

**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 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 November 11, 2021, Virios Therapeutics, Inc. (the “Company”) issued a press release announcing the results of operations for the third quarter ended September 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 November 11, 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: Senior Vice President of Finance and Corporate Secretary

November 12, 2021



Exhibit 99.1

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

- **Over 200 Patients Enrolled in Fibromyalgia Phase 2b Trial**
- **Filed Investigational New Drug Application with FDA to Assess IMC-1 Potential to Treat Irritable Bowel Syndrome**
- **Cash Position Supports Operations into Q1 2023**
- **Management to Host Webcast and Conference Call at 8:30 a.m. EST November 11, 2021**

ATLANTA, Ga., November 11, 2021 --Virios Therapeutics, Inc. (Nasdaq: **VIRI**), a development-stage biotechnology company focused on advancing novel antiviral therapies to treat debilitating chronic diseases, including fibromyalgia, reported today financial results for the third quarter ended September 30, 2021 and provided a corporate update at 8:30 a.m. EST.

"We are pleased to have enrolled over 200 patients into our landmark Phase 2b fibromyalgia clinical trial, referred to as FORTRESS, with the goal to announce top line results in Q3 2022," stated Greg Duncan, Chairman and Chief Executive Officer. "We are also pleased to announce that based on our research collaboration with Dr. Michael Camilleri of the Mayo Clinic, we have filed an investigational new drug ("IND") application with the U.S. Food and Drug Administration ("FDA") to explore the clinical potential of IMC-1 to treat irritable bowel syndrome ("IBS").

Recent Key Highlights and Upcoming Milestones

- Over 200 of the target 460 patients enrolled in ongoing fibromyalgia Phase 2b Trial;
- Filed IND with FDA to explore the utility of IMC-1 in treating patients diagnosed with IBS;
- The United States Patent and Trademark Office granted Virios Therapeutics patent exclusivity on its valacyclovir-celecoxib combination drug candidate ("IMC-2") to 2033, bringing the Company's intellectual property portfolio to 21 issued patents; and
- Virios Therapeutics CEO featured in *Red Chip Money Report* interview on Bloomberg TV on October 30, 2021.

Third Quarter 2021 Financial Results

Research and development expenses were \$3.0 million for the third quarter ended September 30, 2021, compared to \$0.1 million for the third quarter ended September 30, 2020. The \$2.9 million increase was primarily attributable to expenses related to the ongoing FORTRESS clinical trial, the IMC-1 chronic toxicology program and drug development and manufacturing costs.



General and administrative expenses were \$1.1 million for the third quarter ended September 30, 2021, as compared to \$2.5 million for the third quarter ended September 30, 2020. The decrease of \$1.4 million was primarily attributable to compensation expense recognized in 2020 for the issuance of membership interests to the Company's founder offset by an increase in costs associated with being a public company.

Net loss for the third quarter ended September 30, 2021 was \$4.1 million, or (\$0.49) basic and diluted per share, compared to a net loss of \$2.7 million, or (\$0.56) basic and diluted per share, for the third quarter ended September 30, 2020.

As of September 30, 2021, cash totaled \$19.2 million. The Company believes it will have sufficient resources to fund planned operations into Q1 2023.

Conference Call & Webcast Details

Virios Therapeutics management will host a webcast and conference call on November 11, 2021 at 8:30 a.m. EST 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 888-506-0062 (domestic) or 973-528-0011 (international) using the access code: 345081.

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 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”, 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,” “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 FORTRESS 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		Nine Months Ended	
	September 30,		September 30,	
	2021	2020	2021	2020
Revenue	\$ —	\$ —	\$ —	\$ —
Operating expenses:				
Research and development	2,961,122	108,086	7,877,281	161,944
General and administrative	1,150,369	2,554,724	3,576,101	3,421,798
Total operating expenses	4,111,491	2,662,810	11,453,382	3,583,742
Loss from operations	(4,111,491)	(2,662,810)	(11,453,382)	(3,583,742)
Other income (expense)	1,509	(61,219)	4,405	(261,425)
Net loss	\$ (4,109,982)	\$ (2,724,029)	\$ (11,448,977)	\$ (3,845,167)
Net loss per share of common stock — basic and diluted	\$ (0.49)	\$ (0.56)	\$ (1.37)	\$ (0.80)
Weighted average shares outstanding — basic and diluted	8,330,390	4,832,494	8,328,946	4,832,494

Condensed Balance Sheet Data	September 30,	December 31,
	2021	2020
Cash	\$ 19,186,324	\$ 29,795,366
Total assets	20,107,236	31,472,731
Total liabilities	1,226,787	1,531,842
Total stockholders' equity	18,880,449	29,940,889

Source: Virios Therapeutics, Inc. (VIRI)