

**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): **January 3, 2024**

**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 7.01 Regulation FD Disclosure.**

On January 3, 2024, 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.

<b>Exhibit Number</b>	<b>Description</b>
99.1	<a href="#">Shareholder Letter, dated January 3, 2024 (furnished herewith).</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 and Treasurer

January 3, 2024



**Exhibit 99.1**

January 3, 2024

Dear Virios (VIRI) Shareholders,

We would like to thank you for your support this past year and provide you with a corporate progress report as we enter 2024:

- We reached alignment with the Food and Drug Administration (“FDA”) on the IMC-1 (combination of famciclovir and celecoxib) Phase 3 development program for treatment of fibromyalgia (“FM”).
  - We have clarity from the FDA on the development requirements associated with advancing IMC-2 (combination of valacyclovir and celecoxib) into Phase 2 development as a treatment for Long-COVID (“LC”) symptoms. This follows our announcement in 2023 of positive data demonstrating improvement in multiple symptoms following treatment of LC with a combination of valacyclovir and celecoxib in an open-label, proof of concept study conducted by the Bateman Horne Center (“BHC”).
    - ❖ The FDA has agreed to the use of fatigue as the primary endpoint and orthostatic intolerance as a key secondary endpoint to assess the effectiveness of IMC-2 in treating LC symptoms in our proposed Phase 2 proof-of-concept study.
    - ❖ The FDA recommended assessment of a range of IMC-2 doses, including valacyclovir doses above presently approved dosage strengths, to ensure effective inhibition of reactivated herpesvirus.
    - ❖ Following the receipt of FDA feedback, we are exploring options to advance the IMC-2 LC investigational new drug application and its proposed Phase 2 research program. As an interim step, we have provided an investigator initiated unrestricted grant to the BHC, which is currently conducting a placebo-controlled study of up to 60 LC patients in three cohorts evaluating two doses of IMC-2 over the course of 12 weeks. Measures for assessing fatigue, orthostatic intolerance, sleep quality and other important LC related outcomes are incorporated in the BHC study.
    - ❖ There are currently no FDA approved LC treatments, thus IMC-2 has potential to be one of the first approved treatments for LC.
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- New intellectual property protection for IMC-2 as a treatment for LC and other conditions with prominent fatigue symptoms was filed under the Patent Cooperation Treaty with the goal of seeking protection for IMC-2 internationally.
- We continue to actively explore opportunities for three initiatives:
  - ❖ IMC-1 for a Phase 3 Fibromyalgia program;
  - ❖ IMC-2 for a Phase 2 Long-COVID program; and
  - ❖ Complementary opportunities to build shareholder value under VIRI team leadership through mergers or acquisitions.
- Through prudent expense management, the Company has capital to support operations into Q4 2024.

If you have any further questions, please do not hesitate to reach out to me or our SVP of Finance and Corporate Secretary and Treasurer, Angela Walsh at [angela@virios.com](mailto:angela@virios.com).

Warmest regards,

/s/ 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.

For more information, please visit [www.virios.com](http://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, as well as potential future partnerships. 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](mailto:IR@Virios.com)

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