

**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): **May 13, 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 May 13, 2021, Virios Therapeutics, Inc. (the “Company”) issued a press release announcing the results of operations for the first quarter ended March 31, 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	<a href="#">Press Release of the Company, dated May 13, 2021.</a>

**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

May 13, 2021



## Virios Therapeutics Announces First Quarter 2021 Financial Results and Provides Corporate Update

ATLANTA, Ga., May 13, 2021 --Virios Therapeutics, Inc. (Nasdaq: **VIRI**), a clinical-stage biotechnology company focused on advancing novel antiviral therapies to treat diseases associated with virally triggered or maintained immune responses, today reported financial results for the first quarter ended March 31, 2021.

*"Our team has made significant operational progress to ensure the commencement of our landmark Phase 2b fibromyalgia clinical trial, referred to as FORTRESS (Fibromyalgia Outcome Research Trial Evaluating Synergistic Suppression of HSV-1), with top line results projected in mid-2022," stated Greg Duncan, Chairman and Chief Executive Officer. "We are pleased to see the research community's growing excitement about IMC-1 as a potential treatment for fibromyalgia, as evidenced by the rapid sign up of more than 40 clinical trial sites and the acceptance of new analyses from our Phase 2a study results to be presented in June at two major medical meetings, the European Congress of Rheumatology (EULAR), and the International Association for the Study of Pain (IASP) World Congress."*

### Key Highlights

- *Prepared more than 40 research sites to commence recruitment of the FORTRESS Phase 2b study in Q2 2021;*
- *Reported that the gastrointestinal (GI) biopsy study highlighting the role of active HSV-1 replication was accepted for oral presentation at the 2021 Digestive Disease Week medical conference, the largest GI focused meeting in the U.S.;*
- *Commenced chronic toxicology program to support dosing of IMC-1 for intervals of 1 year or more;*
- *Advanced collaboration with Dr. Michael Camilleri of the Mayo Clinic to explore the role of antiviral therapy in managing Irritable Bowel Syndrome (IBS); and*
- *Presented at HC Wainwright Global Healthcare and BioConnect Conferences, BIO CEO & Investor Conference and Needham Healthcare Conference.*



### **First Quarter 2021 Financial Results**

Research and development expenses for the first quarter ended March 31, 2021 were \$1.71 million, compared to \$0.03 million for the first quarter ended March 31, 2020. The \$1.68 million increase was primarily attributable to increases in expenses for the FORTRESS clinical trial and chronic toxicology program.

General and administrative expenses for the first quarter ended March 31, 2021 were \$1.35 million, compared to \$0.35 million for the first quarter ended March 31, 2020. The \$1.0 million increase was primarily attributable to legal and accounting fees and other costs associated with being a public company.

Net loss for the first quarter ended March 31, 2021 was \$3.1 million, or (\$0.37) basic and diluted per share, compared to a net loss of \$0.5 million, or (\$0.10) basic and diluted per share, for the first quarter ended March 31, 2020.

As of March 31, 2021, Virios Therapeutics cash totaled \$24.6 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 May 13, 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 (877) 407-8133 (domestic) or (201) 689-8040 (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, dual mechanism antiviral therapies to treat conditions associated with virally triggered or maintained immune responses, 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](http://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.

#### **Contacts:**

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-Financial Tables Follow-



**VIRIOS THERAPEUTICS**  
**Selected Financial Data**  
(unaudited)

<b>Condensed Statements of Operations Data</b>	<b>Three Months Ended</b>	
	<b>March 31,</b>	
	<b>2021</b>	<b>2020</b>
Revenue	\$ —	\$ —
Operating expenses:		
Research and development	1,706,957	30,539
General and administrative	1,350,476	352,014
Total operating expenses	<u>3,057,433</u>	<u>382,553</u>
Loss from operations	(3,057,433)	(382,553)
Other income (expense)	1,400	(84,000)
Net loss	<u>\$ (3,056,033)</u>	<u>\$ (466,553)</u>
Net loss per share of common stock — basic and diluted	<u>\$ (0.37)</u>	<u>\$ (0.10)</u>
Weighted average shares outstanding — basic and diluted	<u>8,326,010</u>	<u>4,832,494</u>

<b>Condensed Balance Sheet Data</b>	<b>March 31,</b>	<b>December 31,</b>
	<b>2021</b>	<b>2020</b>
Cash	\$ 24,585,560	\$ 29,795,366
Total assets	28,274,537	31,472,731
Total liabilities	1,167,294	1,531,842
Total stockholders' equity	27,107,243	29,940,889

Source: Virios Therapeutics, Inc. (VIRI)