

March 17, 2022



Virios Therapeutics Announces Fourth Quarter and Full Year 2021 Financial Results and Provides Corporate Update

- Top line Data from Phase 2b FORTRESS Study of IMC-1 on Track for Q3 2022 -

- Pipeline Expanded with IMC-2 as Treatment for Long COVID to be Evaluated in New Exploratory Study Targeted to Commence in Q2 2022 -

- Conference Call Today at 8:30 a.m. ET -

ATLANTA--(BUSINESS WIRE)-- [Virios Therapeutics, Inc.](#) (Nasdaq: VIRI), a development-stage biotechnology company focused on advancing novel antiviral therapies to treat chronic diseases including [fibromyalgia](#), today announced financial results for the fourth quarter and full year ended December 31, 2021.

Key Highlights

- Phase 2b FORTRESS fibromyalgia study top line results on track for Q3 2022
- Chronic toxicology studies, required for IMC-1 Phase 3 studies, are progressing as planned and synchronized for completion with the FORTRESS study
- Recently announced clinical development collaboration to assess therapeutic potential of IMC-2 as a treatment for Long COVID, a developing health crisis
- Cash on hand of \$14.0 million on December 31, 2021, provides runway through Q1 2023

“Virios achieved many operational milestones in 2021, most notably launching recruitment and dosing in the Phase 2b FORTRESS study. We project to reach full enrollment for the trial of over 400 patients by mid-April,” said Greg Duncan, Chairman and CEO of Virios Therapeutics. “We also recently announced the expansion of our research pipeline through a collaboration with the Bateman Horne Center, a leading research center in post-viral syndromes. The focus of the collaboration is centered on conducting a new exploratory trial assessing the potential of IMC-2, a combination of valacyclovir and celecoxib, to reduce fatigue and other symptoms associated with Long COVID sequelae, which is estimated to effect up to 30% of former COVID patients.”

“Our most important priority is completing the FORTRESS study, with planned reporting of top line results in Q3 2022. This study will assess the effectiveness of IMC-1 in reducing the systemic pain and other symptoms associated with fibromyalgia. Our cash on hand of \$14.0 million is expected to support the Company’s operations through those important months and into the planning for a Phase 3 study in early 2023,” concluded Angela Walsh, Senior Vice President, Finance, of Virios Therapeutics.

Fourth Quarter 2021 Financial Results

Research and development expenses for the fourth quarter of 2021 were \$2.9 million, compared to \$0.03 million for the fourth quarter of 2020. The \$2.87 million increase was primarily attributable to expenses for our FORTRESS clinical trial, our chronic toxicology program and drug development and manufacturing costs.

General and administrative expenses for the fourth quarter of 2021 were \$1.3 million, compared to \$6.4 million for the fourth quarter of 2020. The \$5.1 million decrease was primarily attributable to IPO-related expenses incurred in 2020, including non-cash share-based compensation expense of \$5.4 million, issued pursuant to executive employment agreements, offset by an increase in costs associated with being a public company.

Net loss for the fourth quarter of 2021 was \$4.5 million, or (\$0.54) basic and diluted per share, compared to a net loss of \$6.5 million, or (\$1.25) basic and diluted per share, for the fourth quarter of 2020.

Full Year 2021 Financial Results

Research and development expenses for the year ended December 31, 2021, were \$10.8 million, compared to \$0.2 million for the year ended December 31, 2020. The \$10.6 million increase was primarily attributable to expenses for our FORTRESS clinical trial and our chronic toxicology program which commenced in 2021 and drug development and manufacturing costs to support these studies.

General and administrative expenses for the year ended December 31, 2021, were \$4.8 million, compared to \$9.8 million for the year ended December 31, 2020. The \$5.0 million decrease was primarily attributable to IPO-related expenses incurred in 2020, including non-cash equity and share-based compensation expense of \$7.4 million, issued pursuant to executive employment agreements, offset by an increase in costs associated with being a public company.

Net loss for the year ended December 31, 2021, was \$16.0 million, or (\$1.92) basic and diluted per share, compared to a net loss of \$10.3 million, or (\$2.10) basic and diluted per share, for the year ended December 31, 2020.

As of December 31, 2021, Virios Therapeutics cash totaled \$14.0 million. The Company believes it will have sufficient resources to fund its planned operations through the end of Q1 2023.

Conference Call & Webcast Details

Virios Therapeutics management will host a webcast and conference call on March 17, 2022, at 8:30 a.m. ET to discuss the Company's financial 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) and asking to be connected to the "Virios Therapeutics Conference Call".

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 (“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 herpes virus replication, with the end goal of reducing virally promoted disease symptoms. 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. Evidence of IMC-1’s efficacy on a broad spectrum of FM outcome measures was previously demonstrated in a Phase 2a clinical trial.

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. The Company has provided Bateman Horne Center (“BHC”) with an unrestricted grant to conduct this study. BHC is a non-profit, interdisciplinary Center of Excellence advancing the diagnosis and treatment of myalgic encephalomyelitis/chronic fatigue syndrome (“ME/CFS”), FM, post-viral syndromes, and related comorbidities.

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 and timing of the FORTRESS trial or any studies relating to the treatment of Long COVID with IMC-2. 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.

-Financial Tables Follow-

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Selected Financial Data

(unaudited)

Condensed Statements of Operations Data

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2021	2020	2021	2020
Revenue	\$ —	\$ —	\$ —	\$ —
Operating expenses:				
Research and development	2,918,407	32,070	10,795,688	194,013
General and administrative	1,269,151	6,389,582	4,845,252	9,811,381
Total operating expenses	4,187,558	6,421,652	15,640,940	10,005,394
Loss from operations	(4,187,558)	(6,421,652)	(15,640,940)	(10,005,394)
Other expense	(323,733)	(79,576)	(319,328)	(341,001)
Net loss	<u>\$ (4,511,291)</u>	<u>\$ (6,501,228)</u>	<u>\$ (15,960,268)</u>	<u>\$ (10,346,395)</u>
Net loss per share of common stock — basic and diluted	<u>\$ (0.54)</u>	<u>\$ (1.25)</u>	<u>\$ (1.92)</u>	<u>\$ (2.10)</u>
Weighted average shares outstanding — basic and diluted	<u>8,330,390</u>	<u>5,212,534</u>	<u>8,329,310</u>	<u>4,926,985</u>

Condensed Balance Sheet Data

	December 31, 2021	December 31, 2020
Cash	\$ 14,008,184	\$ 29,795,366
Total assets	15,776,687	31,472,731
Total liabilities	1,275,623	1,531,842
Total members'/stockholders' equity (deficit)	14,501,064	29,940,889

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IR@Virios.com

PCG Advisory

Kirin Smith

ksmith@pcgadvisory.com

Source: Virios Therapeutics, Inc.