

REFINITIV

DELTA REPORT

10-Q

CTXR - CITIUS PHARMACEUTICALS, I

10-Q - DECEMBER 31, 2023 COMPARED TO 10-Q - JUNE 30, 2023

The following comparison report has been automatically generated

TOTAL DELTAS 743

█ CHANGES 141

█ DELETIONS 281

█ ADDITIONS 321

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

FORM 10-Q

(Mark One)

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

For the quarterly period ended: June 30, 2023 December 31, 2023

OR

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

For the transition period from _____ to _____

Commission File Number 001-38174

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

Nevada

(State or other jurisdiction of
incorporation or organization)

27-3425913

(IRS Employer
Identification No.)

11 Commerce Drive, First Floor, Cranford, NJ

(Address of principal executive offices)

07016

(Zip code 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 (Section (\$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 | <input type="checkbox"/> | Accelerated filer | <input type="checkbox"/> |
| Non-accelerated filer | <input checked="" type="checkbox"/> | Smaller reporting company | <input checked="" type="checkbox"/> |
| Emerging growth company | <input type="checkbox"/> | | |

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

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

As of August 10, 2023 February 10, 2024, there were 158,857,798 159,094,781 shares of common stock, \$0.001 par value, of the registrant issued and outstanding.

Citius Pharmaceuticals, Inc.
FORM 10-Q

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EXPLANATORY NOTE

In this Quarterly Report on Form 10-Q, and unless the context otherwise requires, the “Company,” “we,” “us,” and “our” refer to Citius Pharmaceuticals, Inc. and its wholly-owned subsidiaries Citius Pharmaceuticals, LLC, Leonard-Meron Biosciences, Inc., Citius Oncology, Inc. (formerly Citius Acquisition Corp.), 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;
- the cost, timing and results of our pre-clinical and clinical trials;
- our ability to recruit and retain qualified management and scientific 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; 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)

| | June 30, 2023 | September 30, 2022 | December 31, 2023 | September 30, 2023 |
|--|-----------------------|-----------------------|----------------------|--------------------------|
| ASSETS | | | | |
| Current Assets: | | | | |
| Cash and cash equivalents | \$ 33,281,830 | \$ 41,711,690 | \$ 20,345,618 | \$ 26,480,928 |
| Prepaid expenses | 7,832,320 | 2,852,580 | 7,864,496 | 7,889,506 |
| Total Current Assets | 41,114,150 | 44,564,270 | 28,210,114 | 34,370,434 |
| Property and equipment, net | 2,010 | 4,100 | 854 | 1,432 |
| Operating lease right-of-use asset, net | 503,817 | 646,074 | 403,996 | 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 | 68,784,858 | 68,784,858 |
| Total Assets | \$ 110,404,835 | \$ 113,999,302 | \$ 97,399,822 | \$ 103,611,150 |
| LIABILITIES AND STOCKHOLDERS' EQUITY | | | | |
| Current Liabilities: | | | | |
| Accounts payable | \$ 3,079,667 | \$ 1,165,378 | \$ 2,647,251 | \$ 2,927,334 |
| Accrued expenses | 892,874 | 1,405,394 | 276,897 | 476,300 |
| Accrued compensation | 1,605,445 | 1,762,251 | 2,430,671 | 2,156,983 |
| Operating lease liability | 212,871 | 196,989 | 224,000 | 218,380 |
| Total Current Liabilities | 5,790,857 | 4,530,012 | 5,578,819 | 5,778,997 |
| Deferred tax liability | 5,993,800 | 5,561,800 | 6,281,800 | 6,137,800 |
| Operating lease liability – noncurrent | 320,011 | 481,245 | 204,569 | 262,865 |
| Total Liabilities | 12,104,668 | 10,573,057 | 12,065,188 | 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; 158,857,798 and 146,211,130 shares issued and outstanding at June 30, 2023 and September 30, 2022, respectively | 158,858 | 146,211 | | |
| 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 |
| Additional paid-in capital | 249,828,398 | 232,368,121 | 256,037,851 | 252,903,629 |
| Accumulated deficit | (152,287,469) | (129,688,467) | (171,462,564) | (162,231,379) |
| Total Citius Pharmaceuticals, Inc. Stockholders' Equity | 97,699,787 | 102,825,865 | 84,734,254 | 90,831,108 |
| Non-controlling interest | 600,380 | 600,380 | 600,380 | 600,380 |
| Total Equity | 98,300,167 | 103,426,245 | 85,334,634 | 91,431,488 |
| Total Liabilities and Equity | \$ 110,404,835 | \$ 113,999,302 | \$ 97,399,822 | \$ 103,611,150 |

See notes to unaudited condensed consolidated financial statements.

CITIUS PHARMACEUTICALS, INC.
 CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
 FOR THE THREE **AND NINE** MONTHS ENDED **JUNE 30, DECEMBER 31**, 2023 AND 2022
 (Unaudited)

| | Three Months Ended | | Nine Months Ended | | Three Months Ended | |
|---|-----------------------|-----------------------|------------------------|------------------------|-------------------------|-------------------------|
| | June 30, 2023 | June 30, 2022 | June 30, 2023 | June 30, 2022 | December 31, 2023 | December 31, 2022 |
| | \$ — | \$ — | \$ — | \$ — | \$ — | \$ — |
| Revenues | | | | | | |
| Operating Expenses | | | | | | |
| Research and development | 3,764,675 | 4,888,192 | 11,937,045 | 13,798,251 | 2,621,910 | 3,445,515 |
| General and administrative | 3,733,326 | 3,024,783 | 11,129,463 | 9,038,949 | 3,660,728 | 2,603,287 |
| Stock-based compensation – general and administrative | 1,174,111 | 1,003,677 | 3,540,787 | 2,929,279 | 3,058,185 | 1,201,081 |
| Total Operating Expenses | 8,672,112 | 8,916,652 | 26,607,295 | 25,766,479 | 9,340,823 | 7,249,883 |
| Operating Loss | (8,672,112) | (8,916,652) | (26,607,295) | (25,766,479) | (9,340,823) | (7,249,883) |
| Other Income | | | | | | |
| Interest income | 336,780 | 53,020 | 854,604 | 116,573 | 253,638 | 214,549 |
| Gain on sale of New Jersey net operating losses | — | — | 3,585,689 | — | — | 3,585,689 |
| Total Other Income | 336,780 | 53,020 | 4,440,293 | 116,573 | 253,638 | 3,800,238 |
| Loss before Income Taxes | (8,335,332) | (8,863,632) | (22,167,002) | (25,649,906) | (9,087,185) | (3,449,645) |
| Income tax expense | 144,000 | — | 432,000 | — | 144,000 | 144,000 |
| Net Loss | \$ (8,479,332) | \$ (8,863,632) | \$ (22,599,002) | \$ (25,649,906) | \$ (9,231,185) | \$ (3,593,645) |
| Net Loss Per Share - Basic and Diluted | \$ (0.06) | \$ (0.06) | \$ (0.15) | \$ (0.18) | \$ (0.06) | \$ (0.02) |
| Weighted Average Common Shares Outstanding | | | | | | |
| Basic and diluted | 153,775,380 | 146,129,630 | 148,746,002 | 146,061,108 | 158,955,935 | 146,211,130 |

See notes to unaudited condensed consolidated financial statements.

CITIUS PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY
FOR THE THREE AND NINE MONTHS ENDED JUNE 30, DECEMBER 31, 2023 AND 2022
(Uaudited)

| | Preferred | Common Stock | | | Additional Paid-In Capital | Accumulated Deficit | Total Citius Pharmaceuticals, Inc. Shareholder's Equity | | | Non-Controlling Interest | Total Equity | Preferred Stock | Common Stock | | | Additional Paid-In Capital |
|---|-----------|--------------|-------------|------------|----------------------------|---------------------|---|------------|----------------|--------------------------|--------------|-----------------|--------------|-------------|------------|----------------------------|
| | | Stock | Shares | Amount | | | Capital | Deficit | Equity | | | | Stock | Shares | Amount | |
| Balance, October 1, 2022 | | \$ — | 146,211,130 | \$ 146,211 | \$ 232,368,121 | \$ (129,688,467) | \$ 102,825,865 | \$ 600,380 | \$ 103,426,245 | | | | | | | |
| Balance, September 30, 2023 | | | | | | | | | | | | | \$ — | 158,857,798 | \$ 158,858 | \$ 252,90 |
| Issuance of common stock for services | | | | | | | | | | | | | — | 108,778 | 109 | 7 |
| Stock-based compensation expense | | | | | | | | | | | | | — | — | — | 3,05 |
| Net loss | | | | | | | | | | | | | — | — | — | — |
| Balance, December 31, 2023 | | | | | | | | | | | | | \$ — | 158,966,576 | \$ 158,967 | \$ 256,03 |
| Balance, September 30, 2022 | | | | | | | | | | | | | \$ — | 146,211,130 | \$ 146,211 | \$ 232,36 |
| Stock-based compensation expense | | — | — | — | 1,201,081 | — | 1,201,081 | — | 1,201,081 | — | — | — | — | — | — | 1,20 |
| 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 | \$ — | 146,211,130 | \$ 146,211 | \$ 233,56 | — | — | — |
| Issuance of common stock for services | | — | 100,000 | 100 | 101,900 | — | 102,000 | — | 102,000 | | | | | | | |
| Issuance of common stock upon exercise of stock options | | — | 46,667 | 47 | 31,220 | — | 31,267 | — | 31,267 | | | | | | | |
| Stock-based compensation expense | | — | — | — | 1,165,595 | — | 1,165,595 | — | 1,165,595 | | | | | | | |
| Net loss | | — | — | — | — | (10,526,025) | (10,526,025) | — | (10,526,025) | | | | | | | |
| Balance, March 31, 2023 | | — | 146,357,797 | 146,358 | 234,867,917 | (143,808,137) | 91,206,138 | 600,380 | 91,806,518 | | | | | | | |
| Issuance of common stock in registered direct offering, net of costs of \$1,201,131 | | — | 12,500,001 | 12,500 | 13,786,370 | — | 13,798,870 | — | 13,798,870 | | | | | | | |

| | | | | | | | | |
|---------------------------------------|-------------------------|-------------------|-----------------------|-------------------------|-----------------------|-------------------|-----------------------|-------------|
| Stock-based compensation expense | — | — | — | 1,174,111 | — | 1,174,111 | — | 1,174,111 |
| Net loss | — | — | — | — | (8,479,332) | (8,479,332) | — | (8,479,332) |
| Balance, June 30, 2023 | \$ — 158,857,798 | \$ 158,858 | \$ 249,828,398 | \$ (152,287,469) | \$ 97,699,787 | \$ 600,380 | \$ 98,300,167 | |
| Balance, October 1, 2021 | \$ — 145,979,429 | \$ 145,979 | \$ 228,084,195 | \$ (96,047,821) | \$ 132,182,353 | \$ 600,380 | \$ 132,782,733 | |
| Issuance of common stock for services | — | 50,201 | 50 | 95,834 | — | 95,884 | — | 95,884 |
| Stock-based compensation expense | — | — | — | 904,604 | — | 904,604 | — | 904,604 |
| Net loss | — | — | — | — | (9,225,220) | (9,225,220) | — | (9,225,220) |
| Balance, December 31, 2021 | — 146,029,630 | 146,029 | 229,084,633 | (105,273,041) | 123,957,621 | 600,380 | 124,558,001 | |
| Issuance of common stock for services | — | 100,000 | 100 | 177,900 | — | 178,000 | — | 178,000 |
| Stock-based compensation expense | — | — | — | 1,020,998 | — | 1,020,998 | — | 1,020,998 |
| Net loss | — | — | — | — | (7,561,054) | (7,561,054) | — | (7,561,054) |
| Balance, March 31, 2022 | — 146,129,630 | 146,129 | 230,283,531 | (112,834,095) | 117,595,565 | 600,380 | 118,195,945 | |
| Stock-based compensation expense | — | — | — | 1,003,677 | — | 1,003,677 | — | 1,003,677 |
| Net loss | — | — | — | — | (8,863,632) | (8,863,632) | — | (8,863,632) |
| Balance, June 30, 2022 | \$ — 146,129,630 | \$ 146,129 | \$ 231,287,208 | \$ (121,697,727) | \$ 109,735,610 | \$ 600,380 | \$ 110,335,990 | |

See notes to unaudited condensed consolidated financial statements.

CITIUS PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
FOR THE NINE THREE MONTHS ENDED JUNE 30, DECEMBER 31, 2023 AND 2022
(Uaudited)

| | 2023 | 2022 | 2023 | 2022 |
|---|----------------------|----------------------|----------------------|----------------------|
| Cash Flows From Operating Activities: | | | | |
| Net loss | \$ (22,599,002) | \$ (25,649,906) | \$ (9,231,185) | \$ (3,593,645) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | | | |
| Stock-based compensation expense | 3,540,787 | 2,929,279 | 3,058,185 | 1,201,081 |
| Issuance of common stock for services | 102,000 | 273,884 | 76,146 | — |
| Amortization of operating lease right-of-use asset | 142,257 | 131,235 | 50,430 | 46,457 |
| Depreciation | 2,090 | 2,192 | 578 | 730 |
| Deferred income tax expense | 432,000 | — | 144,000 | 144,000 |
| Changes in operating assets and liabilities: | | | | |
| Prepaid expenses | (4,979,740) | (48,915) | 25,010 | (2,577,545) |
| Accounts payable | 1,914,289 | 413,425 | (280,083) | 372,200 |
| Accrued expenses | (512,520) | 679,239 | (199,403) | (714,992) |
| Accrued compensation | (156,806) | (628,499) | 273,688 | 344,763 |
| Operating lease liability | (145,352) | (130,686) | (52,676) | (47,488) |
| Net Cash Used In Operating Activities | (22,259,997) | (22,028,752) | (6,135,310) | (4,824,439) |
| Cash Flows From Financing Activities: | | | | |
| Net proceeds from registered direct offering | 13,798,870 | — | | |
| Proceeds from common stock option exercise | 31,267 | — | | |
| Net Cash Provided By Financing Activities | 13,830,137 | — | | |
| Net Change in Cash and Cash Equivalents | (8,429,860) | (22,028,752) | (6,135,310) | (4,824,439) |
| Cash and Cash Equivalents - Beginning of Period | 41,711,690 | 70,072,946 | 26,480,928 | 41,711,690 |
| Cash and Cash Equivalents - End of Period | \$ 33,281,830 | \$ 48,044,194 | \$ 20,345,618 | \$ 36,887,251 |

See notes to unaudited condensed consolidated financial statements.

CITIUS PHARMACEUTICALS, INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
FOR THE **NINE THREE** MONTHS ENDED **JUNE 30, DECEMBER 31, 2023 AND 2022**
(Unaudited)

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 pharmaceutical 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 **I/ONTAK, LYMPHIR**, which began operations in April 2022. On **May 2, 2023** October 23, 2023, Citius Acquisition changed its name to **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). Citius has obtained the trade name of **Lymphir** for **I/ONTAK** and it is referred to as **Lymphir** in this Form 10-Q.

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 LYMPHIR** (denileukin diftitox), which is a late-stage oncology immunotherapy for the treatment of cutaneous T-cell lymphoma ("CTCL") (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.

Citius is 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 **product candidates**, **products**, **regulatory approval** and market acceptance of its **product candidates** that might be **approved**, **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, (formerly **Citius Acquisition, Inc.**), and its majority-owned subsidiary NoveCite. **NoveCite began operations in October 2020 and Citius Oncology was inactive until April 1, 2022, 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 **June 30, 2023** December 31, 2023, and the results of its operations and cash flows for the three and nine month periods ended **June 30, 2023** December 31, 2023 and 2022. The operating results for the three- and nine-month periods three months ended **June 30, 2023** December 31, 2023 are not necessarily indicative of the results that may be expected for the year ending **September 30, 2023** 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, 2022** 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

In October 2021, the FASB Other than as disclosed in our Form 10-K, we are not aware of any other recently issued ASU No. 2021-08, *Business Combinations (Topic 805): Accounting for Acquired Contract Assets and Contract Liabilities*. Under the new guidance (ASC 805-20-30-28), the acquirer should determine what contract assets and/or contract liabilities it would have recorded under Accounting Standards Codification ("ASC") 606 (the revenue guidance) as of the acquisition date, as if the acquirer had entered into the original contract at the same date and on the same terms as the acquiree. The recognition and measurement of those contract assets and contract liabilities will likely be comparable to what the acquiree has recorded on its books under ASC 606 as of the acquisition date. ASU 2021-08 is effective for fiscal years beginning after December 15, 2022, including interim periods within those fiscal years. ASU 2021-08 is effective for the Company in the first quarter of fiscal year 2024. Early adoption is permitted, including in an interim period, for any period for which financial statements have accounting standards not yet been issued. However, adoption in an interim period other than the first fiscal quarter requires an entity to apply the new guidance to all prior business combinations adopted that may have occurred since the beginning of the annual period in which the new guidance is adopted. The Company is currently evaluating the adoption date of ASU 2021-08 and the material impact if any, adoption will have on its financial position and results of operations.

2. LIQUIDITY 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 **\$22,259,997** \$6,135,310 for the **three months ended June 30, 2023** December 31, 2023. As a result of the Company's common stock offerings and common stock warrant exercises during the year ended September 30, 2021 and the registered direct offering in May 2023, the Company had working capital of approximately **\$35,323,293** \$22,600,000 at **June 30, 2023** December 31, 2023. The Company estimates that its available cash resources will be sufficient to fund its operations through August 2024, 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 2024, including its development plans for **Lymphir**, **LYMPHIR**, Mino-Lok, Mino-Wrap, Halo-Lido and NoveCite, will depend on its ability to obtain regulatory approval to market **Lymphir** **LYMPHIR** and/or Mino-Lok and generate substantial revenue from the sale of **Lymphir** **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** **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** **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 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 **June 2022** **2023** and **2021** **2022**.

LMB will also pay annual royalties on net sales of licensed products, with royalties royalty rates ranging from the mid-single digits to the 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 an aggregate of \$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 intend to develop terminated the Mino-Wrap as a liquefying gel-based wrap containing minocycline and rifampin for the reduction of infections associated with breast implants following breast reconstructive surgeries. We are required to use commercially reasonable efforts to commercialize Mino-Wrap under several regulatory scenarios and achieve milestones associated with these regulatory options leading to an approval from the U.S. Food and Drug Administration ("FDA").

Under the license agreement the Company paid an annual maintenance fee of \$75,000 and \$60,000 in January 2023 and 2022, respectively. The annual maintenance fee increases by \$15,000 per year up to a maximum of \$90,000. Annual maintenance fees cease on the first sale of product. We also must pay up to an aggregate of \$2.1 million in milestone payments, contingent on the achievement of various regulatory and commercial milestones. Under the terms of the license agreement, we also must pay a royalty of mid- to upper-single digit percentages of net sales, depending on the amount of annual sales, and subject to downward adjustment to lower- to mid-single digit percentages in the event there is no valid patent for the product in the United States at the time of sale. After the first sale of product, we will owe an annual minimum royalty payment of \$100,000 that will increase annually by \$25,000 for the duration of the term. We will be responsible for all patent expenses incurred by Licensor for the term of the agreement although Licensor is responsible for the filing, prosecution and maintenance of all patents. Unless earlier terminated by Licensor, based upon the failure by us to achieve certain development and commercial milestones or for various breaches by us, the agreement expires on the later of the expiration of the patents or January 2, 2034 December 11, 2023.

License Agreement with Novellus 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 license 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, between Novellus and NoveCite, 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 between Novellus and NoveCite 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's** **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) the date on which a biosimilar product is first marketed, sold, or distributed in the applicable country or (ii) the 10-year anniversary of the date of expiration of the last-to-expire valid patent claim in that country. In the case of a country where no licensed patent ever exists, the royalty will end on the later of (i) the date of expiry of such licensed product's regulatory exclusivity and (ii) the 10-year anniversary of the date of the first commercial sale of the licensed product in the applicable country. In addition, NoveCite will pay to 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, the Company Citius Pharma entered into a definitive 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 its an exclusive license of Lymphir 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 this agreement, the agreements, Citius Pharma acquired Dr. Reddy's exclusive license of Lymphir for E7777 from Eisai Co., Ltd. ("Eisai") and other related assets owned by Dr. Reddy's. Citius's The exclusive license include includes rights to develop and commercialize Lymphir E7777 in all markets except for Japan and certain parts of Asia. Additionally, Citius retained we retain an option on the right to develop and market the product in India. Eisai retains exclusive development and marketing rights for denileukin diftitox 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 most Asian countries, 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, 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. **We also are** Citius Oncology was required to reimburse Eisai for up to \$2.65 million of its costs to complete the **ongoing** Phase 3 pivotal clinical trial for **Lymphir LYMPHIR** for the CTCL indication and reimburse Eisai for all reasonable costs associated with the preparation of a **biologics license application** **Biologics License Application** ("BLA") for **Lymphir LYMPHIR**. Eisai **will be** **was** responsible for completing the **current** CTCL clinical trial, and chemistry, manufacturing, and controls (CMC) ("CMC") activities through the filing of the BLA for **Lymphir LYMPHIR** with the FDA. The BLA was filed with the FDA (which was filed in September 2022) 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, **until** 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 (which we initiated in June 2021 and September 2022, respectively) (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 and September 31, 2023 consist of \$129,601 and \$154,611 of prepaid insurance, respectively, and \$7,734,895 of advance payments 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 November 2, 2021 October 10, 2023, the Company issued 50,201 108,778 shares of common stock for media, and public and investor relations services and expensed the \$95,884 \$76,146 fair value of the common stock issued.

On March 21, 2022, the Company issued 100,000 Stock Option Plans

Pursuant to our 2014 Stock Incentive Plan, we reserved 866,667 shares of common stock. As of December 31, 2023, there were options to purchase 795,171 shares outstanding, options to purchase 4,829 shares were exercised, options to purchase 66,667 shares expired, and no shares were available for media, public and investor relations services and expensed the \$178,000 fair value of the common stock issued.

On September 13, 2022, the Company issued 81,500 shares of common stock for media, public and investor relations services and expensed the \$104,320 fair value of the common stock issued.

On March 27, 2023, the Company issued 100,000 shares of common stock for media, public and investor relations services and expensed the \$102,000 fair value of the common stock issued. future grants.

Common Stock Offering

On May 8, 2023, the Company closed a registered direct offering of 12,500,001 common shares and warrants Pursuant to purchase up to 12,500,001 common shares, at a purchase price of \$1.20 per share and accompanying warrant for gross proceeds of \$15,000,001. The warrants have an exercise price of \$1.50 per share, are exercisable six months from the date of issuance, and expire five years from the date of issuance. The estimated fair value of the warrants issued to the investors was approximately \$11,000,000.

Net proceeds were \$13,798,870 after deducting the placement agent fee of \$1,050,000, placement agent expenses of \$85,000, legal fees of \$50,181, and other offering expenses of \$15,950. The Company also issued 875,000 warrants to the placement agent at an exercise price of \$1.50 per share, that are exercisable six months from the date of issuance, and expire five years from the date of issuance. The estimated fair value of the warrants issued to the placement agent was approximately \$771,000.

Stock Option Plans

Under our 2014 Stock Incentive Plan, we reserved 866,667 common shares for issuance to employees, directors, and consultants. As of June 30, 2023, options to purchase 795,171 shares were outstanding and no shares remain available for future grants.

Under our 2018 Omnibus Stock Incentive Plan, we reserved 2,000,000 shares of common shares for issuance to employees, directors, and consultants stock. As of June 30, 2023 December 31, 2023, there were options to purchase 1,760,000 shares outstanding, options to purchase 116,667 shares were outstanding exercised, options to purchase 13,333 shares expired, and no remaining 110,000 shares remain available for future grants.

Under our were transferred to the 2020 Omnibus Stock Incentive Plan ("2020 Plan").

Pursuant to our 2020 Plan, we reserved 3,110,000 shares of common shares for issuance to employees, directors, and consultants stock. As of June 30, 2023 December 31, 2023, there were options to purchase 1,820,000 shares were outstanding, options to purchase 50,000 shares were forfeited, expired and the remaining 1,240,000 shares were transferred to the 2021 Omnibus Stock Incentive Plan ("2021 Stock Plan").

Under Pursuant to our 2021 Omnibus Stock Incentive Plan, we reserved 8,740,000 shares for issuance to employees, directors, and consultants through options, SARs, dividend equivalent rights, restricted stock, restricted stock units, or other rights, of common stock. As of June 30, 2023 December 31, 2023, options to purchase 8,705,000 8,630,000 shares were outstanding, options to purchase 75,000 shares expired and the remaining 35,000 shares were transferred to the 2023 Omnibus Stock Incentive Plan (the "2023 ("2023 Stock Plan").

In November 2022, our Board approved the Citius Pharmaceuticals, Inc. 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 our common stock. As of June 30, 2023 December 31, 2023, options to purchase 300,000 4,385,000 shares were outstanding under the 2023 Stock Plan and 11,735,000 7,650,000 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 2020 Omnibus and Citius Oncology Stock Incentive Plan) 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 October 1, 2022 | 9,400,171 | \$ 2.07 | 7.81 years | \$ 869,509 | | | | |
| Outstanding at September 30, 2023 | | | | | 13,305,171 | \$ 1.79 | 7.41 years | \$ 56,203 |
| Granted | 4,150,000 | 1.26 | | | 4,085,000 | 0.70 | | |
| Exercised | (46,667) | 0.67 | | 34,067 | — | — | | |
| Forfeited or expired | (123,333) | 5.52 | | | — | — | | |
| Outstanding at June 30, 2023 | 13,380,171 | \$ 1.79 | 7.78 years | \$ 815,287 | | | | |
| Outstanding at December 31, 2023 | | | | | 17,390,171 | \$ 1.54 | 7.78 years | \$ 379,421 |
| Exercisable at June 30, 2023 | 6,200,170 | \$ 2.09 | 6.57 years | \$ 747,453 | | | | |
| Exercisable at December 31, 2023 | | | | | 9,231,839 | \$ 1.91 | 6.60 years | \$ 134,921 |
| 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. The weighted average grant date fair value of the options granted during the three months ended December 31, 2023 was estimated at \$0.54 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. On February 7, 2023, the Board of Directors granted options to purchase 150,000 shares to an employee and 75,000 shares to a director at \$1.42 per share. On April 10, 2023, the Board of Directors granted options to purchase 75,000 shares to an employee at \$1.46 per share. The weighted average grant date fair value of the options granted during the nine months ended June 30, 2023 December 31, 2023 was estimated at \$0.98 per share. These options vest over terms of 12 to 36 months and have a term of 10 years. | | | | | | | | |
| On October 11, 2021, the Board of Directors granted options to purchase 2,515,000 shares to employees, 375,000 shares to directors and 175,000 shares to consultants at \$2.04 per share. On November 1, 2021, the Board of Directors granted options to purchase 200,000 shares to an employee at \$1.87 per share. During January and February 2022, options to purchase 300,000 shares were granted to three new employees at exercise prices ranging from \$1.44 to \$1.49 per share. In April and June 2022, options to purchase 80,000 shares were granted to two new employees at exercise prices ranging from \$0.90 to \$1.47 per share. The weighted average grant date fair value of the options granted during the nine months ended June 30, 2022 was estimated at \$1.67 \$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 June 30, 2023 December 31, 2023 and 2022 was \$1,174,111 \$3,058,185 (including \$31,858 \$19,858 for the NoveCite Stock plan and \$1,917,000 for the Citius Oncology Plan) and \$1,003,677 \$1,201,081 (including \$33,333 for the NoveCite Stock Plan), respectively. Stock-based compensation expense for the nine months ended June 30, 2023 and 2022 was \$3,540,787 (including \$98,524 for the NoveCite Stock Plan) and \$2,929,279 (including \$99,999 for the NoveCite Stock Plan), respectively. | | | | | | | | |

At **June 30, 2023** **December 31, 2023**, unrecognized total compensation cost related to unvested awards under the Citius **Pharma** stock plans of **\$5,925,203** **\$5,905,736** is expected to be recognized over a weighted average period of **1.7** **1.75** years.

NoveCite Stock Plan - Under the NoveCite Stock Plan, we reserved 2,000,000 common shares of NoveCite for issuance. The NoveCite 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. As of **June 30, 2023** **December 31, 2023**, 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 **June 30, 2023** **December 31, 2023**, NoveCite has options outstanding to purchase 1,911,500 common shares at a weighted average exercise price of \$0.24 per share, of which **1,514,333** **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 **7.65** **7.14** years. At **June 30, 2023** **December 31, 2023**, unrecognized total compensation cost related to unvested awards under the NoveCite Stock Plan of **\$79,433** **\$27,717** is expected to be recognized over a weighted average period of **0.8** **0.5** 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. On July 5, 2023 During the year ended September 30, 2023, Citius Oncology granted options to purchase **12,550,000** **12,750,000** common shares at **an** 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.

On July 25, 2023 At December 31, 2023, Citius Oncology granted has options outstanding to purchase an additional 200,000 **12,600,000** shares, of which 1,638,889 common shares at an exercise price are exercisable. The weighted average remaining contractual term of \$2.15 per share. These options vest outstanding under the Citius Oncology Stock Plan is 9.5 years. At December 31, 2023, unrecognized total compensation cost related to unvested awards under the Citius Oncology Stock Plan of \$16,925,500 is expected to be recognized over a weighted average period of **12** months and have a term of **10** **2.4** years.

Warrants

As of **June 30, 2023** December 31, 2023, we have reserved shares of common stock for the exercise of outstanding warrants as follows:

| | Exercise price | Number | Expiration Date | Exercise price | Number | Expiration Date |
|--|---------------------------|-------------------|------------------------|---------------------------|-------------------|------------------------|
| March 2018 Registered Direct/Private Placement Investors | \$ 2.86 | 218,972 | October 2, 2023 | | | |
| August 2018 Offering Investors | 1.15 | 3,921,569 | August 14, 2023 | \$ 1.15 | 3,921,569 | August 14, 2024 |
| August 2018 Offering Agent | 1.59 | 189,412 | August 8, 2023 | 1.59 | 189,412 | August 8, 2024 |
| April 2019 Registered Direct/Private Placement Investors | 1.42 | 1,294,498 | April 5, 2024 | 1.42 | 1,294,498 | April 5, 2024 |
| April 2019 Registered Direct/Private Placement Agent | 1.93 | 240,130 | April 5, 2024 | 1.93 | 240,130 | April 5, 2024 |
| September 2019 Offering Investors | 0.77 | 2,793,297 | September 27, 2024 | 0.77 | 2,793,297 | September 27, 2024 |
| September 2019 Offering Underwriter | 1.12 | 194,358 | September 27, 2024 | 1.12 | 194,358 | September 27, 2024 |
| February 2020 Exercise Agreement Agent | 1.28 | 138,886 | August 19, 2025 | 1.28 | 138,886 | August 19, 2025 |
| May 2020 Registered Direct Offering Investors | 1.00 | 1,670,588 | November 18, 2025 | 1.00 | 1,670,588 | November 18, 2025 |
| May 2020 Registered Direct Offering Agent | 1.33 | 155,647 | May 14, 2025 | 1.33 | 155,647 | May 14, 2025 |
| August 2020 Underwriter | 1.31 | 201,967 | August 10, 2025 | 1.31 | 201,967 | August 10, 2025 |
| January 2021 Private Placement Investors | 1.23 | 3,091,192 | July 27, 2026 | 1.23 | 3,091,192 | July 27, 2026 |
| January 2021 Private Placement Agent | 1.62 | 351,623 | July 27, 2026 | 1.62 | 351,623 | July 27, 2026 |
| February 2021 Offering Investors | 1.70 | 20,580,283 | February 19, 2026 | 1.70 | 20,580,283 | February 19, 2026 |
| February 2021 Offering Agent | 1.88 | 2,506,396 | February 19, 2026 | 1.88 | 2,506,396 | February 19, 2026 |
| May 2023 Registered Direct Offering Investors | 1.50 | 12,500,001 | May 8, 2028 | 1.50 | 12,500,001 | May 8, 2028 |
| May 2023 Registered Direct Offering Agent | 1.50 | 875,000 | May 3, 2028 | 1.50 | 875,000 | May 3, 2028 |
| | | 50,923,819 | | | 50,704,847 | |

At **June 30, 2023** **December 31, 2023**, the weighted average remaining life of the outstanding warrants is **2.9** **2.5** years, all warrants are exercisable, **except for the 13,375,001 warrants issued in the May 2023 Registered Direct Offering which become exercisable on November 8, 2023, and the there was no aggregate intrinsic value of the warrants outstanding was \$1,747,081 outstanding.**

Common Stock Reserved

A summary of common stock reserved for future issuances as of **June 30, 2023** **December 31, 2023** is as follows:

| | | |
|---|-------------------|-------------------|
| Stock plan options outstanding | 13,380,171 | 17,390,171 |
| Stock plan shares available for future grants | 11,735,000 | 7,650,000 |
| Warrants outstanding | 50,923,819 | 50,704,847 |
| Total | 76,038,990 | 75,745,018 |

5.6. 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:

| | Three Months Ended December 31, 2023 | Three Months Ended December 31, 2022 |
|--|---|---|
| Lease cost | | |
| Operating lease cost | \$ 59,705 | \$ 59,707 |
| Variable lease cost | 1,204 | 1,158 |
| Total lease cost | <u><u>\$ 60,909</u></u> | <u><u>\$ 60,865</u></u> |
| Other information | | |
| Weighted-average remaining lease term - operating leases | 1.8 Years | 2.8 Years |
| Weighted-average discount rate - operating leases | 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 | |
| 2024 (excluding the 3 months ended December 31, 2023) | \$ 187,072 | |
| 2025 | 253,883 | |
| 2026 | 21,460 | |
| Total lease payments | <u><u>462,415</u></u> | |
| Less: interest | (33,846) | |
| Present value of lease liabilities | <u><u>\$ 428,569</u></u> | |

The elements of lease expense are as follows:

| | Nine Months Ended June 30, 2023 | Nine Months Ended June 30, 2022 |
|---|--|--|
| Lease cost | | |
| Operating lease cost | \$ 179,118 | \$ 179,116 |
| Variable lease cost | 3,567 | 772 |
| Total lease cost | <u><u>\$ 182,685</u></u> | <u><u>\$ 179,888</u></u> |
| Other information | | |
| Weighted-average remaining lease term - operating leases | 2.3 Years | 3.3 Years |
| Weighted-average discount rate - operating leases | 8.0% | 8.0% |
| Maturities of lease liabilities due under the Company's non-cancellable leases as of June 30, 2023 is as follows: | | |
| | June 30, 2023 | |
| Year Ending September 30, | | |
| 2023 (excluding the 9 months ended June 30, 2023) | \$ 61,952 | |
| 2024 | 249,024 | |
| 2025 | 253,883 | |
| 2026 | 21,460 | |
| | <u><u>586,319</u></u> | |
| Total lease payments | | |
| Less: interest | (53,437) | |
| Present value of lease liabilities | <u><u>\$ 532,882</u></u> | |

| Leases | Classification | June 30, 2023 | September 30, 2022 | Classification | December 31, 2023 | September 30, 2023 |
|--------------------------------|----------------|--------------------------|--------------------------|----------------|--------------------------|--------------------------|
| | | Classification | December 31, 2023 | | September 30, 2023 | |
| Assets | | | | | | |
| Lease asset | Operating | \$ 503,817 | \$ 646,074 | Operating | \$ 403,996 | \$ 454,426 |
| Total lease assets | | <u><u>\$ 503,817</u></u> | <u><u>\$ 646,074</u></u> | | <u><u>\$ 403,996</u></u> | <u><u>\$ 454,426</u></u> |
| Liabilities | | | | | | |
| Current | Operating | \$ 212,871 | \$ 196,989 | Operating | \$ 224,000 | \$ 218,380 |
| Non-current | Operating | 320,011 | 481,245 | Operating | 204,569 | 262,865 |
| Total lease liabilities | | <u><u>\$ 532,882</u></u> | <u><u>\$ 678,234</u></u> | | <u><u>\$ 428,569</u></u> | <u><u>\$ 481,245</u></u> |

Interest expense on the lease liability was **\$36,861** **\$9,275** and **\$47,881** **\$13,250** for the **nine three** months ended **June 30, 2023** **December 31, 2023** and 2022, respectively.

6.7. GAIN ON SALE OF NEW JERSEY NET OPERATING LOSSES

The Company recognized a gain of \$3,585,689 for the **nine three** months ended **June 30, 2023** **December 31, 2022** 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.

7.8. 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. If at any time before March 11, 2024, the bid price of the Company's common stock closes at \$1.00 per share or more for a minimum of ten consecutive business days, Nasdaq will provide the Company with a written confirmation of compliance with the Bid Price Rule.

If the Company does not regain compliance with the Bid Price Rule by March 11, 2024, the Company may be eligible for an additional 180-day compliance period. To qualify, the Company would be required to meet the continued listing requirement for market value of publicly held shares and all other initial listing standards for the Nasdaq Capital Market, with the exception of the Bid Price Rule, and would need to provide written notice of its intention to cure the bid price deficiency during the second compliance period by effecting a reverse stock split, if necessary.

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 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

On July 29, 2023 the Company received a Complete Response Letter, ("CRL") from the FDA regarding February 13, 2024, we filed the BLA seeking approval for Lymphir. The FDA has required Citius to incorporate enhanced product testing, and additional controls agreed to resubmission package with the FDA during the market application review. Additionally, the FDA raised no concerns relating to the safety and efficacy clinical data package.

Remediation efforts related to the CRL are not expected to impact the Company's 12-month cash runway. [FDA](#).

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 nine-month periods three months ended **June 30, 2023** December 31, 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, 2022** 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

We are 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 wholly-owned subsidiary in conjunction with the acquisition of LYMPHIR, which began operations in April 2022 and which changed its name to Citius Oncology, Inc. ("Citius Oncology") on May 2, 2023, 2022.

In-process research and development ("IPR&D") consists of (i) the \$19,400,000 represents the acquisition value of LMB's leading drug candidate **Mino-Lok**, **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. Goodwill of \$9,346,796 represents generation, and (ii) the \$40,000,000 acquisition value of LMB's industry relationships and its assembled workforce. Goodwill will not be amortized but will be tested at least annually for impairment. In-process research and development of \$40,000,000 represents the value of our September 2021 acquisition of an exclusive license for **Lympir** **LYMPHIR** (denileukin diftitox), which is a late-stage oncology immunotherapy for the treatment of **CTCL**, 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 **June 30, 2023** December 31, 2023, we have devoted substantially all our efforts to product business planning, research and development, recruiting management and technical staff, and raising capital, building infrastructure through strategic alliances, and coordinating activities relating to our proprietary products. 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 **that 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 digits. In limited circumstances in which the licensed product is not subject to a valid patent claim and a competitor is selling a competing product, the royalty rate is in the low single digits. After a commercial sale is obtained, LMB must pay minimum aggregate annual royalties that increase in subsequent years. LMB must also pay NAT up to \$1,100,000 upon achieving specified regulatory and sales milestones. Finally, LMB must pay NAT a specified percentage of payments received from any sub licensees.

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

Under the license agreement we paid a nonrefundable upfront payment of \$125,000. We are obligated to pay an annual maintenance fee of \$30,000, commencing in January 2020 that increases annually by \$15,000 per year up to a maximum of \$90,000. Annual maintenance fees cease on the first sale of product. We also must pay up to an aggregate of \$2.1 million in milestone payments, contingent on the achievement of various regulatory and commercial milestones. Under the terms of the license agreement, we also must pay a royalty of mid- to upper-single digit percentages of net sales, depending on the amount of annual sales, and subject to downward adjustment to lower- to mid-single digit percentages in the event there is no valid patent for the product in the United States at the time of sale. After the first sale of product, we will owe an annual minimum royalty payment of \$100,000 that will increase annually by \$25,000 for the duration of the term. We will be responsible for all patent expenses incurred by Licensor for the term of the agreement although Licensor is responsible for filing, prosecution, and maintenance of all patents. December 11, 2023

NoveCite – On October 6, 2020, our subsidiary NoveCite entered into a license agreement with Novellus Therapeutics Limited ("Novellus" Licensor"), whereby NoveCite acquired an exclusive, worldwide license, with the right to sublicense, to develop and commercialize a stem cell therapy based on the Novellus's 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 Novellus Licensor and issued to Novellus 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 Inc. ("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 as per the subscription agreement between Novellus and NoveCite was removed.

Under the license agreement, NoveCite is obligated to pay Eterna 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 Novellus 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 Novellus 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 Novellus Licensor receives any revenue involving the original cell line included in the licensed technology, then Novellus Licensor shall remit to NoveCite 50% of such revenue.

Lymphir LYMPHIR - In September 2021, the Company Citius Pharma entered into a definitive asset purchase agreement with Dr. Reddy's and a license agreement with Eisai to acquire its an exclusive license of Lymphir for E7777 (denileukin dittox), 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 this agreement, the agreements, Citius Pharma acquired Dr. Reddy's exclusive license of Lymphir for E7777 from Eisai and other related assets owned by Dr. Reddy's. Citius's Reddy's (now owned by Citius Oncology). The exclusive license rights, through our subsidiary, include rights to develop and commercialize Lymphir E7777 in all markets except for Japan and certain parts of Asia. Additionally, Citius has we, through our subsidiary, retain an option on the right to develop and market the product in India. Eisai retains exclusive development and marketing rights for denileukin dittox 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 Asia. Dr. Reddy's received 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 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 will be 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 current CTCL clinical trial, and chemistry, manufacturing, and controls (CMC) CMC activities through the filing of a BLA Biologics License Application ("BLA") for Lymphir 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 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.

RESULTS OF OPERATIONS

Three months ended **June 30, 2023** December 31, 2023 compared with the three months ended **June 30, 2022** December 31, 2022

| | Three Months Ended June 30, 2023 | Three Months Ended June 30, 2022 | Three Months Ended December 31, 2023 | Three Months Ended December 31, 2022 |
|---|---|---|---|---|
| Revenues | \$ — | \$ — | \$ — | \$ — |
| Operating expenses: | | | | |
| Research and development | 3,764,675 | 4,888,192 | 2,621,910 | 3,445,515 |
| General and administrative | 3,733,326 | 3,024,783 | 3,660,728 | 2,603,287 |
| Stock-based compensation expense | 1,174,111 | 1,003,677 | 3,058,185 | 1,201,081 |
| Total operating expenses | <u>8,672,112</u> | <u>8,916,652</u> | <u>9,340,823</u> | <u>7,249,883</u> |
| Operating loss | (8,672,112) | (8,916,652) | (9,340,823) | (7,249,883) |
| Interest income | <u>336,780</u> | <u>53,020</u> | <u>253,638</u> | <u>214,549</u> |
| Gain on sale of New Jersey net operating losses | | | — | 3,585,689 |
| Loss before income taxes | (8,335,332) | (8,863,632) | (9,087,185) | (3,449,645) |
| Income tax expense | 144,000 | — | 144,000 | 144,000 |
| Net loss | <u>\$ (8,479,332)</u> | <u>\$ (8,863,632)</u> | <u>\$ (9,231,185)</u> | <u>\$ (3,593,645)</u> |

Revenues

We did not generate any revenues for the three months ended **June 30, 2023** December 31, 2023 or 2022.

Research and Development Expenses

For the three months ended **June 30, 2023** December 31, 2023, research and development expenses were **\$3,764,675** **\$2,621,910** as compared to **\$4,888,192** **\$3,445,515** during the three months ended **June 30, 2022** December 31, 2022, a decrease of **\$1,123,517** **\$823,605**.

Research and development costs for Mino-Lok decreased by **\$242,634** **\$276,031** to **\$1,091,500** **\$891,624** for the three months ended **June 30, 2023** December 31, 2023 as compared to **\$1,334,134** **\$1,167,655** for the three months ended **June 30, 2022** December 31, 2022, due primarily to decreased start-up costs associated with Biorasi, LLC ("Biorasi"), a global clinical research organization (CRO) ("CRO"), to help expand the Company's Phase 3 Mino-Lok trial to additional sites outside the United States, which are no longer incurred. On January 2, 2024, Citius announced that it has 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 **increased** decreased by **\$485,081** **\$521,954** to **\$1,002,883** **\$246,572** for the three months ended **June 30, 2023** December 31, 2023 as compared to **\$517,802** **\$768,526** for the three months ended **June 30, 2022** December 31, 2022 due to **higher** **lower** costs associated with the Phase 2b trial incurred in the three months ended **June 30, 2023** December 31, 2023. On April 3, 2023, Citius announced that enrollment in the Phase 2b trial has been completed. 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 **intends to schedule** **Pharma has scheduled** an end of Phase 2 meeting with the FDA, **anticipated to occur in early 2024**, to begin planning the next steps in the regulatory and clinical development program for CITI-002.

Research and development costs for Lymphir LYMPHIR were \$1,658,838 \$1,472,464 during the three months ended June 30, 2023 December 31, 2023 as compared to \$1,992,897 \$1,428,545 for the three months ended June 30, 2022 December 31, 2022. The \$334,059 decrease \$43,919 increase in expenses was primarily due to costs associated with new analytical testing methods related to the completion and filing of our BLA with remediation activities to respond to the FDA in September 2022. Research and development costs for NoveCite decreased by \$992,937 for CRL during the three months ended June 30, 2023 to \$16,650 due primarily to manufacturing start up costs incurred in the three months ended June 30, 2022 which are no longer realized. December 31, 2023.

We expect that research and development expenses will stabilize in fiscal 2023 2024 as we focus on the commercialization of Lymphir and 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 **June 30, 2023** December 31, 2023, general and administrative expenses were **\$3,733,326** \$3,660,728 as compared to **\$3,024,783** \$2,603,287 during the three months ended **June 30, 2022** December 31, 2022. General and administrative expenses increased by **\$708,543** \$1,057,441 in comparison with the prior period. The primary **reason** reasons for the increase were costs associated with pre-launch and market research activities associated with **Lymphir** 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 **June 30, 2023** December 31, 2023, stock-based compensation expense was **\$1,174,111** \$3,058,185 as compared to **\$1,003,677** \$1,201,081 for the three months ended **June 30, 2022** December 31, 2022. For the three months ended **June 30, 2023** December 31, 2023 and 2022, stock-based compensation includes **\$31,858** \$19,858 and \$33,333, respectively, in expense for the NoveCite stock option plan. For the three months ended December 31, 2023, stock-based compensation also includes \$1,917,000 in expense for the recently adopted Citius Oncology stock plan. Stock-based compensation expense for the most recently completed quarter increased by **\$170,434** \$1,857,104 in comparison to the prior period primarily due to **new grants made to employees** (including new hires), directors and consultants, the Citius Oncology stock plan.

Other Income

Interest income for the three months ended **June 30, 2023** December 31, 2023 was **\$336,780** \$253,638 as compared to interest income of **\$53,020** \$214,549 for the prior period. The increase is due to higher interest rates on the investment of the remaining proceeds of our equity offerings and common stock warrant exercises in money market accounts.

Income Taxes

The Company recorded deferred **Other** income tax expense of **\$144,000** for the three months ended **June 30, 2023**, related to the amortization for taxable purposes of its in-process research and development asset. There was no provision for income taxes for the three months ended **June 30, 2022** due to the Company's operating losses and the valuation reserve on deferred tax assets.

Net Loss

For the three months ended **June 30, 2023**, we incurred a net loss of \$8,479,332, compared to a net loss for the three months ended **June 30, 2022** of \$8,863,632. The \$384,300 decrease in the net loss was primarily due to the decrease of \$1,123,517 in research and development expenses offset by the increase of \$708,543 in general and administrative expenses.

Nine months ended June 30, 2023 compared with the nine months ended June 30, 2022

| | Nine Months Ended June 30, 2023 | Nine Months Ended June 30, 2022 |
|---|--|--|
| Revenues | \$ — | \$ — |
| Operating expenses: | | |
| Research and development | 11,937,045 | 13,798,251 |
| General and administrative | 11,129,463 | 9,038,949 |
| Stock-based compensation expense | 3,540,787 | 2,929,279 |
| Total operating expenses | <u>26,607,295</u> | <u>25,766,479</u> |
| Operating loss | (26,607,295) | (25,766,479) |
| Interest income | 854,604 | 116,573 |
| Gain on sale of New Jersey net operating losses | 3,585,689 | — |
| Loss before income taxes | <u>(22,167,002)</u> | <u>(25,649,906)</u> |
| Income tax expense | 432,000 | — |
| Net loss | <u>\$ (22,599,002)</u> | <u>\$ (25,649,906)</u> |

Revenues

We did not generate any revenues for the nine months ended June 30, 2023 or 2022.

Research and Development Expenses

For the nine months ended June 30, 2023, research and development expenses were \$11,937,045 as compared to \$13,798,251 during the nine months ended June 30, 2022, a decrease of \$1,861,206. Research and development costs for Mino-Lok increased by \$92,829 to \$3,309,248 for the nine months ended June 30, 2023 as compared to \$3,216,419 for the nine months ended June 30, 2022, due primarily to increased costs associated with the addition of Biorasi, LLC ("Biorasi"), a global clinical research organization (CRO), to help expand the Company's Phase 3 Mino-Lok trial to additional sites outside the United States.

Research and development costs for Halo-Lido increased by \$1,514,702 to \$3,733,981 for the nine months ended June 30, 2023 as compared to \$2,219,279 for the nine months ended June 30, 2022 due to higher costs associated with the Phase 2b trial incurred in the nine months ended June 30, 2023. On April 3, 2023, Citius announced that enrollment in the Phase 2b trial has been completed. 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 intends to schedule an end of Phase 2 meeting with the FDA to begin planning the next steps in the regulatory and clinical development program for CITI-002.

Research and development costs for Lymphir were \$4,490,291 during the nine months ended June 30, 2023 as compared to \$6,513,262 for the nine months ended June 30, 2022. The \$2,022,971 decrease in expenses was primarily due to costs associated with the completed Lymphir phase 3 clinical trial as well as the preparation of the BLA which were incurred in the nine months ended June 30, 2022.

We expect that research and development expenses will stabilize in fiscal 2023 as we focus on the commercialization of Lymphir and complete our Phase 3 trial for Mino-Lok and our Phase 2b trial for Halo-Lido.

General and Administrative Expenses

For the nine months ended June 30, 2023, general and administrative expenses were \$11,129,463 as compared to \$9,038,949 during the nine months ended June 30, 2022. General and administrative expenses increased by \$2,090,514 in comparison with the prior period. The primary reason for the increase was costs associated with 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 nine months ended June 30, 2023, stock-based compensation expense was \$3,540,787 as compared to \$2,929,279 for the nine months ended June 30, 2022. For the nine months ended June 30, 2023 and 2022, stock-based compensation December 31, 2022 also includes \$98,524 and \$99,999, respectively in expense for the NoveCite stock option plan. Stock-based compensation expense for the most recently completed quarter increased by \$611,508 in comparison to the prior period primarily due to new grants made to employees (including new hires), directors and consultants.

Other Income

Interest income for the nine months ended June 30, 2023 was \$854,604 as compared to interest income of \$116,573 for the prior period. The increase is due to higher interest rates on the investment of the remaining proceeds of our early 2021 equity offerings and common stock warrant exercises in money market accounts.

Other income for the nine months ended June 30, 2023 consists of the \$3,585,689 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 \$432,000 \$144,000 for both the nine three months ended June 30, 2023, December 31, 2023 and 2022, related to the amortization for taxable purposes of its in-process research and development asset. There was no provision for income taxes for the nine months ended June 30, 2022 due to the Company's operating losses and the valuation reserve on deferred tax assets.

Net Loss

For the nine three months ended June 30, 2023 December 31, 2023, we incurred a net loss of \$22,599,002, \$9,231,185, compared to a net loss for the nine three months ended June 30, 2022 December 31, 2022 of \$25,649,906, \$3,593,645. The \$3,050,904 decrease \$5,637,540 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 \$4,323,720 \$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 offset by an aggregate increase in operating expenses of \$840,816 and a \$432,000 increase in income tax expense, \$3,546,600.

LIQUIDITY AND CAPITAL RESOURCES

Liquidity and Working Capital

Citius Pharma has incurred operating losses since inception and incurred a net loss of \$22,599,002 \$9,231,185 for the nine three months ended June 30, 2023 December 31, 2023. At June 30, 2023 December 31, 2023, Citius Pharma had an accumulated deficit of \$152,287,469. Citius' \$171,462,564. Citius Pharma's net cash used in operations during the nine three months ended June 30, 2023 December 31, 2023 was \$22,259,997, \$6,135,310.

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 \$35,300,000 \$22,600,000 at June 30, 2023 December 31, 2023. At June 30, 2023 December 31, 2023, Citius Pharma had cash and cash equivalents of \$33,281,830 \$20,345,618 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 **June 30, 2023** **December 31, 2023**, we expect that we will have sufficient funds to continue our operations through August 2024. We expect to need to raise additional capital in the future to support our operations beyond August 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, 2022** **September 30, 2023**, filed with the **SEC**, **SEC** on December 29, 2023.

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

Not applicable.

Item 4. Controls and **Procedures** **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 **June 30, 2023** **December 31, 2023**. 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 **June 30, 2023** **December 31, 2023**, 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 **June 30, 2023** **December 31, 2023** that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II - OTHER INFORMATION

Item 1. Legal Proceedings

None.

Item 1A. Risk Factors

There has been no change in material changes to the Company's risk factors since 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 22, 2022 December 29, 2023.

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

None. On October 10, 2023, we issued 108,778 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. 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

In August 2023, we extended the term by one year to August 14, 2024 for an aggregate of 3,921,569 warrants with an exercise price of \$1.15 per share of common stock. 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 August 2018 in a private placement conducted simultaneously with a registered direct offering of shares of common stock (the "2018 Offering") managed by H. C. Wainwright & Co., LLC ("Wainwright"). Mr. Mazur and Mr. Holubiak participated in the private placement on the same basis as all other investors. Additionally, 189,412 placement agent warrants with an exercise price of \$1.5938 per share issued in connection with the 2018 Offering were extended by one year to August 8, 2024. Such placement agent warrants are held by certain representatives of Wainwright. There are no other warrants remaining outstanding from the 2018 Offering and if such warrants are fully exercised, the Company would receive \$4,811,680 in cash proceeds. None.

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: **August 14, 2023** **February 14, 2024**

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

Date: **August 14, 2023** **February 14, 2024**

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

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EXHIBIT **Exhibit 31.1**

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

I, **Leonard** **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.

August **February 14, 2023** **2024**

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

EXHIBIT

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 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.

August February 14, 2023 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 **June 30, 2023** **December 31, 2023** as filed with the Securities and Exchange Commission on the date hereof (the "Report"), Leonard Mazur, Chief Executive Officer and Chairman 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: **August 14, 2023** **February 14, 2024**

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

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

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