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): **September 27, 2022**

VIRIOS THERAPEUTICS, INC.
(Exact Name of Registrant as Specified in Charter)

Delaware	**001-39811**	**85-4314201**
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

44 Milton Avenue **Alpharetta, GA**	**30009**
(Address of principal executive offices)	(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 September 27, 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 September 27, 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

September 27, 2022

Exhibit 99.1

September 27, 2022

Dear Virios (VIRI) Shareholders,

On September 19th, we announced our FORTRESS Phase 2b fibromyalgia ("FM") study results. In this trial, IMC-1 did not achieve statistically significant improvement on the primary endpoint measure of reduction in FM related pain as compared to placebo. These results were surprising, 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.

While these results were not what we had hoped for, we did uncover an anomalous bifurcation of results when comparing the patients enrolled during the first half of the study ("Cohort 1") with results from patients enrolled during the second half of the study ("Cohort 2"). More specifically, there was no statistically significant differences between treatment with IMC-1 versus placebo for Cohort 1 patients on any of the outcome measures of interest. Conversely, there were statistically significant differences in multiple outcomes of interest including the primary endpoint of reduction in pain at Week 14 as compared to placebo, as well as fatigue and multiple FM related symptoms for those patients in Cohort 2.

The team and I are encouraged by the Cohort 2 results for two reasons. First, these results are consistent with what we expected to see based on the results from our previously completed Phase 2a FM trial. Second, we have statistically modelled the probability that this difference in outcomes between the two cohorts could be a random event, and as a result, the team and I believe that it is highly unlikely that the encouraging Cohort 2 findings could be a random finding.

The team has begun the process of analyzing the FORTRESS data as a whole, as well as by time frame intervals, to determine what might be driving these disparate results and to ascertain what potential options might exist to advance development of IMC-1. This process will take several weeks to complete, following which we anticipate we will likely engage with the FDA to discuss future development options for IMC-1. We expect this process to extend into 2023.

As communicated as recently as our Q2 earnings update in August, our current capital reserves were expected to be depleted at the end of the year. It was within this context that the Board of Directors made a decision to raise additional capital as we explore forward options for IMC-1 development. Without raising additional capital, we would likely not be

in a position to determine potential development options for IMC-1, as raising capital when our cash reserves would on the verge of expiring was deemed to be more dilutive and potentially not achievable.

On an alternative research front, the Bateman Horne Center has been enrolling patients in our exploratory study assessing the therapeutic potential of the combination of valacyclovir and celecoxib to reduce Long-COVID symptoms such as fatigue, sleep, attention, pain, autonomic function and anxiety. We expect to complete enrollment by the end of 2022, with results expected in first half 2023.

In summary, while the FORTRESS Phase 2b FM study results were not what we had hoped for, we are encouraged by the results seen in the Cohort 2 sub-group analysis. As previously communicated, our cash position prior to our recent public offering would have only enabled us to operate through the end of the year. The fresh injection of capital from last week's capital raising was required to create additional runway to properly assess the FORTRESS results with the goal of creating a viable path forward for IMC-1's continued development.

We plan to provide an update on the ongoing analysis at our Q3 earnings update in November. 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
Chair & 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. 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.

For more information, please visit www.virios.com.

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Forward-Looking Statements

Statements in this letter 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 and our ability to develop any options with respect to the continued development of IMC-1. 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.