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): **November 14, 2022**

VIRIOS THERAPEUTICS, INC.
(Exact Name of Registrant as Specified in Charter)

Delaware	**001-39811**	**85-4314201**
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

44 Milton Avenue **Alpharetta, GA**	**30009**
(Address of principal executive offices)	(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 November 14, 2022, Virios Therapeutics, Inc. (the "Company") issued a press release announcing the results of operations for the third quarter ended September 30, 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 November 14, 2022 (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 and Corporate Secretary

November 14, 2022

Exhibit 99.1

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

- FORTRESS Study Analysis Reveals Fibromyalgia Patients New to Research Demonstrate Significant IMC-1 Pain Reduction Treatment Benefits -

- Company Believes FORTRESS Safety Data Supports Phase 3 Development, Requesting FDA Meeting to Discuss Next Steps -

- Patient Dosing Continues in IMC-2 Exploratory Long-COVID Treatment Study -

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

ATLANTA, Ga., November 14, 2022 --Virios Therapeutics, Inc. (Nasdaq: VIRI) (the "Company"), a development-stage biotechnology company focused on advancing novel, combination antiviral therapies to treat debilitating chronic diseases including fibromyalgia ("FM"), today announced financial results for the third quarter ended September 30, 2022, as well as plans to advance development of its lead antiviral development candidate, IMC-1, as a potential new treatment for FM patients.

Key Highlights and Upcoming Milestones

- Post-hoc analysis of the FORTRESS (Fibromyalgia Outcome Research Trial Evaluating Synergistic Suppression of Herpes Simplex Virus-1) study results indicated that FM patients who were generally more naïve to prior clinical studies and prior FM drug treatment ("new" patients), demonstrated clinically and statistically significant reductions in pain, fatigue, FM symptoms and both anxiety and depression symptoms. In contrast, FM patients who were prior FM trial participants and/or study site database patients ("experienced" patients) did not exhibit a statistically significant treatment benefit in this study.
- The Company believes targeting new FM patients for IMC-1 development is the optimal approach and plans to meet with the U.S. Food & Drug Administration ("FDA") with the goal to progress IMC-1 into Phase 3 development.
- In September, the Company raised $5 million in equity capital to further advance the clinical development of IMC-1 and for working capital and general corporate purposes.

As previously announced, Virios' novel FM development candidate, IMC-1, demonstrated exemplary safety and tolerability in the FORTRESS study but did not achieve statistical significance on the pre-specified primary efficacy endpoint of change from baseline in daily self-

reported average pain severity scores compared to placebo. However, analysis of the top-line data revealed a bifurcation of response based on the timing of patient enrollment in the FORTRESS study that the Company believes is unlikely related to chance. Based on these results, the Company performed a deeper analysis of the FORTRESS data to determine factors driving these results to determine whether, and if so, how, to continue the development of IMC-1.

Initial Analysis

Initial analysis of the efficacy data showed that the roughly 50-60% of patients recruited in the beginning of the trial, from May 2021 to November 2021, had responses that were not consistent with prior research or with the design goals of the study, particularly with respect to the rate of placebo improvement. However, the responses of patients enrolled in the second half of the trial, from November 2021 to April 2022, were consistent with the Company's expected efficacy profile for IMC-1 vs placebo. In a post-hoc analysis, the sub-group of patients recruited from November 2021 to April 2022 demonstrated statistically and clinically significant improvement, which the Company believes was unlikely related to chance. Consistent with the Company's prior communication, the COVID-19 pandemic appeared to impact overall results, particularly in the first half of the FORTRESS study, when extensive quarantining was in place, vaccination rates were far lower than later in the trial, and there was limited access to home COVID-19 testing.

Detailed Sub-Group Analysis

Following the initial analyses, the Company further analyzed populations and factors that may have been particularly sensitive to the pandemic or elevated placebo responses. One of these analyses revealed that "new" patients, recruited into FORTRESS via advertising, demonstrated statistically significant reduction in FM related pain, fatigue, anxiety and depressive symptoms and an overall improvement in their global health status, irrespective of when they enrolled in the FORTRESS trial. In contrast, previous "experienced" FM study subjects and those previously treated for FM, who in the Company's view represent a more treatment refractory cohort of patients, did not exhibit meaningful treatment benefits. Importantly, "new" patients responded to IMC-1 and also exhibited a lower discontinuation rate due to adverse events as compared with placebo. These effects were demonstrated irrespective of when these new patients were recruited, which the Company believes supports the continued progression of IMC-1 to Phase 3 development, even in a research environment in which COVID-19 persists and new COVID-19 strains may emerge.

"As CEO and a Virios shareholder, I was as disappointed as all of our fellow shareholders were in the initial efficacy results from the FORTRESS Phase 2b FM study," said Greg Duncan, Chairman

and CEO of Virios Therapeutics. “However, the team and I believe the in-depth analysis of the FORTRESS data supports IMC-1 development for new, less refractory FM patients, and this conclusion is supported by our external FM expert advisors.”

“While we were pleased to recruit the FORTRESS study in the midst of extraordinary circumstances associated with the pandemic, it remains clear this environment did have unintended impacts on our FORTRESS study results,” said R. Michael Gendreau, MD, PhD, Chief Medical Officer of Virios Therapeutics. “We may be reaching a saturation point in the U.S. FM research patient community, whereby experienced trial subjects and those presently treated for FM may be characterized as more refractory. This trend has been observed in several other research categories, such as depression, where more time and energy must be extended to recruit newer, more treatment naïve patients.”

Third Quarter 2022 Financial Results

Research and development expenses for the third quarter ended September 30, 2022 were $1.6 million, compared to $3.0 million for the third quarter ended September 30, 2021. The decrease was primarily due to a decrease in clinical trial expenses for the FORTRESS study of $0.9 million, a decrease in expenses related to our chronic toxicology program of $0.4 million and a decrease in drug development and manufacturing costs of $0.1 million.

General and administrative expenses for the third quarter ended September 30, 2022 were $0.9 million, compared to $1.1 million for the third quarter ended September 30, 2021. The decrease was due primarily to decreases in expenses in salaries and related costs.

Net loss for the third quarter ended September 30, 2022 was $2.6 million, or $0.28 basic and diluted net loss per share, compared to a net loss of $4.1 million, or $0.49 basic and diluted net loss per share, for the third quarter ended September 30, 2021. The lower net loss was primarily due to a decrease in research and development costs.

As of September 30, 2022, Virios Therapeutics’ cash totaled $9.8 million. The Company believes it will have sufficient resources to support the Long-COVID exploratory program and fund its planned operations through the end of 2023.

The Company believes targeting new FM patients for IMC-1 development is the optimal approach and plans to meet with the U.S. Food & Drug Administration (“FDA”) with the goal to progress IMC-1 into Phase 3 development.

Future IMC-1 FM research or clinical trials will require additional funding.

Conference Call & Webcast Details

Virios Therapeutics management will host a webcast and conference call on November 14, 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: 333300.

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, 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 completion, timing and results of current and future research or 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, 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. 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 September 30,**		**Nine Months Ended September 30,**	
	2022	**2021**	**2022**	**2021**
Revenue	$ —	$ —	$ —	$ —
Operating expenses:				
Research and development	1,622,374	2,961,122	6,797,914	7,877,281
General and administrative	969,946	1,150,369	3,427,679	3,576,101
Total operating expenses	2,592,320	4,111,491	10,225,593	11,453,382
Loss from operations	(2,592,320)	(4,111,491)	(10,225,593)	(11,453,382)
Other income	16,605	1,509	22,315	4,405
Net loss	$ (2,575,715)	$ (4,109,982)	$ (10,203,278)	$ (11,448,977)
Net loss per share of common stock — basic and diluted	$ (0.28)	$ (0.49)	$ (1.18)	$ (1.37)
Weighted average shares outstanding — basic and diluted	9,199,955	8,330,390	8,623,430	8,328,946

Condensed Balance Sheet Data	**September 30, 2022**	**December 31, 2021**
Cash	$ 9,788,397	$ 14,008,184
Total assets	10,857,977	15,776,687
Total liabilities	1,633,142	1,275,623
Total stockholders' equity	9,224,835	14,501,064

Source: Virios Therapeutics, Inc.