
**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 12, 2022**

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 12, 2022, Virios Therapeutics, Inc. (the “Company”) issued a press release announcing the results of operations for the first quarter ended March 31, 2022. 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 12, 2022.
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

May 12, 2022



Exhibit 99.1

Virios Therapeutics Announces First Quarter 2022 Financial Results and Provides Corporate Update

- Enrollment Completed in FORTRESS Study with Top Line Data Expected in September 2022 -

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

ATLANTA, Ga., May 12, 2022 --Virios Therapeutics, Inc. (Nasdaq: VIRI), a development-stage biotechnology company focused on advancing novel, combination antiviral therapies to treat debilitating chronic diseases, including fibromyalgia, today announced financial results for the first quarter ended March 31, 2022.

Key Highlights

- Completed enrollment in Phase 2b FORTRESS fibromyalgia study with top line results expected in September 2022
- Targeting completion of chronic toxicology studies concurrent with FORTRESS study results in preparation for fibromyalgia Phase 3 program
- Presented at 34th Annual Roth and Virtual H.C. Wainwright BioConnect Conferences

“The second half of 2022 is going to be an exciting time for Virios as we continue to deliver on our strategic and operational plans,” said Greg Duncan, Chairman and CEO of Virios Therapeutics. “Based on our team’s extensive experience and strong clinical site relationships, we were able to fully enroll patients on a timely basis in our Phase 2b FORTRESS study of IMC-1 (a combination of famciclovir and celecoxib), with top line data expected in September.”

“We plan to expand our pipeline of novel combination antiviral therapies through an unrestricted investigational grant to the Bateman Horne Center, a leading research center in post-viral syndromes. The Bateman Horne center will assess the potential of IMC-2 (a combination of valacyclovir and celecoxib) to reduce fatigue and other symptoms associated with Long COVID, which is estimated to effect up to 100 million post-COVID patients worldwide,” concluded Mr. Duncan.

First Quarter 2022 Financial Results

Research and development expenses for the first quarter of 2022 were \$2.8 million, compared to \$1.7 million for the first quarter of 2021. The increase was primarily due to an increase in clinical trial expenses.



General and administrative expenses for the first quarter of 2022 were \$1.2 million, compared to \$1.4 million for the first quarter of 2021. This decrease was primarily related to a decrease in accounting and legal fees.

Net loss for the first quarter of 2022 was \$4.0 million, or \$0.48 basic and diluted per share, compared to a net loss of \$3.1 million, or \$0.37 basic and diluted per share, for the first quarter of 2021. The higher net loss was primarily due to increased research and development costs.

As of March 31, 2022, Virios Therapeutics' cash totaled \$11.4 million. The Company believes it will have sufficient resources to fund its planned operations through the end of 2022.

Conference Call & Webcast Details

Virios Therapeutics management will host a webcast and conference call on May 12, 2022, 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 also 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: 658259.

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 and is currently being tested in a multi-center, randomized, double-blind, placebo-controlled trial ("FORTRESS"), designed to potentially serve as a supportive registrational study. Evidence of IMC-1's efficacy on a broad spectrum of FM outcome measures was previously demonstrated in a Phase 2a clinical trial.

The Company is pursuing a second development candidate, IMC-2 (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 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.

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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 success, cost and timing of Virios Therapeutics’ preclinical studies and clinical trials; its ability to obtain regulatory approval for IMC-1, IMC-2 and any future product candidates; the company’s need for additional funding; and Virios Therapeutics’ ability to develop and, if approved, commercialize its 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, 2021, filed with the Securities and Exchange Commission. Forward-looking statements contained in this announcement are made as of this date, and Virios Therapeutics, Inc. (VIRI) 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
March 31,**

	2022	2021
Revenue	\$ —	\$ —
Operating expenses:		
Research and development	2,769,102	1,706,957
General and administrative	1,192,112	1,350,476
Total operating expenses	<u>3,961,214</u>	<u>3,057,433</u>
Loss from operations	(3,961,214)	(3,057,433)
Other income	906	1,400
Net loss	<u>\$ (3,960,308)</u>	<u>\$ (3,056,033)</u>
Net loss per share of common stock — basic and diluted	<u>\$ (0.48)</u>	<u>\$ (0.37)</u>
Weighted average shares outstanding — basic and diluted	<u>8,330,390</u>	<u>8,326,010</u>

Condensed Balance Sheet Data

**March 31,
2022**

**December 31,
2021**

Cash	\$ 11,352,167	\$ 14,008,184
Total assets	12,549,858	15,776,687
Total liabilities	1,877,196	1,275,623
Total stockholders' equity	10,672,662	14,501,064

Source: Virios Therapeutics, Inc.