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

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**FORM 10-Q**

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(Mark One)

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

For the quarterly period ended September 30, 2022

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

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**Virios Therapeutics, Inc.**

(Exact name of registrant as specified in its charter)

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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)

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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 November 11, 2022, 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)**

	September 30, 2022 (Unaudited)	December 31, 2021
<b>Assets</b>		
<b>Current assets:</b>		
Cash	\$ 9,788,397	\$ 14,008,184
Prepaid expenses and other current assets	1,069,580	1,768,503
Total current assets	10,857,977	15,776,687
Total assets	\$ 10,857,977	\$ 15,776,687
<b>Liabilities and stockholders' equity</b>		
<b>Current liabilities:</b>		
Accounts payable	\$ 679,416	\$ 353,863
Accrued expenses	953,726	921,760
Total current liabilities	1,633,142	1,275,623
Total liabilities	1,633,142	1,275,623
<b>Commitments and contingencies (Note 8)</b>		
<b>Stockholders' equity:</b>		
Common stock, \$0.0001 par value; 43,000,000 shares authorized, 18,330,390 shares issued and outstanding at September 30, 2022 and 8,330,390 shares issued and outstanding at December 31, 2021	1,833	833
Preferred stock, \$0.0001 par value; 2,000,000 shares authorized, no shares issued and outstanding at September 30, 2022 and December 31, 2021	—	—
Additional paid-in capital	63,351,653	58,425,604
Accumulated deficit	(54,128,651)	(43,925,373)
Total stockholders' equity	9,224,835	14,501,064
Total liabilities and stockholders' equity	\$ 10,857,977	\$ 15,776,687

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

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Revenue	\$ —	\$ —	\$ —	\$ —
Operating expenses:				
Research and development	1,622,374	2,961,122	6,797,914	7,877,281
General and administrative expenses	969,946	1,150,369	3,427,679	3,576,101
Total operating expenses	2,592,320	4,111,491	10,225,593	11,453,382
Loss from operations	(2,592,320)	(4,111,491)	(10,225,593)	(11,453,382)
Other income:				
Interest income	16,605	1,509	22,315	4,405
Total other income	16,605	1,509	22,315	4,405
Loss before income taxes	(2,575,715)	(4,109,982)	(10,203,278)	(11,448,977)
Income tax provision	—	—	—	—
Net loss	\$ (2,575,715)	\$ (4,109,982)	\$ (10,203,278)	\$ (11,448,977)
Basic and diluted net loss per share	\$ (0.28)	\$ (0.49)	\$ (1.18)	\$ (1.37)
Weighted average number of shares outstanding – basic and diluted	9,199,955	8,330,390	8,623,430	8,328,946

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

**VIROS THERAPEUTICS, INC.**

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

	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Par			
<b>Balance, December 31, 2021</b>	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)
<b>Balance, March 31, 2022</b>	8,330,390	\$ 833	\$ 58,557,510	\$ (47,885,681)	\$ 10,672,662
Share-based compensation expense	—	—	136,957	—	136,957
Net loss	—	—	—	(3,667,255)	(3,667,255)
<b>Balance, June 30, 2022</b>	8,330,390	\$ 833	\$ 58,694,467	\$ (51,552,936)	\$ 7,142,364
Proceeds from public offering of common stock, net of offering costs	10,000,000	1,000	4,492,920	—	4,493,920
Share-based compensation expense	—	—	164,266	—	164,266
Net loss	—	—	—	(2,575,715)	(2,575,715)
<b>Balance, September 30, 2022</b>	<b>18,330,390</b>	<b>\$ 1,833</b>	<b>\$ 63,351,653</b>	<b>\$ (54,128,651)</b>	<b>\$ 9,224,835</b>

	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Par			
<b>Balance, December 31, 2020</b>	8,305,075	\$ 830	\$ 57,905,164	\$ (27,965,105)	\$ 29,940,889
Share-based compensation expense	—	—	24,825	—	24,825
Exercise of warrants	25,315	3	197,559	—	197,562
Net loss	—	—	—	(3,056,033)	(3,056,033)
<b>Balance, March 31, 2021</b>	8,330,390	\$ 833	\$ 58,127,548	\$ (31,021,138)	\$ 27,107,243
Share-based compensation expense	—	—	34,244	—	34,244
Net loss	—	—	—	(4,282,962)	(4,282,962)
<b>Balance, June 30, 2021</b>	8,330,390	\$ 833	\$ 58,161,792	\$ (35,304,100)	\$ 22,858,525
Share-based compensation expense	—	—	131,906	—	131,906
Net loss	—	—	—	(4,109,982)	(4,109,982)
<b>Balance, September 30, 2021</b>	<b>8,330,390</b>	<b>\$ 833</b>	<b>\$ 58,293,698</b>	<b>\$ (39,414,082)</b>	<b>\$ 18,880,449</b>

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

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

	Nine Months Ended September 30,	
	2022	2021
<b>Cash flows from operating activities</b>		
Net loss	\$ (10,203,278)	\$ (11,448,977)
Adjustments to reconcile net loss to net cash used in operating activities:		
Share-based compensation expense	433,129	190,975
Changes in operating assets and liabilities:		
Decrease in prepaid expenses and other current assets	698,923	756,453
Increase in accounts payable	291,873	399,640
Decrease in accrued expenses	(17,034)	(30,696)
Decrease in accrued salaries	—	(378,833)
Net cash used in operating activities	<u>(8,796,387)</u>	<u>(10,511,438)</u>
<b>Cash flows from financing activities</b>		
Proceeds from the exercise of warrants	—	197,562
Payment of offering costs for initial public offering	—	(295,166)
Proceeds from public offering of common stock, net of offering costs	4,576,600	—
Net cash provided by (used in) financing activities	<u>4,576,600</u>	<u>(97,604)</u>
Net decrease in cash	<u>(4,219,787)</u>	<u>(10,609,042)</u>
<b>Cash, beginning of period</b>	<b>14,008,184</b>	<b>29,795,366</b>
<b>Cash, end of period</b>	<b>\$ <u>9,788,397</u></b>	<b>\$ <u>19,186,324</u></b>
<b>Supplemental disclosure of non-cash financing transactions:</b>		
Public offering costs included in accounts payable and accrued expenses	<u>\$ 82,680</u>	<u>\$ —</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 (the “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 (the “Firm Shares”) 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). Pursuant to the Underwriting Agreement, the Company also granted to the Underwriter (1) a 45-day overallotment option to purchase up to 1,500,000 shares (the “Option Shares”) at the public offer price and (2) warrants to purchase up to 5% of the Firm Shares and Option Shares purchased in the Offering at an exercise price of \$0.625 per share, which is 125% of the public offering price. The public offering closed on September 22, 2022 and the gross proceeds from the public offering were \$5.0 million. The net proceeds of the public offering were approximately \$4.5 million after deducting underwriting discounts, commissions and offering expenses payable by the Company, including offering costs of \$82,680 accrued and unpaid as of September 30, 2022. As of September 30, 2022, the Underwriter had not exercised the overallotment option. The overallotment option expired unexercised on November 3, 2022.

#### **Material Uncertainty**

Since its founding, the Company has been engaged in organizational activities, including raising capital, and research and development activities. The Company has not generated any revenues to date. As such, the Company is subject to all of the risks associated with any clinical-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 does not expect to generate positive cash flows from operating activities in the near future.

For the three and nine months ended September 30, 2022 and 2021, the Company incurred net losses of \$2,575,715 and \$10,203,278, respectively, and \$4,109,982 and \$11,448,977, respectively, and had net cash

outflows used in operating activities for the nine months ended September 30, 2022 and 2021 of \$8,796,387 and \$10,511,438, respectively. As of September 30, 2022, the Company had an accumulated deficit of \$54,128,651 and is expected to incur losses in the future as it continues its development activities. Since its inception, the Company has funded its losses primarily through issuance of members' interests, convertible debt instruments and issuance of equity securities.

The Company intends on financing its future development activities and its working capital needs largely on the issuance and sale of equity securities. As of the date these financial statements are issued, based on reasonable estimates, current cash is sufficient to fund foreseeable operating expenses and obligations for at least 12 months. The Company will need to raise additional capital within the next 13 to 15 months to further advance clinical development and to commercially develop its product candidates. There is no assurance that such financing 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, 2021 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, 2021 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 nine months ended September 30, 2022 and 2021, the Company had options to purchase 1,304,147 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. In addition, for the three and nine months ended September 30, 2022, the Company's Underwriter held an overallotment option to purchase up to 1,500,000 shares of common stock outstanding that was anti-dilutive. The overallotment option expired unexercised on November 3, 2022.

### **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**

On November 1, 2022, 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.

In accordance with Nasdaq Rules, the Company has until May 1, 2023 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. The Company may be eligible for an additional 180 calendar day compliance period. At that time, the Company may appeal the Staff's delisting determination to a Nasdaq Hearings Panel. The Company intends to monitor the closing bid price of its common stock and may, if appropriate, consider available options to regain compliance.

### **Recent Accounting Pronouncements**

In December 2019, the FASB issued ASU 2019-12, *Income Taxes (ASC 740): Simplifying the Accounting for Income Taxes*. The standard eliminates the need for an organization to analyze whether the following apply in a given period: (1) the exception to the incremental approach for intraperiod tax allocation; (2) the exceptions to accounting for basis differences when there are ownership changes in foreign investments; and (3) the exception in interim periods income tax accounting for year-to-date losses that exceed anticipated losses. The ASU also is designed to improve financial statement preparers' application of income tax-related guidance and simplify U.S. GAAP for (1) franchise taxes that are partially based on income, (2) transactions with a government that result in a step-up in the tax basis of goodwill, (3) separate financial statements of legal entities that are not subject to tax, (4) enacted changes in tax laws in interim periods and (5) certain income tax accounting for employee stock ownership plans and affordable housing projects. The amendments in this update are effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2021. The adoption of this standard did not have a material impact on the Company's financial statements.

### 3 Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets consist of the following:

	September 30, 2022	December 31, 2021
Prepaid insurance	\$ 318,901	\$ 1,329,385
Prepaid clinical research costs	717,482	422,591
Prepaid services	19,520	15,664
Other miscellaneous current assets	13,677	863
	<u>\$ 1,069,580</u>	<u>\$ 1,768,503</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:

	September 30, 2022	December 31, 2021
Accrued compensation	\$ 261,347	\$ 532,678
Accrued interest on preferred members' interests	188,085	188,085
Accrued clinical research costs	379,721	138,522
Accrued director fees	15,500	31,000
Accrued professional fees	103,575	24,100
Other miscellaneous accrued expenses	5,498	7,375
	<u>\$ 953,726</u>	<u>\$ 921,760</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.

#### ***Overallotment Option***

Pursuant to the Underwriting Agreement and in connection with the Offering, the Company granted the Underwriter a 45-day overallotment option to purchase up to 1,500,000 shares at the public offer price. As of September 30, 2022, the overallotment option (the "Underwriters Option") had not been exercised by the Underwriter. The Underwriters Option is not compensation, but a financial instrument paid for in the transaction, therefore, the Underwriters Option was evaluated to determine if it should be treated as an embedded or a separate free-standing financial instrument (i.e., to determine whether it needed to be bifurcated and accounted for as a separate financial instrument). As the rights and obligations related to the Option Shares are separate from the rights and obligations related to the Firm Shares and the exercise or termination of the Underwriters Option does not impact the Firm Shares under the Underwriting Agreement, the Company determined that the Underwriters Option is considered a free-standing financial instrument. The

Company then considered the classification of the Underwriters Option as a liability or equity under ASC 480, *Distinguishing Liability from Equity*, and it was determined that the Underwriters Option did not meet the criteria for liability classification as the underlying instrument is not mandatorily redeemable, it does not require the Company to buy back its shares, it is fixed in nature and its value is tied to the Company's common stock share price. As an equity-linked contract, the Company then considered applicability of ASC 815-40, *Derivatives and Hedging*, and determined that the Underwriters Option is a derivative that meets all the criteria and qualifies for equity classification without recurring remeasurement to fair value.

The Underwriters Option had an aggregate grant date fair value of \$93,827 that was calculated using the Black-Scholes option-pricing model. Variables used in the Black-Scholes option pricing model include: (1) discount rate of 2.82% based on the daily yield curve rates for U.S. Treasury obligations, (2) expected life of 45 days, (3) expected volatility of 88.6% based on the average historical volatility of comparable companies' stock, (4) no expected dividends and (5) fair market value (Offering price) of the Company's stock of \$0.50 per share.

The Underwriters Option expired unexercised on November 3, 2022.

## 7 Related Parties

The Company uses Gendreau Consulting, LLC, a consulting firm ("Gendreau"), for drug development, clinical trial design, implementation and execution of contracted activities with the clinical research organization. Gendreau's managing member became the Company's Chief Medical Officer ("CMO") effective January 1, 2021. The Company has and will continue to contract the services of the CMO's spouse through the firm to perform certain activities in connection with the Company's ongoing clinical trial in FM. During the three and nine months ended September 30, 2022 and 2021, the Company paid Gendreau \$94,907 and \$283,844, respectively, and \$91,335 and \$233,616, respectively, and had accounts payable of \$27,052 and \$24,840 to Gendreau as of September 30, 2022 and December 31, 2021, 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 September 30, 2022, 1,050,853 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, 2021	749,147	\$ 9.03	9.09
Granted	262,500	4.23	—
Outstanding at September 30, 2022	1,011,647	\$ 7.79	8.71
Exercisable at September 30, 2022	650,681	\$ 9.35	8.31

During the nine months ended September 30, 2022, the Company granted certain individuals options to purchase 262,500 shares of the Company's common stock with an average exercise price of \$4.23 per share, contractual terms of 10 years and vesting periods ranging from 100% after one year to 33.333% after one year and 66.667% in 24 monthly installments, thereafter. The options had an aggregate grant date fair value of \$839,350 that was calculated using the Black-Scholes option-pricing model. Variables used in the Black-Scholes option-pricing model included: (1) discount rates ranging from 3.145% to 3.15% based on the daily par yield curve rates for U.S. Treasury obligations, (2) expected lives ranging from 5.5 years to 6.0 years based on the simplified method (vesting plus contractual term divided by two), (3) expected volatility ranging from 90.62% to 91.86% 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 \$4.23 per share.

As of September 30, 2022 the aggregate intrinsic value of options outstanding was \$0.

The Company recognized share-based compensation expense related to stock options during the three and nine months ended September 30, 2022 and 2021, of \$164,266 and \$433,129, respectively, and \$131,906 and \$190,975, respectively. The unrecognized compensation expense for stock options at September 30, 2022 was \$1,233,623.

#### ***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 8.22 years. As of September 30, 2022, 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 September 30, 2022, 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 have a five-year contractual term and are not exercisable prior to March 18, 2023. The Company has accounted for the warrants as equity-based awards issued to a non-employee. The warrants had an aggregate grant date fair value of \$178,462 that was calculated using the Black-Scholes option-pricing model. Variables used in the Black-Scholes option pricing model include: (1) discount rate of 3.69% based on the daily yield curve rates for U.S. Treasury obligations, (2) expected life of 5.0 years, (3) expected volatility of 96.46% based on the average historical volatility of comparable companies' stock, (4) no expected dividends and (5) fair market value (Offering price) of the Company's stock of \$0.50 per share.

There was no net impact recognized by the Company in the accompanying financial statements as the warrants were equity-based awards issued for services rendered by the Underwriter for the Offering that was offset by the Company recognizing the fair value of the warrants as a direct and incremental costs associated with the Offering by reducing paid-in capital for the same amount. There is no unrecognized compensation

expense for these awards as of September 30, 2022. 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, 2021	172,500	\$ 12.50	3.96
Granted	500,000	0.63	—
Outstanding at September 30, 2022	<u>672,500</u>	<u>\$ 3.67</u>	<u>4.52</u>
Exercisable at September 30, 2022	<u>172,500</u>	<u>\$ 12.50</u>	<u>3.21</u>

As of September 30, 2022, the aggregate intrinsic value of the warrants outstanding was \$0.

## 10 Income Taxes

As the Company was incorporated in December 2020, all tax years of the Company remain open to examination by tax authorities. As of December 31, 2021, the Company had U.S. federal and state net operating loss carryforwards of approximately \$18,266,000, which have an indefinite carryforward.

As of September 30, 2022, 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 nine months ended September 30, 2022 and 2021. The Company does not have any material unrecognized tax benefits as of September 30, 2022.

## 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, 2021 filed with the Security and Exchange Commission ("SEC") on March 18, 2022 (the "2021 Annual Report on Form 10-K"), 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 our Annual Report on Form 10-K filed with the SEC on March 18, 2022. 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;

- 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, irritable bowel disease (“IBS”), chronic fatigue syndrome and other functional somatic syndromes, all of which are characterized by a waxing and waning manifestation of disease symptoms. 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 tablet 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.

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. 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 is providing 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 development candidate, IMC-2, 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 the first half of 2023.

In September 2022, we announced the top line results from our FORTRESS Phase 2b study. 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, analysis of the data suggests a bifurcation of response based on the timing of patient enrollment in the FORTRESS trial. During the first half of the trial (June 2021 to November 2021), for the patients who were enrolled ( $n=208$ ) when the Delta variant of COVID-19 was the dominant strain in the U.S., full vaccination rates were below 50% and some form of quarantining was still in place in most geographies, IMC-1 demonstrated no improvement versus placebo-treated patients. Conversely, during the second half of the trial (November 2021 to April 2022), for the patients who were enrolled ( $n=214$ ) when vaccination rates improved, the less severe Omicron variant of COVID-19 became the dominant U.S. strain and quarantining restrictions were less, IMC-1-treated patients demonstrated a statistically significant improvement on the primary pain reduction endpoint ( $p=0.03$ ) at Week 14, as well as a statistically significant improvement in the key secondary PROMIS Fatigue assessment ( $p=0.006$ ) and the

Fibromyalgia Impact Questionnaire-Revised (FIQR) symptoms domain score ( $p=0.015$ ). The Virios management team believes the likelihood of such a differential response based on the timing of patient enrollment is highly unlikely due to chance or a random occurrence. Based on our continued belief in the potential of IMC-1 to treat patients in the FM community, the team made the decision to raise additional capital to better understand the factors driving this bifurcated clinical response to IMC-1 in the FORTRESS trial, with the goal of exploring viable paths forward for IMC-1's continued development.

Importantly, IMC-1 displayed a first in class safety profile with excellent tolerability and with only 4.6% of IMC-1 treated patients dropping out due to adverse events, as compared with 8.1% of placebo treated patients. No adverse event category in the IMC-1 group exceeded a 4% rate with the exception of COVID-19 infection. Overall discontinuations were 18.5% in the IMC-1 treated group versus 23% in the placebo treated group. Patients in the FORTRESS trial were randomized one-to-one to either IMC-1 or placebo and patient background demographics and baseline pain scores were well matched.

As we continue to analyze the FORTRESS data with our third-party statisticians, it is becoming increasingly clear that in addition to potential COVID pandemic related impacts, a number of factors differed between those patients recruited during the first half versus the second half of the FORTRESS study. For example, the majority of patients enrolled in the first half of the study were patients who have been previously treated and/or were participants in prior FM clinical trials. In contrast, over 50% of the FORTRESS subjects enrolled later in the study were new to FM clinical trials, including naïve patients who had never been treated with FM specific medications previously. Based on this demographic understanding, the team assessed how "new" patients versus "prior" treated/studied patients responded to IMC-1 treatment, in both cases versus placebo. Encouragingly, new patients demonstrated statistically significant improvement on the primary endpoint of reduction in FM related pain versus placebo, across the entire study population. In addition, newly treated IMC-1 patients demonstrated statistical improvement in key secondary measures, including reduction in fatigue, improvement on the FIQR total scores and reductions in depression and anxiety scores, which may be important given depression is associated with the increased rate of suicide amongst FM patients. Conversely, prior patients, including those enrolled in prior clinical trials, did not show improvement in FM related pain when compared with placebo. In addition to the difference in response between prior and naïve patients, we also see differences within these groups based on timing of recruitment. We believe that recruitment early in the FORTRESS study was much more strongly impacted by pandemic related issues, as opposed to those recruited in 2022. Factors such as staffing levels, training, rates of absenteeism, and supply related issues all improved at the site level as we moved into 2022.

Based on the analysis of the FORTRESS data, we believe focusing the forward development of IMC-1 on new FM patients represents a viable and manageable path forward. The Company plans to request an FDA meeting in November 2022 and hopes to garner FDA feedback during the first half of 2023, with the goal of agreeing on the most appropriate next steps in advancing IMC-1 development as a treatment for FM. If alignment can be reached, management will consider raising additional capital to fund future research and/or seek a partner to develop or co-develop IMC-1 as a treatment for FM.

Approximately 50% of the patients targeted for inclusion in the Company's exploratory trial featuring the combination of valacyclovir and celecoxib as a treatment for sequelae associated with Long-COVID have been enrolled in this trial. The Company expects this trial to reach full enrollment in Q4 2022, with top line results projected for the first half of 2023.

We may face future business disruption and related risks resulting from the ongoing outbreak of COVID-19 or from another pandemic, epidemic or outbreak of an infectious disease, any of which could have a significant impact on our business or delay the development of our drug candidates including the enrollment or completion of our proposed clinical trials. Future emergence of widespread health emergencies or pandemics could lead to new quarantines, business shutdowns, disruptions to the healthcare system and overall economic instability. If suppliers, clinical research organizations, clinical trial sites, regulators, consultants and other third parties with whom we conduct business were to experience shutdowns or other business disruptions, our ability to enroll patients and conduct clinical trials in the manner and on the timelines



presently planned could be materially and negatively impacted. In addition, 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 current conflict between Ukraine and Russia 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 September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
<b>Operating expenses:</b>	(Unaudited)		(Unaudited)	
Research and development	\$ 1,622,374	\$ 2,961,122	\$ 6,797,914	\$ 7,877,281
General and administrative	969,946	1,150,369	3,427,679	3,576,101
Total operating expenses	<u>\$ 2,592,320</u>	<u>\$ 4,111,491</u>	<u>\$ 10,225,593</u>	<u>\$ 11,453,382</u>

### *Three and Nine Months Ended September 30, 2022 and 2021*

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

Research and development expenses decreased by \$1.4 million and \$1.1 million for the three and nine months ended September 30, 2022, respectively, compared to the prior year periods. The decrease of \$1.4 million for the three months ended September 30, 2022 was due to decreases in expenses for clinical trials of \$0.9 million, toxicology studies of \$0.4 million and drug development and manufacturing costs of \$0.1 million. The decrease of \$1.1 million for the nine months ended September 30, 2022 was due to decreases in expenses for toxicology studies of \$1.2 million, drug development and manufacturing costs of \$0.3 million and research consulting of \$0.1 million offset by an increase in clinical trials costs of \$0.4 million and salaries and related costs of \$0.1 million.

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

General and administrative expenses decreased by \$0.2 million and \$0.1 million for the three and nine months ended September 30, 2022, respectively, compared to the prior year periods. The decrease of \$0.2 million for the three months ended September 30, 2022 was primarily due to decreases in expenses for salaries and related costs. For the nine months ended September 30, 2022, the decrease of \$0.1 million was attributable to a decrease in accounting and legal fees.

#### **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 September 30, 2022, our principal source of liquidity was our cash, which totaled \$9.8 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, including non-cash financing activities of \$0.1 million for legal and accounting fees that are in accounts payable and accrued liabilities as of September 30, 2022. There were no equity financings during the nine months ended September 30, 2021.

### **Debt Financings**

There were no debt financings during the nine months ended September 30, 2022 and 2021. There was no debt outstanding at September 30, 2022 and December 31, 2021.

### **Future Capital Requirements**

We estimate our current cash of \$9.8 million at September 30, 2022 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 2023 other than the on-going grant to BHC for the investigator-sponsored study in Long-COVID that is fully funded. We completed our FORTRESS study in September 2022 and plan to request an FDA meeting in November 2022 in order to garner FDA feedback during the first half of Q1 2023 on the most appropriate next steps in advancing IMC-1 development as a treatment for FM. We will need to raise additional capital before we exhaust our current cash in order to continue to fund our research and development, including – subject to consultation with the FDA - any plans for a Phase 3 trial 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 nine months ended September 30, 2022 and 2021, respectively:

	Nine Months Ended September 30,	
	2022	2021
	(Unaudited)	
<b>Statement of Cash Flows Data:</b>		
Net cash used in:		
Operating activities	\$ (8,796,387)	\$ (10,511,438)
Financing activities	4,576,600	(97,604)
Decrease in cash	<u>\$ (4,219,787)</u>	<u>\$ (10,609,042)</u>

### **Cash Flows for the Nine Months Ended September 30, 2022 and 2021**

#### **Operating Activities**

For the nine months ended September 30, 2022, net cash used in operations was \$8.8 million and consisted of a net loss of \$10.2 million offset by a net change in operating assets and liabilities of \$1.0 million

attributable to a decrease in prepaid expenses of \$0.7 million and a net increase in accounts payable and accrued liabilities of \$0.3 million and non-cash items of \$0.4 million attributable to share-based compensation.

For the nine months ended September 30, 2021, net cash used in operations was \$10.5 million and consisted of a net loss of \$11.4 million offset by a net change in operating assets and liabilities of \$0.7 million attributable to a decrease in prepaid expenses and non-cash items of \$0.2 million attributable to share-based compensation.

#### **Financing Activities**

Net cash provided by financing activities during the nine months ended September 30, 2022 was \$4.6 million and was attributable to proceeds from our underwritten public offering, net of deal costs and other expenses but excluding non-cash financing activities of \$0.1 million for legal and accounting fees that are in accounts payable and accrued liabilities as of September 30, 2022.

Net cash used in financing activities during the nine months ended September 30, 2021 was \$0.1 million and was attributable to proceeds from the exercise of warrants to purchase our common stock of \$0.2 million offset by payment of initial public offering ("IPO") costs of \$0.3 million.

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

As of September 30, 2022, 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 nine months ended September 30, 2022, there were no significant changes to our critical accounting policies from those described in our annual financial statements for the year ended December 31, 2021, which we included in our Annual Report on Form 10-K for the year ended December 31, 2021.

#### **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 and the material weakness in our internal control over financial reporting discussed below, 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**

<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>
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: November 14, 2022

**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: November 14, 2022

/s/ Greg Duncan  
\_\_\_\_\_  
Greg Duncan  
Chairman of the Board of Directors,  
and Chief Executive Officer

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## 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: November 14, 2022

/s/ Angela Walsh  
Angela Walsh  
Senior Vice President of Finance and Corporate Secretary  
(Principal Financial Officer)

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**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 September 30, 2022 (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: November 14, 2022

/s/ Greg Duncan  
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Greg Duncan  
Chairman of the Board,  
and Chief Executive Officer

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**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 September 30, 2022 (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: November 14, 2022

/s/ Angela Walsh

Angela Walsh

Senior Vice President of Finance and Corporate Secretary  
(Principal Financial Officer)

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