
**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**
Washington, D.C. 20549

FORM 10-Q

(Mark One)

QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended March 31, 2023

or

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from _____ to _____

Commission File Number: 001-39811

Virios Therapeutics, Inc.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

85-4314201
(I.R.S. Employer
Identification Number)

44 Milton Avenue
Alpharetta, GA 30009
(Address of Principal Executive Offices)

(866) 620-8655
(Registrant's telephone number)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes No

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer Accelerated filer
Non-accelerated filer Smaller reporting company Emerging growth company

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.

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes No

Securities registered pursuant to Section 12(b) of the Act:

<u>Title of Each Class</u>	<u>Trading symbol</u>	<u>Name of Exchange on which registered</u>
Common Stock, par value \$0.0001 per share	VIRI	Nasdaq Capital Market

As of May 10, 2023, there were 18,330,390 shares of the registrant's common stock outstanding.

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PART I —FINANCIAL INFORMATION**Item 1. Financial Statements****VIRIOS THERAPEUTICS, INC.****Condensed Balance Sheets
(Unaudited)**

	March 31, 2023 (Unaudited)	December 31, 2022
Assets		
Current assets:		
Cash	\$ 5,332,542	\$ 7,030,992
Prepaid expenses and other current assets	1,188,075	1,338,764
Total current assets	<u>6,520,617</u>	<u>8,369,756</u>
Total assets	<u>\$ 6,520,617</u>	<u>\$ 8,369,756</u>
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 135,094	\$ 573,164
Accrued expenses	414,196	470,098
Total current liabilities	<u>549,290</u>	<u>1,043,262</u>
Total liabilities	<u>549,290</u>	<u>1,043,262</u>
Commitments and contingencies (Note 8)		
Stockholders' equity:		
Common stock, \$0.0001 par value; 43,000,000 shares authorized, 18,330,390 shares issued and outstanding at March 31, 2023 and December 31, 2022	1,833	1,833
Preferred stock, \$0.0001 par value; 2,000,000 shares authorized, no shares issued and outstanding at March 31, 2023 and December 31, 2022	—	—
Additional paid-in capital	63,659,565	63,497,868
Accumulated deficit	<u>(57,690,071)</u>	<u>(56,173,207)</u>
Total stockholders' equity	<u>5,971,327</u>	<u>7,326,494</u>
Total liabilities and stockholders' equity	<u>\$ 6,520,617</u>	<u>\$ 8,369,756</u>

The accompanying notes are an integral part of these condensed financial statements.

VIROS THERAPEUTICS, INC.
Condensed Statements of Operations
(Unaudited)

	Three Months Ended March 31,	
	2023	2022
Revenue	\$ —	\$ —
Operating expenses:		
Research and development	497,714	2,769,102
General and administrative expenses	1,059,573	1,192,112
Total operating expenses	<u>1,557,287</u>	<u>3,961,214</u>
Loss from operations	<u>(1,557,287)</u>	<u>(3,961,214)</u>
Other income:		
Interest income	40,423	906
Total other income	<u>40,423</u>	<u>906</u>
Loss before income taxes	<u>(1,516,864)</u>	<u>(3,960,308)</u>
Income tax provision	<u>—</u>	<u>—</u>
Net loss	<u>\$ (1,516,864)</u>	<u>\$ (3,960,308)</u>
Basic and diluted net loss per share	<u>\$ (0.08)</u>	<u>\$ (0.48)</u>
Weighted average number of shares outstanding – basic and diluted	<u>18,330,390</u>	<u>8,330,390</u>

The accompanying notes are an integral part of these condensed financial statements.

VIRIOS THERAPEUTICS, INC.**Condensed Statements of Changes of Shareholders' Equity
(Unaudited)**

	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Par			
Balance, December 31, 2022	18,330,390	\$ 1,833	\$ 63,497,868	\$ (56,173,207)	\$ 7,326,494
Share-based compensation expense	—	—	161,697	—	161,697
Net loss	—	—	—	(1,516,864)	(1,516,864)
Balance, March 31, 2023	18,330,390	\$ 1,833	\$ 63,659,565	\$ (57,690,071)	\$ 5,971,327

	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Par			
Balance, December 31, 2021	8,330,390	\$ 833	\$ 58,425,604	\$ (43,925,373)	\$ 14,501,064
Share-based compensation expense	—	—	131,906	—	131,906
Net loss	—	—	—	(3,960,308)	(3,960,308)
Balance, March 31, 2022	8,330,390	\$ 833	\$ 58,557,510	\$ (47,885,681)	\$ 10,672,662

The accompanying notes are an integral part of these condensed financial statements.

VIRIOS THERAPEUTICS, INC.
Condensed Statements of Cash Flows
(Unaudited)

	Three Months Ended March 31,	
	2023	2022
Cash flows from operating activities		
Net loss	\$ (1,516,864)	\$ (3,960,308)
Adjustments to reconcile net loss to net cash used in operating activities:		
Share-based compensation expense	161,697	131,906
Changes in operating assets and liabilities:		
Decrease in prepaid expenses and other current assets	150,689	570,812
Decrease in accounts payable	(438,070)	(23,173)
(Decrease) increase in accrued expenses	(55,902)	624,746
Net cash used in operating activities	<u>(1,698,450)</u>	<u>(2,656,017)</u>
Cash flows from financing activities		
Net cash used in financing activities	—	—
Net decrease in cash	(1,698,450)	(2,656,017)
Cash, beginning of period	7,030,992	14,008,184
Cash, end of period	<u>\$ 5,332,542</u>	<u>\$ 11,352,167</u>

The accompanying notes are an integral part of these condensed financial statements.

VIRIOS THERAPEUTICS, INC.

Notes to Condensed Financial Statements (Unaudited)

1 Organization and Nature of Business

Virios Therapeutics, Inc. (the “Company”) was incorporated under the laws of the State of Delaware on December 16, 2020 through a corporate conversion (the “Corporate Conversion”) just prior to the Company’s initial public offering (“IPO”). The Company was originally formed on February 28, 2012 as a limited liability company (“LLC”) under the laws of the State of Alabama as Innovative Med Concepts, LLC. On July 23, 2020, the Company changed its name from Innovative Med Concepts, LLC to Virios Therapeutics, LLC.

The Company operates in one segment as a pre-revenue, development-stage biotechnology company focused on advancing novel combination antiviral therapies to treat diseases associated with a viral triggered abnormal immune response. The Company is developing its initial product candidate, IMC-1, for people who are suffering from fibromyalgia (“FM”). Research has shown that the herpes virus could be a potential root cause of FM. IMC-1 is a novel, proprietary, fixed dose combination of famciclovir and celecoxib, both of which are drugs approved by the U.S. Food and Drug Administration (“FDA”) for other indications. IMC-1 combines these two specific mechanisms of action purposely designed to inhibit herpes virus activation and replication, thereby converting activated herpes virus back to dormancy and/or by keeping the herpes virus in a latent or dormant state. The famciclovir component of IMC-1 inhibits viral DNA replication, thus inhibiting upregulation of the herpes virus. The celecoxib component of IMC-1 inhibits cyclooxygenase-2 (“COX-2”) enzymes used by the herpes virus to amplify or accelerate its own replication. IMC-1’s synergistic antiviral mechanism represents a first-in-class medicine designed specifically to inhibit both herpes virus activation and subsequent replication, with the goal of keeping tissue resident herpes virus in a latent state.

Public Offering

On September 19, 2022, the Company entered into an underwriting agreement with ThinkEquity LLC (the “Underwriter”) in connection with the issuance and sale by the Company in a public offering of 10,000,000 shares of its common stock at a public offering price of \$0.50 per share (the “Offering”), pursuant to an effective shelf registration statement on Form S-3 (File No. 333-263700). The Offering closed on September 22, 2022 and the gross proceeds from the Offering were \$5.0 million. The net proceeds of the Offering were approximately \$4,490,605 after deducting underwriting discounts, commissions and offering expenses payable by the Company. In conjunction with the Offering, the Company granted to the Underwriter 500,000 warrants to purchase shares of the Company’s common stock at an exercise price of \$0.625 per share, which was 125% of the Offering price.

Material Uncertainty

Since its founding, the Company has been engaged in research and development activities as well as organizational activities, including raising capital. The Company has not generated any revenues to date. As such, the Company is subject to all of the risks associated with any development-stage biotechnology company that has substantial expenditures for research and development. Since inception, the Company has incurred losses and negative cash flows from operating activities. The Company has funded its losses primarily through issuance of members’ interests, convertible debt instruments and issuance of equity securities. For the three months ended March 31, 2023 and 2022, the Company incurred net losses of \$1,516,864 and \$3,960,308, respectively, and had net cash outflows used in operating activities for the three months ended March 31, 2023 and 2022 of \$1,698,450 and \$2,656,017, respectively. As of March 31, 2023, the Company had an accumulated deficit of \$57,690,071 and is expected to incur losses in the future as it continues its development activities.

As of the date these financial statements are issued, based on reasonable estimates, current cash is sufficient to fund operating expenses and obligations for at least 12 months. Currently, there are no planned research and development activities for the next 12 months other than carryover costs associated with completing the final reports for the Company's FORTRESS (Fibromyalgia Outcome Research Trial Evaluating Synergistic Suppression of HSV-1) study for the treatment of FM and the chronic toxicology program; regulatory consulting; continued salaries and benefits; the on-going grant to the Bateman Horne Center for the fully funded investigator-sponsored study in Long-COVID; and manufacturing and development of IMC-1 for the proposed pharmacokinetic/food effect study.

In September 2022, the Company announced the top line results from its FORTRESS study in FM. Overall, the FORTRESS study did not achieve statistical significance on the prespecified primary efficacy endpoint of change from baseline to Week 14 in the weekly average of daily self-reported average pain severity scores comparing IMC-1 to placebo ($p=0.302$). However, based on the analysis of the FORTRESS data, community-based patients who have not participated in prior FM clinical trials demonstrated statistically significant improvement on the primary endpoint of reduction in FM related pain versus placebo, irrespective of when they enrolled in the study. The Company believes focusing the forward development of IMC-1 on these "new" patients represents a viable and manageable path forward. The Company met with the Anesthesiology, Addiction Medicine and Pain Medicine division of the FDA in March 2023. In April 2023, the Company received initial feedback that its proposed Phase 3 program is considered acceptable pending review of its final chronic toxicology program results that were submitted to the FDA in May 2023. The Company expects to raise additional capital within the next year to complete clinical development of and to commercially develop its product candidates, including any plans for a Phase 3 program and any new product development. The Company will need to finance its cash needs through public or private equity offerings, debt financings, collaboration and licensing arrangements or other financing alternatives. There is no assurance that such financings will be available when needed or on acceptable terms. The financial statements do not include any adjustments to reflect this uncertainty.

2 Summary of Significant Accounting Policies

Basis of Presentation

The accompanying condensed interim financial statements are unaudited. These unaudited financial statements have been prepared in accordance with the rules and regulations of the U.S. Securities and Exchange Commission ("SEC") for interim financial information. Accordingly, they do not include all the information and notes required by accounting principles generally accepted in the United States of America ("U.S. GAAP") for complete financial statements. These unaudited condensed interim financial statements should be read in conjunction with the audited financial statements and accompanying notes as found in the Company's Annual Report on Form 10-K for the year ended December 31, 2022 filed with the SEC. In the opinion of management, the unaudited condensed interim financial statements reflect all the adjustments (consisting of normal recurring adjustments) necessary to state fairly the Company's financial position, results of operations and cash flows for the interim periods presented. The interim results of operations are not necessarily indicative of the results that may occur for the full fiscal year. The December 31, 2022 balance sheet included herein was derived from the audited financial statements, but does not include all disclosures, including notes, required by U.S. GAAP for complete financial statements. Any reference in these notes to applicable guidance is meant to refer to U.S. GAAP as found in the Accounting Standards Codification ("ASC") and Accounting Standards Updates ("ASU") of the Financial Accounting Standards Board ("FASB").

Use of Estimates

The preparation of these financial statements and accompanying notes in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities at the date of the financial statements and the reported amounts of expenses during the reporting period. The Company's significant estimates and assumptions include estimated work performed but not yet billed by contract manufacturers, engineers and research organizations, the valuation of equity and stock-

based related instruments, and the valuation allowance related to deferred taxes. Some of these judgments can be subjective and complex, and, consequently, actual results could differ from those estimates. Although the Company believes that its estimates and assumptions are reasonable, they are based upon information available at the time the estimates and assumptions were made. Actual results could differ from those estimates.

Basic and Diluted Net Loss per Share

Basic net loss per common share (“EPS”) is computed by dividing net loss by the weighted average number of common shares outstanding during the period. Diluted EPS reflects potential dilution and is computed by dividing net loss by the weighted average number of common shares outstanding during the period increased by the number of additional common shares that would have been outstanding if all potential common shares had been issued and were dilutive. However, potentially dilutive securities are excluded from the computation of diluted EPS to the extent that their effect is anti-dilutive. For the three months ended March 31, 2023 and 2022, the Company had options to purchase 1,912,147 and 1,041,647 shares of common stock, respectively and warrants to purchase 672,500 and 172,500 shares of common stock, respectively, outstanding that were anti-dilutive.

Emerging Growth Company Status

The Company is an emerging growth company, as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. Under the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards issued subsequent to the enactment of the JOBS Act until such time as those standards apply to private companies. The Company has elected to use this extended transition period for complying with new or revised accounting standards that have different effective dates for public and private companies until the earlier of the date that it is (i) no longer an emerging growth company or (ii) affirmatively and irrevocably opts out of the extended transition period provided by the JOBS Act. As a result, these financial statements may not be comparable to companies that comply with the new or revised accounting pronouncements as of public company effective dates.

Subsequent Event

As previously reported, on November 1, 2022, the Company received written notice (the “Notification Letter”) from the Listing Qualifications Department of The Nasdaq Stock Market, LLC (“Nasdaq”) notifying the Company that it was not in compliance with the minimum bid price requirements of Nasdaq Listing Rule 5550(a)(2) (the “Minimum Bid Price Rule”) because the Company’s common stock failed to maintain a minimum bid price of \$1.00 for 30 consecutive business days. The Notification Letter stated that the Company had 180 calendar days, or until May 1, 2023, to demonstrate its compliance with the Minimum Bid Price Rule.

On May 2, 2023, the Company received a second letter from Nasdaq advising that the Company had been granted an additional 180 calendar days, or until October 30, 2023, to regain compliance with the Minimum Bid Price Rule, in accordance with Nasdaq Listing Rule 5810(c)(3)(A).

The Company intends to monitor the closing bid price of its common stock and may, if appropriate, consider available options to regain compliance.

3 Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets consist of the following:

	March 31, 2023	December 31, 2022
Prepaid insurance	\$ 878,702	\$ 1,165,634
Prepaid drug purchases	184,566	—
Prepaid clinical research costs	63,900	154,510
Prepaid services	6,992	11,329
Other miscellaneous current assets	53,915	7,291
	<u>\$ 1,188,075</u>	<u>\$ 1,338,764</u>

4 License Agreement

The Company entered into a Know-How License Agreement (the "Agreement") with the University of Alabama ("UA") in 2012. In consideration for the Agreement, UA received a 10% non-voting membership interest in the Company. Upon the adoption of the Second Amended and Restated Operating Agreement the "Amended Operating Agreement") on May 1, 2020, the non-voting membership interest converted to a voting membership interest. In conjunction with the Corporate Conversion, all of the Company's outstanding membership interest converted into shares of common stock. The Agreement is in effect for 25 years and will terminate on June 1, 2037.

5 Accrued Expenses

Accrued expenses consist of the following:

	March 31, 2023	December 31, 2022
Accrued interest on preferred members' interests	\$ 188,085	\$ 188,085
Accrued compensation	93,149	159,704
Accrued professional fees	69,300	11,600
Accrued director fees	46,500	31,000
Accrued clinical research costs	14,500	78,349
Other miscellaneous accrued expenses	2,662	1,360
	<u>\$ 414,196</u>	<u>\$ 470,098</u>

6 Stockholders' Equity

The Company's certificate of incorporation, adopted on December 16, 2020, authorizes the issuance of two classes of stock: 43,000,000 shares of common stock and 2,000,000 shares of preferred stock, each with a par value of \$0.0001 per share.

7 Related Parties

The Company uses Gendreau Consulting, LLC, a consulting firm ("Gendreau"), for drug development, clinical trial design and planning, implementation and execution of contracted activities with the clinical

research organization. Gendreau's managing member is the Company's Chief Medical Officer ("CMO"). The Company will continue to contract the services of the CMO's spouse through Gendreau to perform certain activities in connection with the Company's ongoing clinical development of its product candidates. During the three months ended March 31, 2023 and 2022, the Company paid Gendreau \$39,973 and \$85,548, respectively, and had accounts payable of \$11,165 and \$21,000 to Gendreau as of March 31, 2023 and December 31, 2022, respectively.

8 Commitments and Contingencies

Litigation and Other

The Company is subject, from time to time, to claims by third parties under various legal disputes. The defense of such claims, or any adverse outcome relating to any such claims, could have a material adverse effect on the Company's liquidity, financial condition and cash flows.

9 Share-based compensation

Equity Incentive Plan

On June 16, 2022, the stockholders of the Company approved the Amended and Restated 2020 Equity Incentive Plan (the "Plan") to increase the total number of shares of common stock reserved for issuance under the Plan by 1,250,000 shares to 2,062,500 total shares issuable under the Plan. As of March 31, 2023, 442,853 shares of common stock were available for future grants under the Plan. The table below sets forth the outstanding options to purchase common shares under the Plan:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (Years)
Outstanding at December 31, 2022	1,631,897	\$ 4.85	9.04
Granted	—	—	—
Forfeited	(12,250)	6.75	—
Outstanding at March 31, 2023	<u>1,619,647</u>	<u>\$ 4.83</u>	<u>8.80</u>
Exercisable at March 31, 2023	<u>666,554</u>	<u>\$ 9.30</u>	<u>7.82</u>

There were no options issued during the three months ended March 31, 2023. As of March 31, 2023 the aggregate intrinsic value of options outstanding was \$57,590.

The Company recognized share-based compensation expense related to stock options during the three months ended March 31, 2023 and 2022, of \$161,697 and \$131,906, respectively. The unrecognized compensation expense for stock options at March 31, 2023 was \$952,376.

Stock Options for Unregistered Securities

In addition to the stock options issued under the Plan, and in conjunction with the IPO, the Company granted non-qualified stock options to purchase 292,500 shares of common stock as provided for in the President's employment agreement (the "President Options"). The President Options are exercisable within 10 years of the date of grant at \$10.00 per share, were 100% vested at the grant date and have a remaining contractual term of 7.72 years. As of March 31, 2023, there was no unrecognized compensation expense related to these options as they were 100% vested upon issuance. The shares of common stock issuable upon exercise of the President Options will be unregistered, and the option agreement does not include any obligation on the part of the Company to register such shares of common stock. Consequently, the Company

has not recognized a contingent liability associated with registering the securities for the arrangement. As of March 31, 2023, the aggregate intrinsic value of the President Options was \$0.

Underwriters Warrants

In conjunction with the IPO, the Company granted the underwriters warrants to purchase 172,500 shares of common stock at an exercise price of \$12.50 per share. The warrants became 100% exercisable on December 21, 2021.

In conjunction with the Offering in September 2022, the Company granted the Underwriter warrants to purchase 500,000 shares of common stock at an exercise price of \$0.625 per share. The warrants became 100% exercisable on March 18, 2023.

There is no unrecognized compensation expense for these awards as of March 31, 2023. The table below sets forth the outstanding warrants to purchase common shares:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (Years)
Outstanding at December 31, 2022	672,500	\$ 3.67	4.27
Granted	—	—	—
Outstanding at March 31, 2023	672,500	\$ 3.67	4.02
Exercisable at March 31, 2023	672,500	\$ 3.67	4.02

As of March 31, 2023, the aggregate intrinsic value of the warrants outstanding was \$0.

10 Income Taxes

As of December 31, 2022, the Company had U.S. federal and state net operating loss carryforwards of approximately \$22,168,000, which have an indefinite carryforward.

On August 16, 2022, the president signed the Inflation Reduction Act ("IRA") into law. The IRA enacted a 15% corporate minimum tax effective in 2024, a 1% tax on share repurchases after December 31, 2022, and created and extended certain tax-related energy incentives. The Company does not expect the tax-related provisions of the IRA to have a material effect on its financial results.

As of March 31, 2023, the Company has not generated sufficient positive evidence for future earnings to support a position that it will be able to realize its net deferred tax asset. The Company has significant negative evidence to overcome in the form of cumulative pre-tax losses from continuing operations since its formation, as well as projected losses for the current year. Therefore, it will continue to maintain a full valuation allowance on its U.S. federal and state net deferred tax asset. The change in the valuation allowance offset the income tax benefit related to the net operating loss for the three months ended March 31, 2023 and 2022. The Company does not have any material unrecognized tax benefits as of March 31, 2023.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

You should read the following discussion and analysis of our financial condition and results of operations in conjunction with the financial statements and the related notes appearing elsewhere in this Quarterly Report on Form 10-Q. This discussion contains forward-looking statements reflecting our current expectations that involve risks and uncertainties. See our Annual Report on Form 10-K for the year ended December 31, 2022 filed with the Security and Exchange Commission ("SEC") on March 14, 2023 (the "2022 Annual Report on Form 10-K"), under "Risk Factors", available on the SEC EDGAR website at www.sec.gov, for a discussion of the uncertainties, risks and assumptions associated with these statements. Actual results and the timing of events could differ materially from those discussed in our forward-looking statements as a result of many factors, including those set forth under "Risk Factors" and elsewhere in this Quarterly Report on Form 10-Q.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains "forward-looking statements", within the meaning of the U.S. Private Securities Litigation Reform Act of 1995, that involve substantial risks and uncertainties. In some cases, you can identify forward-looking statements by the words "anticipate," "believe," "continue," "could," "estimate," "expect," "intend," "may," "might," "objective," "ongoing," "plan," "predict," "project," "potential," "should," "will," or "would," and or the negative of these terms, or other comparable terminology intended to identify statements about the future. These statements involve known and unknown risks, uncertainties and other factors that may cause our actual results, levels of activity, performance or achievements to be materially different from the information expressed or implied by these forward-looking statements, including the risks set forth in our Annual Report on Form 10-K filed with the SEC on March 14, 2023. Although we believe that we have a reasonable basis for each forward-looking statement contained in this Quarterly Report on Form 10-Q, we caution you that these statements are based on a combination of facts and factors currently known by us and our expectations of the future, about which we cannot be certain.

The forward-looking statements contained in this Quarterly Report on Form 10-Q include, among other things, statements about:

- our business strategies;
- our ability to obtain regulatory approval of our product candidate and any other product candidates we may develop, and the labeling under any regulatory approval we may obtain;
- risks relating to the timing and costs of clinical trials and the timing and costs of other expenses;
- timing and likelihood of success of our clinical trials and regulatory approval of our product candidates;
- risks associated with our reliance on third-party organizations;
- our competitive position;
- assumptions regarding the size of the available market, product pricing and timing of commercialization of our product candidates, if approved;
- our intellectual property position and our ability to maintain and protect our intellectual property rights;
- our results of operations, financial condition, liquidity, prospects, and growth strategies;
- our cash needs and financing plans;

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- the industry in which we operate; and
- the trends that may affect the industry or us.

Overview

We are a development-stage biotechnology company focused on advancing novel antiviral therapies to treat diseases associated with a viral triggered abnormal immune response such as fibromyalgia (“FM”). Overactive immune response related to activation of tissue resident herpes virus has been postulated to be a potential root cause of chronic illnesses such as FM, IBS, chronic fatigue syndrome and functional somatic syndrome, all of which are characterized by a waxing and waning manifestation of disease. While not completely understood, there is general agreement in the medical community that activation of the herpes virus is triggered by some form of environmental and/or health stressor. Our lead product candidate, which we have named IMC-1, is a novel, proprietary, fixed dose combination of famciclovir and celecoxib. IMC-1 represents a novel combination antiviral therapy designed to synergistically suppress herpes virus activation and replication, with the end goal of reducing viral mediated disease burden.

IMC-1 combines two specific mechanisms of action purposely designed to inhibit herpes virus activation and replication, thereby keeping the herpes virus in a latent (dormant) state or “down-regulating” the herpes virus from a lytic (active) state back to latency. The famciclovir component of IMC-1 inhibits viral DNA replication. The celecoxib component of IMC-1 inhibits cyclooxygenase-2 (“COX-2”) and to a lesser degree cyclooxygenase-1 (“COX-1”), enzymes used by the herpes virus to amplify or accelerate its own replication. We are unaware of any other antivirals in development for the treatment of FM. We believe this novel approach was a germane consideration in the U.S. Food and Drug Administration (“FDA”) designating IMC-1 for fast-track review status for the treatment of FM. IMC-1 has also been granted a synergy patent based on the fact that neither of the individual components has proven effective in the management of FM, yet the combination therapy generated a result that is greater than the sum of its parts. IMC-1 was the focus of our Phase 2b FORTRESS (Fibromyalgia Outcome Research Trial Evaluating Synergistic Suppression of HSV-1) study.

In September 2022, we announced the top line results from our FORTRESS study in FM. Overall, the FORTRESS study did not achieve statistical significance on the prespecified primary efficacy endpoint of change from baseline to Week 14 in the weekly average of daily self-reported average pain severity scores comparing IMC-1 to placebo (p=0.302). However, based on the analysis of the FORTRESS data, community-based patients who have not participated in prior FM clinical trials demonstrated statistically significant improvement on the primary endpoint of reduction in FM related pain versus placebo, irrespective of when they enrolled in the study. We believe focusing the forward development of IMC-1 on these “new” patients represents a viable and manageable path forward. We met with the Anesthesiology, Addiction Medicine and Pain Medicine division of the FDA in March 2023. In April 2023, we received initial feedback that our proposed Phase 3 program is considered acceptable pending review of our final chronic toxicology program results that were submitted to the FDA in May 2023.

The proposed Phase 3 program consists of four primary components: two adequate and well-controlled clinical studies, one of which would be a full factorial design with each of the individual components of IMC-1 (famciclovir and celecoxib) as separate comparator arms, a long-term safety trial, and a preceding pharmacokinetic/food effect study. The first planned double-blind, placebo controlled Phase 3 clinical study will be a four-arm, multifactorial design to demonstrate the relative safety and efficacy of IMC-1 as compared to celecoxib alone, famciclovir alone and placebo. The second planned double-blind, placebo controlled Phase 3 clinical study will be a two-arm study comparing IMC-1 to placebo. All patients from these two clinical studies will be offered the opportunity to enroll into an open label safety follow-on extension study with all on IMC-1.

We believe that the unique fixed dose, synergistic antiviral mechanism of our approach represents a completely new approach to treating FM and potentially other somatic syndrome disorders, including IBS.

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Furthermore, there is increasing recognition in the scientific community of the potential role of activated viruses, triggering a wide range of morbidities, including FM, IBS, fatigue related disorders and potentially dementia and even long COVID (“Long-COVID”) symptoms. The Company provided the Bateman Horne Center (“BHC”) with an unrestricted grant for an investigator-sponsored study to explore the therapeutic potential of combination antiviral therapy with Virios’ second potential development candidate, a combination of valacyclovir and celecoxib. The study will evaluate changes in common Long-COVID symptoms such as fatigue, sleep, attention, pain, autonomic function and anxiety. BHC began dosing patients for this exploratory study in August 2022. We expect data in June 2023.

We have not generated revenues and have incurred losses since inception. Our net losses for the three months ended March 31, 2023 and 2022, were \$1,516,864 and \$3,960,308, respectively, and our accumulated deficit as of March 31, 2023 was \$57,690,071. We expect to incur losses for the foreseeable future, and we expect these losses to increase as we continue to develop and seek regulatory approvals for our product candidates. Because of the numerous risks and uncertainties associated with product development, we are unable to predict the timing or amount of increased expenses or when, or if, we will be able to achieve or maintain profitability.

The global economy, including credit and financial markets, has experienced extreme volatility and disruptions including severely diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, increases in unemployment rates, increases in inflation rates and uncertainty about economic stability. For example, the ongoing conflict between Ukraine and Russia, the effect of the war and the resulting sanctions by the U.S. and European governments, has created extreme volatility in the global capital markets and is expected to have further global economic consequences, including disruptions of the global supply chain and energy markets. Any such volatility and disruptions may have adverse consequences on us or the third parties on whom we rely. If the equity and credit markets deteriorate, including as a result of political unrest or war, it may make any necessary debt or equity financing more difficult to obtain in a timely manner or on favorable terms, if at all.

Results of Operations

Below is a summary of the results of operations:

	Three Months Ended	
	March 31,	
	2023	2022
Operating expenses:		
Research and development	\$ 497,714	\$ 2,769,102
General and administrative	1,059,573	1,192,112
Total operating expenses	<u>\$ 1,557,287</u>	<u>\$ 3,961,214</u>

Three Ended March 31, 2023 and 2022

Research and Development Expenses

Research and development expenses decreased by \$2.3 million to \$0.5 million for the three months ended March 31, 2023 from \$2.8 million for the three months ended March 31, 2022 due to decreases in expenses for clinical trials of \$2.2 million, toxicology studies of \$0.1 million and salaries and related costs of \$0.1 million offset by an increase in regulatory consulting costs of \$0.1 million.

General and Administrative Expenses

General and administrative expenses decreased by \$0.1 million to \$1.1 million for the three months ended March 31, 2023 from \$1.2 million for the three months ended March 31, 2022 primarily due to a decrease in salaries and related costs.

Liquidity and Capital Resources

Since our inception, we have financed our operations through public offerings of common stock and proceeds from private placements of membership interests and convertible promissory notes. To date, we have not generated any revenue from the sale of products and we do not anticipate generating any revenue from the sales of products for the foreseeable future. We have incurred losses and generated negative cash flows from operations since inception. As of March 31, 2023, our principal source of liquidity was our cash, which totaled \$5.3 million.

Equity Financings

On September 22, 2022, we closed an underwritten public offering raising gross proceeds of \$5.0 million and net proceeds of approximately \$4.5 million, after deducting underwriting discounts, commissions and offering expenses. There were no equity financings during the three months ended March 31, 2023 and 2022.

Debt Financings

There were no debt financings during the three months ended March 31, 2023 and 2022. There was no debt outstanding at March 31, 2023 and December 31, 2022.

Future Capital Requirements

We estimate our current cash of \$5.3 million at March 31, 2023 is sufficient to fund operations and capital requirements for at least the next 12 months. Currently, there are no planned research and development activities for the next 12 months other than carryover costs associated with completing the final reports for the Company's FORTRESS study for the treatment of FM and the chronic toxicology program; regulatory consulting; continued salaries and benefits; the on-going grant to the Bateman Horne Center for the fully funded investigator-sponsored study in Long-COVID; and manufacturing and development of IMC-1 for the proposed pharmacokinetic/food effect study.

We completed our FORTRESS study in September 2022 and held a meeting with the FDA in March 2023. The proposed Phase 3 program has been considered acceptable based on initial feedback from the FDA, pending their review of our final chronic toxicology program results, which were submitted to the FDA in May 2023. We will need to raise additional capital to fund new research and development activities, including any plans for a Phase 3 program and any new product development, as well as to fund operations generally. We will need to finance our cash needs through public or private equity offerings, debt financings, collaboration and licensing arrangements or other financing alternatives. To the extent that we raise additional funds by issuing equity securities, our shareholders will experience dilution. We can give no assurances that we will be able to secure such additional sources of funds to support our operations, or, if such funds are available to us, that such additional financing will be sufficient to meet our needs. Failure to secure the necessary financing in a timely manner and on favorable terms could have a material adverse effect on the Company's strategy and value and could require the delay of product development and clinical trial plans.

Summary of Cash Flows

The following table summarizes our cash flows for the three months ended March 31, 2023 and 2022, respectively:

	Three Months Ended March 31,	
	2023	2022
(Unaudited)		
Statement of Cash Flows Data:		
Net cash used in:		
Operating activities	\$ (1,698,450)	\$ (2,656,017)
Financing activities	—	—
Decrease in cash	<u>\$ (1,698,450)</u>	<u>\$ (2,656,017)</u>

Cash Flows for the Three Months Ended March 31, 2023 and 2022

Operating Activities

For the three months ended March 31, 2023, net cash used in operations was \$1.7 million and consisted of a net loss of \$1.5 million and a net change in operating assets and liabilities of \$0.4 million attributable to a net decrease in accounts payable and accrued liabilities of \$0.5 million offset by a decrease in prepaid expenses and other current assets of \$0.1 million and non-cash items of \$0.2 million attributable to share-based compensation.

For the three months ended March 31, 2022, net cash used in operations was \$2.7 million and consisted of a net loss of \$4.0 million offset by a net change in operating assets and liabilities of \$1.2 million attributable to a decrease in prepaid expenses of \$0.6 million and a net increase in accounts payable and accrued liabilities of \$0.6 million and non-cash items of \$0.1 million attributable to share-based compensation.

Financing Activities

There were no cash flows from financing activities during the three months ended March 31, 2023 and 2022.

Off-Balance Sheet Arrangements

As of March 31, 2023, we did not have any off-balance sheet arrangements or relationships with unconsolidated entities or financial partnerships, such as entities often referred to as structured finance or special purpose entities.

Discussion of Critical Accounting Policies and Significant Judgements and Estimates

The preparation of financial statements in conformity with U.S. GAAP requires us to use judgment in making certain estimates and assumptions that affect the reported amounts of assets and liabilities at the date of the financial statements and the reported amounts of expenses during the reporting period. Critical accounting policies are those that are most important to the portrayal of our financial condition and results of operations and require difficult, subjective and complex judgments by management in order to make estimates about the effect of matters that are inherently uncertain. During the three months ended March 31, 2023, there were no significant changes to our critical accounting policies from those described in our annual financial statements for the year ended December 31, 2022, which we included in our 2022 Annual Report on Form 10-K.

JOBS Act

On April 5, 2012, the Jumpstart Our Business Startups Act of 2012, or JOBS Act, was signed into law. The JOBS Act contains provisions that, among other things, reduce certain reporting requirements for an “emerging growth company.” As an “emerging growth company,” we are electing to take advantage of the extended transition period afforded by the JOBS Act for the implementation of new or revised accounting standards.

Subject to certain conditions set forth in the JOBS Act, as an “emerging growth company,” we are not required to, among other things, (i) provide an auditor’s attestation report on our system of internal controls over financial reporting pursuant to Section 404, (ii) provide all of the compensation disclosure that may be required of non-emerging growth public companies under the Dodd-Frank Wall Street Reform and Consumer Protection Act, (iii) comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor’s report providing additional information about the audit and the financial statements (auditor discussion and analysis), and (iv) disclose certain executive compensation-related items such as the correlation between executive compensation and performance and comparisons of the chief executive officer’s compensation to median employee compensation. These exemptions will apply until the fifth anniversary of the completion of our IPO or until we no longer meet the requirements for being an “emerging growth company,” whichever occurs first.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

This item is not required for smaller reporting companies.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer and Senior Vice President of Finance, has evaluated the effectiveness of our disclosure controls and procedures (as such term is defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) as of the end of the period covered by this Quarterly Report on Form 10-Q. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost benefit relationship of possible controls and procedures.

Based upon that evaluation, our Chief Executive Officer and Senior Vice President of Finance concluded that, as of the end of the period covered by this Quarterly Report on Form 10-Q, our disclosure controls and procedures were effective in ensuring that the information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the rules, regulations and forms of the SEC, including ensuring that such material information is accumulated by and communicated to our management, including our Chief Executive Officer and Senior Vice President of Finance, as appropriate to allow timely decisions regarding required disclosure.

Changes in Internal Control Over Financial Reporting

There was no change in our internal control over financial reporting identified in connection with the evaluation required by Rule 13a-15(d) and 15d-15(f) of the Exchange Act that occurred during the quarter covered by this Quarterly Report on Form 10-Q that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II — OTHER INFORMATION

Item 1. Legal Proceedings

From time to time we may be involved in claims that arise during the ordinary course of business. Regardless of the outcome, litigation can be costly and time consuming, and it can divert management's attention from important business matters and initiatives, negatively impacting our overall operations. Although the results of litigation and claims cannot be predicted with certainty, we do not currently have any pending or ongoing litigation to which we are a party or to which our property is subject that we believe to be material.

Item 1A. Risk Factors

This item is not required for smaller reporting companies.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

None.

Item 3. Defaults Upon Senior Securities

None.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

None.

Item 6. Exhibits

See Exhibit Index.

EXHIBIT INDEX

Exhibit No.	Description
3.1	Certificate of Incorporation of Virios Therapeutics, Inc. (incorporated by reference herein from Exhibit 3.1 to the Company's Registration Statement on Form S-1, filed with the SEC on August 28, 2020)
3.2	Bylaws of Virios Therapeutics, Inc. (incorporated by reference herein from Exhibit 3.2 to the Company's Registration Statement on Form S-1, filed with the SEC on August 28, 2020)
4.1	Specimen Certificate evidencing shares of the Registrant's common stock (incorporated by reference herein from Exhibit 4.1 to the Company's Registration Statement on Form S-1, filed with the SEC on October 16, 2020)
31.1†	Certification of Chief Executive Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2†	Certification of Chief Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1†	Certification of Chief Executive Officer Pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2†	Certification of Chief Financial Officer Pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
101.INS†	XBRL Instance Document – the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document
101.SCH†	XBRL Taxonomy Extension Schema Document
101.CAL†	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF†	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB†	XBRL Taxonomy Extension Label Linkbase Document
101.PRE†	XBRL Taxonomy Extension Presentation Linkbase Document
104†	Cover Page Interactive Data File (formatted in Inline XBRL and contained in Exhibit 101)

† Filed herewith.

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, duly authorized.

Date: May 12, 2023

VIRIOS THERAPEUTICS, INC.

By: /s/ Greg Duncan
Name: Greg Duncan
Title: Chairman of the Board of Directors and Chief
Executive Officer
(Principal Executive Officer)

By: /s/ Angela Walsh
Name: Angela Walsh
Title: Senior Vice President of Finance, Corporate Secretary
and Treasurer
(Principal Financial and Accounting Officer)

CERTIFICATION OF CHIEF EXECUTIVE OFFICER

I, Greg Duncan, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Virios Therapeutics, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's Board of Directors:
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 12, 2023

/s/ Greg Duncan
Greg Duncan
Chairman of the Board of Directors
and Chief Executive Officer
(Principal Executive Officer)

CERTIFICATION OF CHIEF FINANCIAL OFFICER

I, Angela Walsh, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Virios Therapeutics, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's Board of Directors:
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 12, 2023

/s/ Angela Walsh

Angela Walsh

Senior Vice President of Finance, Corporate Secretary and
Treasurer

(Principal Financial and Accounting Officer)

Certification of CEO Pursuant to 18 U.S.C. Section 1350,

As Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

In connection with the quarterly report of Virios Therapeutics, Inc. (the "Company") on Form 10-Q for the period ended March 31, 2023 (the "Report"), as filed with the Securities and Exchange Commission on the date hereof, I, the undersigned, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, to the best of my knowledge, that:

- (1) The Report fully complies with the requirements of Section 13(a) or Section 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: May 12, 2023

/s/ Greg Duncan

Greg Duncan

Chairman of the Board and Chief Executive Officer
(Principal Executive Officer)

Certification of CFO Pursuant to 18 U.S.C. Section 1350,

As Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

In connection with the quarterly report of Virios Therapeutics, Inc. (the "Company") on Form 10-Q for the period ended March 31, 2023 (the "Report"), as filed with the Securities and Exchange Commission on the date hereof, I, the undersigned, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, to the best of my knowledge, that:

- (1) The Report fully complies with the requirements of Section 13(a) or Section 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: May 12, 2023

/s/ Angela Walsh

Angela Walsh

Senior Vice President of Finance, Corporate Secretary and
Treasurer

(Principal Financial and Accounting Officer)
