

August 12, 2021



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

ATLANTA--(BUSINESS WIRE)-- [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](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.

-Financial Tables Follow-

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

| Condensed Statements of Operations Data                 | Three Months Ended<br>June 30, |                     | Six Months Ended<br>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                                                | <u>\$ (4,282,962)</u>          | <u>\$ (654,585)</u> | <u>\$ (7,338,995)</u>        | <u>\$ (1,121,138)</u> |
| Net loss per share of common stock — basic and diluted  | <u>\$ (0.51)</u>               | <u>\$ (0.14)</u>    | <u>\$ (0.88)</u>             | <u>\$ (0.23)</u>      |
| Weighted average shares outstanding — basic and diluted | <u>8,330,390</u>               | <u>4,832,494</u>    | <u>8,328,212</u>             | <u>4,832,494</u>      |
|                                                         |                                |                     |                              |                       |
| Condensed Balance Sheet Data                            | June 30,<br>2021               |                     | December 31,<br>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            |

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Source: Virios Therapeutics, Inc.