
**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): **March 17, 2022**

VIRIOS THERAPEUTICS, INC.

(Exact Name of Registrant as Specified in Charter)

Delaware
(State or other jurisdiction
of incorporation)

001-39811
(Commission
File Number)

45-4618270
(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 March 17, 2022, Virios Therapeutics, Inc. (the “Company”) issued a press release announcing the results of operations for the fourth quarter and full year ended December 31, 2021. 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 March 17, 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

March 17, 2022



Exhibit 99.1

Virios Therapeutics Announces Fourth Quarter and Full Year 2021 Financial Results and Provides Corporate Update

- *Top line Data from Phase 2b FORTRESS Study of IMC-1 on Track for Q3 2022 -*
- *Pipeline Expanded with IMC-2 as Treatment for Long COVID to be Evaluated in New Exploratory Study Targeted to Commence in Q2 2022 -*
- *Conference Call Today at 8:30 a.m. ET -*

ATLANTA, Ga., March 17, 2022 --Virios Therapeutics, Inc. (Nasdaq: VIRI), a development-stage biotechnology company focused on advancing novel antiviral therapies to treat chronic diseases including fibromyalgia, today announced financial results for the fourth quarter and full year ended December 31, 2021.

Key Highlights

- Phase 2b FORTRESS fibromyalgia study top line results on track for Q3 2022
- Chronic toxicology studies, required for IMC-1 Phase 3 studies, are progressing as planned and synchronized for completion with the FORTRESS study
- Recently announced clinical development collaboration to assess therapeutic potential of IMC-2 as a treatment for Long COVID, a developing health crisis
- Cash on hand of \$14.0 million on December 31, 2021, provides runway through Q1 2023

“Virios achieved many operational milestones in 2021, most notably launching recruitment and dosing in the Phase 2b FORTRESS study. We project to reach full enrollment for the trial of over 400 patients by mid-April,” said Greg Duncan, Chairman and CEO of Virios Therapeutics. “We also recently announced the expansion of our research pipeline through a collaboration with the Bateman Horne Center, a leading research center in post-viral syndromes. The focus of the collaboration is centered on conducting a new exploratory trial assessing the potential of IMC-2, a combination of valacyclovir and celecoxib, to reduce fatigue and other symptoms associated with Long COVID sequelae, which is estimated to effect up to 30% of former COVID patients.”

“Our most important priority is completing the FORTRESS study, with planned reporting of top line results in Q3 2022. This study will assess the effectiveness of IMC-1 in reducing the systemic pain and other symptoms associated with fibromyalgia. Our cash on hand of \$14.0 million is expected to support the Company’s operations through those important months and into the planning for a Phase 3 study in early 2023,” concluded Angela Walsh, Senior Vice President, Finance, of Virios Therapeutics.



Fourth Quarter 2021 Financial Results

Research and development expenses for the fourth quarter of 2021 were \$2.9 million, compared to \$0.03 million for the fourth quarter of 2020. The \$2.87 million increase was primarily attributable to expenses for our FORTRESS clinical trial, our chronic toxicology program and drug development and manufacturing costs.

General and administrative expenses for the fourth quarter of 2021 were \$1.3 million, compared to \$6.4 million for the fourth quarter of 2020. The \$5.1 million decrease was primarily attributable to IPO-related expenses incurred in 2020, including non-cash share-based compensation expense of \$5.4 million, issued pursuant to executive employment agreements, offset by an increase in costs associated with being a public company.

Net loss for the fourth quarter of 2021 was \$4.5 million, or (\$0.54) basic and diluted per share, compared to a net loss of \$6.5 million, or (\$1.25) basic and diluted per share, for the fourth quarter of 2020.

Full Year 2021 Financial Results

Research and development expenses for the year ended December 31, 2021, were \$10.8 million, compared to \$0.2 million for the year ended December 31, 2020. The \$10.6 million increase was primarily attributable to expenses for our FORTRESS clinical trial and our chronic toxicology program which commenced in 2021 and drug development and manufacturing costs to support these studies.

General and administrative expenses for the year ended December 31, 2021, were \$4.8 million, compared to \$9.8 million for the year ended December 31, 2020. The \$5.0 million decrease was primarily attributable to IPO-related expenses incurred in 2020, including non-cash equity and share-based compensation expense of \$7.4 million, issued pursuant to executive employment agreements, offset by an increase in costs associated with being a public company.

Net loss for the year ended December 31, 2021, was \$16.0 million, or (\$1.92) basic and diluted per share, compared to a net loss of \$10.3 million, or (\$2.10) basic and diluted per share, for the year ended December 31, 2020.

As of December 31, 2021, Virios Therapeutics cash totaled \$14.0 million. The Company believes it will have sufficient resources to fund its planned operations through the end of Q1 2023.



Conference Call & Webcast Details

Virios Therapeutics management will host a webcast and conference call on March 17, 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".

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 ("IBS"), 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 Phase 2b trial ("FORTRESS") designed to set the stage for registrational studies. 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. The Company has provided Bateman Horne Center ("BHC") with an unrestricted grant to conduct this study. BHC is a non-profit, interdisciplinary Center of Excellence advancing the diagnosis and treatment of myalgic encephalomyelitis/chronic fatigue syndrome ("ME/CFS"), 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 completion and timing of the FORTRESS trial or any studies relating to the treatment of Long COVID with IMC-2. 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, 2020, 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.

Contact:

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PCG Advisory

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-Financial Tables Follow-



VIRIOS THERAPEUTICS
Selected Financial Data
(unaudited)

Condensed Statements of Operations Data	Three Months Ended		Twelve Months Ended	
	December 31,		December 31,	
	2021	2020	2021	2020
Revenue	\$ —	\$ —	\$ —	\$ —
Operating expenses:				
Research and development	2,918,407	32,070	10,795,688	194,013
General and administrative	1,269,151	6,389,582	4,845,252	9,811,381
Total operating expenses	4,187,558	6,421,652	15,640,940	10,005,394
Loss from operations	(4,187,558)	(6,421,652)	(15,640,940)	(10,005,394)
Other expense	(323,733)	(79,576)	(319,328)	(341,001)
Net loss	\$ (4,511,291)	\$ (6,501,228)	\$ (15,960,268)	\$ (10,346,395)
Net loss per share of common stock — basic and diluted	\$ (0.54)	\$ (1.25)	\$ (1.92)	\$ (2.10)
Weighted average shares outstanding — basic and diluted	8,330,390	5,212,534	8,329,310	4,926,985

Condensed Balance Sheet Data	December 31,	December 31,
	2021	2020
Cash	\$ 14,008,184	\$ 29,795,366
Total assets	15,776,687	31,472,731
Total liabilities	1,275,623	1,531,842
Total members'/stockholders' equity (deficit)	14,501,064	29,940,889

Source: Virios Therapeutics, Inc.