

**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 2, 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 30009
(Address of Principal Executive Offices, and Zip Code)

(866) 620-8655
Registrant's Telephone Number, Including Area Code

Not Applicable

(Former Name or Former Address, if Changed Since Last Report)

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))

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

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (17 CFR §230.405) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR §240.12b-2).

Emerging growth company

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 7.01 Regulation FD Disclosure.

On November 2, 2023, Virios Therapeutics Inc. (the “Company”) issued a letter to shareholders. A copy of the letter is included as Exhibit 99.1 to this Current Report on Form 8-K and is hereby incorporated by reference into this Item 7.01. In addition, a copy of this letter will be posted to the Company’s website.

The information in this Item 7.01, including the attached exhibits, is furnished solely pursuant to Item 7.01 of Form 8-K. Consequently, such information is not deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, or otherwise subject to the liabilities of that section. Further, the information in this Item 7.01, including the exhibits, shall not be deemed to be incorporated by reference into the filings of the registrant under the Securities Act of 1933.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

<u>Exhibit Number</u>	<u>Description</u>
99.1	Shareholder Letter, dated November 2, 2023 (furnished herewith).
104	Cover Page Interactive Data File (embedded within Inline XBRL document)

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 2, 2023



Exhibit 99.1

November 2, 2023

Dear Virios (VIRI) Shareholders,

We wanted to provide you with a succinct corporate progress report as we exit the third quarter of 2023, which can be summarized as follows:

- Having secured FDA guidance on our plan to progress IMC-1 to Phase 3 development to treat fibromyalgia, we can convey that several life science companies are engaged and reviewing our Phase 2 data and proposed Phase 3 program as the basis for a potential forward development partnership.
- We have submitted briefing materials to the FDA concerning submission of a proposed investigational new drug application for IMC-2 as a treatment for Long-COVID (“LC”).
 - ❖ There are currently no FDA approved LC treatments.
- Filed new provisional method-of-use intellectual property protection for IMC-2 as treatment for LC and Alzheimer’s disease, which if granted, provides coverage to at least 2043.
- Through prudent expense management, the Company expects to have capital to support operations into Q3 of 2024.

Warmest regards,

Greg Duncan
Chairman & CEO Virios Therapeutics, Inc.

About Virios Therapeutics, Inc.

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** (“LC”). 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, LC, 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 has engaged the FDA in concerning submission of an investigational new drug application to formally



assess IMC-2 (combination of valacyclovir and celecoxib) as a potential treatment for LC sequelae. New intellectual property protection has been filed for IMC-2 as a treatment for LC and Alzheimer's disease under the Patent Cooperation Treaty with the goal of seeking protection for IMC-2 internationally.

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. In particular, there can be no assurance that any development partnership or other transaction involving Virios Therapeutics will be completed on favorable terms, or at all. 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