

**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 10, 2023**

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 August 10, 2023, Virios Therapeutics, Inc. (the “Company”) issued a press release announcing the results of operations for the second quarter ended June 30, 2023. 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 August 10, 2023 (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 and Treasurer

August 10, 2023



Exhibit 99.1

**Virios Therapeutics Announces
Second Quarter 2023 Financial Results and Provides Corporate Update**

*- Continued Progress in Expanding and Advancing Clinical Pipeline -
- Conference Call Today at 8:30 a.m. ET -*

ATLANTA, Ga., August 10, 2023 -- 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, today announced financial results for the second quarter ended June 30, 2023 and provided a corporate update.

Key Highlights and Upcoming Milestones

- The Company announced that the Food & Drug Administration ("FDA") communicated that, following their initial review of the Company's chronic toxicology program, the program's studies appear adequate to support the safety of IMC-1 at the dose proposed by the Company for chronic use treating fibromyalgia.
- The Company plans to initiate its proposed pharmacokinetic and food effect study ("pK") this year, while concurrently submitting a final Phase 3 program outline and associated Phase 3 study protocols for FDA review.
- Following completion of the pK study, the goal will be to begin enrollment in the first fibromyalgia Phase 3 safety and efficacy study in mid-2024.
- With the recent completion of the IMC-2 (fixed combination of valacyclovir and celecoxib) exploratory, open-label, Long-COVID proof of concept study conducted by the Bateman Horne Center, we are planning to sponsor a second investigator-initiated study with the Bateman Horne Center this fall. This follow up study will be a double-blinded placebo-controlled study otherwise very similar to the initial proof of concept study.
- The Company plans to meet with the FDA in the second half of 2023 to discuss a proposal to advance its IMC-2 into Phase 2 development as a potential treatment for the symptoms associated with Long-COVID illness.

"We are encouraged about the potential to expand our pipeline and progress IMC-1 into Phase 3 development as a treatment for FM and IMC-2 into Phase 2 development as a treatment for Long-COVID. Our team is working closely with the FDA to determine next steps in advancing these promising programs," said Greg Duncan, Chairman and CEO of Virios Therapeutics.



Second Quarter 2023 Financial Results

Research and development expenses for the second quarter of 2023 were \$0.6 million, compared to \$2.4 million for the second quarter of 2022. The decrease quarter over quarter was due to decreases in expenses related to human clinical trials of \$1.7 million and animal toxicology studies of \$0.2 million, offset by an increase in drug development and manufacturing costs of \$0.1 million.

General and administrative expenses for the second quarter of 2023 were \$0.9 million, compared to \$1.3 million for the second quarter of 2022. The decrease quarter over quarter was due to decreases in expenses associated with being a public company of \$0.2 million, legal and accounting fees of \$0.1 million and salaries and related costs of \$0.1 million.

Net loss for the second quarter of 2023 was \$1.4 million, or \$0.08 basic and diluted net loss per share, compared to a net loss of \$3.7 million, or \$0.44 basic and diluted net loss per share, for the second quarter of 2022.

As of June 30, 2023, Virios Therapeutics' cash totaled \$4.6 million. As previously disclosed, in July 2023, the Company entered into a Credit on Demand™ Sales Agreement ("Sales Agreement") with JonesTrading Institutional Services LLC. The Company believes that the Company's cash balance at June 30, 2023, together with the additional \$1.4 million raised using the Sales Agreement subsequent to June 30, 2023, is sufficient to fund operating expenses and capital requirements for at least the next 12 months.

Conference Call & Webcast Details

Virios Therapeutics management will host a webcast and conference call on August 10, 2023, 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 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: 133321.

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. 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, Long-COVID, 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 dose combination of famciclovir and celecoxib) has been granted fast track designation by the FDA. The Company plans to engage the FDA in the latter half of 2023 with the goal of filing an investigational new drug application to formally assess IMC-2 (fixed combination of valacyclovir and celecoxib) as a potential treatment for Long-COVID sequelae.

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 Annual Report on Form 10-K for the year ended December 31, 2022, 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		Six Months Ended	
	June 30,		June 30,	
	2023	2022	2023	2022
Revenue	\$ —	\$ —	\$ —	\$ —
Operating expenses:				
Research and development	557,843	2,406,438	1,055,557	5,175,540
General and administrative	919,374	1,265,621	1,978,947	2,457,733
Total operating expenses	1,477,217	3,672,059	3,034,504	7,633,273
Loss from operations	(1,477,217)	(3,672,059)	(3,034,504)	(7,633,273)
Other income	36,313	4,804	76,736	5,710
Net loss	<u>\$ (1,440,904)</u>	<u>\$ (3,667,255)</u>	<u>\$ (2,957,768)</u>	<u>\$ (7,627,563)</u>
Net loss per share of common stock — basic and diluted	<u>\$ (0.08)</u>	<u>\$ (0.44)</u>	<u>\$ (0.16)</u>	<u>\$ (0.92)</u>
Weighted average shares outstanding — basic and diluted	<u>18,411,399</u>	<u>8,330,390</u>	<u>18,371,118</u>	<u>8,330,390</u>

Condensed Balance Sheet Data	June 30,	December 31,
	2023	2022
Cash	\$ 4,590,128	\$ 7,030,992
Total assets	5,212,119	8,369,756
Total liabilities	520,032	1,043,262
Total stockholders' equity	4,692,087	7,326,494

Source: Virios Therapeutics, Inc.