# UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

		FORM 1	10-Q		
(Mark One) ⊠	QUARTERLY REPORT PU 1934	JRSUANT TO SECTION	13 OR 15(d)	OF THE SECURITIES EXC	HANGE ACT OF
		For the quarterly period ende	ed September 3	0, 2021	
	TRANSITION REPORT PU 1934	JRSUANT TO SECTION	13 OR 15(d)	OF THE SECURITIES EXC	HANGE ACT OF
	Fo	r the transition period from _ Commission File Num			
		/irios Therapo (Exact name of registrant as	•		
	Delaware (State or other jurisdiction of incorporation or organization)			85-4314201 (I.R.S. Employer Identification Number)	
		44 Milton Av Alpharetta, GA (Address of Principal Ex	A 30009		
		(866) 620-8 (Registrant's telepho			
the preceding 12				13 or 15(d) of the Securities Excha- orts), and (2) has been subject to su	
	232.405 of this chapter) during the			le required to be submitted pursuan d that the registrant was required to	
	company. See the definitions of "la			-accelerated filer, a smaller reporting reporting company," and "emerging	
Large accelerated		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

Trading symbol VIRI Name of Exchange on which registered Nasdaq Capital Market

As of November 11, 2021, there were 8,330,390 shares of the registrant's common stock outstanding.

revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. □

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

<u>Title of Each Class</u>

Common Stock, par value \$0.0001 per share

## **TABLE OF CONTENTS**

		Page
Part I	Financial Information	
Item 1.	Financial Statements	3
	Condensed Balance Sheets as of September 30, 2021 (Unaudited) and December 31, 2020	3
	Condensed Statements of Operations for the three and nine months ended September 30, 2021 and 2020 (Unaudited)	4
	Condensed Statements of Changes in Members' Deficit/Stockholders' Equity for the three and nine months ended September 30, 2021 and 2020 (Unaudited)	5
	Condensed Statements of Cash Flows for the nine months ended September 30, 2021 and 2020 (Unaudited).	6
	Notes to Condensed Financial Statements (Unaudited)	7
Item 2.	Management's Discussion and Analysis of Financial Condition and Results of Operations	15
Item 3.	Quantitative and Qualitative Disclosures about Market Risk	19
Item 4.	Controls and Procedures	20
Part II	Other Information	
Item 1.	<u>Legal Proceedings</u>	21
Item 1A.	Risk Factors	21
Item 2.	Unregistered Sales of Equity Securities and Use of Proceeds	21
Item 3.	Defaults Upon Senior Securities	21
Item 4.	Mine Safety Disclosures	21
Item 5.	Other Information	21
Item 6.	<u>Exhibits</u>	21
Exhibit Index		
<u>Signatures</u>		

## PART I —FINANCIAL INFORMATION

## Item 1. Financial Statements

## VIRIOS THERAPEUTICS, INC.

## Condensed Balance Sheets (Unaudited)

	_	September 30, 2021 (Unaudited)	 December 31, 2020
Assets			
Current assets:			
Cash	\$	19,186,324	\$ 29,795,366
Prepaid expenses and other current assets		920,912	 1,677,365
Total current assets		20,107,236	31,472,731
Total assets	\$	20,107,236	\$ 31,472,731
Liabilities and stockholders' equity	-		
Current liabilities:			
Accounts payable	\$	483,496	\$ 368,905
Accrued expenses		743,291	784,104
Accrued salaries			378,833
Total current liabilities		1,226,787	1,531,842
Total liabilities		1,226,787	1,531,842
Commitments and contingencies (Note 10)			
Stockholders' equity:			
Common stock, \$0.0001 par value; 43,000,000 shares authorized, 8,330,390 and 8,305,075 shares issued and outstanding at September 30, 2021 and December 31,			
2020, respectively		833	830
Preferred stock, \$0.0001 par value; 2,000,000 shares authorized, no shares issued and outstanding at September 30, 2021 and December 31, 2020		_	_
Additional paid-in capital		58,293,698	57,905,164
Accumulated deficit		(39,414,082)	(27,965,105)
Total stockholders' equity		18,880,449	29,940,889
Total liabilities and stockholders' equity	\$	20,107,236	\$ 31,472,731

## Condensed Statements of Operations (Unaudited)

		Three Mor Septem				Nine Montl Septemb		
		2021		2020		2021		2020
Revenue	\$	_	\$	_	\$	_	\$	_
Operating expenses:								
Research and development		2,961,122		108,086		7,877,281		161,944
General and administrative expenses		1,150,369		2,554,724		3,576,101		3,421,798
Total operating expenses	_	4,111,491	_	2,662,810		11,453,382		3,583,742
Total operating or periods	_	.,,			_		_	2,222,1
Loss from operations		(4,111,491)		(2,662,810)		(11,453,382)		(3,583,742)
	_	(1,111,101)	_	(=,00=,0.0)	_	(11,100,002)		(0,000,: .=)
Other income (expense):								
Interest income (expense), net		1,509		(104,440)		4,405		(304,646)
Other income		.,		43,221		.,		43,221
Total other income (expense)	-	1,509	_	(61,219)		4,405	_	(261,425)
Total other income (expense)	_	1,505	_	(01,219)	_	4,403	_	(201,423)
Loss before income taxes		(4,109,982)		(2,724,029)		(11,448,977)		(3,845,167)
		(4,109,902)		(2,724,029)		(11,440,377)		(3,043,107)
Income tax provision (benefit)	_						_	
Netters	¢	(4 400 000)	r.	(2.724.020)	•	(44 440 077)	¢.	(2.045.167)
Net loss	<b>P</b>	(4,109,982)	\$	(2,724,029)	\$	(11,448,977)	\$	(3,845,167)
Basic and diluted net loss per share (1)	\$	(0.49)	\$	(0.56)	\$	(1.37)	\$	(0.80)
Weighted average number of shares outstanding – basic	;							
and diluted (1)		8,330,390		4,832,494		8,328,946		4,832,494

<sup>(1)</sup> The net loss per share and weighted average shares outstanding for the three and nine months ended September 30, 2020 have been computed to reflect the corporate conversion that occurred on December 16, 2020 prior to the Company's initial public offering (the "IPO").

# Condensed Statements of Changes of Members' Deficit/Shareholders' Equity (Unaudited)

	Common Sto	ck Par	ı	Additional Paid-In Capital	Accumulated Deficit	;	Total Stockholders' Equity
Balance, December 31, 2020	8,305,075 \$	830	\$	57,905,164	\$ (27,965,105)	\$	29,940,889
Share-based compensation expense	_	_		24,825	<u> </u>		24,825
Exercise of warrants	25,315	3		197,559	_		197,562
Net loss	_	_		_	(3,056,033)		(3,056,033)
Balance, March 31, 2021	8,330,390	833		58,127,548	(31,021,138)		27,107,243
Share-based compensation expense	_	_		34,244	<u> </u>		34,244
Net loss	_	_		_	(4,282,962)		(4,282,962)
Balance, June 30, 2021	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)
Balance, September 30, 2021	8,330,390 \$	833	\$	58,293,698	\$ (39,414,082)	\$	18,880,449
	Voting Member Interest	s'		Non-voting Members' Interests	Accumulated Deficit		Total Members' Deficit
Balance, December 31, 2019	Member	s'	\$	Members'	\$ 	\$	Members'
Balance, December 31, 2019 Net loss	Member Interest	s'	\$	Members' Interests	\$ Deficit	\$	Members' Deficit
	Member Interest	s'	\$	Members' Interests	\$ Deficit (17,618,710)	\$	Members' Deficit (5,017,509)
Net loss	Member Interest	s' s — —	\$	Members' Interests 12,601,201	\$ Deficit (17,618,710) (466,553)	\$	Members' Deficit (5,017,509) (466,553)
Net loss Balance, March 31, 2020	Member Interest \$	s' s — —	\$	Members' Interests 12,601,201 — 12,601,201	\$ Deficit (17,618,710) (466,553)	\$	Members' Deficit (5,017,509) (466,553)
Net loss <b>Balance, March 31, 2020</b> Membership conversion to voting interests	Member Interest \$	s' s — — — ,201	\$	Members' Interests 12,601,201 — 12,601,201	\$ Deficit (17,618,710) (466,553) (18,085,263) —	\$	Members' Deficit (5,017,509) (466,553) (5,484,062)
Net loss <b>Balance, March 31, 2020</b> Membership conversion to voting interests  Net loss	Member Interest	s' s — — ,201 — ,201	\$	Members' Interests 12,601,201 — 12,601,201	\$ Deficit (17,618,710) (466,553) (18,085,263) — (654,585)	\$	Members' Deficit (5,017,509) (466,553) (5,484,062) (654,585)
Net loss  Balance, March 31, 2020  Membership conversion to voting interests Net loss  Balance, June 30, 2020	Member Interest \$ 12,601	s' s — ,201 — ,201 ,800	\$	Members' Interests 12,601,201 — 12,601,201	\$ Deficit (17,618,710) (466,553) (18,085,263) — (654,585)	\$	Members' Deficit (5,017,509) (466,553) (5,484,062) (654,585) (6,138,647)
Net loss  Balance, March 31, 2020  Membership conversion to voting interests Net loss  Balance, June 30, 2020  Conversion of convertible promissory notes	12,601 12,601 1,637	s' s — ,201 — ,201 ,800	\$	Members' Interests 12,601,201 — 12,601,201	\$ Deficit (17,618,710) (466,553) (18,085,263) — (654,585)	\$	Members' Deficit (5,017,509) (466,553) (5,484,062) (6,138,647) 1,637,800

## Condensed Statements of Cash Flows (Unaudited)

		nded 0,		
		2021		2020
Cash flows from operating activities				
Net loss	\$	(11,448,977)	\$	(3,845,167)
Adjustments to reconcile net loss to net cash used in operating activities:				
Amortization of issuance costs		_		42,071
Recovery of uncollectable receivables		_		(15,020)
Gain on vendor concession		_		(43,221)
Share-based and equity compensation expense		190,975		2,000,000
Changes in operating assets and liabilities:				
Decrease (increase) in prepaid expenses and other current assets		756,453		(39,478)
Increase in accounts payable		399,640		156,139
(Decrease) increase in accrued expenses		(30,696)		180,129
Decrease in accrued salaries		(378,833)		(44,287)
Net cash used in operating activities		(10,511,438)		(1,608,834)
Cash flows from financing activities				
Proceeds from issuance of convertible promissory notes		_		1,994,133
Proceeds from the exercise of warrants		197,562		_
Payment of issuance costs for promissory notes		_		(57,971)
Payment of offering costs for initial public offering		(295,166)		(137,630)
Net cash (used in) provided by financing activities		(97,604)		1,798,532
Net (decrease) increase in cash		(10,609,042)		189,698
Cash, beginning of period		29,795,366		309,384
Cash, end of period	\$	19,186,324	\$	499,082
	<u> </u>		÷	
Supplemental cash flow disclosures:				
Cash paid for interest	\$	_	\$	3,000
Non-cash financing transactions:				
Public offering costs included in accounts payable and accrued expenses	\$	_	\$	87,648
Conversion of convertible promissory notes and accrued interest into membership				
interests	\$	_	\$	1,637,800

## 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 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 Herpes Simplex Virus-1 ("HSV-1") 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 HSV-1 activation and replication, thereby keeping HSV-1 in a latent or dormant state. The famciclovir component of IMC-1 inhibits viral DNA replication, thus inhibiting upregulation of the HSV-1 virus. The celecoxib component of IMC-1 inhibits cyclooxegenase-2 ("COX-2") enzymes used by HSV-1 to amplify or accelerate its own replication. IMC-1's synergistic antiviral mechanism represents a first-in-class medicine designed specifically to inhibit both HSV-1 activation and subsequent HSV-1 replication, with the goal of keeping tissue resident HSV-1 tissue in a latent state.

#### Corporate Conversion

On December 16, 2020, immediately prior to the effectiveness of the Company's registration statement on Form S-1, the Company converted into a Delaware corporation pursuant to a statutory conversion, and changed its name from Virios Therapeutics, LLC to Virios Therapeutics, Inc. As a result of the Corporate Conversion, all of the membership interests held by the existing members of Virios Therapeutics, LLC converted into shares of common stock of Virios Therapeutics, Inc. The purpose of the Corporate Conversion was to reorganize the corporate structure so that the entity offering common stock to the public was a corporation rather than a limited liability company.

## Initial Public Offering

On December 16, 2020, the Company announced the pricing of its IPO of 3,000,000 shares of its common stock at an initial offering price of \$10.00 per share. In addition, the Company granted the underwriters a 45-day option to purchase up to an additional 450,000 shares of common stock at the public offering price. The Company's common stock commenced trading on the Nasdaq Capital Markets Exchange on December 17, 2020 under the ticker symbol "VIRI". The IPO closed on December 21, 2020 at which time the underwriters exercised their option to purchase 450,000 additional shares of the Company's common stock bringing the total number of shares of common stock sold by the Company to 3,450,000 shares. The gross proceeds from the IPO, including proceeds from the exercise of the underwriters' option to purchase additional shares, were \$34.5 million. The net proceeds of the IPO were approximately \$31.1 million after deducting underwriting discounts, commissions and offering expenses paid by the Company. In conjunction with the IPO, the Company granted the underwriters warrants to purchase 172,500 shares of the Company's common stock at an exercise price of \$12.50 per share, which is 125% of the initial offering price.

#### 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, 2021 and 2020, the Company incurred net losses of \$4,109,982 and \$11,448,977, respectively, and \$2,724,029 and \$3,845,167, respectively, and had net cash outflows used in operating activities for the nine months ended September 30, 2021 and 2020 of \$10,511,438 and \$1,608,834, respectively. As of September 30, 2021, the Company had an accumulated deficit of approximately \$39.4 million 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.

As of the date these financial statements are issued, management believes that the net proceeds from the Company's IPO in December 2020 and the current cash are sufficient to fund operations and capital requirements for at least the next 12 months. The Company will need to raise additional capital to complete 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, 2020 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, 2020 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 Update ("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 Income (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 nine months ended September 30, 2021, the Company had options to purchase 1,041,647 shares of common stock and warrants to purchase 172,500 shares of common stock outstanding that were anti-dilutive. There were no anti-dilutive securities outstanding for the nine months ended September 30, 2020, as the Company was a LLC at that time.

EPS and weighted-average shares outstanding for the three and nine month period ending September 30, 2020 have been computed to give effect to the Corporate Conversion that occurred on December 16, 2020 prior to the Company's IPO. In conjunction with the Corporate Conversion, all of the Company's outstanding members' equity automatically converted into shares of common stock, based on the relative rights of the Company's pre-IPO equity holders.

### **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 Events

The Company's management reviewed all material events through the date that the financial statements were issued for subsequent event disclosure consideration and determined there were none.

#### 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 Company is continuing to evaluate the impacts that ASU 2019-12 will have on its financial statements.

In August 2020, the FASB issued ASU 2020-06, *Debt - Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging - Contracts in Entity's Own Equity (Subtopic 815-40)*. ASU 2020-06 eliminates the beneficial conversion and cash conversion accounting models for convertible instruments. It also amends the accounting for certain contracts in an entity's own equity that are currently accounted for as derivatives because of specific settlement provisions. The new guidance also modifies how particular convertible instruments and certain contracts that may be settled in cash or shares impact the diluted EPS computation. ASU 2020-06 is effective for fiscal years beginning after December 15, 2023, including interim periods within those annual periods. Early adoption is permitted, but no earlier than fiscal years beginning after December 15, 2020, including interim periods within those annual periods. ASU 2020-06 allows companies to adopt the guidance through either a modified retrospective method of transition or a fully retrospective method of transition. The Company is continuing to evaluate the impacts that ASU 2020-06 will have on its financial statements.

## 3 Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets consist of the following:

	Se	ptember 30, 2021	D	ecember 31, 2020
Prepaid insurance	\$	383,569	\$	1,586,042
Prepaid clinical research costs		495,428		85,270
Prepaid services		20,833		5,729
Other miscellaneous current assets		21,082		324
	\$	920,912	\$	1,677,365

#### 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, as discussed in Note 7 below. 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, 2021			cember 31, 2020
Accrued compensation	\$	459,060	\$	573,479
Accrued interest on preferred members' interests		188,085		188,085
Accrued professional fees		33,314		8,992
Accrued director fees		46,500		_
Other		16,332		13,548
	\$	743,291	\$	784,104

## 6 Convertible Promissory Notes, Net

On March 31, 2020, June 10, 2020, and August 21, 2020, the Company completed and closed its first, second, and third round, respectively, of its fifth offering subscription (the "Fifth Offering") for the issuance of convertible promissory notes (collectively with the promissory notes of the Fourth Offering, the "Notes") for convertible preferred membership interests and received \$1,162,500, \$706,633, and \$125,000, respectively.

Notes with an aggregate principal amount of \$4,204,133 were outstanding as of September 30, 2020, after giving effect to the July 2020 maturity of Notes sold in the first round of its fourth offering subscription (the "Fourth Offering"). The outstanding Notes matured and converted into membership interests prior to or in conjunction with the Corporate Conversion, at which time all of the Company's outstanding membership interests converted into shares of common stock.

The Notes bore interest at 8% per annum, with a maximum term of 18 months. The Notes were unsecured obligations and did not contain any financial covenants or restrictions on the payments to members, the incurrence of indebtedness, or the issuance or repurchase of securities by the Company.

The Company recognized interest expense related to the Notes as follows:

		ree Months September				hs Ended ber 30,
	20	021	2020	2021		2020
Fourth offering	\$	<del>-</del> \$	50,940	\$ <b>—</b>	\$	197,324
Fifth offering		_	38,750	_		65,010
	\$	<del></del> \$	89,690	<del>\$ —</del>	\$	262,334

#### 7 Members' Deficit

On May 1, 2020, the Company adopted the Amended Operating Agreement. The Amended Operating Agreement changed the Company's classes of membership from two classes (voting and non-voting) to one class of membership and gave the Company's board of directors (the "Board") the right to make all decisions concerning the business, affairs and properties of the Company. Under the Amended Operating Agreement, the members had the right to vote on the dissolution at termination of the Company, the removal of existing directors, the appointment of new directors and any plan of conversion or merger. As such, at September 30, 2020, all members had the same rights, privileges and powers and were considered as voting members' interests.

In July 2020, the Board approved two issuances of membership interests equal to an aggregate of 5.0% of the Company's total membership interests to the Company's founder. These issuances were considered equity-based compensation award grants that do not have any future service conditions. As a result, all compensation expense associated with such issuances were recognized upon issuance. In order to determine the amount of compensation associated with such issuances, the Company utilized recent observable prices under the terms of its Fifth Offering. For the three and nine months ended September 30, 2020, the Company recognized \$2,000,000 of compensation expense for these issuances.

In July 2020, the Notes issued in the first round of the Fourth Offering matured. As a result, the outstanding principle amount of \$1,465,000 plus accrued interest of \$172,800 converted into membership interest based on the carrying value of the convertible debt with no gain or loss recognized. Accrued interest of \$3,000 was paid in cash.

In conjunction with the Corporate Conversion, all of the Company's outstanding membership interests converted into shares of common stock.

#### 8 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.

#### 9 Related Parties

The Company uses Gendreau Consulting, LLC, a consulting firm ("Gendreau"), for drug development, clinical trial design, and planning, implementation and execution of contracted activities with the clinical research organization. Gendreau's managing member 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, 2021 and 2020, the Company paid Gendreau \$91,335 and \$233,616, respectively, and \$0 and \$450, respectively, and had accounts payable of \$29,443 and \$7,916 to Gendreau as of September 30, 2021 and December 31, 2020, respectively.

#### 10 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.

On August 26, 2021, Torreya Capital LLC ("Torreya") filed a demand for arbitration with the American Arbitration Association in New York, New York in connection with a claim by Torreya that it is entitled to a transaction fee of \$1,035,000 in connection with the Company's IPO, plus the costs of arbitration, based on services Torreya alleges it provided for the Company as a financial advisor to the Company prior to the IPO. The Company believes that Torreya's demand is baseless and without merit. The Company intends to defend itself vigorously.

#### **Employment Agreement and Deferred Compensation Plan**

On February 1, 2021, the Company entered into an employment agreement with its Director of Clinical Operations (the "Director"). Per the terms of the agreement, the Director is entitled to receive a cash bonus with a target amount of no less than 20% of the Director's then-current base salary. The bonus is subject to achievement of annual bonus metrics set by the Board. The employment agreement will continue in effect until terminated by either party pursuant to its terms. If the termination of the agreement is related to a change of control, the Director is entitled to receive a change of control termination payment equal to 50% of the Director's then-current base salary and 50% of the bonus for the year in which the termination occurs.

#### 11 Share-based compensation

#### Equity Incentive Plan

The Company's 2020 Equity Incentive Plan (the "Plan") became effective on December 21, 2020. As of September 30, 2021, 63,353 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	-	Veighted Average Exercise Price	Average Remaining Contractual Term (Years)
Outstanding at December 31, 2020	519,163	\$	10.00	9.98
Granted	229,984		6.85	_
Outstanding at September 30, 2021	749,147	\$_	9.03	9.35
Exercisable at September 30, 2021	530,977	\$	9.92	9.24

As of September 30, 2021 the aggregate intrinsic value of options outstanding was \$0.

During the nine months ended September 30, 2021, the Company granted certain individuals options to purchase 299,984 shares of the Company's common stock with an average exercise price of \$6.85 per share, contractual terms of 10 years and vesting periods ranging from 8.33% monthly over one year to 33.333% vesting after one year with the remaining 66.667% vesting in 24 monthly installments, thereafter. The options had an aggregate grant date fair value of \$1,150,284 as calculated using the Black-Scholes option-pricing model. Variables used in the Black-Scholes option pricing model include: (1) discount rates ranging from 0.505% to 1.075% based on the daily yield curve rates for U.S. Treasury obligations, (2) expected lives ranging from 5.27 years to 6.0 years based on the simplified method (vesting plus contractual term divided by two), (3) expected volatility ranging from 89.04% to 90.16% based on the average historical volatility of comparable companies' stock, (4) no expected dividends and (5) fair market value of the Company's stock ranging from \$6.50 to \$7.51 per share.

The Company recognized share-based compensation expense related to stock options of \$131,906 and \$190,975, respectively, during the three and nine months ended September 30, 2021. The unrecognized compensation expense for stock options at September 30, 2021 was \$959,309.

#### 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 9.22 years. As of September 30, 2021, 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, 2021, 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 have a remaining contractual term of 4.21 years and are not exercisable prior to December 21, 2021. As of September 30, 2021, the aggregate intrinsic value of the warrants outstanding was \$0.

## 12 Income Taxes

Prior to the Company's Corporate Conversion, the Company operated as an Alabama limited liability company that passed through income and losses to its members. As a result, the Company was not subject to any U.S. federal or U.S. state income taxes as the related tax consequences are reported by the individual members. Upon the Corporate Conversion, the Company converted to a Delaware corporation and is now subject to filing U.S. federal and various U.S. state income tax returns. 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, 2020, we had U.S. federal and state net operating loss carryforwards of approximately \$2,316,000, which have an indefinite carryforward.

As of September 30, 2021, 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

## Table of Contents

allowance offset the income tax benefit related to the pre-tax loss for the three and nine months ended September 30, 2021. The Company does not have any material unrecognized tax benefits as of September 30, 2021.

#### 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, 2020 filed with the Security and Exchange Commission ("SEC") on March 23, 2021 (the "2020 Annual Report on Form 10-K"), under "Risk Factors", available on the SEC EDGAR results and twww.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 23, 2021. 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 Simplex Virus-1 ("HSV-1") has been postulated to be a potential root cause of chronic illnesses such as FM, irritable bowel disease ("IBS"), chronic fatigue syndrome and functional somatic syndrome, all of which are characterized by a waxing and waning manifestation of disease. While not completely understood, there is general agreement in the medical community that activation of HSV-1 is triggered by some form of environmental and/or health stressor. Our lead product candidate, which we have named IMC-1, is a novel, proprietary, fixed dose combination of famciclovir and celecoxib. IMC-1 represents a novel combination antiviral therapy designed to synergistically suppress HSV-1 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 HSV-1 activation and replication, thereby keeping HSV-1 in a latent (dormant) state or "down-regulating" HSV-1 from a lytic (active) state back to latency. The famciclovir component of IMC-1 inhibits viral DNA replication and thus inhibits upregulation of the HSV-1 virus. The celecoxib component of IMC-1 inhibits cyclooxegenase-2 ("COX-2") and to a lesser degree cyclooxegenase-1 ("COX-1"), enzymes used by HSV-1 to amplify or accelerate its own replication. We are unaware of any other antivirals in development for the treatment of FM specifically used to inhibit both HSV-1 activation and subsequent HSV-1 replication, with the goal of keeping tissue resident HSV-1 tissue in a latent state. 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.

In June 2021, we announced the dosing of our first patient in our Phase 2b clinical trial in FM, known as the FORTRESS study (an abbreviation of and stands for Fibromyalgia Outcome Research Trial Evaluating Synergistic Suppression of HSV-1). We are presently enrolling 460 female FM patients aged 18 to 65, who will be randomized 1-to-1 either to IMC-1 or placebo, all of whom have been diagnosed using the 2016 American College of Rheumatology diagnostic criteria for FM. The primary endpoint for our FORTRESS study will focus on reduction in pain over time. Pain reduction will be measured daily by the numeric rating scale ("NRS") 24-hour recall scale via an electronic diary that the patient will use at home. In addition to assessing the FM patients pain reduction, we will also assess IMC-1's ability to improve symptoms of fatigue, sleep disturbance, improvements in overall global health status and improved patient function. We have enrolled approximately 40% of patients thus far in the trial and project top line results from FORTRESS in Q3 2022. In parallel to the FORTRESS study, our chronic toxicology studies in two species are progressing as planned. These studies are required by regulatory authorities to support chronic administration of IMC-1 in forward clinical development. The results of our chronic toxicology program are timed to complete in Q3 2022 as well.

In September 2021, the United States and Trademark Office ("UPTO") granted us patent exclusivity on our valacyclovir-celecoxib combination drug candidate to 2033. The addition of this patent brings our total patent portfolio to 21 issued patents, consisting of 13 issued U.S. patents and 8 issued foreign patents.

We recognize the emergence of widespread health emergencies or pandemics, such as the COVID-19 pandemic, could have a significant impact on our business or delay the enrollment or completion of our proposed clinical trials, including the FORTRESS study. 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 our clinical trial in the manner and on the timelines presently planned could be materially and negatively impacted. Although we currently believe our FORTRESS study will be completed on time, we cannot guarantee that the COVID-19 pandemic or any other widespread health emergencies will not have a material impact on our business or the timely completion of our clinical trials.

#### **Results of Operations**

Below is a summary of the results of operations:

	Three Months Ended September 30,				Nine Mont Septem	nths Ended nber 30,	
	2021		2020		2021		2020
Operating expenses:	(Unaudited)				(Unaudited)		
Research and development	\$ 2,961,122	\$	108,086	\$	7,877,281	\$	161,944
General and administrative	1,150,369		2,554,724		3,576,101		3,421,798
Total operating expenses	\$ 4,111,491	\$	2,662,810	\$	11,453,382	\$	3,583,742

#### Three and Nine Months Ended September 30, 2021 and 2020

#### Research and Development Expenses

Research and development expenses increased by \$2.9 million and \$7.7 million for the three and nine months ended September 30, 2021, respectively, compared to the same periods in 2020. The increase of \$2.9 million for the three months ended September 30, 2021 was due to increases in expenses for our clinical trial of \$2.1 million, toxicology studies of \$0.4 million, salaries and related costs of \$0.2 million and drug development and manufacturing costs of \$0.2 million. The increase of \$7.7 million for the nine months ended September 30, 2021 was due to increases in clinical trial expenses of \$4.7 million, toxicology studies of \$1.6 million, salaries and related costs of \$0.7 million, drug development and manufacturing costs of \$0.6 million and consulting costs of \$0.1 million.

#### General and Administrative Expenses

General and administrative expenses decreased by \$1.4 million for the three months ended September 30, 2021 and increased by \$0.1 million for the nine months ended September 30, 2021 compared to the same periods in 2020. The decrease of \$1.4 million for the three months ended September 30, 2021 was due to a decrease of \$1.9 million in salaries, benefits and compensation costs offset by an increase of \$0.5 million in costs associated with being a public company. The increase of \$0.1 million for the nine months ended September 30, 2021 was due to an increase in legal and accounting fees of \$0.2 million and other costs associated with being a public company of \$1.7 million offset by a decrease of \$1.8 million in expenses for salaries, benefits and compensation costs. The significant year over year decrease in compensation expense for the three and nine months ended September 30, 2021 was attributable to the recognition in 2020 of \$2.0 million in equity-based compensation for the issuances of membership interests to the Company's founder.

## **Liquidity and Capital Resources**

Since our inception, we have financed our operations through a public offering 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, 2021, our principal source of liquidity was our cash, which totaled \$19.2 million.

The COVID-19 global pandemic has resulted in travel restrictions and temporary shut-downs of both essential and non-essential businesses in the U.S. and abroad. To date, the pandemic has not had a material impact on our operations as our employees are effectively working from home. FM research and development activities have largely progressed as planned during the pandemic. However, due to many uncertainties, we are unable to estimate the effect of the COVID-19 pandemic on our business, if any, in the future.

#### **Equity Financings**

We closed our IPO on December 21, 2020, raising gross proceeds of \$34.5 million and net proceeds of approximately \$31.1 million, after deducting underwriting discounts, commissions and offering expenses.

#### **Debt Financings**

In 2020, we issued an aggregate of \$2.0 million principal amount of convertible promissory notes. At the Corporate Conversion, these notes converted to common interests at the price of \$400,000 per 1% of common interests. There was no debt outstanding at December 31, 2020.

#### **Future Capital Requirements**

We estimate our current cash of \$19.2 million at September 30, 2021 is sufficient to fund our operations and capital requirements for at least the next twelve months. We believe that these available funds will be sufficient to complete our FORTRESS study and commence the planning of our Phase 3 study in FM for IMC-1. However, it is difficult to predict our spending for our product candidate prior to obtaining regulatory approval from the FDA. Moreover, changing circumstances may cause us to expend cash significantly faster than we currently anticipate, and we may need to spend more cash than currently expected because of circumstances beyond our control. For more information regarding material commitments and contingencies, please refer to Note 10 in the unaudited financial statements above.

To the extent that our capital resources are insufficient to meet our future operating and capital requirements, we will need to finance our cash needs through public or private equity offerings, debt financings, collaboration and licensing arrangements or other financing alternatives. We have no committed external sources of funds. Additional equity or debt financing or collaboration and licensing arrangements may not be available on acceptable terms, if at all.

#### Summary of Cash Flows

The following table summarizes our cash flows for the nine months ended September 30, 2021 and 2020, respectively:

	Nine Months Ended September 30,			
	 2021 2020			
	(Unau	dited	1)	
Statement of Cash Flows Data:				
Net cash (used in) provided by:				
Operating activities	\$ (10,511,438)	\$	(1,608,834)	
Financing activities	(97,604)		1,798,532	
(Decrease) increase in cash	\$ (10,609,042)	\$	189,698	

#### Cash Flows for the Nine Months Ended September 30, 2021 and 2020

#### **Operating Activities**

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.

For the nine months ended September 30, 2020, net cash used in operations was \$1.6 million and consisted of a net loss of \$3.8 million offset by a change in operating assets and liabilities of \$0.2 million and non-cash items of \$2.0 million. The net change in operating assets and liabilities included an increase in operating liabilities of \$0.3 million offset by an increase in prepaid expenses of \$0.1 million and the non-cash items consisted primarily of equity-based compensation expense of \$2.0 million.

#### Financing Activities

Net cash used by financing activities during the nine months ended September 30, 2021 was \$0.1 million and was attributable to \$0.2 million in proceeds received from the exercise of warrants offset by payment of IPO offering costs of \$0.3 million

Net cash provided by financing activities during the nine months ended September 30, 2020 was \$1.8 million and was attributable to \$2.0 million in proceeds from the issuance of convertible promissory notes offset by payment of deferred costs of \$0.2 million

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

As of September 30, 2021, 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.

#### **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 not effective at a reasonable assurance level in ensuring that material 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.

As previously identified and described more fully under Item 9A in our 2020 Annual Report on Form 10-K, we determined that a material weakness in our internal control over financial reporting, due to the size of the organization, arose because we did not maintain effective segregation of duties, financial statement reporting and general technology controls. The material weakness continued to exist as of the end of the period covered by the Quarterly Report on Form 10-Q.

In March 2021, the Board approved, and the Company adopted, a Delegation of Authority Policy to improve segregation of duties in our authorization processes. In April 2021, we contracted with a third party to provide experienced controller assistance for post-closing procedures as well as providing segregation of duties for initiating and approving wire transactions and other payments. In addition, management added additional mitigating controls with regards to cash disbursements. In June 2021, we contracted with a third-party accounting firm to provide outsourced internal audit services (the "IA Firm"). The IA Firm assisted us in designing an internal control framework around key processes and controls. We have identified the gaps in our internal control processes and are working to put in place mitigating controls to address these gaps. The IA Firm will be assisting us with the testing of our controls to help us evaluate the effectiveness our internal controls over financial reporting. However, we cannot assure that the steps and measures we will implement to remediate our material weakness will be sufficient to prevent future material weaknesses or significant deficiencies in our internal control over financial reporting from occurring.

#### **Changes in Internal Control Over Financial Reporting**

Other than as described above, there has been 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, other than as set forth below 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.

On August 26, 2021, Torreya Capital LLC ("Torreya") filed a demand for arbitration with the American Arbitration Association in New York, New York in connection with a claim by Torreya that it is entitled to a transaction fee of \$1,035,000 related to the Company's IPO, plus the costs of arbitration, based on services Torreya alleges to have provided for the Company as a financial advisor to the Company prior to the IPO. The Company believes that Torreya's demand is baseless and without merit. The Company intends to defend itself vigorously.

#### Item 1A. Risk Factors

This item is not required for smaller reporting companies.

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

None.

#### Item 3. Defaults Upon Senior Securities

None

## Item 4. Mine Safety Disclosures

Not applicable.

### Item 5. Other Information

None.

## Item 6. Exhibits

See Exhibit Index.

## **EXHIBIT INDEX**

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

<sup>†</sup> 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 12, 2021

## 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 Wal
Name: Angela Walsh /s/ 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) (Paragraph omitted pursuant to SEC Release Nos. 33-8238/34-47986 and 33-8392/34-49313);
  - (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 12, 2021

By: /s/ Greg Duncan

Name: Greg Duncan

Title: Chairman of the Board 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) (Paragraph omitted pursuant to SEC Release Nos. 33-8238/34-47986 and 33-8392/34-49313);
  - (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 12, 2021

By: /s/ Angela Walsh

Name: Angela Walsh

Title: Senior Vice President of Finance and Corporate Secretary

(Principal Financial 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 September 30, 2021 (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 12, 2021

By: /s/ Greg Duncan

Name: Greg Duncan

Title: 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 September 30, 2021 (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 12, 2021

By: /s/ Angela Walsh

Name: Angela Walsh

Title: Senior Vice President of Finance and Corporate Secretary

(Principal Financial Officer)