

**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 28, 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.

Item 7.01 Regulation FD Disclosure.

On November 28, 2022, 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.

Exhibit Number	Description
99.1	Shareholder letter, dated November 28, 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 28, 2022



Exhibit 99.1

November 28, 2022

Dear Virios (VIRI) Shareholders,

On September 19th, Virios Therapeutics, Inc. (the “Company”) reported that its novel fibromyalgia (“FM”) development candidate, IMC-1, demonstrated exemplary safety and tolerability in the FORTRESS (Fibromyalgia Outcome Research Trial Evaluating Synergistic Suppression of Herpes Simplex Virus-1) study but did not achieve statistical significance on the pre-specified primary efficacy endpoint of pain reduction.

As a fellow shareholder, this outcome was disappointing, especially in light of our previously successful Phase 2a study, as well as prior research demonstrating herpes virus activation in patients diagnosed with FM and a functional gastrointestinal disorder. 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.

We announced the results of these additional analyses on November 14th which can be summarized as follows:

- Post-hoc analysis of the FORTRESS study results indicated that FM patients who were recruited through advertising and were thus new to our study sites and prior FM clinical trials (“new” patients), demonstrated clinically and statistically significant reductions in pain, fatigue, FM symptoms and both anxiety and depression symptoms. This treatment effect persisted throughout the trial.
- In contrast, FM patients who were prior FM trial participants and/or research site database patients (“experienced” patients) did not exhibit a statistically significant treatment benefit in this study. On a related note, there have been at least eight FM trials in the U.S. over the past decade. 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 becoming more refractory (less likely to respond) to therapy. This trend has been observed in several other research categories, such as depression, where more time and energy must be expended to recruit newer, more treatment naïve patients.



- Historically, we have used a combination of dedicated research sites, as well as sites that both recruit patients for clinical trials and provide general care for patients in their local communities (“mixed sites”). Our data indicates that dedicated clinical research sites, that were less likely to experience significant staff turnover as a result of the pandemic, delivered more consistent results, including better management of placebo response, when compared to the mixed sites. Our plan moving forward will be to execute future IMC-1 trials with a specific focus on dedicated research sites.
- On a final note, it’s important to remember that, as was the case in our successful Phase 2a study, IMC-1 was very well tolerated by all study subjects as evidenced by a discontinuation rate due to adverse events that was lower than placebo. This is a feature of IMC-1 that the Company believes supports progression to Phase 3 development and, if successful, could be a highly differentiated feature of IMC-1 treatment versus other approved therapies.
- We have vetted these findings with multiple widely recognized FM research thought leaders who corroborated our view that the FORTRESS study results were unlikely due to chance and that the positive results we observed in these additional analyses support the potential of IMC-1. These thought leaders supported our proposed plan to continue the development of IMC-1 as a treatment for FM.

The extensive data analysis of the FORTRESS study conducted by our research team has uncovered several key insights into which patients are most likely to respond to IMC-1, irrespective of external factors, including COVID-19 related dynamics. This includes recruiting patients new to FM research, with additional emphasis on screening out FM patients with a recent history of treatment failure or patients who have previously participated in FM clinical trials. This proposed approach is supported by data gleaned from the analysis of the FORTRESS study.

We believe these insights will enable us to design a Phase 3 program to be discussed with the U.S. Food & Drug Administration (“FDA”) over the coming months. We hope to reach alignment with the FDA in the first half of 2023, subject to FDA availability for live engagement, and to commence the next phase of our IMC-1 research in the second half of 2023.

The Company has capital to support operations until the end of 2023, but future IMC-1 development will require additional capital and/or partnership support.



In addition to engaging with the FDA, we will also develop a plan for funding and executing IMC-1 development.

Our ultimate goal remains the same - getting IMC-1 to market to enhance the standard of care for FM patients not presently satisfied with current treatment options. 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.

Warmest regards,

/s/ Greg Duncan

Chairman & CEO, Virios Therapeutics, Inc.

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