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 9, 2023**

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** (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 8.01 Other Events.

On August 9, 2023, Virios Therapeutics, Inc. (the "Company") issued a press release announcing that the Food & Drug Administration 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. 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 8.01.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description
99.1	Press Release of the Company, dated August 9, 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 9, 2023

Exhibit 99.1

Virios Therapeutics Announces Plans to Advance Lead Candidate IMC-1 to Phase 3 Development as a New Treatment Option for Fibromyalgia

ATLANTA, Ga., August 9, 2023 -- Virios Therapeutics, Inc. (Nasdaq: VIRI) (the "Company"), a development-stage biotechnology company focused on advancing novel antiviral therapies to treat debilitating chronic diseases such as fibromyalgia ("FM") and Long-COVID, today 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. With this critical feedback in hand, the Company plans to initiate its proposed pharmacokinetic and food effect study ("pK") this year, while concurrently resubmitting a final Phase 3 program outline and 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.

Key Highlights and Upcoming Milestones

- The Company plans to execute the pK study in males and females as a precursor to the FM studies with an updated IMC-1 dose and formulation, which is intended to enable the Company to take advantage of all of the efficiencies afforded with utilization of the 505(b)(2) regulatory pathway.
- Consistent with the previously proposed Phase 3 plan, the Company will concurrently submit its final Phase 3 program outline and associated study protocols to FDA, to progress the following:
    - Two adequate and well-controlled clinical studies; and
    - A long-term extension trial to support chronic administration of IMC-1.
- Based on the results from its recently completed FORTRESS Phase 2b trial, the Company has designed a Phase 3 development program targeting community-based FM patients who have not participated in prior FM trials.

"We look forward to initiating our pK study with the updated formulation of IMC-1 while finalizing the protocols and procedures required for Phase 3 development of IMC-1 as a treatment for FM. The safety and efficacy results from the FORTRESS trial, along with the chronic toxicology program results, have enabled us to define a clinical trial program as well as a formulation and dose of IMC-1 to enhance our chances for success," said R. Michael Gendreau, Chief Medical Officer of Virios Therapeutics.

The Company will share more information about its FM Phase 3 program during its earnings update on Thursday, August 10, 2023 at 8:30 a.m. ET.

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:
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