 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**

	Three Months Ended March 31,	
	2024	2023
Revenue	\$ —	\$ —
Operating expenses:		
Research and development	343,717	497,714
General and administrative	970,384	1,059,573
Total operating expenses	<u>1,314,101</u>	<u>1,557,287</u>
Loss from operations	(1,314,101)	(1,557,287)
Other income	22,766	40,423
Net loss	<u>\$ (1,291,335)</u>	<u>\$ (1,516,864)</u>
Net loss per share of common stock — basic and diluted	<u>\$ (0.07)</u>	<u>\$ (0.08)</u>
Weighted average shares outstanding — basic and diluted	<u>19,257,937</u>	<u>18,330,390</u>

Condensed Balance Sheet Data

	March 31, 2024	December 31, 2023
Cash	\$ 2,379,532	\$ 3,316,946
Total assets	3,224,611	4,165,442
Total liabilities	570,083	358,548
Total stockholders' equity	2,654,528	3,806,894

Source: Virios Therapeutics, Inc.