

---

---

**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 June 30, 2024

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)

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

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

As of August 7, 2024, there were 27,757,937 shares of the registrant's common stock outstanding.

---

---

**TABLE OF CONTENTS**

	<u>Page</u>	
<b><u>Part I</u></b>	<b><u>Financial Information</u></b>	
<u>Item 1.</u>	<u>Financial Statements</u>	3
	<u>Condensed Balance Sheets as of June 30, 2024 (Unaudited) and December 31, 2023</u>	3
	<u>Condensed Statements of Operations for the three and six months ended June 30, 2024 and 2023 (Unaudited)</u>	4
	<u>Condensed Statements of Stockholders' Equity for the three and six months ended June 30, 2024 and 2023 (Unaudited)</u>	5
	<u>Condensed Statements of Cash Flows for the six months ended June 30, 2024 and 2023 (Unaudited)</u>	6
	<u>Notes to Condensed Financial Statements (Unaudited)</u>	7
<u>Item 2.</u>	<u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	15
<u>Item 3.</u>	<u>Quantitative and Qualitative Disclosures about Market Risk</u>	20
<u>Item 4.</u>	<u>Controls and Procedures</u>	21
<b><u>Part II</u></b>	<b><u>Other Information</u></b>	
<u>Item 1.</u>	<u>Legal Proceedings</u>	21
<u>Item 1A.</u>	<u>Risk Factors</u>	21
<u>Item 2.</u>	<u>Unregistered Sales of Equity Securities and Use of Proceeds</u>	21
<u>Item 3.</u>	<u>Defaults Upon Senior Securities</u>	21
<u>Item 4.</u>	<u>Mine Safety Disclosures</u>	21
<u>Item 5.</u>	<u>Other Information</u>	22
<u>Item 6.</u>	<u>Exhibits</u>	22
<u>Exhibit Index</u>		
<u>Signatures</u>		

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

	June 30, 2024 (Unaudited)	December 31, 2023
<b>Assets</b>		
<b>Current assets:</b>		
Cash	\$ 3,020,183	\$ 3,316,946
Prepaid expenses and other current assets	615,706	848,496
Total current assets	3,635,889	4,165,442
Total assets	\$ 3,635,889	\$ 4,165,442
<b>Liabilities and stockholders' equity</b>		
<b>Current liabilities:</b>		
Accounts payable	\$ 217,762	\$ 111,913
Accrued expenses	282,314	246,635
Total current liabilities	500,076	358,548
Total liabilities	500,076	358,548
<b>Commitments and contingencies (Note 8)</b>		
<b>Stockholders' equity:</b>		
Common stock, \$0.0001 par value; 43,000,000 shares authorized; 27,950,888 and 27,757,937 shares issued and outstanding at June 30, 2024, respectively; and 19,450,888 and 19,257,937 shares issued and outstanding at December 31, 2023, respectively	2,776	1,926
Preferred stock, \$0.0001 par value; 2,000,000 shares authorized, no shares issued and outstanding at June 30, 2024 and December 31, 2023	—	—
Additional paid-in capital	67,242,537	65,573,300
Accumulated deficit	(63,810,390)	(61,469,222)
	3,434,923	4,106,004
Less: Treasury stock, 192,951 shares of common stock at cost	(299,110)	(299,110)
Total stockholders' equity	3,135,813	3,806,894
Total liabilities and stockholders' equity	\$ 3,635,889	\$ 4,165,442

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

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
Revenue	\$ —	\$ —	\$ —	\$ —
Operating expenses:				
Research and development	336,084	557,843	679,801	1,055,557
General and administrative expenses	733,740	919,374	1,704,124	1,978,947
Total operating expenses	<u>1,069,824</u>	<u>1,477,217</u>	<u>2,383,925</u>	<u>3,034,504</u>
Loss from operations	<u>(1,069,824)</u>	<u>(1,477,217)</u>	<u>(2,383,925)</u>	<u>(3,034,504)</u>
Other income:				
Interest income	19,991	36,313	42,757	76,736
Total other income	<u>19,991</u>	<u>36,313</u>	<u>42,757</u>	<u>76,736</u>
Loss before income taxes	<u>(1,049,833)</u>	<u>(1,440,904)</u>	<u>(2,341,168)</u>	<u>(2,957,768)</u>
Income tax provision	<u>—</u>	<u>—</u>	<u>—</u>	<u>—</u>
Net loss	<u>\$ (1,049,833)</u>	<u>\$ (1,440,904)</u>	<u>\$ (2,341,168)</u>	<u>\$ (2,957,768)</u>
Basic and diluted net loss per share	<u>\$ (0.05)</u>	<u>\$ (0.08)</u>	<u>\$ (0.11)</u>	<u>\$ (0.16)</u>
Weighted average number of shares outstanding – basic and diluted	<u>22,900,794</u>	<u>18,411,399</u>	<u>21,079,366</u>	<u>18,371,118</u>

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

**VIRIOS THERAPEUTICS, INC.**

**Condensed Statements of Changes of Stockholders' Equity  
(Unaudited)**

	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Treasury Stock	Total Stockholders' Equity
	Shares	Par				
<b>Balance,</b>						
<b>December 31, 2023</b>	19,257,937	\$ 1,926	\$ 65,573,300	\$ (61,469,222)	\$ (299,110)	\$ 3,806,894
Share-based compensation expense	—	—	138,969	—	—	138,969
Net loss	—	—	—	(1,291,335)	—	(1,291,335)
<b>Balance, March 31, 2024</b>	19,257,937	\$ 1,926	\$ 65,712,269	\$ (62,760,557)	\$ (299,110)	\$ 2,654,528
Proceeds from public offering of common stock, net of offering costs	8,500,000	850	1,381,320	—	—	1,382,170
Share-based compensation expense	—	—	148,948	—	—	148,948
Net loss	—	—	—	(1,049,833)	—	(1,049,833)
<b>Balance, June 30, 2024</b>	<b><u>27,757,937</u></b>	<b><u>\$ 2,776</u></b>	<b><u>\$ 67,242,537</u></b>	<b><u>\$ (63,810,390)</u></b>	<b><u>\$ (299,110)</u></b>	<b><u>\$ 3,135,813</u></b>
	Common Stock		Additional	Accumulated	Treasury	Total
	Shares	Par	Paid-In Capital	Deficit	Stock	Stockholders' Equity
<b>Balance,</b>						
<b>December 31, 2022</b>	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)
<b>Balance, March 31, 2023</b>	18,330,390	\$ 1,833	\$ 63,659,565	\$ (57,690,071)	\$ —	\$ 5,971,327
Exercise of warrants	467,625	47	292,208	—	—	292,255
Shares surrendered in cashless warrant exercises	(189,560)	(19)	—	—	(292,236)	(292,255)
Share-based compensation expense	—	—	161,664	—	—	161,664
Net loss	—	—	—	(1,440,904)	—	(1,440,904)
<b>Balance, June 30, 2023</b>	<b><u>18,608,455</u></b>	<b><u>\$ 1,861</u></b>	<b><u>\$ 64,113,437</u></b>	<b><u>\$ (59,130,975)</u></b>	<b><u>\$ (292,236)</u></b>	<b><u>\$ 4,692,087</u></b>

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

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

	Six Months Ended June 30,	
	2024	2023
<b>Cash flows from operating activities</b>		
Net loss	\$ (2,341,168)	\$ (2,957,768)
Adjustments to reconcile net loss to net cash used in operating activities:		
Share-based compensation expense	287,917	323,361
Changes in operating assets and liabilities:		
Decrease in prepaid expenses and other current assets	232,790	716,773
Increase (decrease) in accounts payable	35,622	(358,859)
Increase (decrease) in accrued expenses	35,679	(164,371)
Net cash used in operating activities	<u>(1,749,160)</u>	<u>(2,440,864)</u>
<b>Cash flows from financing activities</b>		
Proceeds from public offering of common stock, net of offering costs	1,452,397	—
Net cash provided by financing activities	<u>1,452,397</u>	<u>—</u>
Net decrease in cash	(296,763)	(2,440,864)
<b>Cash, beginning of period</b>	<b>3,316,946</b>	<b>7,030,992</b>
<b>Cash, end of period</b>	<b><u>\$ 3,020,183</u></b>	<b><u>\$ 4,590,128</u></b>
<b>Non-cash financing transactions:</b>		
Public offering costs included in accounts payable and accrued expenses	\$ 70,227	\$ —
Reduction in equity for shares surrendered in cashless warrant exercises	<u>\$ —</u>	<u>\$ 292,255</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 antiviral therapies to treat diseases associated with activation of previously dormant herpesviruses that trigger an abnormal immune response, such as fibromyalgia (“FM”) and Long-COVID (“LC”). Overactive immune response related to activation of tissue resident herpesvirus has been postulated to be a potential root cause of chronic illnesses such as FM, irritable bowel diseases, LC, chronic fatigue syndrome and other functional somatic syndromes, all of which are characterized by a waxing and waning manifestation of disease, often triggered by events which compromise the immune system. While not completely understood, there is general agreement in the medical community that activation of the herpesvirus is triggered by some form of environmental and/or health stressor. Our lead product candidates, IMC-1 and IMC-2, are novel, proprietary, fixed dose combinations of nucleoside analog, anti-herpes antivirals and the anti-inflammatory agent, celecoxib. IMC-1 is a novel combination of famciclovir and celecoxib intended to synergistically suppress herpesvirus activation and replication, with the end goal of reducing viral mediated disease burden. IMC-2 is a combination of valacyclovir and celecoxib that, like IMC-1, is intended to synergistically suppress herpesvirus activation and replication with a more specific activity against the Epstein-Barr virus (herpesvirus HHV-4). Both of these drug components are approved as independent treatments by the U.S. Food and Drug Administration (“FDA”) for other indications. IMC-1 and IMC-2 combine two specific mechanisms of action purposely designed to inhibit herpesvirus activation and replication, thereby keeping the herpesvirus in a latent (dormant) state or “down-regulating” the herpesvirus from a lytic (active) state back to latency. The famciclovir component of IMC-1 and the valacyclovir component of IMC-2 inhibit viral DNA replication. The celecoxib component of IMC-1 and IMC-2 inhibits cyclooxygenase-2 (COX-2) and to a lesser degree cyclooxygenase-1 (COX-1) enzymes, two proteins which are used by the herpesvirus to amplify or accelerate its own replication. These synergistic antiviral treatments represent first-in-class medicines intended specifically to inhibit both herpesvirus activation and subsequent replication, with the goal of keeping tissue resident herpesvirus in a latent state.

***Going Concern***

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 and six months ended June 30, 2024 and 2023, the Company incurred net losses of \$1,049,833 and \$2,341,168, respectively, and \$1,440,904 and \$2,957,768, respectively, and had net cash outflows used in operating activities for the six months ended June 30, 2024 and 2023 of \$1,749,160 and \$2,440,864, respectively. As of June 30, 2024, the Company had an accumulated deficit of \$63,810,390 and is expected to incur losses in the future as it continues its development activities.

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

[Table of Contents](#)

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 post-hoc analysis of the FORTRESS data, “new” FM research 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 the FDA is amenable to its proposed Phase 3 program, pending review of its final chronic toxicology program. In August 2023, the FDA informed the Company that its chronic toxicology program studies appear adequate to support the safety of IMC-1 at the dose proposed by the Company for chronic use.

In July 2023, the Company received positive data from an exploratory, open-label, proof of concept study in LC funded by an unrestricted grant provided to the Bateman Horne Center (“BHC”). BHC enrolled female patients diagnosed with LC illness, otherwise known as Post-Acute Sequelae of COVID-19 infection (“PASC”). Patients treated with a combination of valacyclovir and celecoxib (“Val/Cel”), as well as routine care, exhibited clinically and statistically significant improvements in fatigue, pain, and symptoms of autonomic dysfunction as well as ratings of general well-being related to LC when treated open-label for 14 weeks, as compared to a control cohort of female LC patients matched by age and length of illness and treated with routine care only. The statistically significant improvements in PASC symptoms and general health status were particularly encouraging given that the majority of patients in the study had been vaccinated for the COVID-19 virus and the mean duration of LC illness was two years for both the treated and control cohort prior to enrollment in this study. These encouraging results led to BHC requesting a second investigator initiated grant from the Company to assess Val/Cel under double-blind, placebo controlled conditions, with results from this ongoing trial expected in October 2024.

As of the issuance date of these financial statements, cash is not sufficient to fund operating expenses and capital requirements for at least the next 12 months. The Company will need to raise additional capital within the next six months to further advance clinical development and to commercially develop its product candidates. Accordingly, there is substantial doubt about the Company’s ability to continue as a going concern within one year after the issuance date.

Currently, the research and development activities for the remainder of this fiscal year include the continued funding of the grant to BHC for the completion of their double-blinded, placebo controlled investigator-sponsored study of LC with the combination of valacyclovir and celecoxib; continued prototype development of IMC-2 to be used for a proposed Phase 2 LC study; and continued salaries and benefits. The BHC study has completed enrollment and results are expected in October 2024.

The Company plans to raise additional capital to continue clinical development of and to commercially develop its product candidates. 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. As a result, the financial statements have been prepared on a going concern basis and do not include any adjustments to the amounts recognized or classifications of assets and liabilities should the Company be unable to continue as a going concern.

***Continued Nasdaq Listing***

As previously reported, on November 2, 2023, the Company received a letter from the Listing Qualifications Department of The Nasdaq Stock Market, LLC (“Nasdaq”) notifying the Company that, for the previous 30 consecutive business days, the bid price for the Company’s common stock had closed below the minimum \$1.00 per share requirement for continued listing on the Nasdaq (the “Minimum Bid Price Requirement”). The letter stated that the Company had 180 calendar days, or until April 30, 2024 to regain compliance such that the closing bid price for the Company’s common stock is at least \$1.00 for a minimum of 10 consecutive business days.

On May 1, 2024, the Company received another letter from Nasdaq informing it that the Company's common stock had failed to comply with the \$1.00 minimum bid price required for continued listing and, as a result, the Company's common stock continues to be subject to delisting. Following receipt of the letter, the Company requested a hearing with Nasdaq. On June 11, 2024, the Company received notice from Nasdaq that the Nasdaq Hearing Panel had granted the Company an exception until October 28, 2024 to regain compliance with the Minimum Bid Price Requirement. The Company prioritizes regaining compliance with the Minimum Bid Price Requirement through other measures before resorting to a reverse stock split. However, in the event the Company fails to achieve compliance with the Minimum Bid Price Requirement by October 11, 2024, it will be required to undertake a reverse stock split to regain compliance by the October 28, 2024 deadline. In the event the Company fails to regain compliance with the Minimum Bid Price Requirement by October 28, 2024, its securities will be delisted.

## **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/A for the year ended December 31, 2023 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, 2023 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 and six months ended June 30, 2024 and 2023, the Company had options to purchase 2,319,422 and 1,943,647 shares of common stock,

respectively, and warrants to purchase 193,875 and 204,875 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.

### **New Accounting Pronouncements Not Yet Adopted**

In December 2023, the Financial Accounting Standards Board (“FASB”) issued Accounting Standards Update (“ASU”) 2023-09, Improvements to Income Tax Disclosures (Topic 740), which establishes new income tax disclosure requirements in addition to modifying and eliminating certain existing requirements. The new guidance requires consistent categorization and greater disaggregation of information in the rate reconciliation, as well as further disaggregation of income taxes paid. This change is effective for annual periods beginning after December 15, 2024. This change will apply on a prospective basis to annual financial statements for periods beginning after the effective date. However, retrospective application in all prior periods presented is permitted. The Company is currently evaluating the impact of this ASU on its financial statements.

## **3 Prepaid Expenses and Other Current Assets**

Prepaid expenses and other current assets consist of the following:

	June 30, 2024	December 31, 2023
Prepaid insurance	\$ 352,204	\$ 702,352
Prepaid clinical research costs	160,636	133,819
Prepaid drug purchases	30,504	—
Prepaid accounting fees	30,450	—
Prepaid services	6,838	8,766
Other miscellaneous current assets	35,074	3,559
	<u>\$ 615,706</u>	<u>\$ 848,496</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:

	June 30, 2024	December 31, 2023
Accrued interest on preferred members' interests	\$ 188,085	\$ 188,085
Accrued vacation	55,922	—
Accrued clinical research costs	27,012	—
Accrued professional fees	11,070	27,550
Accrued director fees	—	31,000
Other miscellaneous accrued expenses	225	—
	<u>\$ 282,314</u>	<u>\$ 246,635</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.

### *At-the-market Offering*

On July 14, 2023, the Company entered into a Capital on Demand™ Sales Agreement (the "Sales Agreement") with JonesTrading Institutional Services LLC ("JonesTrading") relating to shares of common stock, par value \$0.0001 per share. In accordance with the terms of the Sales Agreement, the Company could offer and sell shares of common stock having an aggregate offering price of up to \$6,700,000 from time to time through JonesTrading, acting as sales agent or principal, in which is commonly referred to as an "at-the-market" ("ATM") program. On August 14, 2023, the Company announced a halt to sales under the Sales Agreement and on September 18, 2023, the Company announced the termination of the Sales Agreement with JonesTrading effective September 28, 2023. Before the termination of the Sales Agreement, the Company sold 641,873 shares of common stock under the ATM program at a weighted-average gross sales price of approximately \$2.11 per share and raised \$1,355,090 of gross proceeds. The total commissions and related legal and accounting fees were approximately \$198,650, and the Company received net proceeds of approximately \$1,156,440.

### *Public Offering*

On May 19, 2024, the Company entered into an agreement with Maxim Group LLC as placement agent in connection with the issuance and sale by the Company in a public offering of 8,500,000 shares of its common stock at a public offering price of \$0.20 per share (the "Offering"), pursuant to an effective shelf registration statement on Form S-3 (File No. 333-263700). The Offering closed on May 22, 2024, and the gross proceeds from the Offering were \$1,700,000. The net proceeds of the Offering were \$1,382,170 after deducting placement agent fees and offering expenses payable by the Company.

## 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 clinical research organizations. Gendreau's managing member is the Company's Chief Medical Officer ("CMO"). The Company may continue to contract the services of the CMO's spouse through Gendreau to serve as the Company's Medical Director and to perform certain activities in connection with the Company's ongoing clinical development of its product candidates. During the three and six months ended June 30, 2024 and 2023, the Company paid Gendreau \$0 and \$1,383, respectively, and \$34,807 and \$74,780, respectively, and had no accounts payable to Gendreau as of June 30, 2024 and December 31, 2023.

## 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. 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.

## 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 June 30, 2024, 35,578 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, 2023	1,651,147	\$ 4.78	8.08
Granted	375,775	0.36	—
Exercised	—	—	—
Outstanding at June 30, 2024	2,026,922	\$ 3.96	7.96
Exercisable at June 30, 2024	1,256,148	\$ 5.97	7.33

During the six months ended June 30, 2024, the Company granted certain individuals options to purchase 375,775 shares of the Company's common stock with an average exercise price of \$0.357 per share, contractual terms of 10 years and a vesting period of one year. The options had an aggregate grant date fair value of \$105,931 that was calculated using the Black-Scholes option-pricing model. Variables used in the Black-Scholes option-pricing model included: (1) discount rate of 4.2975% based on the daily par yield curve rates for U.S. Treasury obligations, (2) expected life of 5.5 years based on the simplified method (vesting plus contractual term divided by two), (3) expected volatility of 100.76% based on the average historical volatility of comparable companies' stock, (4) no expected dividends and (5) fair market value of the Company's stock of \$0.357 per share.

During the six months ended June 30, 2023, the Company granted certain individuals options to purchase 31,500 shares of the Company's common stock with an average exercise price of \$1.85 per share, contractual terms of 10 years and a vesting period of one year. The options had an aggregate grant date fair value of \$45,360 that was calculated using the Black-Scholes option-pricing model. Variables used in the Black-Scholes option-pricing model included: (1) discount rate of 3.89% based on the daily par yield curve rates for U.S. Treasury obligations, (2) expected life of 5.5 years based on the simplified method (vesting plus contractual term divided by two), (3) expected volatility of 98.66% based on the average historical volatility of comparable companies' stock, (4) no expected dividends and (5) fair market value of the Company's stock of \$1.85 per share.

As of June 30, 2024 the aggregate intrinsic value of options outstanding was \$0.

[Table of Contents](#)

The Company recognized share-based compensation expense related to stock options during the three and six months ended June 30, 2024 and 2023, of \$148,948 and \$287,917, respectively, and \$161,664 and \$323,361, respectively. The unrecognized compensation expense for stock options at June 30, 2024 was \$357,476.

**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 6.47 years. As of June 30, 2024, 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 June 30, 2024, 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 "Representative Warrants"). The Representative Warrants became 100% exercisable on March 18, 2023.

For the six months ended June 30, 2023, there were 467,625 Representative Warrants cashless exercised. As a result, 189,560 shares of common stock were surrendered at fair value to satisfy the exercise price of these warrants and 278,065 shares of common stock were issued. The surrendered shares are shown as treasury stock at a cost of \$292,236 in stockholders' equity for the three and six months ended June 30, 2023.

There were no warrant exercises for the six months ended June 30, 2024.

For the year ended December 31, 2023, there were 478,625 Representative Warrants cashless exercised. As a result, 192,951 shares of common stock were surrendered at fair value to satisfy the exercise price of these warrants and 285,674 shares of common stock were issued. The surrendered shares are shown as treasury stock at a cost of \$299,110 in stockholders' equity.

There is no unrecognized compensation expense for these awards as of June 30, 2024. 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, 2023	193,875	\$ 11.19	2.16
Granted	—	—	—
Outstanding at June 30, 2024	193,875	\$ 11.19	1.66
Exercisable at June 30, 2024	193,875	\$ 11.19	1.66

As of June 30, 2024, the aggregate intrinsic value of the warrants outstanding was \$0.

**10 Income Taxes**

As of December 31, 2023, the Company had U.S. federal and state net operating loss carryforwards of approximately \$26,496,000, which have an indefinite carryforward and Georgia and Florida state net operating loss carryforwards of approximately \$33,700,000 and \$851,000, respectively, which have a twenty-year carryforward and begin expiring in 2037.

As of June 30, 2024, 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 and six months ended June 30, 2024 and 2023. The Company does not have any material unrecognized tax benefits as of June 30, 2024.

## 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/A for the year ended December 31, 2023 filed with the Security and Exchange Commission ("SEC") on March 8, 2024 (the "2023 Amended Annual Report on Form 10-K/A"), under "Risk Factors", available on the SEC EDGAR website at [www.sec.gov](http://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 the 2023 Amended Annual Report on Form 10-K/A. 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 strategies to maintain the listing of our common stock;

[Table of Contents](#)

- our cash needs and financing plans;
- 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 activation of previously dormant herpesviruses that trigger an abnormal immune response such as fibromyalgia (“FM”) and Long-COVID (“LC”). Overactive immune response related to activation of tissue resident herpesvirus has been postulated to be a potential root cause of chronic illnesses such as FM, irritable bowel diseases, LC, chronic fatigue syndrome and other functional somatic syndromes, all of which are characterized by a waxing and waning manifestation of disease, often triggered by events which compromise the immune system. While not completely understood, there is general agreement in the medical community that activation of the herpesvirus is triggered by some form of environmental and/or health stressor. Our lead product candidates, IMC-1 and IMC-2, are novel, proprietary, fixed dose combinations of nucleoside analog, anti-herpes antivirals and the anti-inflammatory agent, celecoxib. IMC-1 is a novel combination of famciclovir and celecoxib intended to synergistically suppress herpesvirus activation and replication, with the end goal of reducing viral mediated disease burden. IMC-2 is a combination of valacyclovir and celecoxib that like IMC-1, is intended to synergistically suppress herpesvirus activation and replication with a more specific activity against the Epstein-Barr virus (herpesvirus HHV-4).

IMC-1 and IMC-2 combine two specific mechanisms of action purposely designed to inhibit herpesvirus activation and replication, thereby keeping the herpesvirus in a latent (dormant) state or “down-regulating” the herpesvirus from a lytic (active) state back to latency. The famciclovir component of IMC-1 and the valacyclovir component of IMC-2 inhibit viral DNA replication. The celecoxib component of IMC-1 and IMC-2 inhibits cyclooxygenase-2 (COX-2) and to a lesser degree cyclooxygenase-1 (COX-1) enzymes, two proteins which are used by the herpesvirus to amplify or accelerate its own replication. We are unaware of any other antivirals currently in development for the treatment of FM or related conditions. We believe this novel approach was a germane consideration in the 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.

Our novel combination antiviral approach (combining a viral DNA polymerase inhibitor + a COX-2 inhibitor) delivers clinical benefits for patients suffering from diseases with a suspected viral mediated catalyst, including FM and LC. We have received FDA feedback on our proposal to advance IMC-1 into Phase 3 development for the treatment of FM.

As previously reported, in 2023, the Company received positive data from an exploratory, open-label, proof of concept study in LC funded by an unrestricted grant provided to the Bateman Horne Center (“BHC”). BHC is a non-profit, interdisciplinary Center of Excellence advancing the diagnosis and treatment of chronic fatigue disorders including myalgic encephalomyelitis/chronic fatigue syndrome, FM, post-viral syndromes, and related comorbidities. BHC enrolled female patients diagnosed with LC illness, otherwise known as PASC. Patients treated with a combination of Val/Cel, as well as routine care, exhibited clinically and statistically significant improvements in fatigue, pain, and symptoms of autonomic dysfunction as well as ratings of general well-being related to LC when treated open-label for 14 weeks, as compared to a control cohort of female LC patients matched by age and length of illness and treated with routine care only. The statistically significant improvements in PASC symptoms and general health status were particularly encouraging given that the majority of patients in the study had been vaccinated for the COVID-19 virus and the mean duration of LC illness was two years for both the treated and control cohort prior to enrollment in this study. Based on these data, the Company met with the FDA to discuss opening an investigational new drug application to formally assess treatment of symptoms associated with PASC using IMC-2. In December 2023, we received FDA

feedback on our proposed Phase 2b study and project to commence this trial upon securing funding for the program. In addition, in August 2023, we signed an unrestricted grant research agreement with BHC to conduct a second, investigator-initiated, randomized, double-blinded, placebo-controlled study of LC with IMC-2. BHC has completed patient enrollment for this study and we expect results to be available in October 2024.

In order to underscore the management team's alignment as fellow shareholders and to emphasize our commitment to long-term success and value creation, effective March 1, 2024, all of our employees agreed to a 10% salary compensation reduction in exchange for future vesting stock options and all of our directors agreed to a 10% reduction in director fees.

In March 2024, we announced the publication of our global patent for IMC-2 covering antiviral treatment of LC. This will enable us to streamline the process for obtaining patent protection globally, representing a precursor to the national phase of patent examination by targeted countries across the globe.

We continue to explore complementary opportunities that will build shareholder value through strategic partnerships, collaborations or other transactions.

We have not generated revenues and have incurred losses since inception. Our net losses for the three and six months ended June 30, 2024 and 2023, were \$1,049,833 and \$2,341,168, respectively, and \$1,440,904 and \$2,957,768, respectively, and our accumulated deficit as of June 30, 2024 was \$63,810,390. 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 conflicts between Israel-Hamas and Ukraine-Russia, the effect of these wars 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.

#### **Recent Developments**

As previously reported, on November 2, 2023, the Company received a letter from the Listing Qualifications Department of The Nasdaq Stock Market, LLC ("Nasdaq") notifying the Company that, for the previous 30 consecutive business days, the bid price for the Company's common stock had closed below the minimum \$1.00 per share requirement for continued listing on the Nasdaq (the "Minimum Bid Price Requirement"). The letter stated that the Company had 180 calendar days, or until April 30, 2024 to regain compliance such that the closing bid price for the Company's common stock is at least \$1.00 for a minimum of 10 consecutive business days.

On May 1, 2024, the Company received another letter from Nasdaq informing it that the Company's common stock had failed to comply with the \$1.00 minimum bid price required for continued listing and, as a result, the Company's common stock continues to be subject to delisting. Following receipt of the letter, the Company requested a hearing with Nasdaq. On June 11, 2024, the Company received notice from Nasdaq that the Nasdaq Hearing Panel had granted the Company an exception until October 28, 2024 to regain compliance with the Minimum Bid Price Requirement. The Company prioritizes regaining compliance with the Minimum Bid Price Requirement through other measures before resorting to a reverse stock split. However, in the event the Company fails to achieve compliance with the Minimum Bid Price Requirement by October

11, 2024, it will be required to undertake a reverse stock split to regain compliance by the October 28, 2024 deadline. In the event the Company fails to regain compliance with the Minimum Bid Price Requirement by October 28, 2024, its securities will be delisted.

## Results of Operations

Below is a summary of the results of operations:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
<b>Operating expenses:</b>	(Unaudited)		(Unaudited)	
Research and development	\$ 336,084	\$ 557,843	\$ 679,801	\$ 1,055,557
General and administrative	733,740	919,374	1,704,124	1,978,947
Total operating expenses	<u>\$ 1,069,824</u>	<u>\$ 1,477,217</u>	<u>\$ 2,383,925</u>	<u>\$ 3,034,504</u>

### *Three and Six Months Ended June 30, 2024 and 2023*

#### **Research and Development Expenses**

Research and development expenses decreased by \$0.2 million and \$0.4 million for the three and six months ended June 30, 2024, respectively, compared to prior year periods. The decrease of \$0.2 million for the three months ended June 30, 2024 was primarily due to decreases in expenses for drug development and manufacturing. The decrease of \$0.4 million for the six months ended June 30, 2024 was primarily due to decreases in expenses for drug development and manufacturing of \$0.2 million, toxicology studies of \$0.1 million, regulatory consulting costs of \$0.1 million and clinical trial cost of \$0.1 million offset by an increase in costs associated with the grant to BHC for the second proof-of-concept study in LC of \$0.1 million.

#### **General and Administrative Expenses**

General and administrative expenses decreased by \$0.2 million and \$0.3 million for the three and six months ended June 30, 2024, respectively, compared to prior year periods. The decrease of \$0.2 million for the three months ended June 30, 2024 was primarily due to decreases in insurance expenses associated with being a public company of \$0.1 million and a decrease in accounting and legal fees of \$0.1 million. The decrease of \$0.3 million for the six months ended June 30, 2024 was primarily due to a decrease in insurance expenses associated with being a public company of \$0.2 million and a decrease in accounting and legal fees of \$0.1 million.

#### **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 June 30, 2024, our principal source of liquidity was our cash, which totaled \$3.0 million.

#### **Equity Financings**

On May 22, 2024, we closed a public offering raising gross proceeds of \$1.7 million and net proceeds of approximately \$1.4 million, after deducting placement agent fees and offering expenses. There were no equity financings during the six months ended June 30, 2023.

### **Debt Financings**

There were no debt financings during the six months ended June 30, 2024 and 2023. There was no debt outstanding at June 30, 2024 and December 31, 2023.

### **Future Capital Requirements**

We estimate our current cash of \$3.0 million at June 30, 2024 is not sufficient to fund operating expenses and capital requirements for at least the next 12 months. The Company will need to raise additional capital within the next six months to remain a going concern and to further advance clinical development and to commercially develop its product candidates. Currently, the research and development activities for the remainder of this fiscal year include the continued funding of the grant to BHC for the completion of their double-blinded, placebo controlled investigator-sponsored study of LC with the combination of valacyclovir and celecoxib; continued prototype development of IMC-2 to be used for a proposed Phase 2 LC study; and continued salaries and benefits.

We plan to raise additional capital to continue clinical development of our product candidates. We will need to finance our cash needs through public or private equity offerings, debt financings, collaboration and licensing arrangements or other financing alternatives. If 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. As a result, substantial doubt exists regarding our ability to continue as a going concern 12 months from the filing of this report on Form 10-Q. 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 six months June 30, 2024 and 2023, respectively:

	Six Months Ended June 30,	
	2024	2023
	(Unaudited)	
<b>Statement of Cash Flows Data:</b>		
Net cash (used in) provided by:		
Operating activities	\$ (1,749,160)	\$ (2,440,864)
Financing activities	1,452,397	—
Decrease in cash	<u>\$ (296,763)</u>	<u>\$ (2,440,864)</u>

### **Cash Flows for the Six Months Ended June 30, 2024 and 2023**

#### **Operating Activities**

For the six months ended June 30, 2024, net cash used in operations was \$1.7 million and consisted of a net loss of \$2.3 million offset by a net change in operating assets and liabilities of \$0.3 million attributable to an increase in accounts payable and accrued liabilities of \$0.1 million and a decrease in prepaid expenses and other current liabilities of \$0.2 million and non-cash items of \$0.3 million attributable to share-based compensation.

For the six months ended June 30, 2023, net cash used in operations was \$2.4 million and consisted of a net loss of \$2.9 million offset by a net change in operating assets and liabilities of \$0.2 million attributable to a decrease in accounts payable and accrued liabilities of \$0.5 million offset by a decrease in prepaid expenses of \$0.7 million and non-cash items of \$0.3 million attributable to share-based compensation.

### **Financing Activities**

Net cash provided by financing activities during the six months ended June 30, 2024 was \$1.4 million and was attributable to cash proceeds from our public offering in May 2024, net of placement agent fees and offering costs.

There were no cash flows from financing activities during the six months ended June 30, 2023. There were 467,625 common stock warrants that were cashless exercised during the period. As a result, 189,560 shares of common stock were surrendered at fair value to satisfy the exercise price of the warrants and 278,065 shares of common stock were issued.

### **Off-Balance Sheet Arrangements**

As of June 30, 2024, 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 six months ended June 30, 2024, there were no significant changes to our critical accounting policies from those described in our annual financial statements for the year ended December 31, 2023, which we included in our 2023 Amended Annual Report on Form 10-K/A.

### **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 last day of the fiscal year following 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**

**Rule 10b5-1 Trading Arrangements**

During the six months ended June 30, 2024, no director or “officer” (as defined in Rule 16a-1(f) under the Exchange Act) of the Company adopted or terminated any “Rule 10b5-1 trading arrangement” or “non-Rule 10b5-1 trading arrangement,” as each term is defined in Item 408(a) of Regulation S-K.

**Item 6. Exhibits**

See Exhibit Index.

## EXHIBIT INDEX

<b>Exhibit No.</b>	<b>Description</b>
3.1	<a href="#">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)</a>
3.2	<a href="#">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)</a>
4.1	<a href="#">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)</a>
10.1	<a href="#">Placement Agency Agreement, dated as of May 19, 2024, between Virios Therapeutics, Inc. and Maxim Group LLC (incorporated by reference herein from Exhibit 1.1 to the Current Report on Form 8-K, filed with the SEC on May 20, 2024)</a>
31.1†	<a href="#">Certification of Chief Executive Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002</a>
31.2†	<a href="#">Certification of Chief Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002</a>
32.1†	<a href="#">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</a>
32.2†	<a href="#">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</a>
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: August 9, 2024

**VIROS 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: August 9, 2024

/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: August 9, 2024

/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 June 30, 2024 (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: August 9, 2024

/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 June 30, 2024 (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: August 9, 2024

/s/ Angela Walsh

Angela Walsh

Senior Vice President of Finance, Corporate Secretary and  
Treasurer

(Principal Financial and Accounting Officer)

---