

U.S. SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended: March 31, 2021

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 001-38174

**Citius Pharmaceuticals, Inc.**

(Exact name of registrant as specified in its charter)

**Nevada**

(State or other jurisdiction of  
incorporation or organization)

**27-3425913**

(IRS Employer  
Identification No.)

**11 Commerce Drive, First Floor, Cranford, NJ 07016**

(Address of principal executive offices and zip code)

**(908) 967-6677**

(Registrant's telephone number, including area code)

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

Title of Each Class	Trading Symbol(s)	Name of Each Exchange on Which Registered
Common stock, \$0.001 par value	CTXR	Nasdaq Capital Market
Warrants to purchase common stock	CTXRW	Nasdaq Capital Market

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

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (Section 232.405 of this chapter) during the preceding 12 months (or 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	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input checked="" type="checkbox"/>	Smaller reporting company	<input checked="" type="checkbox"/>
Emerging growth company	<input type="checkbox"/>		

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

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

As of May 10, 2021, there were 135,473,947 shares of common stock, \$0.001 par value, of the registrant issued and outstanding.

**Citius Pharmaceuticals, Inc.**  
**FORM 10-Q**

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## EXPLANATORY NOTE

In this Quarterly Report on Form 10-Q, and unless the context otherwise requires, the “Company,” “we,” “us,” and “our” refer to Citius Pharmaceuticals, Inc. and its wholly owned subsidiaries, Citius Pharmaceuticals, LLC and Leonard-Meron Biosciences, Inc., and its majority-owned subsidiary, NoveCite, Inc., taken as a whole.

### CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains “forward-looking statements.” Forward-looking statements include, but are not limited to, statements that express our intentions, beliefs, expectations, strategies, predictions or any other statements relating to our future activities or other future events or conditions. These statements are based on current expectations, estimates and projections about our business based, in part, on assumptions made by management. These statements are not guarantees of future performance and involve risks, uncertainties and assumptions that are difficult to predict. Therefore, actual outcomes and results may, and are likely to, differ materially from what is expressed or forecasted in the forward-looking statements due to numerous factors discussed from time to time in this report and in other documents which we file with the Securities and Exchange Commission. In addition, such statements could be affected by risks and uncertainties related to:

- our ability to raise funds for general corporate purposes and operations, including our pre-clinical and clinical trials;
- the cost, timing and results of our pre-clinical and clinical trials;
- our ability to obtain and maintain required regulatory approvals for our product candidates;
- the commercial feasibility and success of our technology and product candidates;
- our ability to recruit and retain qualified management and scientific and technical personnel to carry out our operations; and
- the other factors discussed in the “Risk Factors” section of our most recent Annual Report on Form 10-K and elsewhere in this report.

Any forward-looking statements speak only as of the date on which they are made, and except as may be required under applicable securities laws, we do not undertake any obligation to update any forward-looking statement to reflect events or circumstances after the filing date of this report.

PART I - FINANCIAL INFORMATION

Item 1. Financial Statements

CITIUS PHARMACEUTICALS, INC.  
CONDENSED CONSOLIDATED BALANCE SHEETS  
(Unaudited)

	March 31, 2021	September 30, 2020
<b>ASSETS</b>		
<b>Current Assets:</b>		
Cash and cash equivalents	\$ 103,697,162	\$ 13,859,748
Prepaid expenses	1,277,029	122,237
<b>Total Current Assets</b>	<b>104,974,191</b>	<b>13,981,985</b>
Property and equipment, net	1,272	1,577
Operating lease right-of-use asset, net	906,092	986,204
<b>Other Assets:</b>		
Deposits	38,062	57,093
In-process research and development	19,400,000	19,400,000
Goodwill	9,346,796	9,346,796
<b>Total Other Assets</b>	<b>28,784,858</b>	<b>28,803,889</b>
<b>Total Assets</b>	<b>\$ 134,666,413</b>	<b>\$ 43,773,655</b>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
<b>Current Liabilities:</b>		
Accounts payable	\$ 1,132,877	\$ 1,856,235
Accrued expenses	240,610	164,040
Accrued compensation	1,172,375	1,654,919
Accrued interest	97,877	89,970
Notes payable – related parties	172,970	172,970
Operating lease liability	167,937	158,999
<b>Total Current Liabilities</b>	<b>2,984,646</b>	<b>4,097,133</b>
Note payable – paycheck protection program	164,583	164,583
Deferred tax liability	4,985,800	4,985,800
Operating lease liability – non current	769,218	855,471
<b>Total Liabilities</b>	<b>8,904,247</b>	<b>10,102,987</b>
<b>Commitments and Contingencies</b>		
<b>Stockholders' Equity:</b>		
Preferred stock – \$0.001 par value; 10,000,000 shares authorized; no shares issued and outstanding	—	—
Common stock – \$0.001 par value; 200,000,000 shares authorized; 134,701,219 and 55,576,996 shares issued and outstanding at March 31, 2021 and September 30, 2020, respectively	134,701	55,577
Additional paid-in capital	210,289,813	104,208,958
Accumulated deficit	(85,262,728)	(70,593,867)
<b>Total Citius Pharmaceuticals, Inc. Stockholders' Equity</b>	<b>125,161,786</b>	<b>33,670,668</b>
Non-controlling interest	600,380	—
<b>Total Equity</b>	<b>125,762,166</b>	<b>33,670,668</b>
<b>Total Liabilities and Equity</b>	<b>\$ 134,666,413</b>	<b>\$ 43,773,655</b>

See notes to unaudited condensed consolidated financial statements.

**CITIUS PHARMACEUTICALS, INC.**  
**CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS**  
**FOR THE THREE AND SIX MONTHS ENDED MARCH 31, 2021 AND 2020**  
**(Unaudited)**

	<u>Three Months Ended</u>		<u>Six Months Ended</u>	
	<u>March 31, 2021</u>	<u>March 31, 2020</u>	<u>March 31, 2021</u>	<u>March 31, 2020</u>
<b>Revenues</b>	\$ —	\$ —	\$ —	\$ —
<b>Operating Expenses</b>				
Research and development	1,551,341	2,015,940	7,742,520	4,680,486
General and administrative	2,293,517	2,258,322	3,982,181	3,821,317
Stock-based compensation – general and administrative	342,962	158,833	619,544	379,217
<b>Total Operating Expenses</b>	<u>4,187,820</u>	<u>4,433,095</u>	<u>12,344,245</u>	<u>8,881,020</u>
<b>Operating Loss</b>	<u>(4,187,820)</u>	<u>(4,433,095)</u>	<u>(12,344,245)</u>	<u>(8,881,020)</u>
<b>Other Income (Expense)</b>				
Other income	—	—	—	110,207
Interest income	69,327	12,106	82,811	31,445
Interest expense	(3,939)	(3,980)	(7,907)	(7,971)
<b>Total Other Income, Net</b>	<u>65,388</u>	<u>8,126</u>	<u>74,904</u>	<u>133,681</u>
<b>Net Loss</b>	<u>\$ (4,122,432)</u>	<u>\$ (4,424,969)</u>	<u>\$ (12,269,341)</u>	<u>\$ (8,747,339)</u>
<b>Net Loss Per Share - Basic and Diluted</b>	<u>\$ (0.04)</u>	<u>\$ (0.13)</u>	<u>\$ (0.16)</u>	<u>\$ (0.28)</u>
<b>Weighted Average Common Shares Outstanding</b>				
Basic and diluted	<u>95,997,427</u>	<u>34,318,761</u>	<u>75,565,121</u>	<u>31,744,379</u>

See notes to unaudited condensed consolidated financial statements.

**CITIUS PHARMACEUTICALS, INC.**  
**CONDENSED CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY**  
**FOR THE THREE AND SIX MONTHS ENDED MARCH 31, 2021 AND 2020**  
**(Unaudited)**

	Preferred Stock	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total Citius Pharmaceuticals, Inc. Shareholder's Equity	Non- Controlling Interest	Total Equity
		Shares	Amount					
<b>Balance, October 1, 2020</b>	\$ —	55,576,996	\$ 55,577	\$ 104,208,958	\$ (70,593,867)	\$ 33,670,668	\$ —	\$ 33,670,668
Issuance of NoveCite common stock	—	—	—	1,799,640	(2,399,520)	(599,880)	600,380	500
Stock-based compensation expense	—	—	—	276,582	—	276,582	—	276,582
Net loss	—	—	—	—	(8,146,909)	(8,146,909)	—	(8,146,909)
<b>Balance, December 31, 2020</b>	—	55,576,996	55,577	106,285,180	(81,140,296)	25,200,461	600,380	25,800,841
Issuance of common stock in private placement offering, net of costs of \$1,549,602	—	15,455,960	15,456	18,434,954	—	18,450,410	—	18,450,410
Issuance of common stock in registered direct offering, net of costs of \$5,520,160	—	50,830,566	50,830	70,929,012	—	70,979,842	—	70,979,842
Issuance of common stock upon exercise of warrants	—	12,787,697	12,788	14,229,755	—	14,242,543	—	14,242,543
Issuance of common stock for services	—	50,000	50	67,950	—	68,000	—	68,000
Stock-based compensation expense	—	—	—	342,962	—	342,962	—	342,962
Net loss	—	—	—	—	(4,122,432)	(4,122,432)	—	(4,122,432)
<b>Balance, March 31, 2021</b>	\$ —	134,701,219	\$ 134,701	\$ 210,289,813	\$ (85,262,728)	125,161,786	\$ 600,380	\$ 125,762,166
<b>Balance, October 1, 2019, as restated</b>	\$ —	28,930,493	\$ 28,930	\$ 80,169,724	\$ (53,045,782)	\$ (27,152,872)	\$ —	\$ 27,152,872
Issuance of common stock upon exercise of warrants	—	1,060,615	1,061	(955)	—	106	—	106
Issuance of common stock for services	—	186,566	187	99,813	—	100,000	—	100,000
Stock-based compensation expense	—	—	—	220,384	—	220,384	—	220,384
Net loss	—	—	—	—	(4,322,370)	(4,322,370)	—	(4,322,370)
<b>Balance, December 31, 2019</b>	—	30,177,674	30,178	80,488,966	(57,368,152)	23,150,992	—	23,150,992
Issuance of common stock upon exercise of warrants	—	7,614,388	7,614	6,019,417	—	6,027,031	—	6,027,031
Issuance of common stock for services	—	286,000	286	305,734	—	306,020	—	306,020
Stock-based compensation expense	—	—	—	158,833	—	158,833	—	158,833
Net loss	—	—	—	—	(4,424,969)	(4,424,969)	—	(4,424,969)
<b>Balance, March 31, 2020</b>	\$ —	38,078,062	\$ 38,078	\$ 86,972,950	\$ (61,793,121)	\$ 25,217,907	\$ —	\$ 25,217,907

See notes to unaudited condensed consolidated financial statements.

**CITIUS PHARMACEUTICALS, INC.**  
**CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS**  
**FOR THE SIX MONTHS ENDED MARCH 31, 2021 AND 2020**  
**(Unaudited)**

	<b>2021</b>	<b>2020</b>
<b>Cash Flows From Operating Activities:</b>		
Net loss	\$ (12,269,341)	\$ (8,747,339)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	619,544	379,217
Issuance of common stock for services	68,000	406,020
Amortization of operating lease right-of-use asset	80,112	81,847
Depreciation	305	354
Changes in operating assets and liabilities:		
Prepaid expenses	(1,154,792)	(5,553)
Deposits	19,031	—
Accounts payable	(723,358)	(1,189,182)
Accrued expenses	76,570	(96,234)
Accrued compensation	(482,544)	(368,812)
Accrued interest	7,907	7,971
Operating lease liability	(77,315)	(50,158)
<b>Net Cash Used In Operating Activities</b>	<b>(13,835,881)</b>	<b>(9,581,869)</b>
<b>Cash Flows From Financing Activities:</b>		
Proceeds from sale of NoveCite, Inc. common stock	500	—
Net proceeds from private placement	18,450,410	—
Net proceeds from registered direct offering	70,979,842	—
Net proceeds from common stock warrant exercises	14,242,543	6,027,137
<b>Net Cash Provided By Financing Activities</b>	<b>103,673,295</b>	<b>6,027,137</b>
<b>Net Change in Cash and Cash Equivalents</b>	89,837,414	(3,554,732)
<b>Cash and Cash Equivalents - Beginning of Period</b>	13,859,748	7,893,804
<b>Cash and Cash Equivalents - End of Period</b>	<b>\$ 103,697,162</b>	<b>\$ 4,339,072</b>
<b>Supplemental Disclosures Of Cash Flow Information and Non-cash Activities:</b>		
Operating lease right-of-use asset and liability recorded upon adoption of ASC 842	\$ —	\$ 1,137,724

See notes to unaudited condensed consolidated financial statements.

**CITIUS PHARMACEUTICALS, INC.**  
**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**  
**FOR THE SIX MONTHS ENDED MARCH 31, 2021 AND 2020**  
**(Unaudited)**

**1. NATURE OF OPERATIONS, BASIS OF PRESENTATION AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES**

***Business***

Citius Pharmaceuticals, Inc. (“Citius,” the “Company,” “we” or “us”) is a specialty pharmaceutical company dedicated to the development and commercialization of critical care products with a focus on anti-infective products in adjunct cancer care, unique prescription products and stem cell therapy.

On March 30, 2016, Citius acquired Leonard-Meron Biosciences, Inc. (“LMB”) as a wholly-owned subsidiary. The Company acquired all of the outstanding stock of LMB by issuing shares of its common stock. The net assets acquired included identifiable intangible assets of \$19,400,000 related to in-process research and development. The Company recorded goodwill of \$9,346,796 for the excess of the purchase price over the net assets.

In-process research and development represents the value of LMB’s leading drug candidate, which is an antibiotic solution used to treat catheter-related bloodstream infections (Mino-Lok®) and is expected to be amortized on a straight-line basis over a period of eight years commencing upon revenue generation. Goodwill represents the value of LMB’s industry relationships and its assembled workforce. Goodwill will not be amortized but will be tested at least annually for impairment.

On September 11, 2020, we formed NoveCite, Inc. (“NoveCite”), a Delaware corporation, of which we own 75% (7,500,000 shares) of the issued and outstanding capital stock (see Note 3).

Citius is subject to a number of risks common to companies in the pharmaceutical industry including, but not limited to, risks related to the development by Citius or its competitors of research and development stage product candidates, market acceptance of its product candidates that might be approved, competition from larger companies, dependence on key personnel, dependence on key suppliers and strategic partners, the Company’s ability to obtain additional financing and the Company’s compliance with governmental and other regulations.

***Basis of Presentation and Summary of Significant Accounting Policies***

*Basis of Preparation* — The accompanying condensed consolidated financial statements include the operations of Citius Pharmaceuticals, Inc., and its wholly-owned subsidiaries, Citius Pharmaceuticals, LLC, and LMB, and its majority-owned subsidiary NoveCite. NoveCite was inactive until October 2020. All significant inter-company balances and transactions have been eliminated in consolidation.

The accompanying unaudited condensed consolidated financial statements of the Company have been prepared on the same basis as the annual consolidated financial statements and, in the opinion of management, reflect all adjustments, which include only normal recurring adjustments, necessary to fairly state the condensed consolidated financial position of the Company as of March 31, 2021, and the results of its operations and cash flows for the three and six month periods ended March 31, 2021 and 2020. The operating results for the three and six month periods ended March 31, 2021 are not necessarily indicative of the results that may be expected for the year ending September 30, 2021. These unaudited condensed consolidated financial statements should be read in conjunction with the audited consolidated financial statements and notes thereto included in the Company’s Annual Report on Form 10-K for the year ended September 30, 2020 filed with the Securities and Exchange Commission.

*Use of Estimates* — Our accounting principles require our management to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of assets and liabilities at the date of the financial statements, and reported amounts of revenues and expenses during the reporting period. Estimates having relatively higher significance include stock-based compensation, accounting for leases, valuation of warrants, and income taxes. Actual results could differ from those estimates and changes in estimates may occur.

*Basic and Diluted Net Loss per Common Share* — Basic and diluted net loss per common share is computed by dividing net loss in each period by the weighted average number of shares of common stock outstanding during such period. For the periods presented, common stock equivalents, consisting of stock options and warrants were not included in the calculation of the diluted loss per share because they were anti-dilutive.

#### ***Recently Issued Accounting Standards***

In December 2019, the FASB issued ASU No. 2019-12 Simplifications to Accounting for Income Taxes. ASU 2019-12 removes certain exceptions for recognizing deferred taxes for investments, performing intra-period allocation, and calculating income taxes in interim periods. The ASU also adds guidance to reduce complexity in certain areas, including deferred taxes for goodwill and allocating taxes for members of a consolidated group. ASU 2019-12 is effective for all entities for fiscal years beginning after December 15, 2020, and earlier adoption is permitted. The Company is currently evaluating the impact of adopting ASU 2019-12 on its consolidated financial statements.

In August 2020, 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): Accounting for Convertible Instruments and Contracts in an Entity's Own Equity, which, among other things, provides guidance on how to account for contracts on an entity's own equity. This ASU 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. In addition, this ASU modifies how particular convertible instruments and certain contracts that may be settled in cash or shares impact the diluted EPS computation. The amendments in this ASU are effective for the public companies for fiscal years beginning after December 15, 2021, including interim periods within those fiscal years. Early adoption is permitted, but no earlier than fiscal years beginning after December 15, 2020. The Company is currently evaluating the impact of ASU 2020-06 on its consolidated financial statements.

## **2. LIQUIDITY AND MANAGEMENT'S PLAN**

The accompanying condensed consolidated financial statements have been prepared on a going concern basis, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. The Company experienced negative cash flows from operations of \$13,835,881 for the six months ended March 31, 2021. As a result of the Company's recent common stock offerings and common stock warrant exercises in its second fiscal quarter of 2021, the Company had working capital of \$101,989,545 at March 31, 2021. The Company estimates that its available cash resources will be sufficient to fund its operations through March 2023.

The Company has generated no operating revenue to date and has principally raised capital through the issuance of debt and equity instruments to finance its operations. However, the Company's continued operations beyond March 2023, including its development plans for Mino-Lok, Mino-Wrap, Halo-Lido and Novecite, will depend on its ability to obtain regulatory approval to market Mino-Lok and generate substantial revenue from the sale of Mino-Lok and on its ability to raise additional capital through various potential sources, such as equity and/or debt financings, strategic relationships, or out-licensing of its products. However, the Company can provide no assurances on future sales of Mino-Lok or that financing or strategic relationships will be available on acceptable terms, or at all. If the Company is unable to raise sufficient capital, find strategic partners or generate substantial revenue from the sale of Mino-Lok, there would be a material adverse effect on its business. Further, the Company expects in the future to incur additional expenses as it continues to develop its product candidates, including regulatory approval, and protect its intellectual property.

## **3. PATENT AND TECHNOLOGY LICENSE AGREEMENTS**

### ***Patent and Technology License Agreement – Mino-Lok***

LMB has a patent and technology license agreement with Novel Anti-Infective Therapeutics, Inc. ("NAT") to develop and commercialize Mino-Lok® on an exclusive, worldwide sub licensable basis. LMB is required to pay an annual maintenance fee each June until commercial sales of a product subject to the license commence. The annual fee paid in June 2020 was \$90,000 (at which level it will remain for as long as it is due).

LMB will also pay annual royalties on net sales of licensed products, with royalties ranging from the mid-single digits to the low double digits or, in the event the licensed product is not subject to a valid patent claim, the royalty is reduced to mid- to lower-single digits. In limited circumstances in which the licensed product is not subject to a valid patent claim and a competitor is selling a competing product, the royalty rate is in the low single digits. After a commercial sale is obtained, LMB must pay minimum aggregate annual royalties of \$100,000 in the first commercial year which is prorated for a less than 12-month period, increasing \$25,000 per year to a maximum of \$150,000 annually. LMB must also pay NAT up to \$1,100,000 upon achieving specified regulatory and sales milestones. Finally, LMB must pay NAT a specified percentage of payments received from any sub licensees.

Unless earlier terminated by NAT, based on the failure by the Company to achieve certain development and commercial milestones or for various breaches by the Company, the license agreement remains in effect until the date that all patents licensed under the agreement have expired and all patent applications within the licensed patent rights have been cancelled, withdrawn or expressly abandoned.

#### ***Patent and Technology License Agreement – Mino-Wrap***

On January 2, 2019, we entered into a patent and technology license agreement with the Board of Regents of the University of Texas System on behalf of the University of Texas M. D. Anderson Cancer Center (“Licensor”), whereby we in-licensed exclusive worldwide rights to the patented technology for any and all uses relating to breast implants. We intend to develop a liquefying gel-based wrap containing minocycline and rifampin for the reduction of infections associated with breast implants following breast reconstructive surgeries (“Mino-Wrap”). We are required to use commercially reasonable efforts to commercialize Mino-Wrap under several regulatory scenarios and achieve milestones associated with these regulatory options leading to an approval from the U.S. Food and Drug Administration (“FDA”).

Under the license agreement, the Company paid annual maintenance fees of \$45,000 and \$30,000 in January 2021 and 2020, respectively. The annual maintenance fee increases by \$15,000 per year up to a maximum of \$90,000. Annual maintenance fees cease on the first sale of product. We also must pay up to an aggregate of \$2.1 million in milestone payments, contingent on the achievement of various regulatory and commercial milestones. Under the terms of the license agreement, we also must pay a royalty of mid- to upper-single digit percentages of net sales, depending on the amount of annual sales, and subject to downward adjustment to lower- to mid-single digit percentages in the event there is no valid patent for the product in the United States at the time of sale. After the first sale of product, we will owe an annual minimum royalty payment of \$100,000 that will increase annually by \$25,000 for the duration of the term. We will be responsible for all patent expenses incurred by Licensor for the term of the agreement although Licensor is responsible for filing, prosecution and maintenance of all patents. Unless earlier terminated by Licensor, based upon the failure by us to achieve certain development and commercial milestones or for various breaches by us, the agreement expires on the later of the expiration of the patents or January 2, 2034.

#### ***License Agreement with Novellus***

On March 31, 2020, we entered into an option agreement with a subsidiary of Novellus, Inc. (“Novellus”) whereby we had the opportunity to in-license from Novellus on a worldwide basis, a novel cellular therapy for acute respiratory distress syndrome (“ARDS”). The option exercise period ran for six months and the option agreement contained the agreed upon financial terms for the license. In April 2020 we paid Novellus \$100,000 for the option and recorded it as a research and development expense.

Our Board Chairman Leonard Mazur, who is also our largest stockholder, is a significant shareholder of Novellus and subsequent to the option agreement as well as the license agreement referred to below, became a director of Novellus. As required by our Code of Ethics, the Audit Committee of our Board of Directors approved the entry into the option agreement with Novellus, as did the disinterested members of our Board of Directors.

On October 6, 2020, we, through NoveCite, our subsidiary that was established specifically for this purpose, exercised the option and signed an exclusive license agreement with Novellus. NoveCite is focused on developing cellular therapies. Upon execution of the agreement, we paid \$5,000,000 to Novellus and issued to Novellus shares of NoveCite’s common stock representing 25% of the outstanding equity. We own the other 75% of NoveCite’s outstanding equity. Pursuant to the terms of the stock subscription agreement between Novellus and NoveCite, if NoveCite issues additional equity, subject to certain exceptions, NoveCite must maintain Novellus’s ownership at 25% by issuing additional shares to Novellus.

The \$5,000,000 payment to Novellus was charged to research and development expense in the six months ended March 31, 2021.

Citius is responsible for the operational activities of NoveCite, and bears all costs necessary to operate NoveCite. Citius's officers are also the officers of NoveCite and oversee the business strategy and operations of NoveCite. As such, NoveCite is accounted for as a consolidated subsidiary with a noncontrolling interest.

Novellus has no contractual rights in the profits or obligations to share in the losses of NoveCite, and the Company has not allocated any losses to the noncontrolling interest.

NoveCite is obligated to pay Novellus up to \$51,000,000 upon the achievement of various regulatory and developmental milestones. NoveCite also must pay a royalty equal to low double-digit percentages of net sales, commencing upon the sale of a licensed product. This royalty is subject to downward adjustment to an upper-single digit percentage of net sales in any country in the event of the expiration of the last valid patent claim or if no valid patent claim exists in that country. The royalty will end on the earlier of (i) the date on which a biosimilar product is first marketed, sold, or distributed in the applicable country or (ii) the 10-year anniversary of the date of expiration of the last-to-expire valid patent claim in that country. In the case of a country where no licensed patent ever exists, the royalty will end on the later of (i) the date of expiry of such licensed product's regulatory exclusivity and (ii) the 10-year anniversary of the date of the first commercial sale of the licensed product in the applicable country. In addition, NoveCite will pay to Novellus an amount equal to a mid-twenties percentage of any sublicensee fees it receives.

Under the terms of the license agreement, in the event that Novellus receives any revenue involving the original cell line included in the licensed technology, then Novellus shall remit to NoveCite 50% of such revenue.

The term of the license agreement will continue on a country-by-country and licensed product-by-licensed product basis until the expiration of the last-to-expire royalty term. Either party may terminate the license agreement upon written notice if the other party is in material default. NoveCite may terminate the license agreement at any time without cause upon 90 days prior written notice.

Novellus will be responsible for preparing, filing, prosecuting and maintaining all patent applications and patents included in the licensed patents in the territory. Provided however, that if Novellus decides that it is not interested in maintaining a particular licensed patent or in preparing, filing, or prosecuting a licensed patent, NoveCite will have the right, but not the obligation, to assume such responsibilities in the territory at NoveCite's sole cost and expense.

#### **4. NOTES PAYABLE**

##### ***Notes Payable – Related Parties***

The aggregate principal balance as of March 31, 2021 consists of notes payable held by our Chairman, Leonard Mazur, in the amount of \$160,470 and notes payable held by our Chief Executive Officer, Myron Holubiak, in the amount of \$12,500. Notes with an aggregate principal balance of \$104,000 accrue interest at the prime rate plus 1.0% per annum and notes with an aggregate principal balance of \$68,970 accrue interest at 12% per annum.

Interest expense on notes payable – related parties was \$3,533 and \$3,980, respectively, for the three months ended March 31, 2021 and 2020. Interest expense on notes payable – related parties was \$7,096 and \$7,971, respectively, for the six months ended March 31, 2021 and 2020.

##### ***Paycheck Protection Program***

On April 12, 2020, due to the business disruption caused by the COVID-19 health crisis, the Company applied for a forgivable loan through the Small Business Association's Paycheck Protection Program (the "PPP"). In accordance with the provisions of the PPP, the loan accrues interest at a rate of 1% and a portion of the loan may be forgiven if it is used to pay qualifying costs such as payroll, rent and utilities. Amounts that are not forgiven will be repaid 2 years from the date of the loan. On April 15, 2020, the Company received funding in the amount of \$164,583 from the Paycheck Protection Program through its bank.

Interest expense was \$406 and \$811 for the three and six months ended March 31, 2021, respectively.

## 5. COMMON STOCK, STOCK OPTIONS AND WARRANTS

### *Common Stock Offerings*

On May 18, 2020, the Company closed a registered direct offering with several institutional and accredited investors for the sale of 7,058,824 shares of common stock at \$1.0625 per share for gross proceeds of \$7,500,001. The Company also agreed to issue 3,529,412 unregistered immediately exercisable warrants to the investors with an exercise price of \$1.00 per share and a term of five and one-half years. The Company paid the placement agent for the offering a fee of 7% of the gross proceeds totaling \$525,000 and issued the placement agent 494,118 immediately exercisable warrants with an exercise price of \$1.3281 per share and a term of five years. The Company also reimbursed the placement agent for \$85,000 in expenses and incurred \$12,901 in other expenses. Net proceeds from the offering were \$6,877,100. The estimated fair value of the 3,529,412 warrants issued to the investors was \$2,138,998 and the estimated fair value of the 494,118 warrants issued to the placement agent was \$275,724.

On August 10, 2020, the Company closed an underwritten public offering of 9,159,524 shares of common stock at a price of \$1.05 per share for gross proceeds of \$9,617,500. The Company paid the underwriter a fee of 7% of the gross proceeds totaling \$673,225 and issued the underwriters 641,166 immediately exercisable warrants with an exercise price of \$1.3125 per share and a term of five years. The Company also reimbursed the placement agent for \$135,000 in expenses and incurred \$109,074 in other expenses. Net proceeds from the offering were \$8,700,201. The estimated fair value of the 641,166 warrants issued to the underwriter was \$569,426.

On January 27, 2021, the Company closed a private placement for 15,455,960 shares of its common stock and warrants to purchase up to 7,727,980 shares of common stock, at a purchase price of \$1.294 per share of common stock and accompanying warrant, for gross proceeds of \$20,000,012. The 7,727,980 warrants are immediately exercisable at \$1.231 per share for a term of five and one-half years. The Company paid the placement agent a fee of 7% of the gross proceeds totaling \$1,400,001 and issued the placement agent 1,081,917 warrants for common stock that are immediately exercisable at \$1.6175 per share for a term of five and one-half years. The Company also reimbursed the placement agent for \$85,000 in expenses and incurred \$64,601 in other expenses. Net proceeds from the offering were \$18,450,410. The estimated fair value of the 7,727,980 warrants issued to the investors was approximately \$7,582,000 and the estimated fair value of the 1,081,917 warrants issued to the placement agent was approximately \$1,025,000.

On February 19, 2021, the Company closed a registered direct offering for 50,830,566 shares of its common stock and warrants to purchase up to 25,415,283 shares of common stock, at a purchase price of \$1.505 per share of common stock and accompanying warrant, for gross proceeds of \$76,500,002. The 25,415,283 warrants are immediately exercisable at \$1.70 per share for a term of five years. The Company paid the placement agent a fee of 7% of the gross proceeds totaling \$5,355,000 and issued the placement agent 3,558,140 warrants for common stock that are immediately exercisable at \$1.881 per share for a term of five years. The Company also reimbursed the placement agent for \$85,000 in expenses and incurred \$80,160 in other expenses. Net proceeds from the offering were \$70,979,842. The estimated fair value of the 25,415,283 warrants issued to the investors was approximately \$42,322,000 and the estimated fair value of the 3,558,140 warrants issued to the placement agent was approximately \$5,850,000.

### *Common Stock Issued for Services*

On November 4, 2019, the Company issued 186,566 shares of common stock for strategic consulting and corporate development services and expensed the \$100,000 fair value of the common stock issued.

On February 10, 2020, the Company issued 150,000 shares of common stock for investor relations services and 136,000 shares of common stock for general advisory and business development advisory services. The Company expensed the \$306,020 fair value of the common stock issued.

On April 6, 2020, the Company issued 50,000 shares of common stock for strategic consulting and corporate development services and expensed the \$22,750 fair value of the common stock issued.

On September 8, 2020, the Company issued 101,174 shares of common stock for investor relations services and expensed the \$100,000 fair value of the common stock issued.

On February 12, 2021, the Company issued 50,000 shares of common stock for investor relations services and expensed the \$68,000 fair value of the common stock issued.

### Stock Option Plans

Pursuant to its 2014 Stock Incentive Plan (the “2014 Plan”) the Company reserved 866,667 shares of common stock for issuance to employees, directors and consultants. As of March 31, 2021, there were options to purchase an aggregate of 855,171 shares of common stock outstanding under the 2014 Plan, options to purchase 4,829 shares were exercised, options to purchase 6,667 shares expired and no shares remain available for future grants.

On February 7, 2018, our stockholders approved the 2018 Omnibus Stock Incentive Plan (the “2018 Plan”) and the Company reserved 2,000,000 shares of common stock for issuance to employees, directors and consultants. As of March 31, 2021, there were options to purchase an aggregate of 1,890,000 shares of common stock outstanding under the 2018 Plan and no shares available for future grants.

On February 10, 2020, the Company’s stockholders approved the 2020 Omnibus Stock Incentive Plan (“2020 Stock Plan”). The 2020 Stock Plan authorizes a maximum of 3,110,000 shares. The 2020 Stock Plan provides incentives to employees, directors, and consultants of the Company in form of granting an option, SAR, dividend equivalent right, restricted stock, restricted stock unit, or other right or benefit under the 2020 Stock Plan. As of March 31, 2021, there were options to purchase 1,870,000 shares outstanding under the 2020 Plan and 1,240,000 shares available for future grants.

The fair value of each stock option award is estimated on the date of grant using the Black-Scholes option pricing model. The risk-free interest rate is based on the U.S. Treasury yield curve in effect at the time of grant commensurate with the expected term assumption. The expected term of stock options granted, all of which qualify as “plain vanilla,” is based on the average of the contractual term (generally 10 years) and the vesting period. For non-employee options, the expected term is the contractual term.

A summary of option activity under the Company’s stock option plans (excluding the NoveCite Stock Plan) is presented below:

	Option Shares	Weighted- Average Exercise Price	Weighted- Average Remaining Contractual Term	Aggregate Intrinsic Value
Outstanding at October 1, 2020	3,390,171	\$ 2.51	8.0 years	\$ 440,336
Granted	1,225,000	1.08		
Exercised	—	—		
Forfeited or expired	—	—		
Outstanding at March 31, 2021	<u>4,615,171</u>	<u>\$ 2.13</u>	8.1 years	<u>\$ 2,659,010</u>
Exercisable at March 31, 2021	<u>1,968,804</u>	<u>\$ 3.56</u>	6.6 years	<u>\$ 787,968</u>

On October 6, 2020, the Board of Directors granted stock options to purchase 800,000 shares to employees, 175,000 shares to directors and 125,000 shares to consultants at \$1.01 per share. On February 16, 2021, the Board of Directors granted stock options to purchase a total of 125,000 shares to directors at \$1.69 per share. All of these options vest over terms of 12 to 36 months and have a term of 10 years.

Stock-based compensation expense for the three months ended March 31, 2021 and 2020 was \$342,962 (including \$18,833 for the NoveCite Stock Plan) and \$158,833, respectively. Stock-based compensation expense for the six months ended March 31, 2021 and 2020 was \$619,544 (including \$31,389 for the NoveCite Stock Plan) and \$379,217, respectively.

At March 31, 2021, unrecognized total compensation cost related to unvested awards under the 2014 Plan, 2018 Plan and 2020 Stock Plan of \$1,669,737 is expected to be recognized over a weighted average period of 1.8 years.

On November 5, 2020, the stockholders of our majority-owned subsidiary, NoveCite, Inc., approved NoveCite's 2020 Omnibus Stock Incentive Plan ("NoveCite Stock Plan"). The NoveCite Stock Plan authorizes a maximum of 2,000,000 shares of NoveCite common stock. The NoveCite Stock Plan provides incentives to employees, directors, and consultants of NoveCite through grants of options, SARs, dividend equivalent rights, restricted stock, restricted stock units, or other rights or benefits under the NoveCite Stock Plan. As of March 31, 2021, there were options outstanding to purchase 1,130,000 shares of NoveCite common stock under the NoveCite Stock Plan and 870,000 shares of NoveCite common stock available for future grants.

On November 5, 2020, NoveCite granted stock options to purchase 1,130,000 shares of NoveCite common stock to employees at a weighted average exercise price of \$0.24 per share, of which, none are exercisable as of March 31, 2021. The weighted average remaining contractual term of options outstanding under the NoveCite Stock Plan is 9.61 years. At March 31, 2021, unrecognized total compensation cost related to unvested awards under the NoveCite Stock Plan of \$194,611 is expected to be recognized over a weighted average period of 2.6 years.

### Warrants

As of March 31, 2021, the Company has reserved shares of common stock for the exercise of outstanding warrants. The following table summarizes the warrants outstanding:

	Exercise price	Number	Expiration Dates
Investor Warrants	\$ 9.00	126,669	April 15, 2021 – April 25, 2021
LMB Warrants	7.50	53,110	March 24, 2022 – April 29, 2022
Financial Advisor Warrants	3.00	25,833	August 15, 2021
2016 Offering Warrants	4.13	140,819	November 23, 2021 – February 27, 2022
2017 Public Offering Investors	4.13	1,622,989	August 2, 2022
2017 Public Offering Underwriter	4.54	65,940	February 2, 2023
December 2017 Registered Direct/Private Placement Offering Investors	4.63	640,180	June 19, 2023
December 2017 Registered Direct/Private Placement Offering Placement Agent	5.87	89,625	December 19, 2022
March 2018 Registered Direct/Private Placement Offering Investors	2.86	218,972	October 2, 2023
March 2018 Registered Direct/Private Placement Offering Placement Agent	3.73	46,866	March 28, 2023
August 2018 Offering Investors	1.15	3,921,569	August 14, 2023
August 2018 Offering Agent	1.59	549,020	August 8, 2023
April 2019 Registered Direct/Private Placement Offering Investors	1.42	1,294,498	April 5, 2021
April 2019 Registered Direct/Private Placement Offering Placement Agent	1.93	240,130	April 5, 2021
September 2019 Offering Investors	0.77	2,793,297	September 27, 2024
September 2019 Offering Underwriter	1.12	194,358	September 27, 2024
February 2020 Exercise Agreement Placement Agent	1.28	143,295	August 19, 2025
May 2020 Registered Direct Offering Investors	1.00	2,400,000	November 18, 2025
May 2020 Registered Direct Offering Placement Agent	1.33	494,118	May 14, 2025
August 2020 Underwriter	1.31	641,166	August 10, 2025
January 2021 Registered Direct Offering Investors	1.23	6,182,384	July 27, 2026
January 2021 Registered Direct Offering Agent	1.62	1,081,917	July 27, 2026
February 2021 Offering Investors	1.70	25,044,164	February 19, 2026
February 2021 Offering Agent	1.88	3,558,140	February 19, 2026
		<u>51,569,059</u>	

At March 31, 2021, the weighted average remaining life of the outstanding warrants is 4.3 years, all warrants are exercisable, and the aggregate intrinsic value of the warrants outstanding was \$14,029,462.

### Common Stock Reserved

A summary of common stock reserved for future issuances as of March 31, 2021 is as follows:

Stock plan options outstanding	4,615,171
Stock plan shares available for future grants	1,240,000
Warrants outstanding	51,569,059
Total	<u>57,424,230</u>

### 6. RELATED PARTY TRANSACTIONS

The Company has outstanding debt due to Leonard Mazur (Chairman of the Board) and Myron Holubiak (Chief Executive Officer) (see Note 4).

Leonard Mazur is a director and significant shareholder of Novellus, Inc. On October 6, 2020, the Company, through its subsidiary NoveCite, entered into an exclusive agreement with Novellus to develop cellular therapies (see Note 3).

### 7. OPERATING LEASE

Effective July 1, 2019, Citius entered into a 76-month lease for office space in Cranford, NJ. Citius will pay its proportionate share of real estate taxes and operating expenses in excess of the base year expenses. These costs are considered to be variable lease payments and are not included in the determination of the lease's right-of-use asset or lease liability.

The Company identified and assessed the following significant assumptions in recognizing its right-of-use assets and corresponding lease liabilities:

- As the Company's current Cranford lease does not provide an implicit rate, the Company estimated the incremental borrowing rate in calculating the present value of the lease payments. The Company estimated its incremental borrowing rate based on the remaining lease term as of the adoption date.
- Since the Company elected to account for each lease component and its associated non-lease components as a single combined component, all contract consideration was allocated to the combined lease component.
- The expected lease terms include noncancelable lease periods.

The elements of lease expense are as follows:

	Six Months Ended March 31, 2021	Six Months Ended March 31, 2020
<b>Lease cost</b>		
Operating lease cost	\$ 119,412	\$ 126,844
Variable lease cost	194	—
Total lease cost	<u>119,606</u>	<u>\$ 126,844</u>
<b>Other information</b>		
Weighted-average remaining lease term - operating leases	4.6 Years	5.6 Years
Weighted-average discount rate - operating leases	8.0%	8.0%

Maturities of lease liabilities due under the Company's non-cancellable leases as of March 31, 2021 is as follows:

<b>Year Ending September 30,</b>	<b>March 31, 2021</b>
2021 (excluding the 6 months ended March 31, 2021)	\$ 117,830
2022	239,306
2023	244,165
2024	249,024
2025 and thereafter	<u>275,343</u>
<b>Total lease payments</b>	1,125,668
Less: interest	<u>(188,513)</u>
Present value of lease liabilities	<u>\$ 937,155</u>

<b>Leases</b>	<b>Classification</b>	<b>March 31, 2021</b>	<b>September 30, 2020</b>
<b>Assets</b>			
Lease asset	Operating	\$ 906,092	\$ 986,204
<b>Total lease assets</b>		<u>\$ 906,092</u>	<u>\$ 986,204</u>
<b>Liabilities</b>			
Current	Operating	\$ 167,937	\$ 158,999
Non-current	Operating	769,218	855,471
<b>Total lease liabilities</b>		<u>\$ 937,155</u>	<u>\$ 1,014,470</u>

Interest expense on the lease liability was \$39,300 and \$44,997 for the six months ended March 31, 2021 and 2020, respectively.

#### **8. FDA REFUND**

In November 2019, the Company received a \$110,207 refund from the FDA for 2016 product and establishment fees because the fees paid by the Company exceeded the costs of the FDA's review of the associated applications. The Company recorded the \$110,207 as other income during the six months ended March 31, 2020.

#### **9. SUBSEQUENT EVENTS**

##### *Special Meeting of Stockholders*

The Company plans to hold a special meeting of stockholders on May 24, 2021 at the Company's headquarters at 11 Commerce Drive, First Floor, Cranford, New Jersey 07016, to 1) approve an amendment to our Articles of Incorporation to increase the authorized number of shares from 210,000,000 to 410,000,000 and the authorized number of common shares from 200,000,000 to 400,000,000, and 2) approve the 2021 Omnibus Stock Incentive Plan. The record date for the Special Meeting is April 7, 2021. Only stockholders of record at the close of business on that date may vote at the meeting or any adjournment thereof.

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

*The following discussion and analysis of our financial condition and results of operations for the three and six months ended March 31, 2021 should be read together with our unaudited consolidated financial statements and related notes included elsewhere in this report and in conjunction with the audited financial statements of Citius Pharmaceuticals, Inc. included in our Annual Report on Form 10-K for the year ended September 30, 2020. The following discussion contains "forward-looking statements" that reflect our future plans, estimates, beliefs and expected performance. Our actual results may differ materially from those currently anticipated and expressed in such forward-looking statements as a result of a number of factors. We caution that assumptions, expectations, projections, intentions or beliefs about future events may, and often do, vary from actual results and the differences can be material. Please see "Cautionary Note Regarding Forward-Looking Statements" on page ii of this Report.*

### **Historical Background**

Citius Pharmaceuticals, Inc. ("Citius," the "Company," "we" or "us") is a specialty pharmaceutical company dedicated to the development and commercialization of critical care products with a focus on anti-infective products in adjunct cancer care, unique prescription products and stem cell therapy. On September 12, 2014, we acquired Citius Pharmaceuticals, LLC as a wholly-owned subsidiary and on March 30, 2016, we acquired Leonard-Meron Biosciences, Inc. ("LMB") as a wholly-owned subsidiary. On September 11, 2020, we formed NoveCite, Inc. ("NoveCite"), a Delaware corporation, of which we own 75% of the issued and outstanding capital stock.

Through March 31, 2021, the Company has devoted substantially all of its efforts to business planning, acquiring our proprietary technology, research and development, recruiting management and technical staff, and raising capital. We are developing three proprietary products: Mino-Lok, an antibiotic lock solution used to treat patients with catheter-related bloodstream infections by salvaging the infected catheter; Mino-Wrap, a liquifying gel-based wrap for reducing tissue expander infections following breast reconstructive surgeries; and Halo-Lido, a corticosteroid-lidocaine topical formulation that is intended to provide anti-inflammatory and anesthetic relief to persons suffering from hemorrhoids. NoveCite is focused on the development and commercialization of its proprietary mesenchymal stem cells for the treatment of acute respiratory disease syndrome ("ARDS").

### **Patent and Technology License Agreements**

Our patent and technology license agreements are discussed in the footnotes to our unaudited consolidated financial statements included in this Report.

**Mino-Lok®** - LMB has a patent and technology license agreement with Novel Anti-Infective Therapeutics, Inc. ("NAT") to develop and commercialize Mino-Lok® on an exclusive, worldwide sub-licensable basis. Since May 2014, LMB has paid an annual maintenance fee, which began at \$30,000 and that increased over five years to \$90,000, where it will remain until the commencement of commercial sales of a product subject to the license. LMB will also pay annual royalties on net sales of licensed products, with royalties ranging from the mid-single digits to the low double digits or, in the event the licensed product is not subject to a valid patent claim, the royalty is reduced to mid- to lower-single digits. In limited circumstances in which the licensed product is not subject to a valid patent claim and a competitor is selling a competing product, the royalty rate is in the low single digits. After a commercial sale is obtained, LMB must pay minimum aggregate annual royalties that increase in subsequent years. LMB must also pay NAT up to \$1,100,000 upon achieving specified regulatory and sales milestones. Finally, LMB must pay NAT a specified percentage of payments received from any sub licensees.

**Mino-Wrap** - On January 2, 2019, we entered into a patent and technology license agreement with the Board of Regents of the University of Texas System on behalf of the University of Texas M. D. Anderson Cancer Center ("Licensor"), whereby we in-licensed exclusive worldwide rights to the patented technology for any and all uses relating to breast implants. We intend to develop a liquefying gel-based wrap containing minocycline and rifampin for the reduction of infections associated with breast implants following breast reconstructive surgeries ("Mino-Wrap"). We are required to use commercially reasonable efforts to commercialize Mino-Wrap under several regulatory scenarios and achieve milestones associated with these regulatory options leading to an approval from the Food and Drug Administration ("FDA").

Under the license agreement, the Company paid a nonrefundable upfront payment of \$125,000. We paid annual maintenance fees of \$45,000 and \$30,000 in January 2021 and 2020, respectively. The annual maintenance fee increases annually by \$15,000 per year up to a maximum of \$90,000. Annual maintenance fees cease on the first sale of product. We also must pay up to an aggregate of \$2.1 million in milestone payments, contingent on the achievement of various regulatory and commercial milestones. Under the terms of the license agreement, we also must pay a royalty of mid- to upper-single digit percentages of net sales, depending on the amount of annual sales, and subject to downward adjustment to lower- to mid-single digit percentages in the event there is no valid patent for the product in the United States at the time of sale. After the first sale of product, we will owe an annual minimum royalty payment of \$100,000 that will increase annually by \$25,000 for the duration of the term. We will be responsible for all patent expenses incurred by Licensor for the term of the agreement although Licensor is responsible for filing, prosecution and maintenance of all patents.

**NoveCite** – On October 6, 2020, our subsidiary NoveCite entered into a license agreement with Novellus Therapeutics Limited (“Licensor”), to develop and commercialize a stem cell therapy based on the Licensor’s patented technology for the treatment of acute pneumonitis of any etiology in which inflammation is a major agent in humans. NoveCite paid a \$5,000,000 license fee and issued 25% of its outstanding equity to the Licensor. We own the other 75% of NoveCite’s currently outstanding equity. If NoveCite issues additional equity, subject to certain exceptions, NoveCite must maintain Novellus’s ownership at 25% by issuing additional shares to Novellus.

Under the license agreement, NoveCite is obligated to pay Licensor up to an aggregate of \$51,000,000 in regulatory and developmental milestone payments. NoveCite also must pay a royalty equal to low double-digit percentages of net sales, commencing upon the first commercial sale of a licensed product. This royalty is subject to downward adjustment on a product-by-product and country-by-country basis to an upper-single digit percentage of net sales in any country in the event of the expiration of the last valid patent claim or if no valid patent claim exists in that country. The royalty will end on the earlier of (i) the date on which a biosimilar product is first marketed, sold, or distributed by Licensor or any third party in the applicable country or (ii) the 10-year anniversary of the date of expiration of the last-to-expire valid patent claim in that country. In the case of a country where no licensed patent ever exists, the royalty will end on the later of (i) the date of expiry of such licensed product’s regulatory exclusivity and (ii) the 10-year anniversary of the date of the first commercial sale of the licensed product in the applicable country. In addition, NoveCite will pay to Licensor an amount equal to a mid-twenties percentage of any sublicensee fees it receives.

Under the terms of the license agreement, in the event that Licensor receives any revenue involving the original cell line included in the licensed technology, then Licensor shall remit to NoveCite 50% of such revenue.

## RESULTS OF OPERATIONS

Three months ended March 31, 2021 compared with the three months ended March 31, 2020

	<b>Three Months Ended March 31, 2021</b>	<b>Three Months Ended March 31, 2020</b>
Revenues	\$ —	\$ —
Operating expenses:		
Research and development	1,551,341	2,015,940
General and administrative	2,293,517	2,258,322
Stock-based compensation expense	342,962	158,833
Total operating expenses	<u>4,187,820</u>	<u>4,433,095</u>
Operating loss	(4,187,820)	(4,433,095)
Interest income	69,327	12,106
Interest expense	(3,939)	(3,980)
Net loss	<u>\$ (4,122,432)</u>	<u>\$ (4,424,969)</u>

### Revenues

We did not generate any revenues for the three months ended March 31, 2021 or 2020.

### Research and Development Expenses

For the three months ended March 31, 2021, research and development expenses were \$1,551,341 as compared to \$2,015,940 during the three months ended March 31, 2020, a decrease of \$464,599. Research and development costs for Mino-Lok® decreased by \$487,986 to \$1,110,331 for the three months ended March 31, 2021 as compared to \$1,598,317 for the three months ended March 31, 2020. Research and development costs for our Halo-Lido product candidate decreased by \$87,307 to \$242,699 for the three months ended March 31, 2021 as compared to \$330,006 for the three months ended March 31, 2020. Research and development costs for our Mino-Wrap product candidate were \$55,000 for the three months ended March 31, 2021 as compared to \$87,617 during the three months ended March 31, 2020, a decrease of \$32,617. During the three months ended March 31, 2021, research and development costs for our recently in-licensed proposed novel cellular therapy for ARDS were \$143,311. The decrease in research and development expense in the quarter was due primarily to a milestone expense of \$621,708 incurred in the three months ended March 31, 2020 associated with the Mino-Lok® phase 3 trial.

As a result of the capital raised in our recent common stock offerings and common stock warrant exercises, we expect that research and development expenses will continue to increase in fiscal 2021 as we continue to focus on our Phase 3 trial for Mino-Lok®, progress the Halo-Lido product candidate and continue our research and development efforts related to ARDS and Mino-Wrap.

### General and Administrative Expenses

For the three months ended March 31, 2021, general and administrative expenses were \$2,293,517 as compared to \$2,258,322 during the three months ended March 31, 2020. General and administrative expenses increased by \$35,195 in comparison with the prior period. General and administrative expenses consist primarily of compensation costs, consulting fees incurred for financing activities and corporate development services, and investor relations expenses.

### Stock-based Compensation Expense

For the three months ended March 31, 2021, stock-based compensation expense was \$342,962 as compared to \$158,833 for the three months ended March 31, 2020. Stock-based compensation expense includes options granted to directors, employees and consultants. For the three months ended March 31, 2021, stock-based compensation includes \$18,833 in expense for the recently adopted NoveCite stock option plan. Stock-based compensation expense for the most recently completed quarter increased by \$184,129 in comparison to the prior period due to new grants made by Citius and the expense for the NoveCite stock plan.

### Other Income (Expense)

Interest income for the three months ended March 31, 2021 was \$69,327 as compared to interest income of \$12,106 for the prior period. We have invested the majority of the proceeds of our recent equity offerings in money market accounts.

Interest expense on notes payable for the three months ended March 31, 2021 was \$3,939 compared to \$3,980 for the three months ended March 31, 2020. The three months ended March 31, 2021 includes \$406 in interest on the paycheck protection program loan received on April 15, 2020.

### Net Loss

For the three months ended March 31, 2021, we incurred a net loss of \$4,122,432 compared to a net loss for the three months ended March 31, 2020 of \$4,424,969. The \$302,537 decrease in the net loss was primarily due to the decrease of \$464,599 in research and development expenses.

### Six months ended March 31, 2021 compared with the six months ended March 31, 2020

	Six Months Ended March 31, 2021	Six Months Ended March 31, 2020
Revenues	\$ —	\$ —
Operating expenses:		
Research and development	7,742,520	4,680,486
General and administrative	3,982,181	3,821,317
Stock-based compensation expense	619,544	379,217
Total operating expenses	<u>12,344,245</u>	<u>8,881,020</u>
Operating loss	(12,344,245)	(8,881,020)
Other income	—	110,207
Interest income	82,811	31,445
Interest expense	(7,907)	(7,971)
Net loss	<u>\$ (12,269,341)</u>	<u>\$ (8,747,339)</u>

### Revenues

We did not generate any revenues for the six months ended March 31, 2021 or 2020.

### **Research and Development Expenses**

For the six months ended March 31, 2021, research and development expenses were \$7,742,520 as compared to \$4,680,486 during the six months ended March 31, 2020, an increase of \$3,062,034. Research and development costs for Mino-Lok® decreased by \$1,881,338 to \$1,829,984 for the six months ended March 31, 2021 as compared to \$3,711,322 for the six months ended March 31, 2020 driven primarily by a decrease of \$1,556,745 in manufacturing research and development for registration batches produced in the six months ended December 31, 2020. Research and development costs for our Halo-Lido product candidate decreased by \$406,474 to \$473,573 for the six months ended March 31, 2021 as compared to \$880,047 for the six months ended March 31, 2020. Research and development costs for our Mino-Wrap product candidate were \$55,237 for the six months ended March 31, 2021 as compared to \$89,117 during the six months ended March 31, 2020, a decrease of \$33,880. During the six months ended March 31, 2021, research and development costs for our recently in-licensed proposed novel cellular therapy for ARDS were \$5,383,726.

We expect that research and development expenses will continue to increase in fiscal 2021 as we continue to focus on our Phase 3 trial for Mino-Lok®, progress the Halo-Lido product candidate and continue our research and development efforts related to ARDS and Mino-Wrap.

### **General and Administrative Expenses**

For the six months ended March 31, 2021, general and administrative expenses were \$3,982,181 as compared to \$3,821,317 during the six months ended March 31, 2020. General and administrative expenses increased by \$160,864 in comparison with the prior period. General and administrative expenses consist primarily of compensation costs, consulting fees incurred for financing activities and corporate development services, and investor relations expenses.

### **Stock-based Compensation Expense**

For the six months ended March 31, 2021, stock-based compensation expense was \$619,544 as compared to \$379,217 for the six months ended March 31, 2020. Stock-based compensation expense includes options granted to directors, employees and consultants. For the six months ended March 31, 2021, stock-based compensation includes \$31,389 in expense for the recently adopted NoveCite stock option plan. Stock-based compensation expense for the most recently completed quarter increased by \$240,327 in comparison to the prior period due to new grants made by Citius and the expense for the NoveCite stock plan.

### **Other Income (Expense)**

In November 2019, we received an additional \$110,207 refund from the FDA for 2016 product and establishment fees because the fees paid by the Company exceeded the costs of the FDA's review of the associated applications. The Company recorded the \$110,207 as other income during the six months ended March 31, 2020.

Interest income for the six months ended March 31, 2021 was \$82,811 as compared to interest income of \$31,445 for the prior period. We have temporarily invested most of the proceeds of our recent equity offerings in money market accounts.

Interest expense on notes payable for the six months ended March 31, 2021 was \$7,907 compared to \$7,971 for the six months ended March 31, 2020. The six months ended March 31, 2021 includes \$811 in interest on the paycheck protection program loan received on April 15, 2020.

### **Net Loss**

For the six months ended March 31, 2021, we incurred a net loss of \$12,269,341 compared to a net loss for the six months ended March 31, 2020 of \$8,747,339. The \$3,522,002 increase in the net loss was primarily due to the increase of \$3,062,034 in research and development expenses.

## LIQUIDITY AND CAPITAL RESOURCES

### Liquidity and Working Capital

Citius has incurred operating losses since inception and incurred a net loss of \$12,269,341 for the six months ended March 31, 2021. At March 31, 2021, Citius had an accumulated deficit of \$85,262,728. Citius' net cash used in operations during the six months ended March 31, 2021 was \$13,835,881.

Our September 30, 2020 consolidated financial statements contain an emphasis of a matter regarding substantial doubt about our ability to continue as a going concern and that the consolidated financial statements have been prepared assuming we will continue as a going concern and do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets, or the amounts and classification of liabilities that may result if we do not continue as a going concern.

As a result of the Company's recent common stock offerings and common stock warrant exercises, the Company had working capital of \$101,989,545 at March 31, 2021. At March 31, 2021, Citius had cash and cash equivalents of \$103,697,162 available to fund its operations. The Company's primary sources of cash flow since inception have been from financing activities. Our primary uses of operating cash were for in-licensing of intellectual property, product development and commercialization activities, employee compensation, consulting fees, legal and accounting fees, insurance and investor relations expenses.

On January 27, 2021, the Company closed a private placement for 15,455,960 shares of its common stock and warrants to purchase up to 7,727,980 shares of common stock, at a purchase price of \$1.294 per share of common stock and accompanying warrant, for gross proceeds of \$20,000,012. Net proceeds from the offering were \$18,450,410.

On February 19, 2021, the Company closed a registered direct offering for 50,830,566 shares of its common stock and warrants to purchase up to 25,415,283 shares of common stock, at a purchase price of \$1.505 per share and accompanying warrant, for gross proceeds of \$76,500,002. Net proceeds from the offering were \$70,979,842.

Based on our cash and cash equivalents at March 31, 2021, we expect that we will have sufficient funds to continue our operations through March 2023. We may need to raise additional capital in the future to support our operations beyond March 2023. There is no assurance, however, that we will be successful in raising the needed capital or that the proceeds will be received in an amount or in a timely manner to support our operations.

### Inflation

Our management believes that inflation has not had a material effect on our results of operations.

### Off Balance Sheet Arrangements

We do not have any off-balance sheet arrangements.

### Critical Accounting Policies and Estimates

The preparation of our financial statements and related disclosures in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, and the disclosure of contingent assets and liabilities as of the date of the financial statements and the amounts of revenues and expenses recorded during the reporting periods. We base our estimates on historical experience, where applicable, and other assumptions that we believe are reasonable under the circumstances. Actual results may differ from our estimates under different assumptions or conditions.

Our critical accounting policies and use of estimates are discussed in, and should be read in conjunction with, the annual consolidated financial statements and notes included in the Company's Annual Report on Form 10-K for the year ended September 30, 2020 as filed with the SEC.

**Item 3. Quantitative and Qualitative Disclosures About Market Risk**

Not applicable.

**Item 4. Controls and Procedures****Evaluation of Disclosure Controls and Procedures**

We maintain disclosure controls and procedures designed to provide reasonable assurance that information required to be disclosed in reports filed under the Securities Exchange Act of 1934, as amended (the “Exchange Act”), is recorded, processed, summarized and reported within the specified time periods and accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding disclosure.

Our Chief Executive Officer (who is our principal executive officer) and Chief Financial Officer (who is our principal financial officer and principal accounting officer), evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) promulgated under the Exchange Act) as of March 31, 2021. In designing and evaluating disclosure controls and procedures, we recognize that any disclosure controls and procedures, no matter how well designed and operated, can only provide reasonable assurance of achieving the desired control objective. As of March 31, 2021, based on the evaluation of these disclosure controls and procedures, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective in ensuring that information required to be disclosed by us in reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC’s rules and forms.

**Changes In Internal Control Over Financial Reporting**

There were no changes in our internal control over financial reporting during the quarter ended March 31, 2021 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

## PART II - OTHER INFORMATION

### Item 1. Legal Proceedings

None.

### Item 1A. Risk Factors

There has been no change in the Company's risk factors since the Company's Form 10-K filed with the SEC on December 16, 2020.

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

On February 26, 2021, we issued 50,000 shares of our common stock to a consultant for media relations, public relations and investor relations services pursuant to the agreed upon compensation terms in the consulting agreement with the entity. The issuance of the shares was exempt from registration under Section 4(a)(2) of the Securities Act.

### Item 3. Defaults Upon Senior Securities

None.

### Item 4. Mine Safety Disclosures

Not applicable.

### Item 5. Other Information

None.

**Item 6. Exhibits**

4.1	<a href="#">Form of Investor Warrant issued February 19, 2021 (incorporated herein by reference to Exhibit 4.1 to the Current Report on Form 8-K filed on February 19, 2021).</a>
4.2	<a href="#">Form of Placement Agent Warrant issued February 19, 2021 (incorporated herein by reference to Exhibit 4.2 to the Current Report on Form 8-K filed on February 19, 2021).</a>
10.1	<a href="#">Form of Securities Purchase Agreement, dated February 16, 2021, by and between Citius Pharmaceuticals, Inc. and the purchaser's signatory thereto (incorporated herein by reference to Exhibit 10.1 to the Current Report on Form 8-K filed on February 19, 2021).</a>
31.1	<a href="#">Certification of the Principal Executive Officer pursuant to Exchange Act Rule 13a-14(a).*</a>
31.2	<a href="#">Certification of the Principal Financial Officer pursuant to Exchange Act Rule 13a-14(a).*</a>
32.1	<a href="#">Certification of the Principal Executive and Principal Financial Officer pursuant to 18 U.S.C. 1350, as adopted pursuant to Section 906 of the Sarbanes Oxley Act of 2002.*</a>
EX-101.INS	XBRL INSTANCE DOCUMENT*
EX-101.SCH	XBRL TAXONOMY EXTENSION SCHEMA DOCUMENT*
EX-101.CAL	XBRL TAXONOMY EXTENSION CALCULATION LINKBASE*
EX-101.DEF	XBRL TAXONOMY EXTENSION DEFINITION LINKBASE*
EX-101.LAB	XBRL TAXONOMY EXTENSION LABELS LINKBASE*
EX-101.PRE	XBRL TAXONOMY EXTENSION PRESENTATION LINKBASE*

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\* 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, thereunto duly authorized.

**CITIUS PHARMACEUTICALS, INC.**

Date: May 13, 2021

By: /s/ Myron Holubiak  
Myron Holubiak  
Chief Executive Officer  
(Principal Executive Officer)

Date: May 13, 2021

By: /s/ Jaime Bartushak  
Jaime Bartushak  
Chief Financial Officer  
(Principal Financial and Accounting Officer)

**CERTIFICATION OF THE PRINCIPAL EXECUTIVE OFFICER  
PURSUANT TO SECTION 302 OF THE  
SARBANES-OXLEY ACT OF 2002**

I, Myron Holubiak, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Citius Pharmaceuticals, 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(s) 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(s) 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 (or persons performing the equivalent functions):
  - 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.

May 13, 2021

By: /s/ Myron Holubiak  
Myron Holubiak  
President and Chief Executive Officer  
(Principal Executive Officer)

**CERTIFICATION OF THE PRINCIPAL FINANCIAL OFFICER  
PURSUANT TO SECTION 302 OF THE  
SARBANES-OXLEY ACT OF 2002**

I, Jaime Bartushak, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Citius Pharmaceuticals, 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(s) 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(s) 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 (or persons performing the equivalent functions):
  - 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.

May 13, 2021

By: /s/ Jaime Bartushak  
Jaime Bartushak  
Chief Financial Officer  
(Principal Financial Officer and  
Principal Accounting Officer)

**CERTIFICATION OF THE PRINCIPAL EXECUTIVE OFFICER AND THE PRINCIPAL FINANCIAL OFFICER  
PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Quarterly Report of Citius Pharmaceuticals, Inc. (the "Company") on Form 10-Q for the quarter ended March 31, 2021 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), Myron Holubiak, President and Chief Executive Officer of the Company, and Jaime Bartushak, Chief Financial Officer of the Company, each hereby certifies, pursuant to 18 U.S.C. section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to his knowledge:

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

Date: May 13, 2021

By: /s/ Myron Holubiak  
Myron Holubiak  
President and Chief Executive Officer  
(Principal Executive Officer)

By: /s/ Jaime Bartushak  
Jaime Bartushak  
Chief Financial Officer  
(Principal Financial Officer and  
Principal Accounting Officer)