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DELTA REPORT

10-Q

CTXR - CITIUS PHARMACEUTICALS, I

10-Q - MARCH 31, 2024 COMPARED TO 10-Q - DECEMBER 31, 2023

The following comparison report has been automatically generated

TOTAL DELTAS	410
CHANGES	154
DELETIONS	121
ADDITIONS	135

REFINITIV

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

FORM 10-Q

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

For the quarterly period ended: December 31, 2023 March 31, 2024

OR

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

For the transition period from _____ to _____

Commission File Number 001-38174

Citius Pharmaceuticals, Inc.
(Exact name of registrant as specified in its charter)

Nevada	**27-3425913**
(*State or other jurisdiction of incorporation or organization*)	(*IRS Employer Identification No.*)
11 Commerce Drive, First Floor, Cranford, NJ	**07016**
(*Address of principal executive offices*)	(*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

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

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

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

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

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

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

As of February 10, 2024 May 10, 2024, there were 159,094,781 180,673,355 shares of common stock, $0.001 par value, of the registrant issued and outstanding.

Citius Pharmaceuticals, Inc.
FORM 10-Q

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December March 31, 2023 2024

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. ("Citius Pharma") and its wholly-owned subsidiaries Citius Pharmaceuticals, LLC, Leonard-Meron Biosciences, Inc., Citius Oncology, Inc. ("Citius Oncology"), 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:

- the cost, timing and results of our pre-clinical and clinical trials;
- our ability to raise funds for general corporate purposes and operations, including our pre-clinical and clinical trials;
- our ability to apply for, obtain and maintain required regulatory approvals for our product candidates;
- our ability to raise funds for general corporate purposes and operations, including our pre-clinical and clinical trials;
- the commercial feasibility and success of our technology and product candidates;
- our ability to recruit and retain qualified management and technical personnel to carry out our operations;
- our ability to realize some or all of the benefits expected to result from the anticipated spinoff of Citius Oncology, Inc., or the delay of such benefits;
- our ongoing businesses may be adversely affected and subject to certain risks and consequences as a result of the anticipated spinoff transaction; of Citius Oncology; and
- the other factors discussed in the "Risk Factors" section of our most recent Annual Report on Form 10-K for the fiscal year ended September 30, 2023, filed with the Securities and Exchange Commission on December 29, 2023, 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)

	December 31, 2023	September 30, 2023	March 31, 2024	September 30, 2023
ASSETS				
Current Assets:				
Cash and cash equivalents	$ 20,345,618	$ 26,480,928	$ 12,559,607	$ 26,480,928
Prepaid expenses	7,864,496	7,889,506	9,014,124	7,889,506
Total Current Assets	28,210,114	34,370,434	21,573,731	34,370,434
Property and equipment, net	854	1,432	275	1,432
Operating lease right-of-use asset, net	403,996	454,426	352,505	454,426
Other Assets:				
Deposits	38,062	38,062	38,062	38,062
In-process research and development	59,400,000	59,400,000	59,400,000	59,400,000
Goodwill	9,346,796	9,346,796	9,346,796	9,346,796
Total Other Assets	68,784,858	68,784,858		
Total Assets	$ 97,399,822	$ 103,611,150	$ 90,711,369	$ 103,611,150
LIABILITIES AND STOCKHOLDERS' EQUITY				
Current Liabilities:				
Accounts payable	$ 2,647,251	$ 2,927,334	$ 2,669,507	$ 2,927,334
Accrued expenses	276,897	476,300	151,204	476,300
Accrued compensation	2,430,671	2,156,983	1,123,076	2,156,983
Operating lease liability	224,000	218,380	229,733	218,380
Total Current Liabilities	5,578,819	5,778,997	4,173,520	5,778,997
Deferred tax liability	6,281,800	6,137,800	6,425,800	6,137,800
Operating lease liability – noncurrent	204,569	262,865	145,098	262,865
Total Liabilities	12,065,188	12,179,662	10,744,418	12,179,662
Commitments and Contingencies				
Stockholders' Equity:				
Preferred stock – $0.001 par value; 10,000,000 shares authorized; no shares issued and outstanding	—	—	—	—
Common stock – $0.001 par value; 400,000,000 shares authorized; 158,966,576 and 158,857,798 shares issued and outstanding at December 31, 2023 and September 30, 2023, respectively	158,967	158,858		
Common stock – $0.001 par value; 400,000,000 shares authorized; 159,094,781 and 158,857,798 shares issued and outstanding at March 31, 2024 and September 30, 2023, respectively			159,095	158,858
Additional paid-in capital	256,037,851	252,903,629	259,214,194	252,903,629
Accumulated deficit	(171,462,564)	(162,231,379)	(180,006,718)	(162,231,379)
Total Citius Pharmaceuticals, Inc. Stockholders' Equity	84,734,254	90,831,108	79,366,571	90,831,108
Non-controlling interest	600,380	600,380	600,380	600,380
Total Equity	85,334,634	91,431,488	79,966,951	91,431,488
Total Liabilities and Equity	$ 97,399,822	$ 103,611,150	$ 90,711,369	$ 103,611,150

See notes to unaudited condensed consolidated financial statements.

CITIUS PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
FOR THE THREE AND SIX MONTHS ENDED DECEMBER MARCH 31, 2023 2024 AND 2022 2023
(Unaudited)

	Three Months Ended		Three Months Ended		Six Months Ended	
	December 31, 2023	December 31, 2022	March 31, 2024	March 31, 2023	March 31, 2024	March 31, 2023
Revenues	$ —	$ —	$ —	$ —	$ —	$ —
Operating Expenses						
Research and development	2,621,910	3,445,515	3,605,898	4,726,855	6,227,808	8,172,370
General and administrative	3,660,728	2,603,287	4,285,911	4,792,850	7,946,639	7,396,137
Stock-based compensation – general and administrative	3,058,185	1,201,081	3,078,392	1,165,595	6,136,577	2,366,676
Total Operating Expenses	9,340,823	7,249,883	10,970,201	10,685,300	20,311,024	17,935,183
Operating Loss	(9,340,823)	(7,249,883)	(10,970,201)	(10,685,300)	(20,311,024)	(17,935,183)
Other Income						
Interest income	253,638	214,549	182,205	303,275	435,843	517,824
Gain on sale of New Jersey net operating losses	—	3,585,689	2,387,842	—	2,387,842	3,585,689
Total Other Income	253,638	3,800,238	2,570,047	303,275	2,823,685	4,103,513
Loss before Income Taxes	(9,087,185)	(3,449,645)	(8,400,154)	(10,382,025)	(17,487,339)	(13,831,670)
Income tax expense	144,000	144,000	144,000	144,000	288,000	288,000
Net Loss	$ (9,231,185)	$ (3,593,645)	$ (8,544,154)	$ (10,526,025)	$ (17,775,339)	$ (14,119,670)
Net Loss Per Share - Basic and Diluted	$ (0.06)	$ (0.02)	$ (0.05)	$ (0.07)	$ (0.11)	$ (0.10)
Weighted Average Common Shares Outstanding						
Basic and diluted	158,955,935	146,211,130	159,072,239	146,251,945	159,013,769	146,231,313

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 DECEMBER MARCH 31, 2023 2024 AND 2022 2023
(Unaudited)

	Preferred Stock	Common Stock Shares	Common Stock Amount	Additional Paid-In Capital	Accumulated Deficit	Total Citius Pharmaceuticals, Inc. Stockholders' Equity	Non-Controlling Interest	Total Equity
Balance, September 30, 2023	$ —	158,857,798	$ 158,858	$ 252,903,629	$ (162,231,379)	$ 90,831,108	$ 600,380	$ 91,431,488
Issuance of common stock for services	—	108,778	109	76,037	—	76,146	—	76,146
Stock-based compensation expense	—	—	—	3,058,185	—	3,058,185	—	3,058,185
Net loss	—	—	—	—	(9,231,185)	(9,231,185)	—	(9,231,185)
Balance, December 31, 2023	$ —	158,966,576	$ 158,967	$ 256,037,851	$ (171,462,564)	$ 84,734,254	$ 600,380	$ 85,334,634
Issuance of common stock for services								
Stock-based compensation expense								
Net loss								
Balance, March 31, 2024								
Balance, September 30, 2022	$ —	146,211,130	$ 146,211	$ 232,368,121	$ (129,688,467)	$ 102,825,865	$ 600,380	$ 103,426,245
Stock-based compensation expense	—	—	—	1,201,081	—	1,201,081	—	1,201,081
Net loss	—	—	—	—	(3,593,645)	(3,593,645)	—	(3,593,645)
Balance, December 31, 2022	$ —	146,211,130	$ 146,211	$ 233,569,202	$ (133,282,112)	$ 100,433,301	$ 600,380	$ 101,033,681
Issuance of common stock for services								
Issuance of common stock upon exercise of stock options								
Stock-based compensation expense								
Net loss								
Balance, March 31, 2023								

	Preferred Stock	Common Stock Shares	Common Stock Amount	Additional Paid-In Capital	Acc
Balance, September 30, 2023	$ —	158,857,798	$ 158,858	$ 252,903,629	$ (16
Issuance of common stock for services	—	108,778	109	76,037	
Stock-based compensation expense	—	—	—	3,058,185	
Net loss	—	—	—	—	(
Balance, December 31, 2023	—	158,966,576	158,967	256,037,851	(17
Issuance of common stock for services	—	128,205	128	97,951	
Stock-based compensation expense	—	—	—	3,078,392	
Net loss	—	—	—	—	(
Balance, March 31, 2024	$ —	159,094,781	$ 159,095	$ 259,214,194	$ (18
Balance, September 30, 2022	$ —	146,211,130	$ 146,211	$ 232,368,121	$ (12
Stock-based compensation expense	—	—	—	1,201,081	
Net loss	—	—	—	—	(
Balance, December 31, 2022	—	146,211,130	146,211	233,569,202	(13
Issuance of common stock for services	—	100,000	100	101,900	
Issuance of common stock upon exercise of stock options	—	46,667	47	31,220	
Stock-based compensation expense	—	—	—	1,165,595	
Net loss	—	—	—	—	(1
Balance, March 31, 2023	$ —	146,357,797	$ 146,358	$ 234,867,917	$ (14

See notes to unaudited condensed consolidated financial statements.

CITIUS PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
FOR THE THREE SIX MONTHS ENDED DECEMBER MARCH 31, 2023 2024 AND 2022 2023
(Unaudited)

	2023	2022	2024	2023
Cash Flows From Operating Activities:				
Net loss	$ (9,231,185)	$ (3,593,645)	$ (17,775,339)	$ (14,119,670)
Adjustments to reconcile net loss to net cash used in operating activities:				
Stock-based compensation expense	3,058,185	1,201,081	6,136,577	2,366,676
Issuance of common stock for services	76,146	—	174,225	102,000
Amortization of operating lease right-of-use asset	50,430	46,457	101,921	93,869
Depreciation	578	730	1,157	1,461
Deferred income tax expense	144,000	144,000	288,000	288,000
Changes in operating assets and liabilities:				
Prepaid expenses	25,010	(2,577,545)	(1,124,618)	(2,983,022)
Accounts payable	(280,083)	372,200	(257,827)	1,560,215
Accrued expenses	(199,403)	(714,992)	(325,096)	845,442
Accrued compensation	273,688	344,763	(1,033,907)	(736,474)
Operating lease liability	(52,676)	(47,488)	(106,414)	(95,932)
Net Cash Used In Operating Activities	(6,135,310)	(4,824,439)	(13,921,321)	(12,677,435)
Cash Flows From Financing Activities:				
Proceed from common stock option exercise			—	31,267
Net Cash Provided By Financing Activities			—	31,267
Net Change in Cash and Cash Equivalents	(6,135,310)	(4,824,439)	(13,921,321)	(12,646,168)
Cash and Cash Equivalents - Beginning of Period	26,480,928	41,711,690	26,480,928	41,711,690
Cash and Cash Equivalents - End of Period	$ 20,345,618	$ 36,887,251	$ 12,559,607	$ 29,065,522

See notes to unaudited condensed consolidated financial statements.

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

Business

Citius Pharmaceuticals, Inc. ("Citius Pharma," and together with its subsidiaries, the "Company," "we" or "us") is a late-stage biopharmaceutical company dedicated to the development and commercialization of first-in-class critical care products with a focus on oncology, anti-infectives in adjunct cancer care, unique prescription products and stem cell therapies.

On March 30, 2016, Citius Pharma acquired Leonard-Meron Biosciences, Inc. ("LMB") as a wholly-owned subsidiary by issuing shares of its common stock.

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).

On August 23, 2021, we formed Citius Oncology, Inc. (formerly named Citius Acquisition Corp.) ("Citius Oncology"), as a wholly-owned subsidiary in conjunction with the acquisition of LYMPHIR, which began operations in April 2022. On October 23, 2023, Citius Pharma and Citius Oncology entered into an agreement and plan of merger and reorganization with TenX Keane Acquisition, and its wholly owned subsidiary, TenX Merger Sub Inc., whereby TenX Merger Sub Inc. will merge with and into Citius Oncology, with Citius Oncology surviving as a wholly owned subsidiary of TenX Keane Acquisition. The newly combined publicly traded company is to be named "Citius Oncology, Inc." (see Note 9).
An inactive subsidiary, Citius Pharmaceuticals, LLC, was dissolved on December 29, 2023.

In-process research and development ("IPR&D") consists of (i) the $19,400,000 acquisition value of LMB's leading drug candidate Mino-Lok®, which is an antibiotic solution used to treat catheter-related bloodstream infections and is expected to be amortized on a straight-line basis over a period of eight years commencing upon revenue generation, and (ii) the $40,000,000 acquisition value of the exclusive license for LYMPHIR (denileukin diftitox), which is a late-stage oncology immunotherapy for the treatment of cutaneous T-cell lymphoma (CTCL), a rare form of non-Hodgkin lymphoma, and is expected to be amortized on a straight-line basis over a period of twelve years commencing upon revenue generation.

Goodwill of $9,346,796 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.

Since its inception, we have devoted substantially all our efforts to business planning, research and development, recruiting management and technical staff, and raising capital. We are 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 Pharma or its competitors of research and development stage products, regulatory approval and market acceptance of its products, 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 unaudited condensed consolidated financial statements include the operations of Citius Pharmaceuticals, Inc., and its wholly-owned subsidiaries, Citius Pharmaceuticals, LLC, LMB, and Citius Oncology, and its majority-owned subsidiary NoveCite. NoveCite began operations in October 2020 and Citius Oncology began operations in April 2022. 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 December 31, 2023 March 31, 2024, and the results of its operations and cash flows for the three months and six month periods ended December 31, 2023 March 31, 2024 and 2022. 2023. The operating results for the three months three- and six-month periods ended December 31, 2023 March 31, 2024 are not necessarily indicative of the results that may be expected for the year ending September 30, 2024. 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 fiscal year ended September 30, 2023 filed with the Securities and Exchange Commission ("SEC") on December 29, 2023.

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 the accounting for in-process research and development and goodwill impairment, stock-based compensation, 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 applicable to common stockholders is computed by dividing net loss applicable to common stockholders 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

Other than as disclosed in our Form 10-K, we are not aware of any other recently issued accounting standards not yet adopted that may have a material impact on our financial statements.

2. GOING CONCERN UNCERTAINTY AND MANAGEMENT'S PLAN

The accompanying unaudited 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 $6,135,310 $13,921,321 for the three six months ended December 31, 2023 March 31, 2024. The Company had working capital of approximately $22,600,000 $17,400,000 at December 31, 2023 March 31, 2024. The As a result of a capital raising that closed on April 30, 2024 (see Note 10), the Company estimates that its available cash resources will be sufficient to fund its operations through August December 2024, which raises substantial doubt about the Company's ability to continue as a going concern within one year after the date that the accompanying condensed consolidated financial statements are issued.

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 August December 2024, including its development plans for LYMPHIR, Mino-Lok, Mino-Wrap, Halo-Lido and NoveCite, will depend on its ability to obtain regulatory approval to market LYMPHIR and/or Mino-Lok and generate substantial revenue from the sale of LYMPHIR and/or 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 product candidates. However, the Company can provide no assurances on regulatory approval, commercialization, or future sales of LYMPHIR and/or 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 LYMPHIR and/or 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 seeking regulatory approval, and protecting 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 sub-licensable basis, as amended. LMB pays an annual maintenance fee each June until commercial sales of a product subject to the license commence. The Company recorded an annual maintenance fee expense of $90,000 in 2023 and 2022.

LMB will also pay annual royalties on net sales of licensed products, with royalty rates ranging from the mid-single digits to the low double low-double 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- to mid-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 to achieve certain development and commercial milestones, 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 terminated the Mino-Wrap license agreement on December 11, 2023.

License Agreement with Eterna

On October 6, 2020, our subsidiary, NoveCite, signed an exclusive license agreement for a novel cellular therapy for acute respiratory distress syndrome (ARDS) with a subsidiary of Novellus, Inc. ("Novellus"). Upon execution of the agreement, we paid $5,000,000 to Novellus, which was charged to research and development expense during the year ended September 30, 2021, and issued 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 original stock subscription agreement, if NoveCite issued additional equity, subject to certain exceptions, NoveCite had to maintain Novellus's ownership at 25% by issuing additional shares to Novellus.

In July 2021, Novellus was acquired by Brooklyn ImmunoTherapeutics, Inc. ("Brooklyn"). In connection with that transaction, the stock subscription agreement was amended to assign to Brooklyn all of Novellus's right, title, and interest in the stock subscription agreement and delete the anti-dilution protection and replace it with a right of first refusal whereby Brooklyn will have the right to purchase all or a portion of the securities that NoveCite intends to sell or in the alternative, at the option of NoveCite, Brooklyn may purchase that amount of the securities proposed to be sold by NoveCite to allow Brooklyn to maintain its then percentage ownership. In October 2022, Brooklyn changed its name to Eterna Therapeutics Inc. ("Eterna").

Citius Pharma is responsible for the operational activities of NoveCite and bears all costs necessary to operate NoveCite. Citius Pharma'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.

Eterna 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 Eterna 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) 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 Eterna an amount equal to a mid-twenties percentage of any sublicensee fees it receives.

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

The term of the license agreement continues 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.

Eterna 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 Eterna 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.

License Agreement with Eisai

In September 2021, Citius Pharma entered into an asset purchase agreement with Dr. Reddy's Laboratories SA, a subsidiary of Dr. Reddy's Laboratories, Ltd. (collectively, "Dr. Reddy's") and a license agreement with Eisai Co., Ltd. ("Eisai") to acquire an exclusive license for E7777 (denileukin diftitox), a late-stage oncology immunotherapy for the treatment of CTCL, a rare form of non-Hodgkin lymphoma. We renamed E7777 as I/ONTAK and also obtained the trade name LYMPHIR for the product. Citius Pharma assigned these agreements to Citius Oncology effective April 1, 2022.

Under the terms of the agreements, Citius Pharma acquired Dr. Reddy's exclusive license for E7777 from Eisai and other related assets owned by Dr. Reddy's. The exclusive license includes rights to develop and commercialize E7777 in all markets except for Japan and certain parts of Asia. Additionally, we retain an option on the right to develop and market the product in India. Eisai retains exclusive development and marketing rights for the agent in Japan, China, Korea, Taiwan, Hong Kong, Macau, Indonesia, Thailand, Malaysia, Brunei, Singapore, India (subject to the India option), Pakistan, Sri Lanka, Philippines, Vietnam, Myanmar, Cambodia, Laos, Afghanistan, Bangladesh, Bhutan, Nepal, Mongolia, and Papua New Guinea. Citius Pharma paid a $40 million upfront payment which represents the acquisition date fair value of the in-process research and development acquired from Dr. Reddy's. Dr. Reddy's is entitled to up to $40 million in development milestone payments related to CTCL approvals in the U.S. and other markets, up to $70 million in development milestones for additional indications, as well as commercial milestone payments and low double-digit tiered royalties on net product sales (within a range of 10% to 15%), and up to $300 million for commercial sales milestones. We also must pay on a fiscal quarter basis tiered royalties equal to low double-digit percentages of net product sales (within a range of 10% to 15%). The royalties will end on the earlier of (i) the 15-year anniversary of the first commercial sale of the latest indication that received regulatory approval in the applicable country and (ii) the date on which a biosimilar product results in the reduction of net sales in the applicable product by 50% in two consecutive quarters, as compared to the four quarters prior to the first commercial sale of the biosimilar product. We will also pay to Dr. Reddy's an amount equal to a low-thirties percentage of any sublicense upfront consideration or milestone payments (or the like) received by us and the greater of (i) a low-thirties percentage of any sublicensee sales-based royalties or (ii) a mid-single digit percentage of such licensee's net sales.

Under the license agreement, Eisai is to receive a $6.0 million development milestone payment upon initial approval and additional commercial milestone payments related to the achievement of net product sales thresholds (which increases to $7 million in the event we have exercised our option to add India to the licensed territory prior to FDA approval) and an aggregate of up to $22 million related to the achievement of net product sales thresholds. Citius Oncology was required to reimburse Eisai for up to $2.65 million of its costs to complete the Phase 3 pivotal clinical trial for LYMPHIR for the CTCL indication and reimburse Eisai for all reasonable costs associated with the preparation of a Biologics License Application ("BLA") for LYMPHIR. Eisai was responsible for completing the CTCL clinical trial, and chemistry, manufacturing, and controls ("CMC") activities through the filing of the BLA for LYMPHIR with the FDA. The BLA was filed with the FDA on September 27, 2022. Citius Oncology will also be responsible for development costs associated with potential additional indications.

The term of the license agreement will continue until (i) if there has not been a commercial sale of a licensed product in the territory, the 10-year anniversary of the original license effective date, March 30, 2016, or (ii) if there has been a first commercial sale of a licensed product in the territory within the 10-year anniversary of the original license effective date, the 10-year anniversary of the first commercial sale on a country-by-country basis. The term of the license may be extended for additional 10-year periods for all countries in the territory by notifying Eisai and paying an extension fee equal to $10 million. Either party may terminate the license agreement upon written notice if the other party is in material breach of the agreement, subject to cure within the designated time periods. Either party also may terminate the license agreement immediately upon written notice if the other party files for bankruptcy or takes related actions or is unable to pay its debts as they become due. Additionally, either party will have the right to terminate the agreement if the other party directly or indirectly challenges the patentability, enforceability or validity of any licensed patent.

Also under the purchase agreement with Dr. Reddy's, we are required to (i) use commercially reasonable efforts to make commercially available products in the CTCL indication, peripheral T-cell lymphoma indication and immuno-oncology indication, (ii) initiate two investigator initiated immuno-oncology trials (both of which have been initiated), (iii) use commercially reasonable efforts to achieve each of the approval milestones, and (iv) complete each specified immuno-oncology investigator trial on or before the four-year anniversary of the effective date of the definitive agreement. Additionally, we are required to commercially launch a product in a territory within six months of receiving regulatory approval for such product in each such jurisdiction.
On July 29, 2023, we received a Complete Response Letter, ("CRL") from the FDA regarding the BLA seeking approval for LYMPHIR. The FDA has required that we incorporate enhanced product testing, and additional controls agreed to with the FDA during the market application review. The FDA raised no concerns relating to the safety and efficacy clinical data package.
On September 8, 2023, we announced that the FDA agreed with our plans to address the requirements outlined in the CRL. The guidance from the FDA provides a path for completing the necessary activities to support the resubmission of the BLA. No additional clinical efficacy or safety trials have been requested by FDA for the resubmission. Based on the feedback from the FDA.
On February 13, 2024, we filed the BLA resubmission package with the FDA.

4. PREPAID EXPENSES

Prepaid expenses at December 31, 2023 March 31, 2024 and September 31, 2023 consist of $129,601 $107,309 and $154,611 of prepaid insurance, respectively, and $8,906,815 and $7,734,895 of advance payments, respectively, made for the preparation of long-lead time drug substance and product costs, which will be utilized in research and development activities or in the manufacturing of LYMPHIR for sales upon approval.

5. COMMON STOCK, STOCK OPTIONS AND WARRANTS

Common Stock Issued for Services

On October 10, 2023, the Company issued 108,778 shares of common stock for media, and public and investor relations services and expensed the $76,146 fair value of the common stock issued.

On January 17, 2024, the Company issued 128,205 shares of common stock for general and business development advisory services and expensed the $98,079 fair value of the common stock issued.
Stock Option Plans

Pursuant to our 2014 Stock Incentive Plan, we reserved 866,667 shares of common stock. As of December 31, 2023 March 31, 2024, there were options to purchase 795,171 736,828 shares outstanding, options to purchase 4,829 shares were exercised, options to purchase 66,667 125,010 shares expired, and no shares were available for future grants.

Pursuant to our 2018 Omnibus Stock Incentive Plan, we reserved 2,000,000 shares of common stock. As of December 31, 2023 March 31, 2024, there were options to purchase 1,760,000 1,720,000 shares outstanding, options to purchase 116,667 shares were exercised, options to purchase 13,333 53,333 shares expired, and the remaining 110,000 shares were transferred to the 2020 Omnibus Stock Incentive Plan ("2020 Plan").

Pursuant to our 2020 Plan, we reserved 3,110,000 shares of common stock. As of December 31, 2023 March 31, 2024, there were options to purchase 1,820,000 1,735,000 shares outstanding, options to purchase 50,000 135,000 shares expired and the remaining 1,240,000 shares were transferred to the 2021 Omnibus Stock Incentive Plan ("2021 Stock Plan").

Pursuant to our 2021 Stock Plan, we reserved 8,740,000 shares of common stock. As of December 31, 2023 March 31, 2024, options to purchase 8,630,000 8,465,000 shares were outstanding, options to purchase 75,000 240,000 shares expired and the remaining 35,000 shares were transferred to the 2023 Omnibus Stock Incentive Plan ("2023 Stock Plan").

In November 2022, our Board approved the 2023 Stock Plan, subject to stockholder approval, which was received on February 7, 2023. The 2023 Stock Plan has reserved for issuance 12,035,000 shares of common stock. stock for issuance. As of December 31, 2023 March 31, 2024, options to purchase 4,385,000 4,460,000 shares were outstanding and 7,650,000 7,575,000 shares remain 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 our stock option plans (excluding the NoveCite and Citius Oncology Stock Plans) is presented below:

	Option Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term	Aggregate Intrinsic Value	Option Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term	Aggregate Intrinsic Value
Outstanding at September 30, 2023	13,305,171	$ 1.79	7.41 years	$ 56,203	13,305,171	$ 1.79	7.41 years	$ 56,203
Granted	4,085,000	0.70			4,160,000	0.70		
Exercised	—	—			—	—		
Forfeited or expired	—	—			(348,343)	1.79		
Outstanding at December 31, 2023	17,390,171	$ 1.54	7.78 years	$ 379,421				
Outstanding at March 31, 2024					17,116,828	$ 1.53	7.57 years	$ 1,067,145
Exercisable at December 31, 2023	9,231,839	$ 1.91	6.60 years	$ 134,921				
Exercisable at March 31, 2024					9,123,494	$ 1.90	6.42 years	$ 239,395

On October 10, 2023, the Board of Directors granted options to purchase 3,725,000 shares to employees, 300,000 shares to directors and 60,000 shares to consultants at $0.70 per share. On March 14, 2024, the Board of Directors granted options to purchase 75,000 shares to a director at $0.69 per share. The weighted average grant date fair value of the options granted during the three six months ended December 31, 2023 March 31, 2024 was estimated at $0.54 $0.53 per share. These options vest over terms of 12 to 36 months and have a term of 10 years.

On October 4, 2022, the Board of Directors granted options to purchase 3,375,000 shares to employees, 375,000 shares to directors and 50,000 shares to a consultant at $1.25 per share. On November 8, 2022, the Board of Directors granted options to purchase 50,000 shares to a consultant at $1.04 per share. The weighted average grant date fair value of the options granted during the three six months ended December 31, 2023 March 31, 2023 was estimated at $0.97 per share. 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 December 31, 2023 March 31, 2024 and 2022 2023 was $3,058,185 $3,078,392 (including $19,858 $13,858 for the NoveCite plan and $1,917,000 $1,957,000 for the Citius Oncology Plan) and $1,201,081 $1,165,595 (including $33,333 for the NoveCite Stock Plan), respectively. Stock-based compensation expense for the six months ended March 31, 2024 and 2023 was $6,136,577 (including $33,716 for the NoveCite plan and $3,874,000 for the Citius Oncology Plan) and $2,366,676 (including $66,666 for the NoveCite Stock Plan), respectively.

At December 31, 2023 March 31, 2024, unrecognized total compensation cost related to unvested awards under the Citius Pharma stock plans of $5,905,736 $4,835,255 is expected to be recognized over a weighted average period of 1.75 1.31 years.

NoveCite Stock Plan - Under the NoveCite Stock Plan, we reserved 2,000,000 common shares of NoveCite for issuance. As of December 31, 2023 March 31, 2024, there were options outstanding to purchase 1,911,500 common shares of NoveCite and 88,500 shares available for future grants. All of the options were issued during the year ended September 30, 2021.

As of December 31, 2023 March 31, 2024, NoveCite has options outstanding to purchase 1,911,500 common shares at a weighted average exercise price of $0.24 per share, of which 1,772,917 are exercisable. These options vest over 36 months and have a term of 10 years. The weighted average remaining contractual term of options outstanding under the NoveCite Stock Plan is 7.14 6.89 years. At December 31, 2023 March 31, 2024, unrecognized total compensation cost related to unvested awards under the NoveCite Stock Plan of $27,717 $13,858 is expected to be recognized over a weighted average period of 0.5 0.25 years.

Citius Oncology Stock Plan - Under the Citius Oncology Stock Plan, adopted on April 29, 2023, we reserved 15,000,000 common shares of Citius Oncology for issuance. The Citius Oncology Stock Plan provides incentives to employees, directors, and consultants through grants of options, SARs, dividend equivalent rights, restricted stock, restricted stock units, or other rights.

During the year ended September 30, 2023, Citius Oncology granted options to purchase 12,750,000 common shares at a weighted average exercise price of $2.15 per share, of which options to purchase 150,000 common shares were forfeited. The weighted average grant date fair value of the options granted during the year ended September 30, 2023 was estimated at $1.65 per share. These options vest over periods from 12 to 36 months and have a term of 10 years.

At December 31, 2023 March 31, 2024, Citius Oncology has options outstanding to purchase 12,600,000 shares, of which 1,638,889 2,622,222 common shares are exercisable. The weighted average remaining contractual term of options outstanding under the Citius Oncology Stock Plan is 9.5 9.27 years. At December 31, 2023 March 31, 2024, unrecognized total compensation cost related to unvested awards under the Citius Oncology Stock Plan of $16,925,500 $14,968,500 is expected to be recognized over a weighted average period of 2.4 2.2 years.

Warrants

As of December 31, 2023 March 31, 2024, we have reserved shares of common stock for the exercise of outstanding warrants as follows:

	Exercise price	Number	Expiration Date
August 2018 Offering Investors	$ 1.15	3,921,569	August 14, 2024
August 2018 Offering Agent	1.59	189,412	August 8, 2024
April 2019 Registered Direct/Private Placement Investors	1.42	1,294,498	April 5, 2024
April 2019 Registered Direct/Private Placement Agent	1.93	240,130	April 5, 2024
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 Agent	1.28	138,886	August 19, 2025
May 2020 Registered Direct Offering Investors	1.00	1,670,588	November 18, 2025
May 2020 Registered Direct Offering Agent	1.33	155,647	May 14, 2025
August 2020 Underwriter	1.31	201,967	August 10, 2025
January 2021 Private Placement Investors	1.23	3,091,192	July 27, 2026
January 2021 Private Placement Agent	1.62	351,623	July 27, 2026
February 2021 Offering Investors	1.70	20,580,283	February 19, 2026
February 2021 Offering Agent	1.88	2,506,396	February 19, 2026
May 2023 Registered Direct Offering Investors	1.50	12,500,001	May 8, 2028
May 2023 Registered Direct Offering Agent	1.50	875,000	May 3, 2028
		50,704,847	

At March 31, 2024, the weighted average remaining life of the outstanding warrants is 2.2 years, all warrants are exercisable, and the aggregate intrinsic value of the warrants outstanding was $363,129.

At December 31, 2023, the weighted average remaining life of the outstanding warrants is 2.5 years, all warrants are exercisable, and there was no aggregate intrinsic value of the warrants outstanding.

Common Stock Reserved

A summary of common stock reserved for future issuances as of December 31, 2023 March 31, 2024 is as follows:

Stock plan options outstanding	17,390,171	17,116,828
Stock plan shares available for future grants	7,650,000	7,575,000
Warrants outstanding		50,704,847
Total	75,745,018	75,396,675

6. OPERATING LEASE

Effective July 1, 2019, Citius Pharma entered into a 76-month lease for office space in Cranford, NJ. Citius Pharma pays its proportionate share of real estate taxes and operating expenses in excess of the base year expenses. These costs are 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 lease does not provide an implicit rate, the Company estimated the incremental borrowing rate in calculating the present value of the lease payments 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:

Lease cost	**Three Months Ended December 31, 2023**	**Three Months Ended December 31, 2022**	**Six Months Ended March 31, 2024**	**Six Months Ended March 31, 2023**
Operating lease cost	$ 59,705	$ 59,707	$ 119,411	$ 119,412
Variable lease cost	1,204	1,158	2,468	2,363
Total lease cost	$ 60,909	$ 60,865	$ 121,879	$ 121,775
Other information				
Weighted-average remaining lease term - operating leases	1.8 Years	2.8 Years	1.6 Years	2.6 Years
Weighted-average discount rate - operating leases	8.0%	8.0%	8.0%	8.0%

Maturities of lease liabilities due under the Company's non-cancellable leases are as follows:

Year Ending September 30,	**December 31, 2023**	**March 31, 2024**
2024 (excluding the 3 months ended December 31, 2023)	$ 187,072	
2024 (excluding the 6 months ended March 31, 2024)		$ 125,119
2025	253,883	253,883
2026	21,460	21,460
Total lease payments	462,415	400,462
Less: interest	(33,846)	(25,631)
Present value of lease liabilities	$ 428,569	$ 374,831

Leases	Classification	December 31, 2023	September 30, 2023	Classification	March 31, 2024	September 30, 2023
Assets						
Lease asset	Operating	$ 403,996	$ 454,426	Operating	$ 352,505	$ 454,426
Total lease assets		$ 403,996	$ 454,426		$ 352,505	$ 454,426
Liabilities						
Current	Operating	$ 224,000	$ 218,380	Operating	$ 229,733	$ 218,380
Non-current	Operating	204,569	262,865	Operating	145,098	262,865
Total lease liabilities		$ 428,569	$ 481,245		$ 374,831	$ 481,245

Interest expense on the lease liability was $9,275 $17,490 and $13,250 $25,543 for the three six months ended December 31, 2023 March 31, 2024 and 2022, 2023, respectively.

7. GAIN ON SALE OF NEW JERSEY NET OPERATING LOSSES

The Company recognized a gain of $2,387,842 and $3,585,689 for the three six months ended December 31, 2022 March 31, 2024 and 2023, respectively, in connection with the sale sales of certain New Jersey income tax net operating losses to a third party parties under the New Jersey Technology Business Tax Certificate Transfer Program.

8. NASDAQ LISTING

On September 12, 2023, we received a notification letter from the Nasdaq Stock Market LLC ("Nasdaq") indicating that we were not in compliance with Nasdaq Listing Rule 5550(a)(2) because the minimum bid price of our common stock on the Nasdaq Capital Market closed below $1.00 per share for 30 consecutive business days. In accordance with Nasdaq Listing Rule 5810(c)(3)(A), the Company has a compliance period of 180 calendar days, or until March 11, 2024, to regain compliance with the Bid Price Rule.
On March 12, 2024, Nasdaq granted our request for an extension through September 9, 2024 to evidence compliance with the $1.00 per share requirement for continued inclusion on the Nasdaq Capital Market. If at any time before March 11, 2024 September 9, 2024, the bid price of the Company's our common stock closes at $1.00 per share or more for a minimum of ten consecutive business days, Nasdaq will provide the Company us with a written confirmation of compliance with the Bid Price Rule.
If the Company does we do not regain compliance with the Bid Price Rule by March 11, 2024 September 9, 2024, Nasdaq will provide notice to us that our common stock is subject to delisting. At that time, we may appeal the Company may be eligible determination to a Nasdaq hearings panel. The request for an additional 180-day compliance period. To qualify, a hearing will stay any suspension or delisting action pending the Company would be required issuance of the hearing panel's decision. The Extension Notice has no effect at this time on the listing of our common stock, which will continue to meet the continued listing requirement for market value of publicly held shares and all other initial listing standards for the trade on The Nasdaq Capital Market, Market. We are currently evaluating our options for regaining compliance. There can be no assurance that we will be able to regain compliance with the exception of the Bid Price Rule, and would need to provide written notice of its intention to cure even if we maintain compliance with the bid price deficiency during the second compliance period by effecting a reverse stock split, if necessary. other listing requirements.

9. MERGER AGREEMENT

On October 23, 2023, Citius Pharma and Citius Oncology entered into an agreement and plan of merger and reorganization (the "Merger Agreement") with TenX Keane Acquisition, a Cayman Islands exempted company ("TenX"), and its wholly owned subsidiary, TenX Merger Sub Inc. ("Merger Sub"), a Delaware corporation. The Merger Agreement provides, among other things, (i) on the terms and subject to the conditions set forth therein, that Merger Sub will merge with and into Citius Oncology, with Citius Oncology surviving as a wholly owned subsidiary of TenX (the "Merger"), and (ii) that prior to the effective time of the Merger (the "Effective Time"), TenX will migrate to and domesticate as a Delaware corporation in accordance with Section 388 of the General Corporation Law of the State of Delaware and the Cayman Islands Companies Act (As Revised) (the "Domestication"). The newly combined publicly traded company is to be named "Citius Oncology, Inc." (the "Combined Company"). The Domestication, Merger and the other transactions contemplated by the Merger Agreement are referred to as the "Business Combination."

In the Merger, all shares of Citius Oncology would be converted into the right to receive common stock of the Combined Company. As a result, upon closing, Citius Pharma would receive 67.5 million shares of common stock of the Combined Company. As part of the transaction, Citius Pharma will contribute $10 million in cash to the Combined Company. The 12.6 million existing Citius Oncology common stock options will be assumed by the Combined Company. Citius Pharma and the Combined Company will also enter into an amended and restated shared services agreement, which, among other things, will govern certain management and scientific services that Citius Pharma will continue to provide to the Combined Company following the Effective Time.

The Merger Agreement, Business Combination and the transactions contemplated thereby were unanimously approved by the boards of directors of each of Citius Pharma, Citius Oncology and TenX. The transaction is expected to be completed in the first half third quarter of 2024, subject to approval by stockholders of TenX and other customary closing conditions, including final regulatory approvals and SEC filings. There can be no assurance regarding the ultimate timing of the proposed transaction or that the transaction will be completed at all.

10. SUBSEQUENT EVENTS

Warrants

On February 13, 2024 April 3, 2024, we filed the BLA resubmission package Board of Directors approved a one-year extension to April 5, 2025 for warrants to purchase 1,294,498 shares of common stock with an exercise price of $1.42 per share. The warrants are held by Leonard Mazur, the Company's Chief Executive Officer and Chairman of the Board of Directors, and Myron Holubiak, the Company's Executive Vice President and member of the Board of Directors, and were originally issued in April 2019 in a registered direct offering of common stock. Mr. Mazur and Mr. Holubiak participated in the offering on the same basis as all other investors. Additionally, 240,130 warrants with an exercise price of $1.9313 per share issued in connection with the FDA. registered direct offering were extended by one-year to April 5, 2025. These warrants are held by certain representatives of the registered direct offering placement agent. The terms of the warrants were previously extended in April 2021 to April 5, 2024. If these warrants are fully exercised, the Company would receive approximately $2.3 million in cash proceeds.

Registered Direct Offering

On April 25, 2024, the Company entered into a securities purchase agreement with certain institutional investors for the purchase of an aggregate of 21,428,574 shares of its common stock and accompanying warrants to purchase up to an aggregate of 21,428,574 shares of its common stock, at a purchase price of $0.70 per share and accompanying warrant in a registered direct offering. The warrants have an exercise price of $0.75 per share, are exercisable six months after the date of issuance, and will expire five years from the initial exercise date.

The aggregate gross proceeds to the Company from the offering were $15 million, before deducting the placement agent fees and other offering expenses payable by the Company, and approximately $13.8 million after deducting placement agent fees and offering expenses.

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 December 31, 2023 March 31, 2024 and 2023 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, 2023, filed with the Securities and Exchange Commission ("SEC") on December 29, 2023. 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 Pharma," and together with its subsidiaries, the "Company," "we" or "us") is a late-stage biopharmaceutical company dedicated to the development and commercialization of first-in-class critical care products with a focus on oncology, anti-infectives in adjunct cancer care, unique prescription products and stem cell therapies. On September 12, 2014, we acquired Citius Pharmaceuticals, LLC as a wholly-owned subsidiary.

On March 30, 2016, we acquired all of the outstanding stock of Leonard-Meron Biosciences, Inc. ("LMB") by issuing shares of our common stock. We acquired identifiable intangible assets of $19,400,000 related to in-process research and development and recorded goodwill of $9,346,796 for the excess of the purchase consideration over the net assets acquired.

On September 11, 2020, we formed NoveCite, Inc. ("NoveCite"), a Delaware corporation, of which we own 75% of the issued and outstanding capital stock.

On August 23, 2021, we formed Citius Oncology, Inc. (formerly named Citius Acquisition Corp.) ("Citius Oncology"), as a wholly-owned subsidiary in conjunction with the acquisition of LYMPHIR, which began operations in April 2022.

In-process research and development ("IPR&D") consists of (i) the $19,400,000 acquisition value of LMB's leading drug candidate Mino-Lok®, which is an antibiotic solution used to treat catheter-related bloodstream infections and is expected to be amortized on a straight-line basis over a period of eight years commencing upon revenue generation, and (ii) the $40,000,000 acquisition value of the exclusive license for LYMPHIR (denileukin diftitox), which is a late-stage oncology immunotherapy for the treatment of cutaneous T-cell lymphoma ("CTCL"), a rare form of non-Hodgkin lymphoma, and is expected to be amortized on a straight-line basis over a period of twelve years commencing upon revenue generation.

Goodwill of $9,346,796 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.

Through December 31, 2023 March 31, 2024, we have devoted substantially all our efforts to business planning, research and development, recruiting management and technical staff, and raising capital. We have not yet realized any revenues from our operations.

Recent Developments

On October 23, 2023, Citius Pharma and Citius Oncology entered into an agreement and plan of merger and reorganization with TenX Keane Acquisition, and its wholly owned subsidiary, TenX Merger Sub Inc., whereby TenX Merger Sub Inc. will merge with and into Citius Oncology, with Citius Oncology surviving as a wholly owned subsidiary of TenX Keane Acquisition. The newly combined publicly traded company is to be named "Citius Oncology, Inc." There can be no assurance regarding the ultimate timing of the proposed transaction or that the transaction will be completed at all.

Patent and Technology License Agreements

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, as amended. Since May 2014, LMB has paid an annual maintenance fee, which began at $30,000 and has 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 low-double 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 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 terminated the Mino-Wrap license agreement on December 11, 2023.

NoveCite – On October 6, 2020, our subsidiary NoveCite entered into a license agreement with Novellus Therapeutics Limited (“Licensor”), whereby NoveCite acquired an exclusive, worldwide license, with the right to sublicense, 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. Upon execution of the license agreement, NoveCite paid an upfront payment of $5,000,000 to Licensor and issued to Licensor shares of Novecite’s common stock representing 25% of NoveCite’s currently outstanding equity. We own the other 75% of NoveCite’s currently outstanding equity.

Citius Pharma is responsible for the operational activities of NoveCite and bears all costs necessary to operate NoveCite. Citius Pharma’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.

In July 2021, Novellus was acquired by Brooklyn ImmunoTherapeutics (“Brooklyn”). Pursuant to this transaction, the NoveCite license was assumed by Brooklyn with all original terms and conditions. In October 2021, Brooklyn changed its name to Eterna Therapeutics Inc. (“Eterna”).
As part of the Novellus and Brooklyn merger transaction, the 25% non-dilutive position per the subscription agreement between Novellus and NoveCite was removed. In October 2021, Brooklyn changed its name to Eterna Therapeutics Inc. (“Eterna”).

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) 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.

LYMPHIR - In September 2021, Citius Pharma entered into an asset purchase agreement with Dr. Reddy’s and a license agreement with Eisai to acquire an exclusive license for E7777 (denileukin diftitox), a late-stage oncology immunotherapy for the treatment of CTCL, a rare form of non-Hodgkin lymphoma. Citius Pharma renamed E7777 as I/ONTAK and also obtained the trade name LYMPHIR for the product. Citius Pharma assigned these agreements to Citius Oncology effective April 1, 2022.

Under the terms of the agreements, Citius Pharma acquired Dr. Reddy's exclusive license for E7777 from Eisai and other related assets owned by Dr. Reddy's (now owned by Citius Oncology). The exclusive license rights, through our subsidiary, Citius Oncology, include rights to develop and commercialize E7777 in all markets except for Japan and certain parts of Asia. Additionally, we, through our subsidiary, Citius Oncology, retain an option on the right to develop and market the product in India. Eisai retains exclusive development and marketing rights for the agent in Japan, China, Korea, Taiwan, Hong Kong, Macau, Indonesia, Thailand, Malaysia, Brunei, Singapore, India (subject to the India option), Pakistan, Sri Lanka, Philippines, Vietnam, Myanmar, Cambodia, Laos, Afghanistan, Bangladesh, Bhutan, Nepal, Mongolia, and Papua New Guinea. Citius Pharma paid a $40 million upfront payment, which represents the acquisition date fair value of the in-process research and development acquired from Dr. Reddy's. Dr. Reddy's is entitled to up to $40 million in development milestone payments related to CTCL approvals in the U.S. and other markets, up to $70 million in development milestones for additional indications, as well as commercial milestone payments and low double-digit tiered royalties on net product sales (within a range of 10% to 15%), and up to $300 million for commercial sales milestones. We also must pay on a fiscal quarter basis tiered royalties equal to low double-digit percentages of net product sales (within a range of 10% to 15%). The royalties will end on the earlier of (i) the 15-year anniversary of the first commercial sale of the latest indication that received regulatory approval in the applicable country and (ii) the date on which a biosimilar product results in the reduction of net sales in the applicable product by 50% in two consecutive quarters, as compared to the four quarters prior to the first commercial sale of the biosimilar product. We will also pay to Dr. Reddy's an amount equal to a low-thirties percentage of any sublicense upfront consideration or milestone payments (or the like) received by us and the greater of (i) a low-thirties percentage of any sublicensee sales-based royalties or (ii) a mid-single digit percentage of such licensee's net sales.

Under the license Agreement, agreement, Eisai is to receive a $6 million development milestone payment upon initial approval and additional commercial milestone payments related to the achievement of net product sales thresholds (which increases to $7 million in the event we have exercised our option to add India to the licensed territory prior to FDA approval) and an aggregate of up to $22 million related to the achievement of net product sales thresholds. Citius Oncology was also required to reimburse Eisai for up to $2.65 million of its costs to complete the Phase 3 pivotal clinical trial for LYMPHIR for the CTCL indication and reimburse Eisai for all reasonable costs associated with the preparation of a BLA for LYMPHIR.. Eisai was responsible for completing the CTCL clinical trial, and CMC activities through the filing of a Biologics License Application ("BLA") for LYMPHIR with the FDA. The BLA was filed with the FDA on September 27, 2022. We, through Citius Oncology, will be responsible for development costs associated with potential additional indications.

On July 29, 2023, we received a Complete Response Letter ("CRL") from the FDA regarding the BLA seeking approval for LYMPHIR. The FDA has required that we incorporate enhanced product testing, and additional controls agreed to with the FDA during the market application review. The FDA raised no concerns relating to the safety and efficacy clinical data package.

On September 8, 2023, we announced that the FDA agreed with our plans to address the requirements outlined in the CRL. The guidance from the FDA provides a path for completing the necessary activities to support the resubmission of the BLA. No additional clinical efficacy or safety trials have been were requested by the FDA for the resubmission. Based on the feedback from the FDA.
On February 13, 2024, we filed the BLA resubmission package with the FDA. FDA and on March 18, 2024, the FDA accepted the resubmission of the BLA and assigned a Prescription Drug User Fee Act ("PDUFA") goal date of August 13, 2024.

RESULTS OF OPERATIONS

Three months ended December 31, 2023 March 31, 2024 compared with the three months ended December 31, 2022 March 31, 2023

	Three Months Ended December 31, 2023	Three Months Ended December 31, 2022	Three Months Ended March 31, 2024	Three Months Ended March 31, 2023
Revenues	$ —	$ —	$ —	$ —
Operating expenses:				
Research and development	2,621,910	3,445,515	3,605,898	4,726,855
General and administrative	3,660,728	2,603,287	4,285,911	4,792,850
Stock-based compensation expense	3,058,185	1,201,081	3,078,392	1,165,595
Total operating expenses	9,340,823	7,249,883	10,970,201	10,685,300
Operating loss	(9,340,823)	(7,249,883)	(10,970,201)	(10,685,300)
Interest income	253,638	214,549	182,205	303,275
Gain on sale of New Jersey net operating losses	—	3,585,689	2,387,842	—
Loss before income taxes	(9,087,185)	(3,449,645)	(8,400,154)	(10,382,025)
Income tax expense	144,000	144,000	144,000	144,000
Net loss	$ (9,231,185)	$ (3,593,645)	$ (8,544,154)	$ (10,526,025)

Revenues

We did not generate any revenues for the three months ended December 31, 2023 March 31, 2024 or 2022. 2023.

Research and Development Expenses

For the three months ended December 31, 2023 March 31, 2024, research and development expenses were $2,621,910 $3,605,898 as compared to $3,445,515 $4,726,855 during the three months ended December 31, 2022 March 31, 2023, a decrease of $823,605. $1,120,957.

Research and development costs for Mino-Lok decreased increased by $276,031 $588,194 to $891,624 $1,638,287 for the three months ended December 31, 2023 March 31, 2024 as compared to $1,167,655 $1,050,093 for the three months ended December 31, 2022 March 31, 2023, due primarily to decreased start-up study close out costs associated with Biorasi, LLC ("Biorasi"), a global clinical research organization ("CRO"), related to help expand the Company's Phase phase 3 Mino-Lok trial to additional sites outside the United States, which are no longer incurred. trial. On January 2, 2024, Citius Pharma announced that it has had completed enrollment in its pivotal Phase 3 clinical trial for Mino-Lok, an antibiotic lock solution to salvage catheters in patients with catheter-related bloodstream infections. A total of 109 catheter failure events were observed in the event-based trial; a minimum of 92 catheter failure events were required to complete the trial. The study enrolled 241 patients at clinical sites in the U.S. and India.

Research and development costs for Halo-Lido decreased by $521,954 $1,760,602 to $246,572 $201,970 for the three months ended December 31, 2023 March 31, 2024 as compared to $768,526 $1,962,572 for the three months ended December 31, 2022 March 31, 2023 due to lower costs associated with the Phase 2b trial incurred in the three months ended December 31, 2023. current quarter. On June 20, 2023, we announced that the high dose formulation of CITI-002, a lidocaine and halobetasol propionate combination formulation, provided a meaningful reduction in symptom severity, as reported by patients, when compared to individual components alone. Moreover, there were no reported significant adverse events and CITI-002 was well tolerated by patients in the study. Citius Pharma has scheduled an end of Phase 2 meeting with the FDA, anticipated to occur in early the second calendar quarter of 2024, to begin planning the next steps in the regulatory and clinical development program for CITI-002.

Research and development costs for LYMPHIR were $1,472,464 $1,760,916 during the three months ended December 31, 2023 March 31, 2024 as compared to $1,428,545 $1,402,908 for the three months ended December 31, 2022 March 31, 2023. The $43,919 $358,008 increase in expenses was primarily due to costs associated with new analytical testing methods related to the remediation activities to respond to the CRL during CRL. On February 13, 2024, we filed the three months ended December 31, 2023 BLA resubmission package with the FDA and on March 18, 2024, the FDA accepted the resubmission of the BLA and assigned a PDUFA goal date of August 13, 2024.

We expect that research and development expenses will stabilize at current levels in fiscal 2024 as we focus on the commercialization of LYMPHIR, complete our Phase 3 trial for Mino-Lok, and analyze the data from our Phase 2b trial and begin planning our Phase 3 trial for Halo-Lido.

General and Administrative Expenses

For the three months ended December 31, 2023 March 31, 2024, general and administrative expenses were $3,660,728 $4,285,911 as compared to $2,603,287 $4,792,850 during the three months ended December 31, 2022 March 31, 2023. General and administrative expenses increased decreased by $1,057,441 $506,939 in comparison with the prior period. The primary reasons reason for the increase decrease were lower costs associated with for pre-launch and market research activities associated with LYMPHIR. General and administrative expenses consist primarily of compensation costs, professional fees for legal, regulatory, accounting, and corporate development services, and investor relations expenses.

Stock-based Compensation Expense

For the three months ended December 31, 2023 March 31, 2024, stock-based compensation expense was $3,058,185 $3,078,392 as compared to $1,201,081 $1,165,595 for the three months ended December 31, 2022 March 31, 2023. For the three months ended December 31, 2023 March 31, 2024 and 2022, 2023, stock-based compensation includes $19,858 $13,858 and $33,333, respectively, in expense for the NoveCite stock plan. For the three months ended December 31, 2023 March 31, 2024, stock-based compensation also includes $1,917,000 $1,957,000 in expense for the recently adopted Citius Oncology stock plan. Stock-based compensation expense for the most recently completed quarter increased by $1,857,104 $1,912,797 in comparison to the prior period primarily due to the Citius Oncology stock plan.

Other Income

Interest income for the three months ended December 31, 2023 March 31, 2024 was $253,638 $182,205 as compared to interest income of $214,549 $303,275 for the prior period. The increase decrease is due to higher interest rates on the investment lower investable balances of the remaining proceeds of our 2021 and 2023 equity offerings and the 2021 common stock warrant exercises in money market accounts.

Other income for the three months ended December 31, 2022 March 31, 2024 also includes the $3,585,689 a $2,387,842 gain recognized in connection with the sale of certain New Jersey income tax net operating losses to a third party under the New Jersey Technology Business Tax Certificate Transfer Program.

Income Taxes

The Company recorded deferred income tax expense of $144,000 for both the three months ended December 31, 2023 March 31, 2024 and 2022, 2023, related to the amortization for taxable purposes of its in-process research and development asset.

Net Loss

For the three months ended December 31, 2023 March 31, 2024, we incurred a net loss of $9,231,185, $8,544,154, compared to a net loss for the three months ended December 31, 2022 March 31, 2023 of $3,593,645. $10,526,025. The $5,637,540 $1,981,871 decrease in the net loss was due to decreases of $1,120,957 in research and development expenses and $506,939 in general and administrative expenses, and the increase in other income of $2,266,772, being partially offset by the increase in stock-based compensation expense of $1,912,797.

Six months ended March 31, 2024 compared with the six months ended March 31, 2023

	Six Months Ended March 31, 2024	Six Months Ended March 31, 2023
Revenues	$ —	$ —
Operating expenses:		
Research and development	6,227,808	8,172,370
General and administrative	7,946,639	7,396,137
Stock-based compensation expense	6,136,577	2,366,676
Total operating expenses	20,311,024	17,935,183
Operating loss	(20,311,024)	(17,935,183)
Interest income	435,843	517,824
Gain on sale of New Jersey net operating losses	2,387,842	3,585,689
Loss before income taxes	(17,487,339)	(13,831,670)
Income tax expense	288,000	288,000
Net loss	$ (17,775,339)	$ (14,119,670)

Revenues

We did not generate any revenues for the six months ended March 31, 2024 or 2023.

Research and Development Expenses

For the six months ended March 31, 2024, research and development expenses were $6,227,808 as compared to $8,172,370 during the six months ended March 31, 2023, a decrease of $1,944,562.

Research and development costs for Mino-Lok increased by $312,163 to $2,529,911 for the six months ended March 31, 2024 as compared to $2,217,748 for the six months ended March 31, 2023, due primarily to study close out costs associated with the phase 3 trial. On January 2, 2024, Citius Pharma announced that it had completed enrollment in its pivotal Phase 3 clinical trial for Mino-Lok, an antibiotic lock solution to salvage catheters in patients with catheter-related bloodstream infections. A total of 109 catheter failure events were observed in the event-based trial; a minimum of 92 catheter failure events were required to complete the trial. The study enrolled 241 patients at clinical sites in the U.S. and India.

Research and development costs for Halo-Lido decreased by $2,282,556 to $448,542 for the six months ended March 31, 2024 as compared to $2,731,098 for the six months ended March 31, 2023 due to lower costs associated with the Phase 2b trial. On June 20, 2023, we announced that the high dose formulation of CITI-002, a lidocaine and halobetasol propionate combination formulation, provided a meaningful reduction in symptom severity, as reported by patients, when compared to individual components alone. Moreover, there were no reported significant adverse events and CITI-002 was well tolerated by patients in the study. Citius Pharma has scheduled an end of Phase 2 meeting with the FDA, anticipated to occur in the second quarter of 2024, to begin planning the next steps in the regulatory and clinical development program for CITI-002.

Research and development costs for LYMPHIR were $3,233,380 during the six months ended March 31, 2024 as compared to $2,831,453 for the six months ended March 31, 2023. The $401,927 increase in expenses was primarily due to costs associated with new analytical testing methods related to the remediation activities to respond to the CRL. On February 13, 2024, we filed the BLA resubmission package with the FDA and on March 18, 2024, the FDA accepted the resubmission of the BLA and assigned a PDUFA goal date of August 13, 2024.

We expect that research and development expenses will stabilize at current levels in fiscal 2024 as we focus on the commercialization of LYMPHIR, complete our Phase 3 trial for Mino-Lok, and analyze the data from our Phase 2b trial and begin planning our Phase 3 trial for Halo-Lido.

General and Administrative Expenses

For the six months ended March 31, 2024, general and administrative expenses were $7,946,639 as compared to $7,396,137 during the six months ended March 31, 2023. General and administrative expenses increased by $550,552 in comparison with the prior period. The primary reason for the increase were higher costs for pre-launch and market research activities associated with LYMPHIR. General and administrative expenses consist primarily of compensation costs, professional fees for legal, regulatory, accounting, and corporate development services, and investor relations expenses.

Stock-based Compensation Expense

For the six months ended March 31, 2024, stock-based compensation expense was $6,136,577 as compared to $2,366,676 for the six months ended March 31, 2023. For the six months ended March 31, 2024 and 2023, stock-based compensation includes $33,716 and $66,666, respectively, in expense for the NoveCite stock plan. For the six months ended March 31, 2024, stock-based compensation also includes $3,874,000 in expense for the Citius Oncology stock plan. Stock-based compensation expense for the most recently completed quarter increased by $3,769,901 in comparison to the prior period primarily due to the Citius Oncology stock plan.

Other Income

Interest income for the six months ended March 31, 2024 was $435,843 as compared to interest income of $517,824 for the prior period. The decrease is due to lower investable balances of the remaining proceeds of our 2021 and 2023 equity offerings and the 2021 common stock warrant exercises in money market accounts.

Other income for the six months ended March 31, 2024 and 2023 includes gains of $2,387,842 and $3,585,689, respectively, recognized in connection with the sale of certain New Jersey income tax net operating losses to third parties under the New Jersey Technology Business Tax Certificate Transfer Program.

Income Taxes

The Company recorded deferred income tax expense of $288,000 for both the six months ended March 31, 2024 and 2023, related to the amortization for taxable purposes of its in-process research and development asset.

Net Loss

For the six months ended March 31, 2024, we incurred a net loss of $17,775,339 compared to a net loss for the six months ended March 31, 2023 of $14,119,670. The $3,655,669 increase in the net loss was primarily due to the decrease of $823,605 in research and development expenses being offset by the increase of $1,057,441 in general and administrative expenses, the increase in stock-based compensation expense of $1,857,104 and the decrease in other income of $3,546,600. $3,769,901.

LIQUIDITY AND CAPITAL RESOURCES

Liquidity and Working Capital

Citius Pharma has incurred operating losses since inception and incurred a net loss of $9,231,185 $17,775,339 for the three six months ended December 31, 2023 March 31, 2024. At December 31, 2023 March 31, 2024, Citius Pharma had an accumulated deficit of $171,462,564. $180,006,718. Citius Pharma's net cash used in operations during the three six months ended December 31, 2023 March 31, 2024 was $6,135,310. $13,921,321.

As a result of the Company's common stock offerings and common stock warrant exercises during the year ended September 30, 2021 and the May 2023 registered direct offering, the Company had working capital of approximately $22,600,000 $17,400,000 at December 31, 2023 March 31, 2024. At December 31, 2023 March 31, 2024, Citius Pharma had cash and cash equivalents of $20,345,618 $12,559,607 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.

Based on our cash and cash equivalents at December 31, 2023 March 31, 2024, and after giving effect to a capital raising that closed on April 30, 2024, we expect that we will have sufficient funds to continue our operations through August December 2024. We expect to need to raise additional capital in the future to support our operations beyond August December 2024. 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, 2023, filed with the SEC on December 29, 2023.

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 December 31, 2023 March 31, 2024. 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 December 31, 2023 March 31, 2024, 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 December 31, 2023 March 31, 2024 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 have been no material changes to the Company's risk factors as disclosed in the Company's Annual Report on Form 10-K for the fiscal year ended September 30, 2023, filed with the SEC on December 29, 2023.

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

On October 10, 2023 January 17, 2024, we issued 108,778 128,205 shares of our common stock to a consultant for investor relations services pursuant to the agreed upon compensation terms in the consulting agreement with the entity. general and financial advisory services. 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. During the quarter ended March 31, 2024, none of our directors or officers adopted or terminated any contract or written plan for the purchase or sale of our securities.

Item 6. Exhibits.

2.1+	Agreement and Plan of Merger and Reorganization, dated as of October 23, 2023, by and among Citius Pharmaceuticals, Inc., Citius Oncology, Inc., TenX Keane Acquisition, and TenX Merger Sub, Inc. (incorporated herein by reference to Exhibit 2.1 to the Current Report on Form 8-K filed on October 24, 2023).
10.1+	Sponsor Support Agreement, dated as of October 23, 2023, by and among 10XYZ Holdings LP, TenX Keane Acquisition, Citius Pharmaceuticals, Inc. and Citius Oncology, Inc. (incorporated herein by reference to Exhibit 10.1 to the Current Report on Form 8-K filed on October 24, 2023).
10.2	Form of Amended and Restated Registration Rights Agreement (incorporated herein by reference to Exhibit 10.2 to the Current Report on Form 8-K filed on October 24, 2023).
10.3+	Form of Amended and Restated Shared Services Agreement (incorporated herein by reference to Exhibit 10.3 to the Current Report on Form 8-K filed on October 24, 2023).
31.1	Certification of the Principal Executive Officer pursuant to Exchange Act Rule 13a-14(a).*
31.2	Certification of the Principal Financial Officer pursuant to Exchange Act Rule 13a-14(a).*
32.1	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.*
EX-101.INS	Inline XBRL Instance Document*
EX-101.SCH	Inline XBRL Taxonomy Extension Schema Document*
EX-101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document*
EX-101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document*
EX-101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document*
EX-101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document*
EX-104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)

* Filed herewith.

\+ Certain of the exhibits and schedules to this exhibit have been omitted in accordance with Regulation S-K Item 601(b)(2) or 601(a)(5), as applicable. Citius Pharma agrees to furnish supplementally a copy of all omitted exhibits and schedules to the SEC upon its request.

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: February 14, 2024 May 14, 2024

By: /s/ *Leonard Mazur*
Leonard Mazur
Chief Executive Officer
(Principal Executive Officer)

Date: February 14, 2024 May 14, 2024

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

Exhibit 31.1

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

I, Leonhard Mazur, 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.

February May 14, 2024

By: /s/ Leonard Mazur
Leonard Mazur
Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

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. 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 reporting.

February May 14, 2024

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

Exhibit 32.1

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 December 31, 2023 March 31, 2024 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), Leonard Mazur, 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: February 14, 2024 May 14, 2024

By: /s/ Leonard Mazur
Leonard Mazur
Chief Executive Officer
(Principal Executive Officer)

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

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