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**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): **August 11, 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.

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**Item 2.02 Results of Operations and Financial Condition.**

On August 11, 2022, Virios Therapeutics, Inc. (the “Company”) issued a press release announcing the results of operations for the second quarter ended June 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.

<b>Exhibit Number</b>	<b>Description</b>
99.1	<a href="#">Press Release of the Company, dated August 11, 2022.</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 and Corporate Secretary

August 11, 2022



Exhibit 99.1

**Virios Therapeutics Announces Second Quarter 2022  
Financial Results and Provides Corporate Update**

*- Top Line FORTRESS Study Data Expected in September 2022 -*

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

ATLANTA, Ga., August 11, 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 second quarter ended June 30, 2022.

**Key Highlights and Upcoming Milestones**

- Completed patient dosing in Phase 2b FORTRESS fibromyalgia study
- Top line FORTRESS results expected in September 2022

“Data published earlier this year provide evidence of a mechanistic correlation between activated herpes viruses and patients suffering from fibromyalgia (FM) and comorbid functional gastrointestinal disorders,” said Greg Duncan, Chairman and CEO of Virios Therapeutics. “Furthermore, evidence of the potential of our lead development candidate, oral IMC-1, to improve treatment outcomes for FM patients had been established in a previously completed Phase 2a clinical study. If our forthcoming Phase 2b study results are consistent with our previously successful Phase 2a study, we believe our combination antiviral development candidate, IMC-1, has the potential to raise the standard of care for over 100 million FM patients worldwide.”

“I could not be prouder of the highly commendable efforts of the Virios Therapeutics research team in completing the Phase 2b FORTRESS study on time, despite the extraordinary circumstances associated with conducting a clinical study during the COVID-19 pandemic,” said Michael Gendreau, MD, PhD, Chief Medical Officer of Virios Therapeutics. “If the FORTRESS results are positive, we will immediately approach FDA for a guidance meeting to determine Phase 3 requirements, with the goal of moving IMC-1 forward into late-stage development as soon as possible.”



## **Second Quarter 2022 Financial Results**

Research and development expenses for the second quarter ended June 30, 2022 were \$2.4 million, compared to \$3.2 million for the second quarter ended June 30, 2021. The decrease was primarily due to a decrease in expenses related to our toxicology studies.

General and administrative expenses for the second quarter ended June 30, 2022 were \$1.3 million, compared to \$1.1 million for the second quarter ended June 30, 2021. The increase was due primarily to increases in expenses for legal and accounting fees of \$0.1 million and an increase in salaries and related costs of \$0.1 million.

Net loss for the second quarter ended June 30, 2022 was \$3.7 million, or \$0.44 basic and diluted net loss per share, compared to a net loss of \$4.3 million, or \$0.51 basic and diluted net loss per share, for the second quarter ended June 30, 2021. The lower net loss was primarily due to a decrease in research and development costs.

As of June 30, 2022, Virios Therapeutics' cash totaled \$7.7 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 August 11, 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: 179784.

## **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 antiviral development combination, IMC-2 (valacyclovir and celecoxib), as a potential treatment for managing the various symptoms 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](http://www.virios.com).

#### **Follow Virios Therapeutics**

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Twitter: <https://twitter.com/ViriosBiotech>

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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.

**Contact:**

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PCG Advisory

Kirin Smith

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-Financial Tables Follow-



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

<b>Condensed Statements of Operations Data</b>	<b>Three Months Ended</b>		<b>Six Months Ended</b>	
	<b>June 30,</b>		<b>June 30,</b>	
	<b>2022</b>	<b>2021</b>	<b>2022</b>	<b>2021</b>
Revenue	\$ —	\$ —	\$ —	\$ —
Operating expenses:				
Research and development	2,406,438	3,209,201	5,175,540	4,916,159
General and administrative	1,265,621	1,075,256	2,457,733	2,425,732
Total operating expenses	3,672,059	4,284,457	7,633,273	7,341,891
Loss from operations	(3,672,059)	(4,284,457)	(7,633,273)	(7,341,891)
Other income	4,804	1,495	5,710	2,896
Net loss	\$ (3,667,255)	\$ (4,282,962)	\$ (7,627,563)	\$ (7,338,995)
Net loss per share of common stock — basic and diluted	\$ (0.44)	\$ (0.51)	\$ (0.92)	\$ (0.88)
Weighted average shares outstanding — basic and diluted	8,330,390	8,330,390	8,330,390	8,328,212

<b>Condensed Balance Sheet Data</b>	<b>June 30,</b>	<b>December 31,</b>
	<b>2022</b>	<b>2021</b>
Cash	\$ 7,695,040	\$ 14,008,184
Total assets	9,040,095	15,776,687
Total liabilities	1,897,731	1,275,623
Total stockholders' equity	7,142,364	14,501,064

Source: Virios Therapeutics, Inc.