

**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 12, 2021**

VIRIOS THERAPEUTICS, INC.

(Exact Name of Registrant as Specified in Charter)

Delaware
(State or other jurisdiction
of incorporation)

001-39811
(Commission
File Number)

45-4618270
(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 2.02 Results of Operations and Financial Condition.

On August 12, 2021, Virios Therapeutics, Inc. (the “Company”) issued a press release announcing the results of operations for the second quarter ended June 30, 2021. 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 2.02.

The information provided pursuant to this Item 2.02, including Exhibit 99.1, is being furnished and shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934 (the “Exchange Act”) or otherwise subject to the liabilities under that Section and shall not be deemed to be incorporated by reference into any filing of the Company under the Securities Act of 1933 or the Exchange Act.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

<u>Exhibit Number</u>	<u>Description</u>
99.1	Press Release of the Company, dated August 12, 2021.
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: SVP of Finance and Corporate Secretary

August 12, 2021



Virios Therapeutics Announces Second Quarter 2021 Financial Results and Provides Corporate Update

ATLANTA, Ga., August 12, 2021 --[Virios Therapeutics, Inc.](#) (Nasdaq: **VIRI**), a clinical-stage biotechnology company focused on advancing novel antiviral therapies to treat debilitating chronic diseases, today reported financial results for the second quarter ended June 30, 2021 and provided a corporate update.

“Our landmark Phase 2b fibromyalgia clinical trial, referred to as FORTRESS, has rapidly progressed and patients are being enrolled at more than 40 clinical trial sites, keeping us on track to announce top line results in mid-2022,” stated Greg Duncan, Chairman and Chief Executive Officer. “There is increasing recognition in the scientific community of the potential role of activated viruses triggering a wide range of conditions, including fibromyalgia, irritable bowel syndrome and fatigue-related disorders. We are exploring the feasibility and timing of executing additional HSV-1 targeted research programs complementary to our fibromyalgia program and expect to provide an update on these plans later this year.”

Key Highlights and Upcoming Milestones

- Enrollment is ongoing in the FORTRESS (Fibromyalgia Outcome Research Trial Evaluating Synergistic Suppression of HSV-1) Phase 2b trial;
- 41 clinical trial sites are activated and enrolling patients for the FORTRESS trial;
- Top line results of the FORTRESS Phase 2b clinical trial are expected in mid-2022;
- Orally presented gastrointestinal (GI) biopsy study data highlighting the role of active HSV-1 as a potential root cause of chronic GI disorders at Digestive Disease Week 2021;
- Poster presentation of safety data from the Phase 2a Fibromyalgia Trial at the International Association of the Study of Pain;
- Poster presentation of the Phase 2a Fibromyalgia Trial data on efficacy analyses of key secondary endpoints at the EULAR European Congress of Rheumatology;
- Presented at the Needham Healthcare Conference and the Benzinga Global Small Cap Conference;
- Bloomberg News interview in July 2021 with our CEO, Greg Duncan;
- Upcoming corporate presentations at two investor conferences: SNN Network Summer Virtual Event being held August 17-19, 2021, and H.C. Wainwright 23rd Annual Global Investment Conference being held September 13-15, 2021.



Second Quarter 2021 Financial Results

Research and development expenses for the second quarter ended June 30, 2021 were \$3.2 million, compared to \$0.02 million for the second quarter ended June 30, 2020. The \$3.2 million increase was primarily attributable to increases in expenses for the FORTRESS clinical trial, the chronic toxicology program and drug development and manufacturing costs.

General and administrative expenses for the second quarter ended June 30, 2021 were \$1.1 million, compared to \$0.5 million for the second quarter ended June 30, 2020. The \$0.6 million increase was primarily attributable to costs associated with being a public company.

Net loss for the second quarter ended June 30, 2021 was \$4.3 million, or (\$0.51) basic and diluted per share, compared to a net loss of \$0.7 million, or (\$0.14) basic and diluted per share, for the second quarter ended June 30, 2020.

As of June 30, 2021, cash totaled \$21.8 million. The Company believes it will have sufficient resources to fund its planned operations through the end of 2022.

Conference Call & Webcast Details

Virios Therapeutics management will host a webcast and conference call on August 12, 2021 at 8:30 a.m. ET to discuss the results and provide a corporate update. The live and archived webcast of the call may be accessed on the Virios Therapeutics website under the Investors section: [Events and Presentations](#). The live call can also be accessed by dialing (844) 602-0380 (domestic) or (862) 298-0970 (international) and asking to be connected to the "Virios Therapeutics Conference Call".

About Virios Therapeutics

Virios Therapeutics (Nasdaq: **VIRI**) is a clinical-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 Simplex Virus-1 ("HSV-1") have been postulated as a potential root cause triggering and/or sustaining chronic illnesses such as FM, irritable bowel disease ("IBS"), 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 HSV-1 replication, with the end goal of reducing virally promoted disease symptoms.



Evidence of IMC-1's efficacy on a broad spectrum of FM outcome measures was previously demonstrated in a Phase 2a clinical trial. These trial results are suggestive that IMC-1 may represent a new and novel treatment for fibromyalgia. IMC-1 has been granted fast track designation by the FDA and is currently being tested in a multi-center, randomized, double-blind, placebo-controlled Phase 2b trial ("FORTRESS") designed to set the stage for registrational studies. The company is led by an executive team highly experienced in the successful development and commercialization of novel therapies. For more information, please visit www.virios.com.

Forward-Looking Statements

Statements in this press release contain "forward-looking statements" 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," "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 and timing of the Phase 2b trial. 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, 2020 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.

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-Financial Tables Follow-



VIRIOS THERAPEUTICS
Selected Financial Data
(unaudited)

Condensed Statements of Operations Data	Three Months Ended		Six Months Ended	
	June 30,		June 30,	
	2021	2020	2021	2020
Revenue	\$ —	\$ —	\$ —	\$ —
Operating expenses:				
Research and development	3,209,201	23,320	4,916,159	53,859
General and administrative	1,075,256	515,060	2,425,732	867,073
Total operating expenses	4,284,457	538,380	7,341,891	920,932
Loss from operations	(4,284,457)	(538,380)	(7,341,891)	(920,932)
Other income (expense)	1,495	(116,205)	2,896	(200,206)
Net loss	\$ (4,282,962)	\$ (654,585)	\$ (7,338,995)	\$ (1,121,138)
Net loss per share of common stock — basic and diluted	\$ (0.51)	\$ (0.14)	\$ (0.88)	\$ (0.23)
Weighted average shares outstanding — basic and diluted	8,330,390	4,832,494	8,328,212	4,832,494

Condensed Balance Sheet Data	June 30,	December 31,
	2021	2020
Cash	\$ 21,835,092	\$ 29,795,366
Total assets	23,764,782	31,472,731
Total liabilities	906,257	1,531,842
Total stockholders' equity	22,858,525	29,940,889

Source: Virios Therapeutics, Inc. (VIRI)