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

FORM 10-K

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

For the Fiscal Year Ended September 30, 2025

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

Commission File Number 001-38174

Citius Pharmaceuticals, Inc.
(Exact name of Registrant as specified in its Charter)

Nevada	**27-3425913**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

11 Commerce Drive, First Floor, Cranford, NJ 07016
(Address of principal executive offices) (Zip Code)

(908) 967-6677
(Registrant's telephone number, including area code)

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

Title of Each Class	**Trading Symbol(s)**	**Name of Each Exchange on Which Registered**
Common Stock, par value $0.001 per share	**CTXR**	**The NASDAQ Capital Market**

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. ☐ Yes ☒ No

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. ☐ Yes ☒ No

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 during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). ☒ Yes ☐ No

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

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

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

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act by the registered public accounting firm that prepared or issued its audit report. ☐

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

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

The aggregate market value of the voting and non-voting common equity held by non-affiliates computed by reference to the price at which the common equity

was last sold, or the average bid and asked price of such common equity, as of the last business day of the registrant's most recently completed second fiscal quarter (March 31, 2025) was approximately $11,390,000.

Affiliates for the purpose of this item refers to the issuer's executive officers and directors and/or any persons or firms (excluding those brokerage firms and/or clearing houses and/or depository companies holding issuer's securities as record holders only for their respective clients' beneficial interest) owning 10% or more of the issuer's common stock, both of record and beneficially.

Indicate the number of shares outstanding of each of the registrant's classes of common stock, as of the latest practicable date:

20,762,917 shares as of December 17, 2025, all of one class of common stock, $0.001 par value.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Company's Proxy Statement for the Annual Meeting of Stockholders expected to be filed in January 2026 are incorporated by reference in Part III of this Report.

Citius Pharmaceuticals, Inc.

FORM 10-K
September 30, 2025

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NOTES

In this annual report on Form 10-K, and unless the context otherwise requires, the "Company," "we," "us" and "our" refer to Citius Pharmaceuticals, Inc. and its wholly-owned subsidiaries Citius Pharmaceuticals, LLC and Leonard-Meron Biosciences, Inc., and its majority-owned subsidiaries, Citius Oncology, Inc. (Nasdaq: CTOR) ("Citius Oncology") and NoveCite, Inc., taken as a whole.

Mino-Lok® and LYMPHIR™ (denileukin diftitox) are our registered trademarks. All other trade names, trademarks and service marks appearing in this annual report are the property of their respective owners. We have assumed that the reader understands that all such terms are source-indicating. Accordingly, such terms, when first mentioned in this report, appear with the trade name, trademark or service mark notice and then throughout the remainder of this report without trade name, trademark or service mark notices for convenience only and should not be construed as being used in a descriptive or generic sense.

FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains "forward-looking statements." Forward-looking statements include, but are not limited to, statements that express our intentions, beliefs, expectations, plans, 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, including the risks described under Item 1A - "Risk Factors," and Item 7 - "Management's Discussion and Analysis of Financial Condition and Results of Operations" in this report and in other documents which we file with the Securities and Exchange Commission ("SEC"). In addition, such statements could be affected by risks and uncertainties related to:

- our independent registered public accounting firm's report includes an explanatory paragraph stating that there is substantial doubt about our ability to continue as a going concern;
- our need for substantial additional funds and its ability to raise those funds;
- our ongoing evaluation of strategic alternatives;
- the ability of Citius Oncology to commercialize LYMPHIR, including covering the costs of licensing payments, product manufacturing and other third-party goods and services;
- our ability to recognize the anticipated benefits of the August 2024 reverse merger whereby Citius Oncology became a standalone publicly-traded company and our majority-owned subsidiary (the "Merger"), which may not be realized fully, if at all, or may take longer to realize than expected;
- our ability to obtain regulatory approval for and successfully commercialize Mino-Lok;
- the cost, timing, and results of our pre-clinical and clinical trials for our other product candidates;
- our ability to apply for, obtain and maintain required regulatory approvals for our other product candidates;
- our ability to maintain compliance with the continued listing requirements of the Nasdaq Stock Market LLC ("Nasdaq");
- our ability to obtain, perform under and maintain financing and strategic agreements and relationships;
- the commercial feasibility and success of our technology and our product candidates;
- our ability to recruit qualified management and technical personnel to carry out our operations; and
- other risks and uncertainties set forth under the section entitled "Risk Factors."

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.

SUMMARY OF RISK FACTORS

An investment in our securities involves a high degree of risk. You should carefully consider the risks summarized in Item 1A, "Risk Factors" included in this report. These risks include, but are not limited to, the following:

- Our independent registered public accounting firm's report includes an explanatory paragraph stating that there is substantial doubt about our ability to continue as a going concern.
- We require substantial additional funding, which may not be available on acceptable terms, or at all. Failure to obtain this necessary capital when needed on acceptable terms, or at all, or execute on alternative strategic paths, could force us to delay, limit, reduce or terminate our commercialization efforts and business operations.
- We have a history of net losses and expect to incur losses for the foreseeable future. We may never generate revenues or, if we are able to generate revenues, achieve profitability.
- Our exploration of alternative strategic paths may not result in completing a transaction and the process or conclusion thereof could adversely affect our stock price. If we do not successfully complete a strategic transaction, our Board of Directors (the "Board") may decide to pursue a dissolution and liquidation of our Company.
- Both the Company and Citius Oncology are heavily dependent on the launch and commercial success of LYMPHIR.
- We, through Citius Oncology, have one approved product, LYMPHIR, that we launched in December 2025, and have an unproven business strategy, and a limited operating history upon which to evaluate it, and may never achieve successful commercialization of LYMPHIR or any future product candidates or achieve or maintain profitability.
- We are the guarantor of milestone payments to the licensor and former licensee of the LYMPHIR intellectual property, which could adversely affect our profitability. A material breach under our license agreements, including timely payment, gives the licensor party the right to terminate the license agreement, which would materially harm our business.
- Our failure to abide by our contractual obligations with third parties upon whom we rely on to formulate and manufacture our product candidates, including timely payment, could result in the loss third-party support.
- We face significant risks in our development and commercialization efforts of LYMPHIR and development of our other product candidates.
- We may choose not to continue developing any of our product candidates at any time during development, which would reduce or eliminate our potential return on investment for those product candidates.
- While our business strategy generally is to focus on the development of late-stage product candidates to lessen the development risk, there is still significant risk to successfully developing a product candidate.
- If we are unable to file for approval of Mino-Lok or Halo-Lido under Section 505(b)(2) of the Federal Food, Drug and Cosmetic Act, or if we are required to generate additional data related to safety and efficacy under Section 505(b)(2), we may be unable to meet our anticipated development and commercialization timelines.
- Two of our product candidates, Mino-Lok and Halo-Lido, are combination products consisting of components that have each been separately approved by the FDA for other indications and which are commercially available and marketed by other companies. Our approval under Section 505(b)(2), if received, would not preclude physicians, pharmacists, and patients from obtaining individual drug products and titrating the dosage of these drug products as close to our approved dose as possible.
- Any fast track designation or grant of priority review status by the FDA may not actually lead to a faster development or regulatory review or approval process, nor will it assure FDA approval of our product candidates. Additionally, our product candidates may treat indications that do not qualify for priority review vouchers.
- We do not own Citius Oncology or NoveCite, Inc. outright and will share any benefits from the commercialization of LYMPHIR and the development of the NoveCite product candidate with the other stockholders.
- Even if we receive regulatory approval to commercialize a product candidate, that product may not gain market acceptance among physicians, patients, healthcare payers or the medical community and may not generate significant revenue.
- Even if approved for marketing by applicable regulatory bodies, we will not be able to create a market for any of our product candidates if we fail to establish marketing, sales, and distribution capabilities, either on our own or through arrangements with third parties.
- Our projections regarding the market opportunity for LYMPHIR and our other product candidates may not be accurate.
- The markets in which we operate are highly competitive and we may be unable to compete successfully against new entrants or established companies.

- Our ability to generate product revenues will be diminished if any of our product candidates that may be approved sell for inadequate prices or patients are unable to obtain adequate levels of reimbursement.
- Healthcare reform measures could hinder or prevent our product candidates' commercial success.
- We are and will be dependent on third-party contract research organizations to conduct all of our clinical trials.
- We rely exclusively on third parties to formulate and manufacture our product candidates.
- Any termination, or breach by, or conflict with our strategic partners could harm our business.
- We rely on the specialized expertise of the executive management and other key personnel and the loss of any of them or our inability to successfully hire their successors could harm our business.
- If we are unable to retain or hire additional qualified personnel, our ability to grow our business might be harmed.
- We are subject to information technology and cyber-security threats which could have an adverse effect on our business and results of operations.
- The results of pre-clinical studies and completed clinical trials are not necessarily predictive of future results, and our current and any future product candidates may not have favorable results in later studies or trials.
- Conflicts of interest may arise from our relationships with Citius Oncology and NoveCite.
- We might not obtain the necessary U.S. or foreign regulatory approvals to commercialize any current product candidates.
- Following any regulatory approval of any product candidate, we will be subject to ongoing regulatory obligations and restrictions, which may result in significant expense and limit our ability to commercialize our other product candidates.
- We could be forced to pay substantial damage awards if product liability claims that may be brought against us are successful.
- Failure to protect our intellectual property may be adversely affect our business. Our business may also suffer, and/or we may have to pay damages or defend against litigation, if we infringe the rights of third parties.
- The U.S. government could have "march-in rights" to certain of our intellectual property.
- We may be unable to achieve some or all of the benefits that we expect to achieve from the Merger.
- A planned distribution by Citius Pharma to its stockholders of shares of Citius Oncology could result in significant tax liability to Citius Pharma and our stockholders.
- Our failure to maintain compliance with Nasdaq's continued listing requirements could result in the delisting of our common stock.
- The market price of our common stock is highly volatile, and you may lose some or all of your investment. Volatility in our share price could also subject us to securities litigation.
- You may experience dilution of your ownership interests because of the future issuance of additional shares of our common stock or securities convertible into common stock.
- Our Certificate of Incorporation allows our Board of Directors to create new series of preferred stock without further approval by our stockholders, which could adversely affect the rights of the holders of the common stock.
- We have not paid cash dividends in the past and we do not expect to pay cash dividends in the foreseeable future. Any return on investment may be limited to the capital appreciation, if any, of our common stock.
- Provisions in our Amended and Restated Articles of Incorporation, as amended, and under Nevada law could discourage a takeover that stockholders may consider favorable and may lead to entrenchment of management.
- If our estimates or judgments relating to our critical accounting policies prove to be incorrect or applicable standards or interpretations change, the Company's results of operations could be adversely affected.

PART I

Item 1. Business

Overview

Citius Pharmaceuticals, Inc., headquartered in Cranford, New Jersey, is a 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 and unique prescription products. Our goal generally is to achieve leading market positions by providing therapeutic products that address unmet medical needs yet have a lower development risk than usually is associated with new chemical entities. New formulations of previously approved drugs with substantial existing safety and efficacy data are a core focus. We seek to reduce development and clinical risks associated with drug development, yet still focus on innovative applications. Our strategy centers on products that have intellectual property and regulatory exclusivity protection, while providing competitive advantages over other existing therapeutic approaches.

In December 2025, we became a commercial company with the launch of LYMPHIR by our majority owned subsidiary Citius Oncology. We also have late-stage product candidates in development.

Since its inception, the Company has devoted substantially all of its efforts to business planning, acquiring our proprietary technology, research and development, recruiting management and technical staff, and raising capital. We are developing three proprietary products Mino-Lok, an antibiotic lock solution used to treat patients with catheter-related bloodstream infections by salvaging the infected catheter; Halo-Lido, a corticosteroid-lidocaine topical formulation that is intended to provide anti-inflammatory and anesthetic relief to persons suffering from hemorrhoids; and NoveCite, a mesenchymal stem cell therapy for the treatment of ARDS. Citius Oncology achieved the approval from the FDA for LYMPHIR, in-licensed by Citius Pharma in September 2021 (now owned by Citius Oncology), an engineered IL-2 diphtheria toxin fusion protein, for the treatment of patients with persistent or recurrent cutaneous T-cell lymphoma ("CTCL"). We believe these unique markets for our products are large, growing, and underserved by the current prescription products or procedures.

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 us or our competitors of research and development stage products, market acceptance of our products that receive regulatory approval, 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.

The Company was founded as Citius Pharmaceuticals, LLC, a Massachusetts limited liability company, on January 23, 2007. On September 12, 2014, Citius Pharmaceuticals, LLC entered into a Share Exchange and Reorganization Agreement, with Citius Pharma (formerly Trail One, Inc.), a publicly traded company incorporated under the laws of the State of Nevada. Citius Pharmaceuticals, LLC became a wholly-owned subsidiary of Citius Pharma. On March 30, 2016, Citius Pharma acquired Leonard-Meron Biosciences, Inc. ("LMB") as a wholly-owned subsidiary. LMB was a pharmaceutical company focused on the development and commercialization of critical care products with a concentration on anti-infectives. On September 11, 2020, we formed NoveCite, Inc. ("NoveCite"), a Delaware corporation, of which we own 75% of the issued and outstanding capital stock. NoveCite is focused on the development and commercialization of its proprietary mesenchymal stem cells for the treatment of acute respiratory disease syndrome ("ARDS").

Citius Oncology and the Merger

On August 23, 2021, we formed Citius Acquisition Corp. ("SpinCo") as a wholly-owned subsidiary in conjunction with the acquisition of LYMPHIR. SpinCo began operations in April 2022, when Citius Pharma transferred the assets related to LYMPHIR to SpinCo, including the related license agreement with Eisai Co., Ltd. ("Eisai") and the related asset purchase agreement with Dr. Reddy's Laboratories SA, a subsidiary of Dr. Reddy's Laboratories, Ltd. (collectively, "Dr. Reddy's").

On October 23, 2023, Citius Pharma and SpinCo entered into an agreement and plan of merger and reorganization (the "Merger Agreement") with TenX Keane Acquisition, a Cayman Islands exempted company ("TenX"), and TenX Merger Sub Inc., a Delaware corporation and a wholly owned subsidiary of TenX ("Merger Sub"). On August 12, 2024, pursuant to the terms and conditions of the Merger Agreement, Merger Sub merged with and into SpinCo, with SpinCo surviving as a wholly owned subsidiary of TenX, which was subsequently renamed Citius Oncology Sub. Prior to the closing of the Merger (the "Closing"), TenX migrated to and domesticated 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"). As part of the Domestication, TenX changed its name to "Citius Oncology, Inc." (Nasdaq: CTOR). Immediately after the closing of the Merger, Citius Pharma owned approximately 92% of the outstanding shares of common stock of Citius Oncology. As of December 17, 2025, Citius Pharma owned approximately 77.9% of Citius Oncology (excluding pre-funded warrants to purchase up to 15,229,358 shares of Citius Oncology common stock in a transaction that closed on December 10, 2025).

Since its inception, Citius Pharma has funded and continues to fund Citius Oncology, and Citius Pharma and Citius Oncology are party to an amended and restated shared services agreement (the "A&R Shared Services Agreement"), which governs certain management and scientific services that Citius Pharma provides Citius Oncology.

LYMPHIR™ (denileukin diftitox-cdxl)

Overview

In September 2021, the Company announced that it had entered into an asset purchase agreement with Dr. Reddy's to acquire its exclusive license of E7777 (denileukin diftitox). E7777, an engineered IL-2-diphtheria toxin fusion protein, is an improved formulation of oncology agent, ONTAK®, which was previously approved by the FDA for the treatment of patients with persistent or recurrent CTCL. Dr. Reddy's had previously exclusively licensed E777 in select markets from Eisai and as part of the transaction, Eisai entered into a license agreement whereby Eisai assigned all of its rights to E7777 to Citius Pharma. Citius Pharma renamed E7777 as I/ONTAK and also obtained the trade name LYMPHIR for the product. Denileukin diftitox is referred to in this report as E7777, I/ONTAK or LYMPHIR, depending on the period of time and context that is being discussed. In April 2022 LYMPHIR was assigned to Citius Oncology.

LYMPHIR is a recombinant DNA-derived fusion protein designed to direct the cytocidal action of diphtheria toxin (DT) to cells which express the IL-2 receptor. After uptake into the cell, the DT fragment is cleaved and the free DT fragments inhibit protein synthesis, resulting in cell death. Consequently, LYMPHIR's differentiated mechanism of action supports two therapeutic effects: (i) killing tumors by binding to IL-2 receptors to deliver diphtheria toxin directly to the tumor cells, and (ii) depleting immunosuppressive regulatory T lymphocytes (Tregs) to enhance antitumor activity.

Phase 3 Trial (E7777-G000-302) Design

LYMPHIR is an improved formulation of oncology agent, ONTAK®, which was previously approved by the FDA for the treatment of patients with persistent or recurrent CTCL. ONTAK was marketed in the U.S. previously. The manufacturing formulation improvements were substantial enough that the FDA required a new clinical study to be performed (Study E7777-G000-302). The safety profile of LYMPHIR from study E7777-G000-302 is comparable to Study 93-04-11/L4389-11, which served as the basis for the full approval of ONTAK. Study E7777-G000-302, a global, multicenter, open-label single-arm pivotal clinical trial for the treatment of patients with persistent or recurrent CTCL, commenced (first subject consented) in May 2013 and completed (data cutoff for primary analysis) in December 2021. The study was sponsored by Eisai and was conducted at 17 sites in the United States and three sites in Australia. Inclusion criteria for the study were to evaluate patients in advanced stage CTCL (Mycosis Fungoides or Sézary Syndrome), who received at least one prior CTCL therapy. The objectives were met for Study E7777-G000-302, in both the lead-in phase and the main phase. Overall, the primary and secondary endpoints of Study E7777-G000-302 demonstrate the tolerability and clinical benefit of 9 µg/kg/day LYMPHIR for the treatment of adult patients with relapsed or refractory Stage I-III CTCL. No new safety signals were identified compared to ONTAK.

The pivotal trial of E7777 was divided into two phases, a lead-in phase with 21 subjects that evaluated dose finding, pharmacokinetics and immunogenicity, and assessed the Objective Response Rate (the "ORR"). An ORR is defined as a greater than 50% reduction in tumor burden. Patients received a daily intravenous infusion of denileukin diftitox from Day 1 through Day 5 of each 21-day cycle. In the lead-in phase, the main objectives were to determine the maximum tolerated dose (MTD) of LYMPHIR and to select the dose of LYMPHIR to be used in the main phase (subjects were treated at doses ranging from 6 to 15 µg/kg/day). The MTD was 12 µg/kg/day and, based on data of the lead-in phase, 9 µg/kg/day was selected for the main phase of the study. The objectives of the main phase were to evaluate the efficacy and safety of LYMPHIR (at the dose determined in the lead-in phase of 9 µg/kg/day).

The primary efficacy endpoint was tumor response rate, i.e. ORR per the Independent Review Committee (IRC) assessment based on International Society for Cutaneous Lymphomas/ European Organization for Research and Treatment of Cancer Global Response Score (GRS; Olsen, et al., 2011).

The secondary efficacy endpoints were:

- Duration of response (DOR) based on GRS;
- Time to response based on GRS;
- ORR assessed by investigator using GRS;
- Objective response assessed by IRC using Prince (Prince, et al., 2010);
- Skin response (according to modified Severity Weighted Assessment Tool [mSWAT]);
- Duration of skin response; and
- Time to skin response.

Overall, there were 25 responders out of 69 subjects in the Primary Efficacy Analysis Set (i.e., subjects with CTCL disease Stages I to III (9 µg/kg/day)) as assessed by the IRC, with an ORR of 36.2% (95% CI: 25.0%, 48.7%), with 8.7% (6/69) achieving a Complete Response (CR) and 27.5% (19/69) achieving a Partial Response.

Among responders, the median follow-up for duration of response was 6.5 months (range: 3.5+, 23.5+ months). Median time to response was 1.4 months (range: 0.7 to 5.6 months).

ORR (95% CI) by investigator was 42.3% (30.6%, 54.6%) (30 of 71 subjects), with 8.5% (6 subjects) achieving a CR. ORR (95% CI) by IRC assessment using the Prince (2010) criteria was 36.2% (25.0%, 48.7%) (25 of 69 subjects). Further, an ORR of 38.1% in the intent to treat population and 44.4% in the efficacy evaluable populations were observed. The 2-sided, exact 95% CI of ORR was calculated using the Clopper-Pearson method. Per protocol, LYMPHIR demonstrated clinical benefit if the lower bound of the 2-sided 95% exact CI of the ORR exceeded 25%.

Skin responses were the same as GRS objective responses, for both IRC and investigator assessments. Responses were deep, reflected by the substantial decrease in skin tumor burden, including 8 subjects with 100% clearance of skin lesions per IRC.

In the second and main phase of the pivotal trial, 70 patients were administered the 9 µg/kg/day rate for 5 consecutive days in 21-day cycles. The inclusion criteria were identical to the lead-in phase.

Phase 3 Trial Efficacy & Safety Results

The efficacy population of the main phase included 69 patients with relapsed or refractory stage I to III CTCL. Of the 69 patients, the median age was 64 years (range: 28 to 87 years), 65% were male, 73% were White, 19% Black or African American, 1% Asian, and 14% Hispanic or Latino. The CTCL disease stage was IA in 7%, IB in 23%, IIA in 13%, IIB in 35%, IIIA in 12%, and IIIB in 10%. The median number of prior therapies was 4 (range: 1 to 18), including both skin-directed and systemic therapies. Prior therapies included photodynamic therapy (56%), total skin electron beam therapy (42%), systemic retinoids (49%), methotrexate/pralatrexate (49%), histone deacetylase inhibitor (35%), brentuximab vedotin (26%) and mogamulizumab (12%).

Efficacy was established based on ORR, according to ISCL/EORTC Global Response Score (GRS) per Independent Review Committee (Olsen 2011). Efficacy results are shown in the table below.

Efficacy Results of E7777-G000-302	**LYMPHIR 9 µg/kg/day (N = 69)**
ORR (GRS)%[a]	36%
(95% CI[b])	(25, 49)
Complete Response	9%
Partial Response	27%
Duration of Response	
Median (range), months	6.5 (3.0 +, 23.5 +)
Duration ≥ 6 months, n (%)	52%
Median Time to Response, months	1.4
(95% CI[b])	(0.7, 5.6)

(a) ORR, Objective Response Rate per Olsen, et all (2011) Global Response Score (GRS), by Independent Review Committee (IRC)

(b) CI = confidence interval

Both the endpoints and objectives of Study E7777-G000-302 were met, while the statistical confidence interval (95% CI) resulted in a marginal shortfall (25% actual achievement vs. >25% from the statistical plan). Throughout the initial BLA review period, the FDA accepted the Study E7777-G000-302 data which demonstrated both tolerability and clinical benefit.

Overall, LYMPHIR was well-tolerated with the use of pre-medications, close patient monitoring, and prompt initiation of supportive measures and drug management. There was no evidence of cumulative toxicity and most patients experienced low grade 1 or 2 treatment emergent adverse events.

Serious adverse reactions occurred in 38% of patients who received LYMPHIR. Serious adverse reactions in > 2% of patients included capillary leak syndrome (10%), infusion-related reaction (9%), sepsis (7%), skin infection (2.9%), pyrexia (2.9%), and rash (2.9%). There were no Grade 5 adverse events in the Study E7777-G000-302, Stage I-III Safety Set (which is the safety set FDA required for inclusion in the package insert/label).

Adverse Reactions (≥ 10%) in Patients with Relapsed or Refractory Stage I-III CTCL Who Received LYMPHIR in E7777-G000-302

Adverse Reaction	LYMPHIR N = 69	
	All Grades (%)	Grade 3 or 4 (%)
Gastrointestinal disorders		
Nausea	43	1.4
Diarrhea	19	0
Vomiting	13	0
Constipation	12	0
General disorders and administration site conditions		
Fatigue[a]	38	0
Edema[b]	33	1.4
Chills	27	1.4
Fever[c]	16	1.4
Musculoskeletal and connective tissue disorders		
Musculoskeletal pain[d]	27	2.9
Arthralgia[e]	12	0
Nervous system disorders		
Headache[f]	25	0
Dizziness	13	0
Mental status changes[g]	13	0
Injury, poisoning and procedural complications		
Infusion-related reaction	25	6
Skin and subcutaneous tissue disorders		
Rash[h]	23	6
Pruritis[i]	19	6
Vascular disorders		
Capillary leak syndrome	20	6
Metabolism and nutrition disorders		
Decreased appetite	13	1.4
Eye disorders		
Vision changes[j]	13	0
Investigations		
Weight increased	13	0
Infections and infestations		
Skin infection	13	1.4
Renal and urinary disorders		
Renal insufficiency[l]	12	2.9
Psychiatric disorders		
Insomnia	10	0

(a) Includes fatigue, asthenia, and lethargy.

(b) Includes edema, edema peripheral generalized edema, face edema, swelling face, peripheral swelling.

(c) Includes fever, pyrexia, tumor associated fever.

(d) Includes musculoskeletal pain, back pain, neck pain, pain in extremity, myalgia, bone pain, flank pain.

(e) Includes arthralgia, joint swelling, joint range of motion decreased, musculoskeletal stiffness.

(f) Includes headache, migraine.

(g) Includes mental status changes, amnesia, confusional state, delirium, altered state of consciousness, hallucinations (including auditory), memory impairment, disturbance in attention, somnolence, cognitive disorder.

(h) Includes rash, dermatitis, drug eruption, erythema, palmar erythema, toxic skin eruption, rash maculo-papular, rash papular, rash pustular, rash pruritic, dermatitis exfoliative generalized, acute generalized exanthematous pustulosis.

(i) Includes pruritis, itching.

(j) Includes vision blurred, photopsia, visual impairment.

(k) Includes skin infection, skin bacterial infection, staphylococcal skin infection, cellulitis, impetigo.

(l) Includes renal failure, nephropathy, acute kidney injury, blood creatinine increased, renal impairment.

Grade refers to the severity of the adverse reaction. The Common Terminology Criteria for Adverse Events displays Grades 1 through 5 with unique clinical descriptions of severity for each adverse reaction based on this general guideline:

- Grade 1 - Mild; asymptomatic or mild symptoms; clinical or diagnostic observations only; intervention not indicated.

- Grade 2 - Moderate; minimal, local or noninvasive intervention indicated; limiting age-appropriate instrumental activities of daily living.

- Grade 3 - Severe or medically significant but not immediately life-threatening; hospitalization or prolongation of hospitalization indicated; disabling; limiting self-care activities of daily living.

- Grade 4 - Life-threatening consequences; urgent intervention indicated.

- Grade 5 - Death related to the adverse reaction.

Investigator Initiated Trials

We believe there is an opportunity in the field of immuno-oncology and have undertaken two investigator-initiated trials to evaluate the potential safety and efficacy of LYMPHIR as an immuno-oncology combination therapy.

A Phase 1 trial was initiated in June 2021 at the University of Minnesota, Masonic Cancer Center. This study is a single-arm open-label trial which has an estimated enrollment of 20 participants who will be administered denileukin diftitox prior to Chimeric Antigen Receptor ("CAR-T") therapies. The Phase 1 study consists of two components: dose finding to establish a maximum tolerated dose ("MTD") of denileukin diftitox in combination with CART-T therapies, and an extension component to provide an estimate of efficacy at that MTD. (Title: Phase I/II Trial Using E7777 to Enhance Regulatory T-Cell Depletion Prior to CAR-T Therapy for Relapsed/Refractory B-Cell Lymphoma (DLBCL). NCT04855253). Preliminary results are anticipated in the first quarter of 2026.

A second Phase 1 Study was initiated in September 2022 at the University of Pittsburg Medical Center, Hillman Cancer Center. This study is an open label, Phase 1/1b study to investigate the safety and efficacy of a combined regimen of pembrolizumab with T-regulatory cell depletion and denileukin diftitox in patients diagnosed with recurrent or metastatic solid tumors in the second line setting. (Title: The efficacy of T-regulatory cell depletion with E7777 combined with immune checkpoint inhibitor, pembrolizumab, in recurrent or metastatic solid tumors: Phase I/II Study. NCT05200559).

The study consists of two parts. Part I is a dose escalation study of four cohorts (3,6,9,12 mcg of LYMPHIR) and is expected to enroll 18-30 patients. Part II is a dose expansion study of approximately 40 patients to evaluate the safety and tolerability of the recommended combination dose of LYMPHIR and pembrolizumab (to include ovarian cancer and MSI-H cancer cohorts). The study will also investigate the alteration of the immune microenvironment within tumors and peripheral blood. Secondary endpoints include the objective response (complete response plus partial response), progression-free survival, and overall survival.

In November 2024, the Company announced promising preliminary results of the Phase I Clinical Trial of Pembrolizumab (KEYTRUDA®) and LYMPHIR™ in cancer patients with recurrent solid tumors conducted at the University of Pittsburg Hillman Cancer Center.

Preliminary Results

The results of this chemotherapy-free regimen combining two immuno-modulator agents, pembrolizumab (anti-PD-1) and LYMPHIR (transient Treg depletion) demonstrated:

- An overall response rate (ORR) of 27% (4/15) and a clinical benefit rate of 33% (5/15) among evaluable patients; and,

- Median progression-free survival (PFS) for patients achieving clinical benefit of 57 weeks, with a range of 30 to 96 weeks.

  Notably, two of the four patients who achieved partial remission had received prior checkpoint inhibitors (i.e. anti-PD-1 therapy). This highlights the therapeutic potential of LYMPHIR plus immune checkpoint inhibitors to be effective in patients who fail prior anti-PD-1/L1 therapy.

The trial enrolled 21 patients with recurrent or metastatic solid tumors. Among the evaluable participants, four patients achieved a partial response, and one patient demonstrated durable stable disease lasting over six months. The combination regimen was generally well tolerated, with most adverse events related to the patients' underlying disease. Importantly, no significant immune-related adverse events were observed, and only one case of dose-limiting toxicity (capillary leak syndrome) was reported at the highest dose level (12 mcg/kg).

Table 1: Efficacy Data

	Value
Patients Enrolled	21
Patients Evaluable for Response	15
Partial Responses (PR)	4 (27%)
Stable Disease (≥ 6 months)	1
Clinical Benefit Rate (CBR)	33% (PR + SD ≥ 6 months)
Median Progression-Free Survival (PFS)	57 weeks (range: 30-96 weeks)

Table 2: Safety Data

	Value
Dose-Limiting Toxicities (DLTs)	1 (Capillary Leak Syndrome at 12 mcg/kg)
Immune-Related Adverse Events (irAEs)	None documented (≥ Grade 3)
Adverse Events (Grade ≥ 3)	Most related to underlying disease

Regulatory Development

In the 1990s, denileukin diftitox was developed at Boston University and the National Cancer Institute ("NCI") in collaboration with Seragen, Inc.

In 1999, ONTAK® (denileukin diftitox) was granted accelerated approval by the FDA for the treatment of persistent or recurrent CTCL. Ligand Pharmaceuticals, Inc. ("Ligand") acquired the marketing rights in that same year.

In 2006, Eisai acquired the commercial rights to ONTAK from Ligand.

In 2008, the FDA granted full approval to ONTAK for CTCL.

In 2011, a new formulation of denileukin diftitox was developed under the code name E7777 in response to a post-marketing condition established by the FDA upon approval. As the FDA considered this a new product, an Investigational New Drug Application ("IND") was filed. As a part of ensuing discussions, the FDA agreed to a development plan that included a single arm, open label study to confirm the safety and efficacy of E7777 and a chemistry, manufacturing, and controls ("CMC") development plan that demonstrates the new process results in a comparable drug product.

In 2011, the FDA Office of Orphan Products Development granted E7777 orphan drug designation status for the treatment of Peripheral T-Cell Lymphoma ("PTCL"). In 2013, the FDA Office of Orphan Products Development granted E7777 orphan drug designation status for the treatment of CTCL.

In 2013, the first patient was enrolled into the lead-in phase of the pivotal study for the E7777 U.S. CTCL clinical trial.

In 2014, commercial sales of ONTAK were discontinued when the product was voluntarily withdrawn from the market due to manufacturing issues at the contract manufacturer.

In 2015, the last patient enrolled exited the lead-in phase of the E7777 U.S. CTCL clinical trial.

In March 2016, Dr. Reddy's exclusively licensed the global rights to E7777 from Eisai, other than the rights in countries retained by Eisai, which consists of Japan, China, Korea, Taiwan, Hong Kong, Macau, Indonesia, Thailand, Malaysia, Brunei, Singapore, India, Pakistan, Sri Lanka, Philippines, Vietnam, Myanmar, Cambodia, Laos, Afghanistan, Bangladesh, Bhutan, Nepal, Mongolia and Papua New Guinea. The license included an option on the right to develop and market the product in India prior to FDA approval.

In June 2016, the first patient was enrolled in the main phase of the Phase 3 U.S. CTCL clinical trial for E7777.

In March 2020, Eisai filed a New Drug Application ("NDA") for E7777 in Japan for both CTCL and PTCL, and in March 2021 received approvals in both indications.

In September 2021, Citius Pharma acquired the marketing rights to E7777 in selected markets. Citius Pharma subsequently renamed E7777 as LYMPHIR.

In December 2021, patient enrollment for the Phase 3 Pivotal study of LYMPHIR was completed.

In April 2022, we reported that topline results from the Phase 3 trial were consistent with the prior formulation. Moreover, no new safety signals were identified.

In December 2022, a Biologics License Application ("BLA") for LYMPHIR was accepted for filing with the FDA and a PDUFA goal date was set for July 28, 2023.

In July 2023, the FDA issued a complete response letter ("CRL") requiring us to incorporate enhanced product testing and additional controls agreed to with the FDA during the market application review. There were no concerns relating to the safety and efficacy clinical data package submitted with the BLA, or the proposed prescribing information.

In September 2023, we announced that the FDA agreed with the plans to address the requirements outlined in the CRL, which guidance provided the Company with a path for completing the necessary activities to support the resubmission of the BLA for LYMPHIR.

In February 2024, based on the feedback from the FDA, Citius Pharma completed the CRL remediation activities and filed the resubmission.

In March 2024, Citius Pharma announced the acceptance of the BLA by the FDA. The FDA assigned a PDUFA goal date of August 13, 2024 and approved LYMPHIR on August 8, 2024.

In August 2024, Citius Pharma announced that the FDA had approved LYMPHIR. Citius Oncology launched LYMPHIR in December 2025.

Market Opportunity

CTCL's are a heterogeneous subset of extranodal non-Hodgkin lymphomas ("NHL") of mature, skin-homing T-cells that are mainly localized to the skin. The most common types of CTCL are mycosis fungoides ("MF") and primary cutaneous CD30+ anaplastic large cell lymphoma (pcALCL), jointly representing an estimated 80 to 85% of all CTCL. Sézary Syndrome ("SS"), a very rare subtype (~2 to 5% of CTCL) characterized by diffuse inflammatory, often exfoliative, erythroderma and by leukemic and nodal involvement, displays a significant degree of clinical and biological overlap with MF and has long been considered a clinical variant of MF, although recent evidence suggests that it may be a separate entity. The rest is represented by extremely rare, generally more aggressive subtypes.

In light of the overlap between MF and SS, and considering that many of the systemic therapy options for the two neoplasms are the same, some consider the treatment approach to MF and SS as if they were a single disease entity (MF/SS). However, some of the drugs currently in use, or in development, for MF/SS appear to be more effective in clearing different anatomical compartments (skin versus blood, for example) and therefore have differential efficacy in MF and SS.

Based on Surveillance Epidemiology and End Results (SEER) data from 2001 to 2007, the estimated incidence rate of MF/SS in the U.S. is 0.5/100,000 or about 2,500 to 3,000 new cases per year representing about 25% of all T-cell lymphomas. In total, the Company estimates that there are approximately 30,000 to 40,000 patients living with CTCL in the U.S.

Based on internal estimates, the Company believes the addressable U.S. market for LYMPHIR exceeds $400 million and may further expand with the introduction of a new therapeutic.

Mino-Lok®

Overview

Mino-Lok is a patented solution containing minocycline, disodium ethylenediaminetetraacetic acid (edetate), and ethyl alcohol, all of which act synergistically to treat and salvage infected central venous catheters ("CVCs") in patients with catheter related bloodstream infections ("CRBSIs"). Mino-Lok breaks down biofilm barriers formed by bacterial colonies, eradicates the bacteria, and provides anti-clotting properties to maintain patency in CVCs.

The administration of Mino-Lok consists of filling the lumen of the catheter with 0.8 ml to 2.0 ml of Mino-Lok solution. The catheter is then "locked", meaning that the solution remains in the catheter without flowing into the vein. The lock is maintained for a dwell-time of two hours while the catheter is not in use. If the catheter has multiple lumens, all lumens may be locked with the Mino-Lok solution either simultaneously or sequentially. If patients are receiving continuous infusion therapy, the catheters alternate between being locked with the Mino-Lok solution and delivering therapy. The Mino-Lok therapy is two hours per day for at least five days, usually with two additional locks in the subsequent two weeks. After locking the catheter for two hours, the Mino-Lok solution is aspirated, and the catheter is flushed with normal saline. At that time, either the infusion will be continued, or will be locked with the standard-of-care lock solution until further use of the catheter is required. In a clinical study conducted by MD Anderson Cancer Center ("MDACC"), there were no serum levels of either minocycline or edetate detected in the sera of several patients who underwent daily catheter lock solution with minocycline and edetate ("M-EDTA") at the concentration level proposed in Mino-Lok treatment. Thus, it has been demonstrated that the amount of either minocycline or edetate that leaks into the serum is very low or none at all.

Phase 2b Results

From April 2013 to July 2014, 30 patients with CVC-related bloodstream infection were enrolled at MDACC in a prospective Phase 2b study. Patients received Mino-Lok therapy for two hours once daily for a minimum of five days within the first week, followed by two additional locks within the next two weeks. Patients were followed for one month post-lock therapy. Demographic information, clinical characteristics, laboratory data, therapy, as well as adverse events and outcome were collected for each patient. Median age at diagnosis was 56 years (range: 21-73 years). In all patients, prior to the use of lock therapy, systemic treatment with a culture-directed, first-line intravenous antibiotic was started. Microbiological eradication was achieved at the end of therapy in all cases. None of the patients experienced any serious adverse event related to the lock therapy.

The active arm, which is the Mino-Lok treated group of patients, was then compared to 60 patients in a matched cohort that experienced removal and replacement of their CVCs within the same contemporaneous timeframe. The patients were matched for cancer type, infecting organism, and level of neutropenia. All patients were cancer patients and treated at MDACC. The efficacy of Mino-Lok therapy was 100% in salvaging CVCs, demonstrating equal effectiveness to removing the infected CVC and replacing it with a new catheter.

The main purpose of the study was to show that Mino-Lok therapy was at least as effective as the removal and replacement of CVCs when CRBSIs are present, and that the safety was better, that is, the complications of removing an infected catheter and replacing with a new one could be avoided. In addition to having a 100% efficacy rate with all CVCs being salvaged, Mino-Lok therapy had no significant adverse events ("SAEs"), compared to an 18% SAE rate in the matched cohort where patients had the infected CVCs removed and replaced with a fresh catheter. There were no overall complication rates in the Mino-Lok arm group compared to 11 patients with events (18%) in the control group. These events included bacterial relapse (5%) at four weeks post-intervention, and a number of complications associated with mechanical manipulation in the removal or replacement procedure for the catheter (10%) or development of deep-seated infections such as septic thrombophlebitis and osteomyelitis (8%). As footnoted, six patients had more than one complication in the control arm group.

	Mino-Lok® Arm		Control Arm	
Parameter	**N**	**(%)**	**N**	**(%)%**
Patients	**30**	**(100)%**	**60**	**(100)%**
Cancer type				
- Hematologic	20	(67)	48	(80)
- Solid tumor	10	(33)	12	(20)
ICU Admission	**4**	**(13)**	**4**	**(7)**
Mech.Ventilator	**3**	**(10)**	**0**	**(0)**
Bacteremia				
- Gram+	17	(57)*	32	(53)
- Gram-	14	(47)*	28	(47)
Neutropenia (<500)	**19**	**(63)**	**36**	**(60)**
Microbiologic Eradication	**30**	**(100)**	**60**	**(100)**
- Relapse	0	(0)	3	(5)
Complications	**0**	**(0)**	**8**	**(13)**
SAEs related R&R	**0**	**(0)**	**6**	**(10)**
Overall Complication Rate	**0**	**(0)%**	**11****	**(18)%**

* 1 Polymicrobial patient had a Gram+ and a Gram- organism cultured

** 6 Patients had > 1 complication

Source: Dr. Issam Raad, Antimicrobial Agents and Chemotherapy, June 2016, Vol. 60 No. 6, Page 3429

Phase 3 Trial

In November 2016, the Company initiated site recruitment for Phase 3 clinical trials. From initiation through the first quarter of 2017, the Company received input from several sites related to the control arm as being less than standard-of-care for some of the respective institutions. The Company worked closely with the FDA with respect to the design of the Phase 3 trial and received feedback on August 17, 2017. The FDA stated that they recognized that there is an unmet medical need in salvaging infected catheters and agreed that an open label, superiority design would address the Company's concerns and would be acceptable to meet the requirements of a new drug application. The Company amended the Phase 3 study design to remove the saline and heparin placebo control arm and to use an active control arm that conforms with today's current standard-of-care. Patient enrollment commenced in February 2018.

The Mino-Lok Phase 3 Trial was originally planned to enroll 700 patients in 50 participating institutions, all located in the U.S. There were interim analyses at both the 50% and 75% points of the trial as measured by the number of patients treated. In September 2019, the Company announced that the FDA agreed to a new primary efficacy endpoint of "time to catheter failure" in comparing Mino-Lok to the antibiotic lock control arm. This change in the trial design reduced the required patient sample size of the trial from 700 subjects to approximately 144 available subjects to achieve the pre-specified 92 catheter failure events needed to conclude the trial. Additionally, the Company submitted a response to the FDA that it would implement this change in the primary endpoint and expected it to result in less than 150 subjects needed in its Phase 3 trial. The new primary endpoints require that the time to catheter failure be at least 38 days for Mino-Lok versus 21 days for the standard of care antibiotic locks.

In October 2019, the FDA agreed that the patient sample size of approximately 144 patients was acceptable.

In October 2019, the Company announced that the Phase 3 trial had reached the 40% completion triggering an interim futility analysis by the data monitoring committee (the "DMC"). The DMC is an independent panel of experts that review progress regarding the safety and efficacy of drugs in clinical trials, and to determine if the trial may be futile in achieving its endpoints or if the trial should be modified in any way.

In December 2019, the DMC convened and recommended that the trial continue with no changes because the analysis showed a positive outcome, as it met the prespecified interim futility analysis criteria.

In May 2020, we announced that we are providing free access to Mino-Lok for healthcare providers under an Expanded Access protocol to ease the burden associated with the COVID-19 pandemic. Through the Expanded Access protocol, an infected central venous catheter can now be treated with Mino-Lok, potentially avoiding the need for the removal and replacement procedure.

In June 2020, we announced that we had received positive feedback from the FDA on our proposed catheter compatibility studies for Mino-Lok. The studies, if and when successfully completed, should allow Mino-Lok to be labeled for use with all commercially available CVCs and peripherally inserted central catheters (PICCs) on the U.S. market. We further assume that these studies will meet European and world standards. The ability to be labeled without restrictions with respect to catheter type would allow Mino-Lok unrestricted access to the full U.S. and world markets for an effective antibiotic lock therapy for central line associated blood stream infections ("CLABSIs").

In September 2020, we announced that another DMC meeting was held to review the data being generated and analyzed in the Mino-Lok Phase 3 trial based on progress to date, and to make recommendations to us as to any action that may be necessary regarding the study. After reviewing these data, the DMC members stated that they did not find any safety signals; and they also recommended continuing the trial without any modifications. The DMC further conducted an *ad hoc* meeting and agreed with the Company that a 75% interim analysis be conducted as planned in which superior efficacy is evaluated. The 75% interim analysis was subsequently changed to a 65% interim analysis by the Company.

In September 2020, the Company announced that the three registration batches for all components of Mino Lok were manufactured and that clinical sites were resupplied with registration product.

In November 2020, the Company announced that the three components of Mino-Lok, minocycline, disodium edetate ("EDTA"), and ethanol, were superior to EDTA and ethanol in their ability to eradicate resistant staphylococcal biofilms.

The 65% interim analysis was completed in June 2021. In July 2021, the Company announced that following an unblinded data review of safety and efficacy, the independent DMC for the trial recommended proceeding with the trial as planned. The DMC did not identify any safety concerns and no modifications were recommended to the protocol-defined sample size or power to achieve the primary endpoint.

In May 2022, the Company selected Biorasi, LLC ("Biorasi"), a global clinical research organization ("CRO"), to help expand the Company's Phase 3 Mino-Lok trial by implementing additional sites outside the U.S The Mino-Lok Phase 3 study enrolled 241 patients across 34 sites in the U.S. and India. Eligible patients were randomized 1:1 to receive either Mino-Lok or site-specific standard-of-care lock solution plus systemic antibiotics.

In August 2023, the Company announced all 92 events required to complete the trial had been achieved. Several patients remain in active treatment, which may result in additional events.

In late December 2023, the Company determined that patient enrollment for the Mino-Lok trial was complete and that it would begin site shutdown activities.

In May 2024, the Company announced positive topline results of the trial. The study met its primary endpoint with a statistically significant improvement in the time to failure event in patients receiving Mino-Lok compared to Control arm patients receiving clinician-directed anti-infective lock solution. The data demonstrates that Mino-Lok is well-tolerated. Key findings include:

- Median time to catheter failure in the Mino-Lok arm was significantly prolonged in both the intent-to-treat (ITT) and modified ITT populations ($p \leq 0.0006$);

- Catheter retention was achieved in 57% of patients treated with Mino-Lok versus 38% in the control arm ($p = 0.0025$);

- Rates of clinical failure and microbiological failure were significantly lower in the Mino-Lok arm (*p = 0.0058* and *p = 0.012*, respectively); and
- No drug-related serious adverse events (SAEs) were reported; the safety profile was comparable between groups.

A subset analysis of the Phase 3 trial, focused on hemodialysis patients, examined the impact of Mino-Lok in this subgroup and found favorable outcomes for catheter salvage and infection control compared to the overall study population. Key findings in this hemodialysis population include:

- Longer catheter survival with Mino-Lok: Patients receiving standard-of-care (SOC) therapy experienced a significantly shorter time to catheter failure compared with those treated with Mino-Lok (*p=0.03):*
    - SOC arm: 25% of catheters failed by Day 6, 50% failed by Day 22; and
    - Mino-Lok arm: 25% catheter failure delayed until Day 37.
- Lower catheter failure rate with Mino-Lok:
    - 57% (16/28) of SOC patients experienced catheter failure; and
    - 31% (8/26) of Mino-Lok patients experienced catheter failure.
- Adverse events and serious adverse events were comparable between groups, and no drug-related SAEs occurred.

These outcomes demonstrate that the differentiated efficacy and safety profile of Mino-Lok extends into an important hemodialysis subgroup of patients who often have limited vascular access and face increased risk from catheter removal and replacement. Moreover, this subset reinforces Mino-Lok's potential clinical utility in one of the most vulnerable patient populations.

In November 2024, the Company held a Type C meeting with the FDA to discuss the results of the Phase 3 study and to obtain the FDA's view on development plans for Mino-Lok. The FDA provided clear, constructive, and actionable guidance during the discussion, underscoring a pathway to support a future New Drug Application (NDA) submission for Mino-Lok. Citius continues to engage with the FDA to define the regulatory path forward. No FDA-approved alternative currently exists to salvage infected indwelling central venous catheters.

Fast Track Designation

In October 2017, the Company received official notice from the FDA that the investigational program for Mino-Lok was granted "Fast Track" status. Fast Track is a designation that expedites FDA review to facilitate development of drugs which treat a serious or life-threatening condition and fill an unmet medical need. A drug that receives Fast Track designation is eligible for the following:

- More frequent meetings with the FDA to discuss the drug's development plan and ensure collection of appropriate data needed to support drug approval;
- More frequent written correspondence from the FDA about the design of the clinical trials;
- Priority review to shorten the FDA review process for a new drug from ten months to six months; and
- Rolling review, which means we can submit completed sections of our NDA for review by the FDA, rather than waiting until every section of the application is completed before the entire application can be submitted for review.

Mino-Lok International Study

In October 2017, data from an international study on Mino-Lok was presented at the Infectious Disease Conference, ("ID Week"), in San Diego, California. The 44-patient study was conducted in Brazil, Lebanon and Japan and showed Mino-Lok therapy was an effective intervention to salvage long-term, infected CVCs in CRBSIs in patients who had cancer with limited vascular access. This study showed 95% effectiveness for Mino-Lok therapy in achieving microbiological eradication of the CVCs as compared to 83% for the control. The single failure in the Mino-Lok arm was due to a patient with *Burkholderia cepacia* that was resistant to all antibiotics tested.

Stability Patent Application for Mino-Lok

In October 2018, the U.S. Patent and Trademark Office ("USPTO") issued U.S. Patent No. 10,086,114, entitled "Antimicrobial Solutions with Enhanced Stability." On October 9, 2019, the European Patent Office ("EPO") granted European Patent No. 3370794, entitled "Antimicrobial Solutions with Enhanced Stability." The grant of this European patent strengthens the intellectual property protection for Mino-Lok through November of 2036. This invention overcomes limitations in mixing antimicrobial solutions in which components have precipitated because of physical and/or chemical factors, thus limiting the stability of the post-mix solutions. The scientists and technologists at MDACC have been able to improve the stability of the post-mixed solutions through adjustments of the post-mixed pH of the solution. This may allow for longer storage time of the ready-to-use solution. Citius Pharma holds the exclusive worldwide license which provides access to this patented technology for development and commercialization of Mino-Lok.

Market Opportunity

In spite of best clinical practice, catheters contribute to approximately 70% of blood stream infections that occur in the intensive care unit or are associated with hemodialysis or cancer patients (approximately 470,000 per year). Bacteria enter the catheter either from the skin or intraluminally through the catheter hub. Once in the catheter, bacteria tend to form a protective biofilm on the interior surface of the catheter that is resistant to most antimicrobial solutions. The most frequently used maintenance flush, heparin, actually stimulates biofilm formation. Heparin is widely used as a prophylactic lock solution, in spite of the evidence that it contributes to the promotion of biofilm formation. The formation of bacterial biofilm usually precedes CRBSIs.

The standard of care in the management of CRBSI patients consists of removing the infected CVC and replacing it with a new catheter at a different vascular access site. However, in cancer and hemodialysis patients with long-term surgically implantable silicone catheters, removal of the CVC and reinsertion of a new one at a different site might be difficult, or even impossible, because of the unavailability of other accessible vascular sites and the need to maintain infusion therapy. Furthermore, critically ill patients with short-term catheters often have underlying coagulopathy, which makes reinsertion of a new CVC at a different site, in the setting of CRBSIs, risky in terms of mechanical complications, such as pneumothorax, misplacement, or arterial puncture. Studies have also revealed that CRBSI patients may be associated with serious complications, including septic thrombosis, endocarditis and disseminated infection, particularly if caused by *Staphylococcus aureus* or *Candida* species. Furthermore, catheter retention in patients with CRBSIs is associated with a higher risk of relapse and poor response to antimicrobial therapy.

According to Maki et al., published in the *Mayo Clinic Proceedings* in 2006, there are approximately 250,000 CRBSIs annually in the U.S. Subsequent to this study, our estimates have ranged upwards to over 450,000 CLABSIs annually (see analysis in the table below). CRBSIs are associated with a 12% to 35% mortality rate and an attributable cost of $35,000 to $56,000 per episode.

We estimate that the potential market for Mino-Lok in the U.S. to be approximately $500 million to $1 billion as shown in the table below based on a target price of up to $400 per dose of each salvage flush treatment.

	Short-Term CVC	Long-Term CVC	Total
No. of Catheters	3 million	4 million	7 million
Avg. Duration (Days)	12	100	N/A
Catheter Days	36 million	400 million	436 million
Infection Rate	2/1,000 days	1/1,000 days	N/A
Catheters Infected	72,000	400,000	472,000
Flushes/Catheter	5	7	6.7
Total Salvage Flushes	360,000	2,800,000	3,160,000

Sources: Ann Intern Med 2000; 132:391-402, Clev Clin J Med 2011; 78(1):10-17, JAVA 2007; 12(1):17-27, J Inf Nurs 2004; 27(4):245-250, Joint Commission website Monograph, CLABSI and Internal Estimates.

Under various plausible pricing scenarios, we believe that Mino-Lok would be cost-saving to the healthcare system given that the removal of an infected CVC and replacement of a new catheter in a different venous access site is estimated by us to cost between $8,000 and $10,000. Furthermore, there are potential additional medical benefits, a reduction in patient discomfort and avoidance of serious adverse events with the Mino-Lok approach since the catheter remains in place and is not subject to manipulation. We believe there will be an economic argument to enhance the adoption of Mino-Lok by infection control committees at acute care institutions.

In January of 2017, we commissioned a primary market research study with MEDACore, a subsidiary of Leerink, a healthcare focused network with more than 35,000 healthcare professionals, including key opinion leaders, experienced practitioners and other healthcare professionals throughout North America, Europe, Asia and other locations around the world. This network includes approximately 55 clinical specialties, 21 basic sciences and 20 business specialties. As part of this market research project, we commissioned a third-party survey of 31 physicians to qualify the need for catheter salvage in patients with infected, indwelling central venous lines, especially when the catheter is a tunneled or an implanted port. There were 19 infectious disease experts and 12 intensivists surveyed who all agreed that salvage would be preferable to catheter exchange to avoid catheter misplacements, blood clots, or vessel punctures that can potentially occur during reinsertion. Most were also concerned that viable venous access may not be available in patients who were vitally dependent on a central line.

Halo-Lido

Overview

Halo-Lido is a topical formulation of halobetasol propionate, a corticosteroid, and lidocaine that is intended for the treatment of hemorrhoids. To our knowledge, there are currently no FDA-approved prescription drug products for the treatment of hemorrhoids. Some physicians are known to prescribe topical steroids for the treatment of hemorrhoids. In addition, there are various topical combination prescription products containing halobetasol propionate along with lidocaine or pramoxine, each a topical anesthetic, that are prescribed by physicians for the treatment of hemorrhoids. These products contain drugs that were in use prior to the start of the Drug Efficacy Study Implementation ("DESI") program and are commonly referred to as DESI drugs. However, none of these single-agent or combination prescription products have been clinically evaluated for safety and efficacy and approved by the FDA for the treatment of hemorrhoids. Further, many hemorrhoid patients use over the counter ("OTC") products as their first line therapy. OTC products contain any one of several active ingredients including glycerin, phenylephrine, pramoxine, white petrolatum, shark liver oil and/or witch hazel, for symptomatic relief.

Development of Hemorrhoids Drugs

Hemorrhoids are a common gastrointestinal disorder, characterized by anal itching, pain, swelling, tenderness, bleeding and difficulty defecating. In the U.S., hemorrhoids affect nearly 5% of the population, with approximately 10 million persons annually admitting to having symptoms of hemorrhoidal disease. Of these persons, approximately one third visit a physician for evaluation and treatment of their hemorrhoids. The data also indicate that for both sexes a peak of prevalence occurs from age 45 to 65 years with a subsequent decrease after age 65 years. Caucasian populations are affected significantly more frequently than African Americans, and increased prevalence rates are associated with higher socioeconomic status in men but not women. Development of hemorrhoids before age 20 is unusual. In addition, between 50% and 90% of the general U.S., Canadian and European population will experience hemorrhoidal disease at least once in life. Although hemorrhoids and other anorectal diseases are not life-threatening, individual patients can suffer from agonizing symptoms which can limit social activities and have a negative impact on the quality of life.

Hemorrhoids are defined as internal or external according to their position relative to the dentate line. Classification is important for selecting the optimal treatment for an individual patient. Accordingly, physicians use the following grading system referred to as the Goligher's classification of internal hemorrhoids:

Grade I Hemorrhoids not prolapsed but bleeding.

Grade II Hemorrhoids prolapse and reduce spontaneously with or without bleeding.

Grade III Prolapsed hemorrhoids that require reduction manually.

Grade IV Prolapsed and cannot be reduced including both internal and external hemorrhoids that are confluent from skin tag to inner anal canal.

Development Activities to Date

In the fall of 2015, we completed dosing patients in a double-blind dose ranging placebo-controlled Phase 2a study where six different formulations containing hydrocortisone and lidocaine in various strengths were tested against the vehicle control. The objectives of this study were to: (1) demonstrate the safety and efficacy of the formulations when applied twice daily for two weeks in subjects with Grade I or II hemorrhoids, and (2) assess the potential contribution of lidocaine hydrochloride and hydrocortisone acetate, alone or in combination for the treatment of symptoms of Goligher's Classification Grade I or II hemorrhoids.

Symptom improvement was observed based on a global score of disease severity ("GSDS") and based on some of the individual signs and symptoms of hemorrhoids, specifically itching and overall pain and discomfort. Within the first few days of treatment, the combination products (containing both hydrocortisone and lidocaine) were directionally favorable versus the placebo and their respective individual active treatment groups (e.g., hydrocortisone or lidocaine alone) in achieving 'almost symptom free' or 'symptom free' status according to the GSDS scale. These differences suggested the possibility of a benefit for the combination product formulation. As a result of this study, we determined that the performance of the active arms of the study relative to the vehicle could be improved by re-formulating our topical preparation. Therefore, we initiated work on vehicle formulation and evaluation of higher potency steroids.

Overall, results from adverse event reporting support the safety profile of all test articles evaluated in this study and demonstrate similar safety profiles as compared to the vehicle. The safety findings were unremarkable. There was a low occurrence of adverse events and a similar rate of treatment related adverse events across all treatment groups. The majority of adverse events were mild and only one was severe. None of the adverse events were an SAE and the majority of adverse events were recovered/resolved at the end of the study. There were only two subjects who were discontinued from the study due to adverse events.

As part of this Phase 2 trial, information was obtained relating to the use of the GSDS as an assessment tool for measuring the effectiveness of the test articles. Individual signs and symptoms were also assessed but can vary from patient to patient. Therefore, the goal of the GSDS was to provide an assessment tool that could be used for all patients regardless of which signs and symptoms they are experiencing. The GSDS proved to be a more effective tool for assessing the severity of the disease and the effectiveness of the drug when compared to the assessment of the individual signs and symptoms.

We developed this assessment tool as well as other patient reported outcome endpoints for use in the Phase 2b trial begun in April 2022 and in subsequent trials. In June and July 2016, we engaged the Dominion Group, a leading provider of healthcare and pharmaceutical marketing research services. The primary market research was conducted to understand the symptoms that are most bothersome to patients better in order to develop meaningful endpoints for the clinical trials. We also learned about the factors that drive patients to seek medical attention for hemorrhoids in an effort to understand the disease impact on quality of life. The results of this survey, along with the information from the Phase 2b trial, allowed us to develop our patient reported outcome evaluation tool, ePro. This tool can be used in clinical trials to evaluate the patients' conditions and to assess the performance of the test articles.

In March 2018, we announced that we had selected a higher potency corticosteroid in our steroid/anesthetic topical formulation program for the treatment of hemorrhoids. The original topical preparation, which we referred to as Hydro-Lido or CITI-001, which was used in the Phase 2a study, was a combination of hydrocortisone acetate and lidocaine hydrochloride. The new formulation, CITI-002, which we refer to as Halo-Lido, combine lidocaine with the higher potency corticosteroid halobetasol propionate for symptomatic relief of the pain and discomfort of hemorrhoids.

We held a Type C meeting with the FDA in December 2017 to discuss the results of the Phase 2a study and to obtain the FDA's view on development plans to support the potential formulation change for the planned Phase 2b study. We also requested the FDA's feedback on our Phase 2b study design, including target patient population, inclusion/exclusion criteria, and efficacy endpoints. The pre-clinical and clinical development programs for CITI-002 are planned to be similar to those conducted for the development of CITI-001 to support the design for a planned Phase 3 clinical trial.

CITI-002 Phase 2b Trial Overview

Approximately 300 adults with a clinical diagnosis of symptomatic hemorrhoids were enrolled in the Halo-Lido Phase 2b study (NCT05348200), a multi-center, randomized, dose-ranging, double-blind, parallel group comparison clinical trial, which was initiated in April 2022. The study assessed a high dose (CITI-002H) and low dose (CITI-002L) formulation of the combination drug products in comparison to the single active drug monads: high dose halobetasol, low dose halobetasol and lidocaine.

Recently, there has been a shift from the use of traditional clinical analysis and outcomes to patients' perspectives and patients' experiences in assessing treatment efficacy. Following the 21st Century Cures Act, higher emphasis is placed on using Patient Reported Outcome ("PRO") instruments in clinical trials. Currently, for hemorrhoidal disease, there are no validated clinical outcomes assessment ("COA") tools available in the U.S. The FDA directed Citius Pharma to develop a "fit for purpose" PRO instrument to assess the efficacy of treatments in this disease. Symptom intensity and impact data (Hemorrhoid Quality of Life Index or "HQLI") were recorded by patients utilizing a proprietary mobile-enabled PRO instrument developed by the Company for this study.

Data collected using the HQLI was analyzed to derive a meaningful change threshold ("MCT") to test for the change in hemorrhoidal symptoms considered relevant to the patient during and following treatment.

CITI-002 Phase 2b Trial Results

In June 2023, we announced positive results from the Phase 2b study of Halo-Lido for the treatment of hemorrhoids. Treatment effect on hemorrhoidal symptoms was analyzed using the MCT. At the end of the seven-day treatment period, 42% of the patients in the high dose CITI-002 (CITI-002H) group reached MCT compared to patients treated with high dose halobetasol alone (29%) or patients treated with lidocaine alone (21%). Moreover, proportionally more patients in the CITI-002H cohort reported meaningful and statistically significant improvement as compared to patients treated with lidocaine alone (*CMH test, $p = 0.035$*).

We additionally assessed clinical treatment efficacy outcomes during seven-day treatment and seven-day follow-up periods using an analysis of covariance, which analyzed changes from baseline. Substantial improvements were seen across all active treatment groups. Although no statistical significance was determined in the changes between the comparison groups, directionally the data signaled that the combination products provided faster relief compared to individual monads, and the relief persisted after completing treatment.

In addition, results from the study indicated that there were no material clinical safety concerns across the five active treatment groups during the seven-day treatment or follow-up periods. There were no serious adverse events reported.

Data from the Phase 2b trial confirmed that the HQLI is appropriate to measure patient-reported changes in hemorrhoidal symptoms. Consequently, Citius Pharma believes the instrument can be used in future Phase 3 trial development. Citius Pharma is actively pursuing intellectual property protections for its groundbreaking work in developing the fit for purpose PRO instrument and has filed patent applications on its CITI-002 formulations.

Based on the positive clinical results utilizing the Meaningful Change Threshold analysis, Citius Pharma had a Phase 2 meeting with the FDA in April 2024 to discuss the go-forward path for the program. Citius Pharma will continue to have ongoing engagement with the FDA regarding the next steps of development.

Market Opportunity

The current market for OTC and topical prescription ("Rx") products for the symptomatic treatment of hemorrhoids is highly fragmented and includes approximately 20 million units of OTC and over 4 million prescriptions. None of the Rx products have received FDA approval and are only available due to the DESI program, which started decades ago after enactment of the 1962 Kefauver-Harris Drug Amendments. These DESI products have no FDA reviewed evidence of efficacy or safety and may be subject to withdrawal if an approved product were to be introduced. Several topical combination prescription products for the treatment of hemorrhoids are available containing hydrocortisone in strengths ranging from 0.5% to 3.0%, combined with lidocaine in strengths ranging from 1.0% to 3.0%. The various topical formulations include creams, ointments, gels, lotions, enemas, pads, and suppositories. The most commonly prescribed topical combination gel is sold as a branded generic product and contains 2.5% hydrocortisone and 3.0% lidocaine.

We believe there are currently no FDA-approved prescription drug products for the treatment of hemorrhoids. Although there are numerous Rx and OTC products commonly used to treat hemorrhoids, none possess proven safety and efficacy data generated from rigorously conducted clinical trials. We believe that a novel topical formulation of halobetasol propionate and lidocaine designed to provide anti-inflammatory and anesthetic relief and which has an FDA-approved label specifically claiming the treatment of hemorrhoids will become an important treatment option for physicians who want to provide their patients with a therapy that has demonstrated safety and efficacy in treating this uncomfortable and often recurring disease. We believe that our Halo-Lido product represents an attractive, low-risk product opportunity with meaningful upside potential.

Citius Pharma intends to monetize the value of Halo-Lido by seeking a strategic or financial partner.

Market Exclusivity

We believe that we will be the first company to conduct rigorous clinical trials and receive FDA approval of a topical corticosteroid-lidocaine combination product for the treatment of hemorrhoids. If we receive FDA approval, we will qualify for three years of market exclusivity for our dosage strength and formulation. In addition, to our knowledge as of the date of this report, we would also be the only product on the market specifically proven to be safe and effective for the treatment of hemorrhoids. Generally, if a company conducts clinical trials and receives FDA approval of a product for which there are similar, but non FDA-approved, prescription products on the market, the manufacturers of the unapproved but marketed products are required to withdraw them from the market. However, the FDA has significant latitude in determining how to enforce its regulatory powers in these circumstances. We have not had any communication with the FDA regarding this matter and cannot predict what action, if any, the FDA would take with respect to the unapproved products.

We believe that should Halo-Lido demonstrate proven safety and efficacy data and receive FDA approval, and if Halo-Lido obtains three years of market exclusivity based on our dosage strength and formulation, we are likely to have a meaningful advantage in our pursuit of achieving a significant position in the market for topical combination prescription products for the treatment of hemorrhoids.

NoveCite

Overview

In October 2020, we, through our subsidiary, NoveCite, signed an exclusive agreement with Novellus Therapeutics Limited ("Novellus") to license iPSC-derived mesenchymal stem cells (iMSCs). Under this worldwide exclusive license, we are focused on developing cellular therapies. Specifically, we are seeking to develop and commercialize the NoveCite mesenchymal stem cells ("NC-*i*MSCs") to treat acute respiratory conditions with a near term focus on ARDS.

NC-*i*MSCs are the next generation mesenchymal stem cell therapy. We believe them to be differentiated and superior to donor-derived MSCs. Human donor-derived MSCs are sourced from human bone marrow, adipose tissue, placenta, umbilical tissue, etc. and have significant challenges (e.g., variable donor and tissue sources, limited supply, low potency, inefficient and expensive manufacturing). NC-iMSCs overcome these challenges because they:

- Are more potent and secrete exponentially higher levels of immunomodulatory proteins;
- Have practically unlimited supply for high doses and repeat doses;
- Are from a single donor and clonal so they are economically produced at scale with consistent quality and potency, as well as being footprint free (compared to viral reprogramming methods); and
- Have a significantly higher expansion capability.

Several cell therapy companies using donor-derived MSC therapies in treating ARDS have demonstrated that MSCs reduce inflammation, enhance clearance of pathogens and stimulate tissue repair in the lungs. Almost all these positive results are from early clinical trials or under the FDA's emergency authorization program.

In December 2020, the Company announced interim data from a proof-of-concept ("POC") large animal study of its proprietary NC-iMSC therapy. The available results of NC-iMSC therapy in the study show improvement in critical parameters, such as improved oxygenation, less systemic shock, and reduced lung injury, compared to the control group. The study was conducted in a widely accepted large animal model.

In the third quarter of 2021, the Company completed the characterization and expansion of its NC-iMSC accession cell bank (ACB) at Waisman Biomanufacturing at the University of Wisconsin-Madison to create a cGMP master cell bank (MCB).

In July 2021, Novellus was acquired by Brooklyn ImmunoTherapeutics, Inc. ("Brooklyn"). Pursuant to this transaction, the NoveCite license was assumed by Brooklyn with all of the original terms and conditions in the exclusive license agreement.

In October 2022, Brooklyn changed its name to Eterna Therapeutics Inc.

At this time the Company has paused most development initiatives for NoveCite to prioritize LYMPHIR and its other product candidates.

Market Opportunity

Globally, there are 3 million cases of ARDS every year, out of which approximately 200,000 cases are in the U.S. The COVID-19 outbreak added significantly to the number of ARDS cases during that pandemic. Once COVID-19 patients advance to ARDS, they are put on mechanical ventilators. Death rate among patients on ventilators can be as high as 50% depending on associated co-morbidities. There are no approved treatments for ARDS, and the current standard of care only attempts to provide symptomatic relief.

Sales and Marketing

We are primarily focused on identifying opportunities within the critical care and cancer care market segments. In our product acquisition criteria, we concentrate on markets that are highly influenced by key opinion leaders, commonly referred to as KOLs, and in which products are prescribed by a relatively small number of physicians, yet provide opportunities for growth and market share. This strategy allows for a manageable commercialization effort for our Company in terms of resources and capital. We also seek to provide cost-effective therapies that would be endorsed by payers, patients, and providers. We believe that we will be able to commercialize products within the scope of these criteria ourselves, and that we can create marketing synergies by having a common narrow audience for our marketing efforts ("several products in the bag for the same customer").

For our product candidates that fall out of the narrow scope criteria, we have identified pharmaceutical companies with large sales forces, experienced sales and marketing management teams, direct-to-consumer capabilities, significantly larger resources than ours, and non-competing product portfolios that we believe would make excellent sales and marketing partners. We intend to license our mass audience, non-specialty product candidates to such companies for sales and marketing.

LYMPHIR Sales and Marketing

Citius Oncology does not currently have its own commercial infrastructure and has finalized its initial sales and marketing capabilities by contracting with a large third-party commercial sales and marketing organization with an existing commercial infrastructure and product launch experience to assist in its commercial efforts. Through this third-party organization, Citius Oncology has developed a dedicated field force combined with various marketing programs which will be tailored to both physicians and patients to facilitate the successful launch of LYMPHIR and grow its market share. We, through Citius Oncology, plan to focus our commercial efforts on a concentrated group of prescribing hematologists, oncologists and dermatologist-oncologists, along with key opinion leaders and advocacy groups who play an important role in the CTCL treatment regimen.

To support the launch and commercialization of LYMPHIR, Citius Oncology has entered into distribution agreements with Cardinal Health, Cencora and McKesson Corporation. In addition, Citius Oncology has contracted with EVERSANA an innovative AI platform, to support the launch and commercialization of LYMPHIR whereby EVERSANA provides an integrated suite of pre- and post-launch services, including medical information, pharmacovigilance, revenue cycle management, program management, data and analytics, and channel management. In addition, in October 2025, Citius Oncology announced that it is actively engaging with regional distribution partners to make LYMPHIR available to eligible patients through country-specific Named Patient Programs (NPPs) in Europe, South America and the Middle East. As part of its NPP strategy, Citius Oncology has entered into an exclusive distribution agreement with Integris Pharma S.A., headquartered in Athens, Greece. The partnership covers Greece, Cyprus, Malta, Bulgaria, Romania, Croatia, Serbia, Albania, Bosnia Herzegovina, Kosovo, Montenegro and North Macedonia.

In September 2024, the Company announced the inclusion of LYMPHIR in the National Comprehensive Cancer Network (“NCCN”) guidelines and compendia. LYMPHIR was included bases on an NCCN Category 2A recommendation which indicates a uniform NCCN consensus that LYMPHIR is appropriate as an option for patients with CTCL. The Company believes that LYMPHIR’s addition to the NCCN guidelines will assist LYMPHIR in obtaining coverage and reimbursement from the Centers for Medicare and Medicaid Services (“CMS”).

In February 2025, Citius Pharma announced that LYMPHIR had been assigned a unique, permanent Healthcare Common Procedure Coding System (HCPCS) J-code (J9161) by CMS.

Intellectual Property

We rely on a combination of patent, trade secret, copyright, and trademark laws, as well as confidentiality, licensing and other agreements, to establish and protect our proprietary rights. Our policy is to actively seek to obtain, where appropriate, the broadest intellectual property protection possible for our current product candidates and any future product candidates both in the U.S. and abroad. However, patent protection may not provide us with complete protection against competitors who seek to circumvent our patents. To help protect our proprietary know-how that is not patentable, and for inventions for which patents may be difficult to enforce, we currently rely and will in the future rely on trade secret protection and confidentiality agreements to protect our interests.

LYMPHIR Intellectual Property

On September 3, 2021, Citius Pharma acquired the exclusive license of E7777 (denileukin diftitox), an oncology immunotherapy for the treatment of CTCL, from Dr. Reddy’s, who had exclusively licensed it previously from Eisai. The exclusive license, which was amended as part of the transaction, is with Eisai and includes rights to develop and commercialize LYMPHIR in all markets except for Japan, China, Korea, Taiwan, Hong Kong, Macau, Indonesia, Thailand, Malaysia, Brunei, Singapore, India, Pakistan, Sri Lanka, Philippines, Vietnam, Myanmar, Cambodia, Laos, Afghanistan, Bangladesh, Bhutan, Nepal, Mongolia, and Papua New Guinea. Citius Pharma renamed E7777 as I/ONTAK and also obtained the trade name LYMPHIR for the product. In April 2022, Citius Pharma assigned the license agreement to SpinCo, at which time SpinCo began operations. Upon the completion of the Merger, SpinCo became a wholly owned subsidiary of Citius Oncology. Citius Pharma remains a guarantor on all of Citius Oncology’s payment obligations thereunder.

Obligations to Eisai under the License Agreement

Under the license agreement, Eisai is to receive a $5.9 million development milestone payment upon initial approval by the FDA of LYMPHIR for the CTCL indication and an aggregate of up to $22 million related to the achievement of net product sales thresholds. Pursuant to the terms of the license agreement, through 2022, Citius Pharma reimbursed Eisai for approximately $2.65 million of Eisai's costs to complete the ongoing Phase 3 pivotal clinical trial for LYMPHIR for the CTCL indication and for all reasonable costs associated with the preparation of a BLA for LYMPHIR. The Company has accrued the $2.9 million unpaid balance of the development milestone payment as of September 30, 2025.

Pursuant to the terms of the license agreement, Eisai was responsible for completing the current CTCL clinical trial, and chemistry, manufacturing and controls development activities through the production of the BLA, which Citius Pharma filed with the FDA in September 2022. Citius Pharma is responsible for the costs of correcting any major deficiencies in the BLA, as well as the costs of any further studies and development costs associated with potential additional indications.

On March 28, 2025, Citius Oncology and Eisai entered into a letter agreement that amended the license agreement to provide for a payment schedule to Eisai for the milestone payment and certain unpaid invoices. We agreed to pay Eisai on or before July 15, 2025, an aggregate amount of $2,535,318 and thereafter on the 15th of each of the next four months to pay Eisai $2.35 million and make a final payment of $2,197,892 to Eisai on or before December 15, 2025, in each case with interest on each obligation from its original due date through the date of actual payment under the letter agreement at the rate of 2% per annum. During the year ended September 30, 2025, we recorded $218,032 in interest expense under the agreement. The parties released each other from any and all claims, losses, damages, costs and expenses that arise from or related to our failure to pay the milestone payment or the other incurred costs under the license agreement except for any claims arising out of a breach of the letter agreement. All other terms of the license agreement remain in full force and effect. During the year ended September 30, 2025, we paid $3 million of the development milestone and the balance of $2.9 million is included in license fee payable at September 30, 2025. On July 21, 2025, we made a payment to Eisai of $1,616,522 for other invoices and accumulated interest associated with the letter agreement.

The term of the license agreement will continue until (i) March 30, 2026, if there has not been a commercial sale of a licensed product in the territory, or (ii) if there has been a first commercial sale of a licensed product in the territory by March 30, 2026, the 10-year anniversary of the first commercial sale on a country-by-country basis. Citius Oncology expects the first commercial sale to occur in the December 2025. 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.

The Company, through its subsidiary, is responsible for preparing, filing, prosecuting, and maintaining all patent applications and patents included in the licensed patents that we intend to pursue within the territory.

Obligations to Dr. Reddy's under the Asset Purchase Agreement

The Company and Dr. Reddy's entered into an asset purchase agreement whereby Dr. Reddy's transferred to the Company the then-existing patents, know-how, regulatory documentation and other assets related to LYMPHIR and the Company agreed to assume certain liabilities associated with Dr. Reddy's development of LYMPHIR. The agreement was assigned to Citius Oncology in April 2022.

Under the terms of the asset purchase agreement with Dr. Reddy's and subsequent to the April 2022 assignment to SpinCo, Citius Oncology, as guaranteed by Citius Pharma, will be obligated to pay up to an aggregate of $40 million related to CTCL approvals in the U.S. and other markets, up to $70 million in development milestones for additional indications, and up to $300 million for commercial sales milestones. Citius Oncology will also be obligated to 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. Citius Oncology 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 Citius Oncology 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.

Also under the agreement with Dr. Reddy's, the Company, through Citius Oncology, is 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, (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, the Company, through Citius Oncology, is required to commercially launch a product in a territory within six months of receiving regulatory approval for such product in each such jurisdiction. The Company, through Citius Oncology, is responsible for these and any and all further developmental activities relating to LYMPHIR.

Dr. Reddy's agreed to not compete against the Company in the development of products containing compounds in LYMPHIR in the territory covered by the license for a designated period of time. There are no termination provisions included in the asset purchase agreement other than those related to the term of the royalties. To assist in the transfer of the LYMPHIR assets, the Company and Dr. Reddy's entered into a transition services agreement at the closing of the transaction, which was in effect until March 2022.

At the time of the FDA approval for LYMPHIR, a $27.5 million milestone became payable to Dr. Reddy's, of which a balance of $19.75 million included in license fee payable, remained due as of September 30, 2025. After discussions, Dr. Reddy's agreed to a partial deferral without penalty of this milestone payment. During the years ended September 30, 2025 and 2024, we paid $2,750,000 and $5,000,000, respectively, against the outstanding milestone fee.

LYMPHIR Patents

As part of the definitive agreement with Dr. Reddy's, Citius Pharma acquired, and later transferred to Citius Oncology, the method of use patents in which E7777 is administered in combination with the programmed cell death protein 1 ("PD-1") pathway inhibitor drug class. PD-1 plays a vital role in inhibiting immune responses and promoting self-tolerance through modulating the activity of T-cells, activating apoptosis of antigen-specific T cells and inhibiting apoptosis of regulatory T cells.

The following patents were acquired:

- U.S. Provisional Application No. 63/070,645, which was filed on August 26, 2020, and subsequently published as US 2022/0062390 A1 on March 3, 2022, entitled Methods of Treating Cancer. Expiration date of August 23, 2041.

- International Patent Application Number: PCT/IB2021/0576733, which was filed with the World Intellectual Property Organization on August 23, 2021 for Europe, and subsequently published as WO 2022/043863 A1 on March 3, 2022, entitled, Combination for Use in Methods of Treating Cancer. Expiration date of August 23, 2041.

Mino-Lok Intellectual Property

In May 2014, our subsidiary LMB entered into a patent and technology license agreement with Novel Anti-Infective Therapeutics, Inc. ("NAT"), who licensed the intellectual property from MDACC, to develop and commercialize Mino-Lok on an exclusive, worldwide (except for South America), sub-licensable basis. LMB incurred a one-time license fee in May 2014. On March 20, 2017, LMB entered into an amendment to the license agreement that expanded the licensed territory to include South America, providing LMB with worldwide rights. We are obligated to pay annual maintenance fees that increase annually until reaching a designated amount, which we must pay until the first sale of product. We also must pay up to an aggregate of approximately $1.1 million in milestone payments, depending on the achievement of various regulatory and commercial milestones. Under the terms of the license agreement, we also must pay a royalty equal to mid-single digit percentages to low-double digit percentages of net sales, depending on the level of sales in that year, 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 country of sale at the time of sale. After the first sale of product, we will owe an annual minimum royalty payment that will increase annually until reaching a designated amount, which we must pay for the duration of the term. We will be responsible for all patent expenses for the term of the agreement although MDACC is responsible for filing, prosecution and maintenance of all patents.

Unless earlier terminated by NAT based on the failure to achieve certain development or 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. The license agreement will terminate in the event we breach any of our payment or reporting obligations or NAT breaches any of its obligations under the agreement. NAT will have the right to terminate the agreement if we bring or participate in an action to challenge NAT's ownership of any of the licensed patent rights. We may terminate the license agreement upon 180 days' notice. The license agreement may also be terminated upon our and NAT's mutual consent.

Mino-Lok is covered in relation to the composition by issued U.S. patent No. 7,601,731, entitled "Antimicrobial Flush Solutions," which was issued on October 13, 2009. Mino-Lok is further covered in relation to its method of use by issued U.S. Patent No. 9,078,441, which was issued on July 14, 2015. The patents provide intellectual property protection until June 7, 2024. There are corresponding patents granted in Europe and Canada (European Patent No. EP 1644024, and Canadian Patent No. 2528522).

Stability Patent Application for Mino-Lok

In October 2018, the USPTO issued U.S. Patent No. 10,086,114 (the "114 patent"), entitled "Antimicrobial Solutions with Enhanced Stability." On October 9, 2019, the European Patent Office ("EPO") granted European Patent No. 3370794, which corresponds to the 114 patent. The grant of these patents strengthens the intellectual property protection for Mino-Lok through November 2036. While the original patents for Mino-Lok (discussed above) cover the basic composition, this invention overcomes limitations in mixing antimicrobial solutions in which components have precipitated because of physical and/or chemical factors, thus limiting the stability of the post-mix solutions. The scientists and technologists at MDACC have been able to improve the stability of the post-mixed solutions through adjustments of the post-mixed pH of the solution. This may allow for longer storage time of the ready-to-use solution. As such, the patents claiming the enhanced stability may effectively extend patent protection for Mino-Lok beyond the 2024 expiration of the original patents since it is expected that the compositions providing enhanced stability would be preferred over any non-stabilized versions that a competitor may introduce after June 7, 2024. Citius Pharma holds the exclusive worldwide license which provides access to this patented technology for development and commercialization of Mino-Lok.

Mino-Lok has received a Qualified Infectious Disease Product ("QIDP") designation. The QIDP designation provides New Drug Applications an additional five years of market exclusivity, which together with the potential three years of exclusivity for the new strength and formulation of Mino-Lok, would result in a combined total of eight years of market exclusivity regardless of patent protection.

Halo-Lido Intellectual Property

We are developing Halo-Lido to have a unique combination of excipients as well as unique concentrations of the active ingredients. The goal is to have a product that is optimized for stability and activity. Once the formulation development is completed and data is obtained, we intend to apply for a patent on this new topical formulation.

We seek to achieve approval for Halo-Lido by utilizing the FDA's 505(b)(2) pathway. This pathway allows an applicant to file an NDA that contains full reports of investigations of safety and effectiveness, but where at least some of the information required for approval comes from prior studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference to such prior third-party studies. This pathway would provide three years of market exclusivity.

NoveCite Intellectual Property

In October 2020, we, through our subsidiary NoveCite, Inc., entered into a license agreement with Novellus Therapeutics Limited, whereby NoveCite acquired an exclusive, worldwide license, with the right to sublicense, to develop and commercialize a stem cell therapy based on Novellus's patented technology for the treatment of acute pneumonitis of any etiology in which inflammation is a major agent in humans. The patented technology consists of mesenchymal stem cells ("MSCs") derived from an induced pluripotent stem cell line that is made by Novellus using the mRNA cell reprogramming methods in the patents covering the licensed technology.

Upon execution of the license agreement, NoveCite paid an upfront payment of $5,000,000 and issued to Novellus 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.

NoveCite is obligated to pay Novellus up to an aggregate of $51,000,000 in milestone payments upon the achievement of various regulatory and developmental milestones. NoveCite also must pay on a fiscal quarter basis a royalty equal to low double-digit percentages of net sales, commencing upon the first commercial sale of a licensed product. This royalty is subject to downward adjustment on a product-by-product and country-by-country basis to an upper-single digit percentage of net sales in any country in the event of the expiration of the last valid patent claim or if no valid patent claim exists in that country. The royalty will end on the earlier of (i) the date on which a biosimilar product is first marketed, sold, or distributed by Novellus 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 an amount equal to a mid-twenties percentage of any sublicensee fees it receives.

During the term of the license agreement, NoveCite is required to use commercially reasonable efforts to make commercially available at least one product in at least two markets: the U.S. and either the United Kingdom, France, Germany, China or Japan. Additionally, NoveCite shall (i) on or before the five-year anniversary of the date of the license agreement, file an IND for a licensed product in the field of acute pneumonitis treatment and (ii) receive regulatory approval for a licensed product in the field of acute pneumonitis treatment in the U.S. or in a major market country on or before the ten-year anniversary of the date of the license agreement.

Pursuant to the terms of the license agreement, NoveCite has been granted a right of first negotiation to exclusively license the rights to any new products developed or acquired by Novellus which cannot include MSC's, that may be used within the field of acute pneumonitis treatment. After receiving notice from Novellus of the new product opportunity, NoveCite has 30 days to notify Novellus of its desire to negotiate a license agreement for the new product. If such notice is given by NoveCite, the parties shall then have a period of 150 days from the date of Novellus's notice to NoveCite to negotiate, exclusively and in good faith, the terms and conditions for the new product license agreement.

The term of the license agreement will continue on a country-by-country and licensed product-by-licensed product basis until the expiration of the last-to-expire royalty term for any and all licensed products unless earlier terminated in accordance with its terms. Either party may terminate the license agreement upon written notice if the other party is in material default or breach of the agreement, subject to cure within the designated time periods. Either party also may terminate the license agreement if the other party files for bankruptcy or takes related actions or is unable to pay its debts as they become due, subject to cure within the designated time period. Additionally, Novellus will have the right to terminate the agreement if NoveCite directly or indirectly challenges the patentability, enforceability or validity of any licensed patent. NoveCite may terminate the license agreement at any time without cause upon 90 days prior written notice.

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

During the term of the license agreement, Novellus is prohibited from commercializing or exploiting (directly or indirectly) any product that includes mesenchymal stem cells for any purpose in acute pneumonitis treatment (subject to certain sponsored research exceptions), or exploiting (directly or indirectly) or enabling a third party to exploit, for any purpose in acute pneumonitis treatment or otherwise, the original licensed cell banks line or any GMP-grade cell banks of a cell line derived therefrom and that can be used as starting material for the manufacture of products derived from the licensed technology. During the term of the license agreement, each party is prohibited from soliciting any employee of the other party, subject to certain exceptions.

In July 2021, Novellus was acquired by Brooklyn. Pursuant to this transaction, the NoveCite license was assumed by Brooklyn with all of its original terms and conditions. In October 2021, Brooklyn changed its name to Eterna Therapeutics Inc.

Competition

We operate in a highly competitive and regulated industry which is subject to change. We face significant competition from organizations that are pursuing drugs that would compete with the drug candidates that we are developing and the same or similar products that target the same conditions we intend to treat. Due to our limited resources, we may not be able to compete successfully against these organizations, which include many large, well-financed and experienced pharmaceutical and biotechnology companies, as well as academic and research institutions and government agencies.

LYMPHIR Competition

There are currently several approved targeted therapeutics for patients with persistent or recurrent CTCL. However, there are limitations to these targeted therapies, which are often discontinued due to toxicity, adverse events, or a limited duration of response due to resistance over time. Consequently, we believe there continues to be an unmet medical need for patients with CTCL and an opportunity for LYMPHIR to be included among the treatment armamentarium for advanced-stage CTCL.

The following products are approved for the systemic treatment of advanced CTCL:

- Mogamulizumab, sold under the brand name Poteligeo, is a humanized, afucosylated monoclonal antibody targeting CC chemokine receptor 4. The FDA approved it for treatment of relapsed or refractory mycosis fungoides and Sézary disease.

- Brentuximab vedotin, sold under the brand name Adcetris, is an antibody-drug conjugate medication used to treat relapsed or refractory Hodgkin lymphoma and systemic anaplastic large cell lymphoma, a type of T-cell non-Hodgkin lymphoma. It selectively targets tumor cells expressing the CD30 antigen, a defining marker of Hodgkin lymphoma and ALC.

- Romidepsin sold under the brand name Istodax, is a histone deacetylase (“HDAC”) inhibitor indicated for the treatment of CTCL in adult patients who have received at least one prior systemic therapy.

- Vorinostat sold under the brand name Zolinza, is a HDAC inhibitor indicated for the treatment of cutaneous manifestations in patients with CTCL who have progressive, persistent or recurrent disease on or following two systemic therapies.

Mino-Lok Competition

Currently, the only alternative to Mino-Lok in the treatment of infected CVCs in CRBSI/CLABSI patients of which we are aware, is the standard of care of removing the culprit CVC and replacing a new CVC at a different vascular site. The Company is not aware of any INDs for a salvage antibiotic lock solution and does not expect any to be forthcoming due to the difficulty of meeting the necessary criteria to be effective and practical.

At this time, there are no pharmacologic agents approved in the U.S. for the prevention or treatment of CRBSIs or CLABSIs in central venous catheters. The Company is aware that there are several agents either approved or in development for prevention but none for salvage. The most prominent of these appear to be Defencath from CorMedix Inc. ("Cormedix") and B-Lock from Great Lakes Pharmaceuticals, Inc. ("GLP"). Neither of these lock solutions have been shown to be effective in salvaging catheters in bacteremic patients as Mino-Lok is intended to do, and Citius Pharma does not expect that either would be pursued for this indication.

Defencath™ (CorMedix Inc.)

Defencath is a formulation of Taurolidine 1.35%, Citrate 3.5%, and Heparin 1000 units/mL. Neutrolin is an anti-microbial catheter lock solution approved by the FDA in November 2023 to reduce the incidence of catheter-related bloodstream infections (CRBSIs) for the limited population of adult patients with kidney failure receiving chronic hemodialysis through a central venous catheter (CVC). Defencath was shown to reduce the risk of CRBSIs by up to 71% in a Phase 3 clinical study. The FDA approved Defencath in November 2023 and Cormedix, launched Defencath in April 2024.

B-Lock™ (Great Lakes Pharmaceuticals, Inc.)

B-Lock is a triple combination of trimethoprim, EDTA and ethanol from Great Lakes Pharmaceuticals, Inc. ("GLP"). On July 24, 2012, GLP announced the initiation of a clinical study of B-Lock. We are unaware as to the progress or results of these studies. In addition, we are not aware of any IND being filed in the U.S. for B-Lock, nor are we aware of any clinical studies to support salvage of infected catheters in bacteremic patients.

There has been no further public information available on GLP. GLP's web site and phone number are no longer active and the Company believes that they have ceased operations.

Halo-Lido Competition

The primary competition in the hemorrhoid market is non-prescription OTC products. If approved by the FDA, to our knowledge as of the date of this report, Halo-Lido would be the only prescription product for the treatment of hemorrhoids.

NoveCite Competition

There are multiple participants in the cell therapy field both in the U.S. and abroad. We believe that the following companies most directly compete with NoveCite in our licensed field of acute pneumonitis treatment.

Cynata Therapeutics Limited ("Cynata") develops and commercializes a proprietary mesenchymal stem cell technology under the Cymerus brand for human therapeutic use in Australia. The company's lead therapeutic product candidate is CYP-001, which has completed a Phase 1 clinical trial and for which Cynata is actively recruiting patients for a Phase 2 clinical trial for the treatment of graft versus host disease. Cynata also develops products for the treatment of asthma, heart attack, diabetic wounds, coronary artery disease, acute respiratory distress syndrome, brain cancer, melanoma, sepsis, osteoarthritis, and critical limb ischemia, which are in a preclinical model.

Healios K.K. is a biotechnology company that focuses on the research and development activities in the field of regenerative medicine. Its clinical development programs are focused on treating neurological conditions, cardiovascular diseases, inflammatory and immune disorders, and pulmonary and other conditions. The company's lead platform product includes MultiStem cell therapy, an allogeneic stem cell product, for which it is preparing for a Phase 3 clinical trial for the treatment of ARDS and has an ongoing clinical trial in Japan for the treatment of RDS. The MultiStem therapy also is in a Phase 3 clinical study for the treatment of patients suffering from neurological damage from an ischemic stroke.

Mesoblast Limited is a biopharmaceutical company that develops and commercializes allogeneic cellular medicines. The company offers products in the areas of cardiovascular, spine orthopedic disorder, oncology, hematology, and immune-mediated and inflammatory diseases. Its proprietary regenerative medicine technology platform is based on specialized cells known as mesenchymal lineage adult stem cells. In April 2020, Mesoblast initiated a Phase 3 trial using mesenchymal stromal cells for the treatment of moderate to severe COVID-19 acute respiratory distress syndrome. The trial was halted in December 2020 after the Data Safety Monitoring Board (DSMB) performed a third interim analysis on the trial's first 180 patients, noting that the trial was not likely to meet the 30-day mortality reduction endpoint at the planned 300 patient enrolment. The trial was powered to achieve a primary endpoint of 43% reduction in mortality at 30 days for treatment with remestemcelL on top of maximal care. The DSMB recommended that the trial complete with the enrolled 222 patients, and that all be followed-up as planned. At follow-up through day 60, remestemcel-L showed a positive but non-significant trend in overall mortality reduction across the entire population of treated patients (n=217). In the pre-specified population of patients under age 65 (n=123), remestemcel-L reduced mortality through day 60 by 46%, but not in patients 65 or older (n=94). In an exploratory analysis through day 60, remestemcelL reduced mortality by 75% and increased days alive off mechanical ventilation in patients under age 65 when combined with dexamethasone, in comparison with controls on dexamethasone.

Supply and Manufacturing

We do not currently have and we do not intend to set up our own manufacturing facilities. We rely on and will continue to rely on approved contract manufacturers for manufacturing our product candidates in all stages of development after we file for FDA approval. Each of our domestic and foreign contract manufacturing establishments, including any contract manufacturers we may decide to use, must be listed in the NDA or the BLA, as applicable, and must be registered with the FDA. Also, the FDA imposes substantial annual fees on manufacturers of branded products.

In general, our suppliers purchase raw materials and supplies on the open market. Substantially all such materials are obtainable from a number of sources so that the loss of any one source of supply would not have a material adverse effect on us.

Our product development and manufacturing for LYMPHIR is subject to regulation under various federal and state laws, including the Food, Drug and Cosmetic Act, Occupational Safety and Health Act, the Environmental Protection Act, the Toxic Substances Control Act, the Resource Conservation and Recovery Act, the Controlled Substances Act and other present and potential future federal, state or local regulations.

We have contracted with proven suppliers and manufacturers for active pharmaceutical ingredients, commercial supply, development and packaging. We are confident that all materials meet or will meet specifications discussed at the chemistry, manufacturing and controls meeting with the FDA.

If we fail to raise additional capital, and as a result are unable to abide by our contractual obligations with these third-party manufacturers and suppliers, including making timely payment, the necessary third-party support to continue to commercialize LYMPHIR could be delayed or terminated.

Supply and Manufacturing of LYMPHIR

We have either contracted directly or contracted through Citius Oncology, to secure supply agreements with third-party cGMP facilities who are in compliance with current good manufacturing practices as generally accepted by the FDA. We are confident that all drug substance and drug product materials meet or will meet specifications as agreed with the FDA.

We believe our contract manufacturers have sufficient capacity to support demand for our products as our business grows. In addition to our supply agreements with third-party manufacturers, we, through Citius Oncology, have contracted with other proven suppliers for, testing, labeling, packaging, and distribution of LYMPHIR.

Regulation

U.S. Government Regulation

The research, development, testing, manufacture, labeling, promotion, advertising, distribution, and marketing, among other things, of our product candidates, is extensively regulated by governmental authorities in the U.S. and other countries.

In the U.S., the FDA regulates drugs under the Federal Food, Drug, and Cosmetic Act (the "FDCA") and the agency's implementing regulations. If the Company fails to comply with the applicable U.S. requirements at any time during the product development process, including clinical testing, as well as at any time before and after the approval process, we may become subject to administrative or judicial sanctions, or other actions, such as the FDA's delay in review of or refusal to approve a pending NDA or BLA, withdrawal of an approval, imposition of a clinical hold or study termination, issuance of Warning Letters or Untitled Letters, mandated modifications to promotional materials or issuance of corrective information, requests for product recalls, consent decrees, corporate integrity agreements, deferred prosecution agreements, product seizures or detentions, refusal to allow product import or export, total or partial suspension of or restriction of or imposition of other requirements relating to production or distribution, injunctions, fines, debarment from government contracts and refusal of future orders under existing contracts, exclusion from participation in federal and state healthcare programs, FDA debarment, restitution, disgorgement or civil or criminal penalties, including fines and imprisonment. Any enforcement action could have a material adverse effect on the Company and our operations.

FDA Marketing Approval

Before any one of the Company's drug product candidates may be marketed in the U.S., it must be approved by the FDA. Obtaining FDA marketing approval for new products requires substantial time, effort and financial resources. In order for the FDA to determine that a product is safe and effective for the proposed indication, the product must first undergo testing in animals (nonclinical studies). The data generated from nonclinical studies is used to support the filing of an IND under which human studies are conducted. Human testing is generally conducted under an IND in three phases following Good Clinical Practices ("GCP") regulations:

- Phase 1 studies evaluate the safety and tolerability of the drug, generally in normal, healthy volunteers;
- Phase 2 studies evaluate safety and efficacy, as well as appropriate doses; these studies are typically conducted in patient volunteers who suffer from the particular disease condition that the drug is designed to treat; and
- Phase 3 studies evaluate safety and efficacy of the product at specific doses in one or more larger pivotal trials.

In addition to human testing, the manufacturing process of the potential product must be developed in accordance with cGMP regulations. Prior to the approval of a new product, the FDA will inspect the facilities at which the proposed drug product is manufactured to ensure cGMP compliance.

The cumulative safety and efficacy data generated from the clinical trials described above, chemistry, manufacturing and control ("CMC") information, nonclinical study data and proposed labeling are used as the basis to support approval of a marketing application (NDA or BLA) to the FDA. The preparation of an NDA or BLA requires the expenditure of substantial funds and the commitment of substantial resources. Additionally, at the time of an NDA or BLA submission a user fee is required (unless the product has ODD) to be paid. The FDA conducts a preliminary administrative review upon receipt of the NDA or BLA submission, the FDA either accepts the NDA or BLA submission or does not. If the application is not accepted for review by FDA, the sponsor of the application must resolve the deficiencies and re-submit the application, re-starting the review clock.

After evaluating the NDA or BLA and all related information, including the advisory committee recommendation, if any, and inspection reports regarding the manufacturing facilities and clinical trial sites, the FDA may issue an approval letter, or, in some cases, a CRL. A CRL generally contains a statement of specific conditions that must be met in order to secure final approval of the NDA or BLA and may require additional clinical or preclinical studies, or other information, in order for FDA approval. Even with submission of this additional information, the FDA may decide that the NDA or BLA does not satisfy the regulatory criteria for approval. If and when those conditions have been met to the FDA's satisfaction, the FDA may issue an approval letter. An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications.

Data obtained from the development program are not always conclusive and may be susceptible to varying interpretations. These instances may delay, limit or prevent regulatory approval. The FDA may not grant approval on a timely basis, or at all. We may encounter difficulties or unanticipated costs in our efforts to secure necessary governmental approvals, which could delay or preclude us from marketing our products. The FDA may limit the indications for use or place other conditions on any approvals that could restrict the commercial application of the product.

FDA Post-Approval Considerations

Drugs manufactured or distributed pursuant to FDA approvals are subject to continuing regulation by the FDA, including, among other things, requirements relating to recordkeeping, manufacturing, periodic reporting, product sampling and distribution, advertising and promotion, and reporting of adverse experiences with the product and drug shortages. During the approval process, the FDA and the sponsor may agree that specific studies or clinical trials should be conducted as post-marketing commitments, but they are not required. The FDA may also impose post-marketing requirements as a condition of approval of an NDA or BLA. For example, the FDA may require post-marketing testing, including Phase 4 clinical trials and surveillance, to further assess and monitor the product's safety and effectiveness after commercialization. Once an approval is granted, the FDA may withdraw the approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product becomes available in the market.

After approval, most changes to the approved product, such as manufacturing changes and adding new indications or other labeling claims, are subject to FDA review and approval. There are also annual user fee requirements for any marketed product and new application fees for supplemental applications with clinical data. Additionally, the FDA strictly regulates the labeling, advertising and promotion of products under an approved NDA or BLA. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly marketed or promoted off-label uses may be subject to significant liability, including criminal and civil penalties under the FDCA and False Claims Act, exclusion from participation in federal healthcare programs, debarment from government contracts, refusal of future orders under existing contracts and mandatory compliance programs under corporate integrity agreements or deferred prosecution agreements.

Other Regulations of the Healthcare Industry

In addition to FDA regulations governing the marketing of pharmaceutical products, there are various state and federal laws that may restrict business practices in the biopharmaceutical industry. These include the following:

- The federal Anti-Kickback laws and implementing regulations, which prohibit persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce either the referral of an individual, or furnishing or arranging for a good or service, for which payment may be made under federal healthcare programs such as the Medicare and Medicaid programs;

- Other Medicare laws, regulations, rules, manual provisions and policies that prescribe the requirements for coverage and payment for services performed by our customers, including the amount of such payment;

- The federal False Claims Act, which imposes civil and criminal liability on individuals and entities who submit, or cause to be submitted, false or fraudulent claims for payment to the government;

- The Foreign Corrupt Practices Act ("FCPA"), which prohibits certain payments made to foreign government officials;

- State and foreign law equivalents of the foregoing and state laws regarding pharmaceutical company marketing compliance, reporting and disclosure obligations;

- The Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education Affordability Reconciliation Act of 2010 (collectively, the "Affordable Care Act" or "ACA"), which among other things: changes access to healthcare products and services; creates new fees for the pharmaceutical and medical device industries; changes rebates and prices for health care products and services; and requires additional reporting and disclosure;

- The Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, and its implementing regulations (collectively, "HIPAA"), which creates federal criminal laws that prohibit executing a scheme to defraud any healthcare benefit program and which also imposes certain obligations on entities with respect to the privacy, security and transmission of individually identifiable health information; and

- The federal Physician Payment Sunshine Act, which requires certain pharmaceutical and biological manufacturers to engage in extensive tracking of payments or transfers of value to physicians and teaching hospitals and public reporting of the payment data.

If our operations are found to be in violation of any of these laws, regulations, rules or policies or any other law or governmental regulation, or if interpretations of the foregoing change, we may be subject to civil and criminal penalties, damages, fines, exclusion from the Medicare and Medicaid programs and the curtailment or restructuring of our operations.

To the extent that any of our products are sold in a foreign country, we may be subject to similar foreign laws and regulations, which may include, for instance, applicable post-marketing requirements, including safety surveillance, anti-fraud and abuse laws, and implementation of corporate compliance programs and reporting of payments or transfers of value to healthcare professionals. This is currently not applicable as our only approved product is not currently sold in a foreign country nor have we applied for any foreign approvals. Citius Oncology has signed international distribution agreements covering Greece, Cyprus other Balkan countries as well as Turkey, Bahrain, Qatar, Oman, Kuwait, Saudi Arabia, and the UAE through named patient programs which allows access to LYMPHIR where permitted by local law without constituting commercial approval outside the United States.

Coverage and Reimbursement

The commercial success of our product candidates and our ability to commercialize any approved product candidates successfully will depend in part on the extent to which governmental authorities, private health insurers and other third-party payers provide coverage for and establish adequate reimbursement levels for our therapeutic product candidates. In the United States, the European Union and other potentially significant markets for our product candidates, government authorities and third-party payers are increasingly imposing additional requirements and restrictions on coverage, attempting to limit reimbursement levels or regulate the price of drugs and other medical products and services, particularly for new and innovative products and therapies, which often has resulted in average selling prices lower than they would otherwise be. For example, in the United States, federal and state governments reimburse covered prescription drugs at varying rates generally below average wholesale price. Federal programs also impose price controls through mandatory ceiling prices on purchases by federal agencies and federally funded hospitals and clinics and mandatory rebates on retail pharmacy prescriptions paid by Medicaid and Tricare. These restrictions and limitations influence the purchase of healthcare services and products. Legislative proposals to reform healthcare or reduce costs under government programs may result in lower reimbursement for our products and product candidates or exclusion of our products and product candidates from coverage. Moreover, the Medicare and Medicaid programs increasingly are used as models for how private payers and other governmental payers develop their coverage and reimbursement policies.

In addition, the increased emphasis on managed healthcare in the United States and on country and regional pricing and reimbursement controls in the European Union will put additional pressure on product pricing, reimbursement and utilization, which may adversely affect our future product sales and results of operations. These pressures can arise from rules and practices of managed care groups, competition within therapeutic classes, availability of generic equivalents, judicial decisions and governmental laws and regulations related to Medicare, Medicaid and healthcare reform, coverage and reimbursement policies and pricing in general. The cost containment measures that healthcare payers and providers are instituting and any healthcare reform implemented in the future could significantly reduce our revenues from the sale of any approved products. We cannot provide any assurances that we will be able to obtain and maintain third-party coverage or adequate reimbursement for our approved products in whole or in part.

Healthcare Reform

The United States and many foreign jurisdictions have enacted or proposed legislative and regulatory changes affecting the healthcare system. The United States government, state legislatures and foreign governments also have shown significant interest in implementing cost-containment programs to limit the growth of government-paid healthcare costs, including price controls, restrictions on reimbursement and requirements for substitution of generic products for branded prescription drugs.

In recent years, Congress has considered reductions in Medicare reimbursement levels for drugs administered by physicians. Further, CMS, the agency that administers the Medicare and Medicaid programs, also has authority to revise reimbursement rates and to implement coverage restrictions for some drugs. Cost reduction initiatives and changes in coverage implemented through legislation or regulation could decrease utilization of and reimbursement for any approved products. While Medicare regulations apply only to drug benefits for Medicare beneficiaries, private payers often follow Medicare coverage policy and payment limitations in setting their own reimbursement rates. Therefore, any reduction in reimbursement that results from federal legislation or regulation may result in a similar reduction in payments from private payers.

The ACA substantially changed the way healthcare is financed by both governmental and private insurers, and significantly impacts the pharmaceutical industry. The ACA was intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against healthcare fraud and abuse, add new transparency requirements for healthcare and health insurance industries, impose new taxes and fees on pharmaceutical and medical device manufacturers, and impose additional health policy reforms. Since its passage, there have been significant ongoing efforts to modify or eliminate the ACA.

The first Trump administration pushed for modifications to the ACA. In addition, the Tax Cuts and Jobs Act (the "TCJA"), enacted on December 22, 2017, repealed the shared responsibility payment for individuals who fail to maintain minimum essential coverage under section 5000A of the Internal Revenue Code of 1986, as amended (the "IRC"), as amended, commonly referred to as the individual mandate. While the Biden administration rolled back many of the executive orders issued by President Trump in his first term, ongoing repeal and reform efforts impacting the ACA and the healthcare sector more broadly are being sought and are likely under the current Trump administration.

Other legislative changes have been proposed and adopted since passage of the ACA. These have, among other things, reduced Medicare payments to several types of providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers.

Further legislative and regulatory changes under the ACA remain possible. The Inflation Reduction Act of 2022, enacted on August 16, 2022, includes several provisions to lower prescription drug costs for Medicare patients and reduce drug spending by the federal government. It is unknown what form any future changes or any law would take under the current Trump administration and how or whether it may affect our business in the future. We expect that changes or additions to the ACA, the Medicare and Medicaid programs, changes allowing the federal government to directly negotiate drug prices (which becomes effective in January 2026 for 10 prescription drugs) and changes stemming from other healthcare reform measures, especially with regard to healthcare access, financing or other legislation in individual states, could have a material adverse effect on the healthcare industry. In addition, the Affordable Care Act has also been subject to challenges in the courts, which remain ongoing.

Payment methodologies may be subject to changes in healthcare legislation and regulatory initiatives as well. In addition, at the state level, legislatures have passed and implemented regulations, and may pass additional legislation, designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

We expect that additional federal, state and foreign healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in limited coverage and reimbursement and reduced demand for our products, once approved, or additional pricing pressures.

Foreign Regulation

The Company and any of our collaborative partners may be subject to widely varying foreign regulations, which may be different from those of the FDA, governing clinical trials, manufacture, product registration and approval and pharmaceutical sales. Whether or not FDA approval has been obtained, the Company or our collaborative partners must obtain a separate approval for a product by the comparable regulatory authorities of foreign countries prior to the commencement of product marketing in such countries. In certain countries, regulatory authorities also establish pricing and reimbursement criteria. The approval process varies from country to country, and the time may be longer or shorter than that required for FDA approval. In addition, under current U.S. law, there are restrictions on the export of products not approved by the FDA, depending on the country involved and the status of the product in that country.

Employees

As of September 30, 2025, we had 23 employees and various consultants providing support. Through our consulting and collaboration arrangements, and including our Scientific Advisory Board, we have access to more than 30 additional professionals, who possess significant expertise in business development, legal, accounting, regulatory affairs, clinical operations, and manufacturing. We also rely upon a network of consultants to support our clinical studies and manufacturing efforts.

Executive Officers of Citius Pharma

Leonard Mazur, Chief Executive Officer, Chairman and Secretary – Mr. Mazur, 80, was appointed Chief Executive Officer effective May 1, 2022, and has been a member of the Board since September 2014. Mr. Mazur previously served as Chief Executive Officer, President, and Chief Operating Officer from September 2014 until March 2016.

Myron Holubiak, Executive Vice Chairman and Director – Mr. Holubiak, 78, was appointed Executive Vice Chairman effective May 1, 2022, and has been a member of the Board since October 2015. He previously served as President and Chief Executive Officer from March 2016 through April 2022. He was also the founder and Chief Executive Officer and President of Leonard-Meron Biosciences, Inc., an acquired subsidiary of Citius Pharma, from March 2013 until March 2016.

Jaime Bartushak, Chief Business Officer, Chief Financial Officer and Principal Financial Officer – Mr. Bartushak, 58, was appointed as Chief Financial Officer in November 2017. Previously, he was one of the founders and Chief Financial Officer of Leonard-Meron Biosciences, Inc., an acquired subsidiary of Citius Pharma.

Myron Czuczman, Chief Medical Officer and Executive Vice President – Dr. Czuczman, 66, was appointed as Chief Medical Officer and Executive Vice President in July 2020. Dr. Czuczman previously served as Vice President, Global Clinical Research and Development, Therapeutic Head of Lymphoma/CLL at Celgene Corporation.

Item 1A. Risk Factors

This report contains forward-looking statements that involve risks and uncertainties. Our actual results could differ materially from those discussed in this report. Factors that could cause or contribute to these differences include, but are not limited to, those discussed below and elsewhere in this report.

If any of the following risks, or other risks not presently known to us or that we currently believe to not be significant, develop into actual events, then our business, financial condition, results of operations or prospects could be materially adversely affected. If that happens, the market price of our securities could decline, and stockholders may lose all or part of their investment.

Risks Related to Our Financial Position and Need for Additional Capital

Our independent registered public accounting firm's report includes an explanatory paragraph stating that there is substantial doubt about our ability to continue as a going concern.

At September 30, 2025, we estimated that we have sufficient capital to continue our operations through March 2026, after taking into account the $6.0 million raised by us in October 2025 and the $18.0 million raised by Citius Oncology in December 2025. You should not rely on our consolidated balance sheet as an indication of the amount of proceeds that would be available to satisfy claims of creditors, and potentially be available for distribution to stockholders, in the event of liquidation.

The Company has generated no operating revenue to date and has principally raised capital through the issuance of debt and equity instruments to finance its operations. However, the Company's continued operations beyond March 2026 including its continued commercialization of LYMPHIR (through Citius Oncology) and its development plans for Mino-Lok, Halo-Lido and NoveCite, will depend on its ability to successfully launch LYMPHIR and/or obtain regulatory approval to market Mino-Lok and generate substantial revenue from the sale of LYMPHIR and/or Mino-Lok and on its ability to raise additional capital through various potential sources, such as equity and/or debt financings, strategic relationships, or out-licensing of its product candidates. However, the Company can provide no assurances on the commercialization, or future sales of LYMPHIR and/or the approval, commercialization, or future sales of Mino-Lok or that financing or strategic relationships will be available on acceptable terms, or at all. If the Company is unable to raise sufficient capital, find strategic partners or generate substantial revenue from the sale of LYMPHIR and/or Mino-Lok (if approved), 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.

We require substantial additional funding in the near future to support our operations, complete the commercialization of LYMPHIR, and continue the development of our other product candidates, which capital may not be available on acceptable terms, or at all.

Our operations have consumed substantial amounts of cash since inception. We have significantly increased our spending to continue our commercialization efforts for LYMPHIR through Citius Oncology, advance development of LYMPHIR for other indications, and advance development of our other product candidates. Furthermore, following the Merger, Citius Oncology has additional costs associated with operating as a public company and requires additional capital to fund our other operating expenses and capital expenditures. As a result, we continue to evaluate strategic alternatives, including but not limited to, partnerships, joint ventures, mergers, acquisitions, licensing or other strategic transactions.

As of September 30, 2025, and without giving effect to subsequent capital raises in October and December 2025, our cash and cash equivalents were approximately $4.3 million and we had an accumulated deficit of approximately $238.8 million. The amount and timing of our future funding requirements will depend on many factors, some of which are outside of our control, including but not limited to:

- the costs and expenses associated with our ongoing commercialization efforts for LYMPHIR, including the continuing costs of maintaining or contracting for sales, marketing, and distribution capabilities for LYMPHIR;

- the degree of success we experience in commercializing LYMPHIR;
- the revenue generated by sales of LYMPHIR and other future product candidates that may be approved, if any;
- the extent to which LYMPHIR or any of our other potential product candidates, if approved for commercialization, is adopted by the physician community;
- the effect of competing products and product candidates and other market developments;
- the scope, progress, results and costs of conducting studies and clinical trials for our other future product candidates, if any, resulting from our ongoing research with LYMPHIR for other possible indications;
- the timing of, and the costs involved in, obtaining regulatory approvals for our product candidates;
- the costs of manufacturing LYMPHIR and any other potential product candidates we develop;
- the timing and amount of any milestone, royalty or other payments we are required to make pursuant to any current or future license agreements;
- the number and types of future product candidates we might develop and commercialize;
- any product liability or other lawsuits related to our products;
- the expenses needed to attract, hire and retain skilled personnel;
- the costs associated with being a public company;
- costs of preparing, filing and prosecuting patent applications and maintaining, enforcing and defending intellectual property-related claims; and
- the extent and scope of our general and administrative expenses.

Until we are able to generate significant revenue, if ever, we expect to finance our operations through a combination of equity offerings, debt financings, collaborations or other strategic transactions. We cannot be sure that any additional funding, if needed, will be available on terms favorable to us, or at all. Any additional fundraising efforts may divert our management from their day-to-day activities, which may adversely affect our ability to develop and commercialize our product candidates. Furthermore, any additional equity or equity-related financing may be dilutive to our stockholders, and debt or equity financing, if available, may subject us to restrictive covenants and significant interest costs. If we raise additional funds through collaborations or strategic alliances with third parties, we may have to relinquish valuable rights to our product candidates, future revenue streams, research programs or technologies, or grant licenses on terms that may not be favorable to us. If we are unsuccessful in our efforts to raise additional financing on acceptable terms or execute on other strategic alternatives, we may be required to significantly reduce or cease our operations.

We have a history of net losses and expect to incur losses for the foreseeable future. We may never generate revenues or, if we are able to generate revenues, achieve profitability.

We were formed in 2007 and since our inception have incurred a net loss in each of our previous operating years. Our ability to become profitable depends upon our ability to obtain marketing approval for and generate revenues from sales of our product candidates. We have been focused on product development, have not received approval for any of our product candidates, and have not generated any revenues to date. Our subsidiary, Citius Oncology, received approval for LYMPHIR in August 2024 and launched LYMPHIR in December 2025, but has not generated any revenues to date. We have incurred losses in each period of our operations, and we expect to continue to incur losses for the foreseeable future. These losses are likely to continue to adversely affect our working capital, total assets, and stockholders' equity. The process of developing our product candidates requires significant clinical development, laboratory testing and clinical trials. In addition, commercialization of our product candidates will require that we obtain necessary regulatory approvals and establish sales, marketing, and manufacturing capabilities, either through internal hiring or through contractual relationships with others. We expect to incur substantial losses for the foreseeable future as a result of anticipated increases in our research and development costs, including costs associated with conducting preclinical testing and clinical trials, and regulatory compliance activities. We expect Citius Oncology to begin generating revenues following the launch of LYMPHIR, which occurred in December 2025. We incurred net losses of $39,740,269 and $39,425,839 for the years ended September 30, 2025 and 2024, respectively. At September 30, 2025, we had stockholders' equity of $77,527,600 and an accumulated deficit of $238,804,129. Our net cash used in operating activities was $26,552,738 and $28,201,375 for the years ended September 30, 2025 and 2024, respectively.

As of September 30, 2025, we had outstanding liabilities of $38.4 million and outstanding commitments of $22.7 million to third parties for LYMPHIR licensing, supply and other costs, that, if left unpaid, could result in an interruption in the commercialization of LYMPHIR, breach of contract, loss of licensing rights or other events that would have a material adverse effect on our business and operations.

Our ability to generate revenues and achieve profitability will depend on numerous factors, including success in:

- Citius Oncology successfully commercializing LYMPHIR;
- developing and testing product candidates;
- receiving regulatory approvals for our other product candidates;
- commercializing our other product candidates that receive regulatory approval;
- manufacturing commercial quantities of our products and product candidates at acceptable cost levels;
- obtaining medical insurance coverage for any approved product candidate; and
- establishing a favorable competitive position for any approved product candidates.

Many of these factors will depend on circumstances beyond our control. We cannot assure you that any of our product candidates will be approved by the FDA or any foreign regulatory body or obtain medical insurance coverage, that we will successfully bring any approved product to market or, if so, that we will ever become profitable.

Our and Citius Oncology's ongoing explorations of alternative strategic paths may not result in entering into or completing transactions, when necessary, and the process of reviewing alternative strategic paths or their conclusion could adversely affect our stock price.

We and Citius Oncology continue to evaluate strategic paths to provide the resources necessary to successfully commercialize LYMPHIR, continue the development of our other product candidates, and maximize stockholder value. Potential strategic paths may include partnerships, joint ventures, mergers, acquisitions, or licensing transactions, a combination of these, or other strategic transactions. There can be no assurance, however, that our evaluation will result in transactions or other alternatives, even when deemed necessary. There is no set timetable for our strategic process, and we do not intend to provide updates unless or until the Board approves a specific action or otherwise determines that disclosure is appropriate or necessary.

Any potential transaction would be dependent on a number of factors that may be beyond our control, including, among other things, market conditions, industry trends, the interest of third parties in a potential transaction with us, obtaining stockholder approval and the availability of financing to third parties in a potential transaction with us on reasonable terms. The process of reviewing alternative strategic paths may be time consuming and may involve the dedication of significant resources and may require us to incur significant costs and expenses. It could negatively impact our ability to attract, retain and motivate employees, and expose us to potential litigation in connection with this process or any resulting transaction. If we are unable to effectively manage the process, our financial condition and results of operations could be adversely affected. In addition, speculation regarding any developments related to the review of strategic alternatives and perceived uncertainties related to the future of our Company could cause our stock price to fluctuate significantly. Further, any alternative strategic paths that may be pursued and completed ultimately may not deliver the anticipated benefits or enhance stockholder value. There can be no guarantee that the process of evaluating alternative strategic paths will result in our Company or Citius Oncology entering into or completing potential transactions within the anticipated timing or at all.

In the event we or Citius Oncology do not successfully complete a strategic transaction, should this be deemed necessary, our Board may decide to pursue a dissolution and liquidation of our Company. In such an event, the amount of cash available for distribution to our stockholders will depend heavily on the timing of such liquidation as well as the amount of cash that will need to be reserved for commitments and contingent liabilities.

There can be no guarantee that the process to identify strategic transactions will result in successfully completed transactions when necessary. If additional transactions are not completed that enable us or Citius Oncology to successfully commercialize LYMPHIR and sustain our business operations, our Board may decide that it is in the best interest of our stockholders to dissolve our Company and liquidate our assets. In that event, the amount of cash available for distribution to our stockholders will depend heavily on the timing of such decision and, ultimately, such liquidation since the amount of cash available for distribution continues to decrease as we fund our operations and evaluate our strategic alternatives. In addition, if our Board were to approve and recommend, and our stockholders were to approve, a dissolution of our Company, we would be required under Nevada corporate law to pay our outstanding obligations, as well as to make reasonable provision for contingent and unknown obligations, prior to making any distributions in liquidation to our stockholders. As a result of this requirement, a portion of our assets may need to be reserved pending the resolution of such obligations. In addition, we may be subject to litigation or other claims related to a dissolution and liquidation of our Company. If a dissolution and liquidation were pursued, our Board, in consultation with its advisors, would need to evaluate these matters and make a determination about a reasonable amount to reserve. Accordingly, holders of our common stock could lose all or a significant portion of their investment in the event of a dissolution, liquidation or winding up of our Company.

Risks Related to Our Business and our Industry

If we are unable to execute our commercial strategy for LYMPHIR, fail to satisfy the conditions of our marketing approval for LYMPHIR, or if we experience significant delays in accomplishing such goals, our business will be materially harmed.

We have invested a significant portion of our efforts and financial resources to bring LYMPHIR to market. Our ability to generate product revenues will depend heavily on the successful commercialization of LYMPHIR. Further, while we believe we have sufficient funds on hand for the successful commercialization of LYMPHIR, which began with its launch in December 2025, various factors could increase the cost to successfully commercialize LYMPHIR, which we expect would require us to obtain additional capital to complete those efforts. Financing might not be available on acceptable terms or at all.

If we do not receive new marketing approvals in other jurisdictions for LYMPHIR, our ability to generate additional revenue will be jeopardized and, consequently, our business will be materially harmed. Additionally, our ability to make LYMPHIR available within the U.S. is largely dependent upon the maintenance of our marketing approval. The success of LYMPHIR will depend on a number of additional factors, including the following:

- our ability to negotiate, secure and maintain adequate pricing, coverage and reimbursement terms on a timely basis, or at all;
- the timing, scope and outcome of our commercial launch in the U.S. and in other potential jurisdictions;
- the maintenance and expansion of a commercial infrastructure capable of supporting product sales, marketing and distribution;
- the implementation and maintenance of marketing and distribution relationships with third parties;
- our ability to establish and maintain commercial manufacturing arrangements with third-party manufacturers;
- our ability or the ability of our third-party manufacturers to successfully produce commercial and clinical supply of LYMPHIR on a timely basis sufficient to meet the needs of our commercial and clinical activities;
- successful identification of eligible patients;
- acceptance of LYMPHIR as a treatment for the approved indication by patients, the medical community and third-party payors;
- effectively competing with other therapies;
- global trade policies;
- a continued acceptable safety profile of LYMPHIR;
- the costs, timing and outcome of post-marketing studies and trials required for LYMPHIR;
- protecting our rights in our intellectual property portfolio, obtaining and maintaining regulatory exclusivity; and
- our ability to successfully prepare and advance regulatory submissions for marketing approval for LYMPHIR in additional territories and for additional or expanded indications and whether and in what timeframe we may obtain such approval.

If we do not achieve one or more of these factors in a timely manner or at all, we could experience significant delays or an inability to continue to commercialize our products, either of which would have a material adverse effect on our business, results of operations and financial condition.

We need to secure additional financing in the future to complete the development of our other current product candidates and support our operations.

We anticipate that we will incur operating losses for the foreseeable future as we continue developing our product candidates which have not received regulatory approval. The amount and timing of our future funding requirements will depend on many factors, including, but not limited to:

- the rate of progress and cost of our trials and other product development and commercialization programs for our current product candidates;
- the costs and timing of obtaining licenses for additional product candidates or acquiring other complementary technologies;
- the timing of any regulatory approvals of any of our product candidates;
- the costs of establishing or contracting for sales, marketing, and distribution capabilities for our product candidates; and
- the status, terms and timing of any collaborative, licensing, co-promotion, or other arrangements.

We expect to need to access the capital markets in the near future for additional capital for research and development and for operations. Traditionally, pharmaceutical companies have funded their research and development expenditures through raising capital in the equity markets. Declines and uncertainties in these markets over the past several years have severely restricted raising new capital and have affected companies' abilities to continue to expand or fund existing research and development efforts. If economic conditions continue to be uncertain or become worse, our future cost of equity or debt capital and access to the capital markets could be adversely affected. If we are not successful in securing additional financing, we may be required to significantly delay, reduce the scope of or eliminate one or more of our research or development programs, downsize our general and administrative infrastructure, or seek alternative measures to avoid insolvency, including arrangements with collaborative partners or others that may require us to relinquish rights to certain of our technologies or product candidates.

We are primarily a commercial and late-stage development company with an unproven business strategy and may never achieve commercialization of all our therapeutic product candidates or profitability.

Citius Pharma has no approved products. Our subsidiary, Citius Oncology, received approval for LYMPHIR in August 2024 and launched LYMPHIR in December 2025, but has not generated any revenues to date. All other current product candidates of Citius Pharma are in the pre-clinical or clinical stage. We rely on third parties to conduct the research and development activities for our product candidates and our product commercialization capabilities are unproven. We, through Citius Oncology, have developed our sales and marketing capabilities for LYMPHIR and have contracted with Innovation Partners, a large third-party commercial sales and marketing organization with an existing commercial infrastructure and product launch experience to assist in our commercial efforts related to LYMPHIR. Citius Oncology also has distribution agreements with three national companies and an agreement with EVERSANA to support the launch and commercialization of LYMPHIR. Citius Pharma has no sales or marketing capabilities with respect to our other product candidates. Our success will depend upon the sales and marketing infrastructure developed by Citius Oncology for LYMPHIR and also on Citius Pharma's ability to develop such capabilities on its own or to enter into and maintain collaboration agreements on favorable terms and to select an appropriate commercialization strategy for each product candidate that it chooses to pursue and that receives approval, whether on its own or in collaboration. If we are not successful in implementing our strategy to commercialize our product candidates, we may never achieve, maintain, or increase profitability. Our ability to successfully commercialize any of our other product candidates will depend, among other things, on our ability to:

- successfully complete pre-clinical and clinical trials for our product candidates;

- receive marketing approvals from the FDA and similar foreign regulatory authorities for our product candidates;
- establish commercial manufacturing arrangements with third-party manufacturers for our product candidates;
- produce, through a validated process, sufficiently large quantities of our drug compound(s) to permit successful commercialization of our product candidates;
- build and maintain strong sales, distribution, and marketing capabilities sufficient to launch commercial sales of any approved products or establish collaborations with third parties for such commercialization;
- secure acceptance of any approved products from physicians, health care payers, patients, and the medical community; and
- manage our spending as costs and expenses increase due to clinical trials, regulatory applications and development and commercialization activities.

There are no guarantees that we will be successful in completing these tasks. If we are unable to successfully complete these tasks, we may not be able to commercialize any of our product candidates in a timely manner, or at all, in which case we may be unable to generate sufficient revenues to sustain and grow our business. If we experience unanticipated delays or problems, our development costs could substantially increase and our business, financial condition and results of operations will be adversely affected.

We have a limited operating history upon which to evaluate our ability to successfully commercialize our product candidates.

Citius Oncology has only recently launched its one product, LYMPHIR. Citius Pharma has one late-stage stage product candidate, Mino-Lok, while our other product candidates are clinical stage. As a result, our success is dependent upon Citius Oncology's success in commercializing LYMPHIR and Citius Pharma's ability to obtain regulatory approval for and commercialize our product candidates and we, as a company, have not demonstrated an ability to perform the functions necessary for the successful commercialization of any product candidates, given the recent launch of LYMPHIR. While various members of our executive management and key employees have significant prior experience in pharmaceutical development, as a company we have to date successfully completed only one late-stage clinical trial (much of which had been undertaken by Eisai prior to our in-licensing of the intellectual property of LYMPHIR) and have just launched LYMPHIR (through Citius Oncology). Despite our progress with LYMPHIR, our operations have been limited primarily to business planning, acquiring our proprietary technology, research and development, recruiting management and technical staff, and raising capital. These operations provide a limited basis for you to assess our ability to successfully commercialize our product candidates and the advisability of investing in our securities.

We may choose not to continue developing any of our product candidates at any time during development, which would reduce or eliminate our potential return on investment for those product candidates.

At any time, we may decide to discontinue the development of any of our product candidates for a variety of reasons, including inadequate financial resources, the appearance of new technologies that render our product candidates obsolete, competition from a competing product or changes in or failure to comply with applicable regulatory requirements. If we terminate a program in which we have invested significant resources, we will not receive any return on our investment and we will have missed the opportunity to allocate those resources to potentially more productive uses.

As an example, on July 1, 2016, we announced that we were discontinuing the development of Suprenza, which was our first commercial product candidate, for strategic reasons and not due to safety or regulatory concerns, in order to focus our management and cash resources on the Phase 3 development of Mino-Lok and the Phase 2b development of Halo-Lido. Further, in December 2023, we terminated development of Mino-Wrap to devote resources to the development of LYMPHIR. The resources expended on Suprenza and Mino-Wrap therefore did not provide us any benefit.

We face significant risks in our product candidate development efforts.

Our business depends on the successful development and commercialization of our product candidates. We are not permitted to market any of our product candidates in the U.S. until we receive approval from the FDA, or in any foreign jurisdiction until we receive the requisite approvals from such jurisdiction. The process of developing new drugs and/or therapeutic products is inherently complex, unpredictable, time-consuming, expensive and uncertain. We must make long-term investments and commit significant resources before knowing whether our development programs will result in products that will receive regulatory approval and achieve market acceptance. As an example, in response to the submission of our BLA for LYMPHIR, the FDA issued a complete response letter ("CRL") on July 28, 2023. The FDA required us to incorporate enhanced product testing and additional controls agreed to with the FDA during the market application review. There were no concerns relating to the safety and efficacy clinical data package submitted with the BLA, or the proposed prescribing information. In September 2023, we announced that the FDA had agreed with our plans to address the requirements outlined in the CRL, which guidance provided us with a path for completing the necessary activities to support the resubmission of the BLA for LYMPHIR and we received approval from the FDA in August 2024.

Product candidates that appear to be promising at some or all stages of development may not receive approval or reach the market for a number of reasons that may not be predictable based on results and data of the clinical program. Product candidates may be found ineffective or may cause harmful side effects during clinical trials, may take longer to progress through clinical trials than had been anticipated, may not be able to achieve the pre-defined clinical endpoints due to statistical anomalies even though clinical benefit may have been achieved, may fail to receive necessary regulatory approvals, may prove impracticable to manufacture in commercial quantities at reasonable cost and with acceptable quality, or may fail to achieve market acceptance.

We cannot predict whether or when we will obtain regulatory approval to commercialize our other product candidates that are under development, notably Mino-Lok. In addition, we expect that it will take time for LYMPHIR to be accepted in the market, generate revenues and a return on investment. For example, while LYMPHIR received FDA approval in August 2024, we had incurred significant expenses in its development and planned commercialization prior to its launch in December 2025; as of September 30, 2025, we had outstanding commitments of approximately $21.1 million to third parties for LYMPHIR licensing, supply and other costs. We cannot, therefore, predict the timing of any future revenues from LYMPHIR or any other product candidate.

The FDA has substantial discretion in the drug approval process, including the ability to delay, limit or deny approval of a product candidate for many reasons. For example, the FDA:

- may not find the data from clinical trials sufficient to support the submission of an NDA or BLA or to obtain marketing approval in the U.S., including any findings that the clinical and other benefits of our product candidates outweigh their safety risks;

- could determine that the information provided by us was inadequate, contained clinical deficiencies or otherwise failed to demonstrate the safety and effectiveness of any of our product candidates for any indication;

- may disagree with our trial design or our interpretation of data from preclinical studies or clinical trials, or may change the requirements for approval even after it has reviewed and commented on the design for our trials;

- could determine that we cannot rely on Section 505(b)(2) for Mino-Lok or Halo-Lido or any future product candidate whose composition includes components previously approved by the FDA;

- may determine that we have identified the wrong reference listed drug or drugs or that approval of a Section 505(b)(2) application for any of our product candidates is blocked by patent or non-patent exclusivity of the reference listed drug or drugs;

- may identify deficiencies in the manufacturing processes or facilities of third-party manufacturers with which we enter into agreements for the manufacture of our product candidates;

- may approve our product candidates for fewer or more limited indications than we request, or may grant approval contingent on the performance of costly post-approval clinical trials;

- may change its approval policies or adopt new regulations that could adversely impact our product candidate development programs; or

- may not approve the labeling claims that we believe are necessary or desirable for the successful commercialization of our product candidates, or may require labeling claims that impair the potential market acceptance of our product candidates.

These same risks are generally applicable to the regulatory process in foreign countries. Any failure to obtain regulatory approval of our product candidates would significantly limit our ability to generate revenues, and any failure to obtain such approval for all of the indications and labeling claims we deem desirable could reduce our potential revenues.

We, through Citius Oncology, may be required to make milestone payments to the licensor and former licensee of the LYMPHIR intellectual property in connection with its development and commercialization of LYMPHIR, which could adversely affect the profitability of LYMPHIR.

Under the terms of the License Agreement with Eisai, Citius Oncology was required to pay Eisai a $5.9 million development milestone payment upon initial approval by the FDA of LYMPHIR for the CTCL indication, which occurred in August 2024, and an aggregate of up to $22 million related to the achievement of net product sales thresholds. Under the terms of the agreement with Dr. Reddy's, Citius Oncology is obligated to pay up to an aggregate of $40 million related to CTCL approvals in the U.S. and other markets, up to $70 million in development milestones for additional indications, and up to $300 million for commercial sales milestones. Further, under the agreement with Dr. Reddy's, Citius Oncology is 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, (iii) use commercially reasonable efforts to achieve each of the approval milestones, and (iv) complete each specified immuno-oncology investigator trial on or before September 1, 2025, the four-year anniversary of the effective date of the definitive agreement. Additionally, Citius Oncology is required to commercially launch a product in a territory within six months of receiving regulatory approval for such product in each such jurisdiction; the launch of LYMPHIR in December 2025 satisfied this requirement in the U.S. Citius Pharma is a guarantor of the obligations of Citius Oncology under the Asset Purchase Agreement.

Pending further discussions with Dr. Reddy's, Dr. Reddy's agreed to a partial deferral without penalty of a milestone payment by Citius Oncology, which was triggered upon regulatory approval of LYMPHIR by the FDA and due on September 9, 2024, pursuant to the terms of the Asset Purchase Agreement. These development and milestone obligations impose substantial additional costs on us, and could divert resources from other aspects of our business and adversely affect the overall profitability of LYMPHIR. We, through Citius Oncology, need to obtain additional financing to satisfy these milestone payments, and cannot be sure that any additional funding will be available on terms favorable to us, or at all.

On March 28, 2025, Citius Oncology and Eisai entered into a letter agreement that amended the license agreement to provide for a payment schedule to Eisai for the milestone payment and certain unpaid invoices. We agreed to pay Eisai on or before July 15, 2025, an aggregate amount of $2,535,318 and thereafter on the 15th of each of the next four months to pay Eisai $2.35 million and make a final payment of $2,197,892 to Eisai on or before December 15, 2025, in each case with interest on each obligation from its original due date through the date of actual payment under the letter agreement at the rate of 2% per annum. During the year ended September 30, 2025, we recorded $218,032 in interest expense under the agreement. The parties released each other from any and all claims, losses, damages, costs and expenses that arise from or related to our failure to pay the milestone payment or the other incurred costs under the license agreement except for any claims arising out of a breach of the letter agreement. All other terms of the license agreement remain in full force and effect. During the year ended September 30, 2025 we paid $3 million of the development milestone and the balance of $2.9 million is included in license fee payable at September 30, 2025. On July 21, 2025, we made a payment to Eisai of $1,616,522 for other invoices and accumulated interest associated with the letter agreement.

A material breach or default under any of our license agreements, including failure to make timely payments when due, gives the licensor party to such agreement the right to terminate the license agreement, which termination would materially harm our business.

Our commercial success will depend in part on the maintenance of our current and any future license agreements. Our license agreements impose, and we expect that future license agreements will impose on us, various diligence, milestone payment, royalty and other obligations. For example, under the license agreement and related purchase agreement for the intellectual property for LYMPHIR, we, through our subsidiary Citius Oncology, are required to use commercially reasonable diligence to develop and commercialize a product and to satisfy specified payment obligations for various developmental and regulatory milestones. Specifically, upon the approval of LYMPHIR, we, through Citius Oncology, became subject to the payment of an aggregate of $33.4 million under the license and asset purchase agreements covering LYMPHIR.

At the time of the FDA approval for LYMPHIR, a $27.5 million milestone became payable to Dr. Reddy's, of which a balance of $19.75 million included in license fee payable, remained due as of September 30, 2025. After discussions, Dr. Reddy's agreed to a partial deferral without penalty of this milestone payment. During the years ended September 30, 2025 and 2024, we paid $2,750,000 and $5,000,000, respectively, against the outstanding milestone fee.

On March 28, 2025, Citius Oncology and Eisai entered into a letter agreement that amended the license agreement to provide for a payment schedule to Eisai for the milestone payment and certain unpaid invoices. We agreed to pay Eisai on or before July 15, 2025, an aggregate amount of $2,535,318 and thereafter on the 15th of each of the next four months to pay Eisai $2.35 million and make a final payment of $2,197,892 to Eisai on or before December 15, 2025, in each case with interest on each obligation from its original due date through the date of actual payment under the letter agreement at the rate of 2% per annum. During the year ended September 30, 2025, we recorded $218,032 in interest expense under the agreement. The parties released each other from any and all claims, losses, damages, costs and expenses that arise from or related to our failure to pay the milestone payment or the other incurred costs under the license agreement except for any claims arising out of a breach of the letter agreement. All other terms of the license agreement remain in full force and effect. During the year ended September 30, 2025 we paid $3 million of the development milestone and the balance of $2.9 million is included in license fee payable at September 30, 2025. On July 21, 2025, we made a payment to Eisai of $1,616,522 for other invoices and accumulated interest associated with the letter agreement.

If we fail to comply with our obligations under the current license agreements or any future license agreements with any party, or we are subject to a bankruptcy, the licensor may have the right to terminate the license, in which event we would not be able to market products covered by the license. Each of our license agreements provides the licensor with a right to terminate the license agreement for our material breach or default under the agreement, including the failure to make any required milestone or other payments. Should the licensor under any of the license agreements exercise such a termination right, we would lose our right to the intellectual property under the respective license agreement, which loss would materially harm our business.

We rely exclusively on third parties to formulate and manufacture our product candidates. Our failure to abide by our contractual obligations with these third parties, including timely payment, could result in a delay or the loss of necessary third-party support.

We do not have and do not intend to establish our own manufacturing facilities. Consequently, we lack the physical plant to formulate and manufacture our product candidates, which have to be produced by third-party manufacturers. If we fail to raise additional capital, and as a result are unable to abide by our contractual obligations with these third-party manufacturers and suppliers, including making timely payment, the necessary third-party support to commercialize LYMPHIR could be delayed or terminated.

We, through Citius Oncology, have secured supply agreements for LYMPHIR with two third-party facilities who are in compliance with current good manufacturing practices ("cGMP") as generally accepted by the FDA. We rely on these third-party contractors for our manufacturing. Manufacturing of drugs for clinical and commercial purposes must comply with the FDA's cGMP and applicable non-U.S. regulatory requirements and before any of our collaborators can begin to commercially manufacture our product candidates, each must obtain regulatory approval of the manufacturing facility and process. If, for any reason, we become unable to rely on these sources or any future source or sources to manufacture LYMPHIR or any future product candidates, either for pre-clinical or clinical trials or for commercial quantities, then we would need to identify and contract with additional or replacement third-party manufacturers to manufacture compounds for preclinical, clinical, and commercial purposes. We might not be successful in identifying additional or replacement third-party manufacturers, or in negotiating acceptable terms with any that we might identify. If we are unable to secure and maintain third-party manufacturing capacity, the commercialization and sales of LYMPHIR, and any future product candidates, and our financial performance might be materially and adversely affected.

Additionally, if any of our collaborators fails to comply with the cGMP requirements, we would be subject to possible regulatory action which could limit the jurisdictions in which we are permitted to sell LYMPHIR, or any future product candidate. As a result, our business, financial condition, and results of operations might be materially harmed.

Our reliance on a limited number of third-party manufacturers exposes us to the following risks:

- We might be unable to identify manufacturers for commercial supply on acceptable terms or at all because the number of potential manufacturers is limited and the FDA must approve any replacement contractor. This approval would generally require compliance inspections. In addition, a new manufacturer would have to be educated in, or develop substantially equivalent processes for, the production of LYMPHIR and any product candidate approved by the FDA;

- Our third-party manufacturers might be unable to formulate and manufacture LYMPHIR and any product candidate in the volume and of the quality required to meet our clinical and commercial needs;

- Our contract manufacturers might not perform as agreed or might not remain in the contract manufacturing business for the time required to supply our clinical trials or to successfully produce, store and distribute LYMPHIR, and any future product candidate approved by the FDA, for commercialization;

- Currently, one of the contract manufacturers for LYMPHIR is foreign (located in Italy), which increases the risk of shipping delays, adds the risk of import restrictions, and adds the risk of political and environmental uncertainties that might affect those countries;

- Drug manufacturers are subject to ongoing periodic unannounced inspection by the FDA and corresponding state agencies to ensure strict compliance with cGMP and other government regulations and corresponding foreign standards. We do not have control over third-party manufacturers' compliance with these regulations and standards;

- If any third-party manufacturer makes improvements in the manufacturing process for our product candidates, we might not own, or might have to share, the intellectual property rights to the innovation with our licensors;

- Operations of our third-party manufacturers or suppliers could be disrupted by conditions unrelated to our business or operations, including a bankruptcy of the manufacturer or supplier or a natural disaster or a pandemic such as COVID-19; and

- We might compete with other companies for access to these manufacturers' facilities and might be subject to manufacturing delays if the manufacturers give other clients higher priority.

Each of these risks could delay our clinical trials or the approval, if any, of our product candidates by the FDA or any foreign regulatory agency or the commercialization of any approved product candidate and could result in higher costs or deprive us of potential product revenues. As a result, our business, financial condition, and results of operations might be materially harmed.

While our business strategy generally is to focus on the development of late-stage product candidates to lessen the development risk, there is still significant risk to successfully developing a product candidate.

Our goal in generally pursuing late-stage therapeutic product candidates with what we believe is a promising pre-clinical and early clinical stage track record is to avoid the risk of failure at the pre-clinical and early clinical stages. However, there is still significant risk to obtaining regulatory approval and successfully commercializing any late-stage product candidate that we pursue. For example, we acquired LYMHIR in September 2021, received approval in August 2024 and launched it in December 2025, during which time we expended significant resources on the acquisition, development and launch of LYMPHIR. All of the risks inherent in drug development of initial stage product candidates also apply to late-stage candidates. We cannot assure you that our business strategy will be successful.

The results of pre-clinical studies and completed clinical trials are not necessarily predictive of future results, and our current product candidates may not have favorable results in later studies or trials.

Pre-clinical studies and Phase 1 and Phase 2 clinical trials are not primarily designed to test the efficacy of a product candidate in the general population, but rather to test initial safety, to study pharmacokinetics and pharmacodynamics, to study limited efficacy in a small number of study patients in a selected disease population, and to identify and attempt to understand the product candidate's side effects at various doses and dosing schedules. Success in pre-clinical studies or completed clinical trials does not ensure that later studies or trials, including continuing pre-clinical studies and large-scale clinical trials, will be successful nor does it predict future results. Favorable results in early studies or trials may not be repeated in later studies or trials, and product candidates in later stage trials may fail to show acceptable safety and efficacy despite having progressed through earlier trials. In addition, the placebo rate in larger studies may be higher than expected.

We may be required to demonstrate through large, long-term outcome trials that our product candidates are safe and effective for use in a broad population prior to obtaining regulatory approval. This would increase the duration and cost of any such trial.

There is typically a high rate of attrition from the failure of product candidates proceeding through clinical trials. In addition, certain subjects in our clinical trials may respond positively to placebo treatment – these subjects are commonly known as "placebo responders" – making it more difficult to demonstrate efficacy of the trial drug compared to placebo. This effect is likely to be observed in the treatment of hemorrhoids, which could negatively impact the development program for Halo-Lido.

If any of our product candidates fail to demonstrate sufficient safety and efficacy in any clinical trial, we will experience potentially significant delays and cost increases in, or may decide to abandon development of, that product candidate. If we abandon or are delayed, or experience increased costs, in our development efforts related to any of our product candidates, we may not have sufficient resources to continue or complete development of that product candidate or any other product candidates. We may not be able to continue our operations and clinical studies, or generate any revenue or become profitable. Our reputation in the industry and in the investment community would likely be significantly damaged. Further, it might not be possible for us to raise funds in the public or private markets, and our stock price would likely decrease significantly.

If we are unable to file for approval of Mino-Lok or Halo-Lido under Section 505(b)(2) of the Federal Food, Drug and Cosmetic Act, or if we are required to generate additional data related to safety and efficacy in order to obtain approval of Mino-Lok or Halo-Lido under Section 505(b)(2), we may be unable to meet our anticipated development and commercialization timelines.

Our current plans for filing NDAs or BLAs for our product candidates include efforts to minimize the data we will be required to generate in order to obtain marketing approval for certain of our product candidates and therefore possibly reduce the time and cost of development of a product candidate and obtain a shortened review period for the application. The timeline for filing and review of our planned NDA for each of Mino-Lok and Halo-Lido is based upon our plan to submit each such NDA under Section 505(b)(2) of the Federal Food, Drug and Cosmetic Act, wherein we will rely in part on data generated by third parties and that is in the public domain or elsewhere. Depending on the data that may be required by the FDA for approval, some of the data may be related to products already approved by the FDA. If the data relied upon is related to products already approved by the FDA and covered by third-party patents, we would be required to certify that we do not infringe the listed patents or that such patents are invalid or unenforceable. As a result of the certification, the third party would have 45 days from notification of our certification to initiate an action against us. In the event that an action is brought in response to such a certification, the approval of our NDA could be subject to a stay of up to 30 months or more while we defend against such a suit. Approval of any product candidate under Section 505(b)(2) may therefore be delayed until patent exclusivity expires or until we successfully challenge the applicability of those patents applicable to our product candidates. Alternatively, we may elect to generate sufficient additional clinical data so that we no longer rely on data which triggers a potential stay of the approval of any product candidate. Even if no exclusivity periods apply to an application under Section 505(b)(2), the FDA has broad discretion to require us to generate additional data on the safety and efficacy of our product candidates to supplement third-party data on which we may be permitted to rely. In either event, we could be required, before obtaining marketing approval for such product candidate, to conduct substantial new research and development activities beyond those in which we currently plan to engage in order to obtain approval of that product candidate. Such additional new research and development activities would be costly and time consuming.

We may not be able to obtain shortened review of our applications where available, and in any event the FDA may not agree that any of our product candidates qualify for marketing approval. If we are required to generate additional data to support approval, we may be unable to meet our anticipated development and commercialization timelines, may be unable to generate the additional data at a reasonable cost, or at all, and may be unable to obtain marketing approval of that product candidate. In addition, notwithstanding the approval of many products by the FDA pursuant to Section 505(b)(2), over the last few years, some pharmaceutical companies and others have objected to the FDA's interpretation of Section 505(b)(2). If the FDA changes its interpretation of Section 505(b)(2), or if the FDA's interpretation is successfully challenged in court, this could delay or even prevent the FDA from approving any Section 505(b)(2) application that we submit.

Two of our product candidates, Mino-Lok and Halo-Lido, are combination products consisting of components that have each been separately approved by the FDA for other indications and which are commercially available and marketed by other companies. Our approval under Section 505(b)(2), if received, would not preclude physicians, pharmacists, and patients from obtaining individual drug products and titrating the dosage of these drug products as close to our approved dose as possible.

Our Mino-Lok solution contains minocycline, disodium ethylenediaminetetraacetic acid (edetate), and ethyl alcohol, all of which have been separately approved by the FDA for other indications or are used as excipients in other parenteral products. Assuming FDA approval as a branded pharmaceutical product, we would need to obtain hospital formulary acceptance to generate sales of Mino-Lok. Additionally, we may encounter reluctance by the infectious disease physician community to vary from the existing standard of care to remove and replace an infected catheter. Currently, hospitals are reimbursed for the treatment of CRBSIs CMS through a Diagnosis Related Group ("DRG") classification or code. Commercial insurance plans reimburse for CRBSIs in a similar manner. With Mino-Lok being priced as a branded FDA-approved pharmaceutical product, this could result in the participating hospital retaining a lower share of CMS or commercial reimbursement which may impact the acceptance and use of Mino-Lok by these institutions.

Our Halo-Lido product candidate for the treatment of hemorrhoids is a combination product consisting of two drugs, halobetasol propionate, a corticosteroid, and lidocaine, that have each been separately approved by the FDA for other indications and which are commercially available and marketed by other companies. Halobetasol propionate cream is available in a 0.05% strength, and lidocaine creams are also available in strengths up to 5%. From our market analysis and discussions with a limited number of physicians, we know that patients sometimes obtain two separate cream products and co-administer them as prescribed, giving them a combination treatment that could be very similar to what we intend to continue to study and seek approval for. As a branded, FDA-approved product with safety and efficacy data, we intend to price our product substantially higher than the generically available individual creams. We will then have to convince third-party payers and pharmacy benefit managers of the advantages of our product and justify our premium pricing. We may encounter resistance from these entities and will then be dependent on patients' willingness to pay the premium and not seek alternatives. In addition, pharmacists often suggest lower cost prescription treatment alternatives to both physicians and patients. If approved, our Section 505(b)(2) approval and the market exclusivity we may receive will not guarantee that such alternatives will not exist, that substitution will not occur, or that there will be immediate or any acceptance to our pricing by payer formularies.

Any fast track designation or grant of priority review status by the FDA may not actually lead to a faster development or regulatory review or approval process, nor will it assure FDA approval of our product candidates. Additionally, our product candidates may treat indications that do not qualify for priority review vouchers.

We have received fast track designation for Mino-Lok to treat and salvage infected central venous catheters in patients with CRBSIs. We may seek fast track designation for some of our other product candidates or priority review of applications for approval of our product candidates for certain indications. If a drug is intended for the treatment of a serious or life-threatening condition and the drug demonstrates the potential to address unmet medical needs for this condition, the drug sponsor may apply for the FDA fast track designation. If a product candidate offers major advances in treatment, the FDA may designate it eligible for priority review. The FDA has broad discretion whether or not to grant these designations, so even if we believe a particular product candidate is eligible for these designations, we cannot assure you that the FDA would decide to grant them. Even with the fast track designation for Mino-Lok and if we do receive fast track designation or priority review for any other product candidate, we may not experience a faster development process, review or approval compared to conventional FDA procedures. The FDA may withdraw fast track designation from Mino-Lok or any other product candidate to be so designated if it believes that the designation is no longer supported by data from our clinical development program.

We do not own Citius Oncology or NoveCite, Inc. outright and will share any benefits from the commercialization of LYMPHIR and the development of the NoveCite product candidate with the other stockholders.

As of December 17, 2025, we owned approximately 77.9% of the outstanding common stock of Citius Oncology (excluding pre-funded warrants to purchase up to 15,229,358 shares of Citius Oncology common stock in a transaction that closed on December 10, 2025) and 75% of the outstanding common stock of NoveCite. As a result, we will only be entitled to a portion of any benefits that flow from the commercialization by Citius Oncology of LYMPHIR and the development by NoveCite of its NoveCite product candidate or any other product candidates that either company might develop. In the event that Citius Oncology or NoveCite were to issue additional equity securities in the future this would likely reduce our percentage ownership, which would further reduce the portion of any benefit that might be derived from that company's successful development and/or commercialization of its approved drugs and drug candidates, unless we were to increase our investment.

Additionally, as previously announced by the Company, Citius Pharma intends to distribute Citius Oncology shares to its stockholders at a yet-to-be-determined date in the future, following the expiration of the six-month lockup period, in accordance with terms of the amended and restated registration rights agreement entered into in connection with the Merger. Following the distribution of the Citius Oncology shares, Citius Pharmaceuticals will not be entitled to any benefits that flow to those shares from the commercialization by Citius Oncology of LYMPHIR or would otherwise be derived from Citius Oncology, based on its ownership as of December 17, 2025.

Because our NoveCite product candidate is based on novel technologies, it is difficult to predict the regulatory approval process and the time, the cost and our ability to successfully initiate, conduct and complete clinical development, and obtain the necessary regulatory and reimbursement approvals, required for commercialization of our NoveCite product candidate.

NoveCite's cell programming technology and platform for generating cell therapy products using allogenic mesenchymal stem cells derived from iPSCs represent novel therapeutic approaches, and to our knowledge there are currently no iPSC-derived cell products approved anywhere in the world for commercial sale. As such, it is difficult to accurately predict the type and scope of challenges that NoveCite may incur during development of its NoveCite product candidate, and it faces uncertainties associated with the preclinical and clinical development, manufacture and regulatory requirements for the initiation and conduct of clinical trials, regulatory approval, and reimbursement required for successful commercialization of its NoveCite product candidate. In addition, because NoveCite's iPSC-derived cell product candidate is in the pre-clinical stage, NoveCite is currently assessing safety in humans and has not yet been able to assess the long-term effects of treatment. Animal models and assays may not accurately predict the safety and efficacy of our product candidate in our target patient populations, and appropriate models and assays may not exist for demonstrating the safety and purity of the NoveCite product candidate, as required by the FDA and other regulatory authorities for ongoing clinical development and regulatory approval.

The pre-clinical and clinical development, manufacture, and regulatory requirements for approval of the NoveCite product candidate may be more expensive and take longer than for other more well-known or extensively studied pharmaceutical or biopharmaceutical product candidates due to a lack of prior experiences on the side of both developers and regulatory agencies. Additionally, due to the uncertainties associated with the pre-clinical and clinical development, manufacture, and regulatory requirements for approval of the NoveCite product candidate, NoveCite may be required to modify or change its pre-clinical and clinical development plans or its manufacturing activities and plans or be required to meet stricter regulatory requirements for approval. Any such modifications or changes could delay or prevent NoveCite's ability to develop, manufacture, obtain regulatory approval for or commercialize its NoveCite product candidate, which would adversely affect NoveCite's and our business, financial condition and results of operations.

Cellular immunotherapies, and stem cell therapies and iPSC-derived cell therapies in particular, represent relatively new therapeutic areas, and the FDA has cautioned consumers about potential safety risks associated with cell therapies. To date, there are relatively few approved cell therapies. As a result, the regulatory approval process for a product candidate such as NoveCite is uncertain and may be more expensive and take longer than the approval process for product candidates based on other, better known or more extensively studied technologies and therapeutic approaches. For example, there are currently no FDA approved products with a label designation that supports the use of a product to treat and reduce the severity of ARDS in patients with COVID-19, which makes it difficult to determine the clinical endpoints and data required to support an application or regulatory approval, and the time and cost required to obtain regulatory approval in the U.S. for our product candidate.

Regulatory requirements in the U.S. governing cell therapy products have changed frequently and the FDA or other regulatory bodies may change the requirements, or identify different regulatory pathways, for approval of the NoveCite product candidate. For example, within the FDA, the Center for Biologics Evaluation and Research ("CBER") restructured and created a new Office of Tissues and Advanced Therapies to better align its oversight activities with FDA Centers for Drugs and Medical Devices. It is possible that over time new or different divisions may be established or be granted the responsibility for regulating cell and/or gene therapy products, including iPSC-derived cell products, such as the NoveCite product candidate. As a result, NoveCite may be required to change its regulatory strategy or to modify its applications for regulatory approval, which could delay and impair its ability to complete the pre-clinical and clinical development and manufacture of, and obtain regulatory approval for, its NoveCite product candidate. Changes in regulatory authorities and advisory groups, or any new requirements or guidelines they promulgate, may lengthen the regulatory review process, require NoveCite to perform additional studies, increase its development and manufacturing costs, lead to changes in regulatory pathways, positions and interpretations, delay or prevent approval and commercialization of the NoveCite product candidate or lead to significant post-approval limitations or restrictions. As NoveCite advances its NoveCite product candidate, NoveCite will be required to consult with the FDA and other regulatory authorities, and its NoveCite product candidate will likely be reviewed by an FDA advisory committee. NoveCite also must comply with applicable requirements, and if it fails to do so, it may be required to delay or discontinue development of its NoveCite product candidate. Delays or unexpected costs in obtaining, or the failure to obtain, the regulatory approval necessary to bring the NoveCite product candidate to market could impair NoveCite's and our ability to generate sufficient product revenues to maintain our respective businesses.

NoveCite has assumed that the biological capabilities of iPSCs and adult-donor derived cells are likely to be comparable. If it is discovered that this assumption is incorrect, the NoveCite product candidate research and development activities could be harmed.

NoveCite anticipates that its research and development for its NoveCite product candidate will involve iPSCs, rather than adult-donor derived cells. With respect to iPSCs, NoveCite believes that scientists are still somewhat uncertain about the clinical utility, life span, and safety of such cells, and whether such cells differ in any clinically significant ways from adult-donor derived cells. If NoveCite discovers that iPSCs will not be useful for whatever reason for its NoveCite product candidate program, this would negatively affect NoveCite's ability to develop a marketable product and it and we may never become profitable, which would have an adverse effect on our respective businesses, prospects, financial condition and results of operations.

Any FDA programs related to the development and approval of treatments for COVID-19 and its symptoms may not be available to us or actually lead to a faster development or regulatory review or approval process for NoveCite, our proposed treatment for ARDS, nor will it assure FDA approval of such a treatment.

In late April 2020, we made a pre-IND submission to the FDA for NoveCite as a treatment for ARDS. The submission was made under the FDA's Coronavirus Treatment Acceleration Program ("CTAP") and we requested the FDA's feedback to support the most expeditious pathway for clinical development of the therapy. The CTAP program is relatively new and the FDA has broad discretion in administering the CTAP program and therefore we cannot assure you what the FDA might decide and whether there would be a faster development process.

Even if we receive regulatory approval to commercialize a product candidate, that product may not gain market acceptance among physicians, patients, healthcare payers or the medical community and may not generate significant revenue.

Even if one of our product candidates obtains regulatory approval, that product may not gain market acceptance among physicians, patients, healthcare payers or the medical community. The indication may be limited to a subset of the population or we may implement a distribution system and patient access program that is limited. Coverage and reimbursement of our product candidates by third-party payers, including government payers, generally is also necessary for commercial success. While LYMPHIR's approval was not so restricted, its acceptance in the marketplace as an effective treatment will depend on various factors as discussed herein. We believe that the degree of market acceptance and our ability to generate revenues from any approved product candidate, such as LYMPHIR, or acquired approved product will depend on a number of factors, including:

- strength of sales, marketing and distribution support;
- potential or perceived advantages or disadvantages over alternative treatments;

- availability of coverage and reimbursement from government and other third-party payers;
- the willingness of patients to pay out of pocket in the absence of government or third-party coverage;
- the relative convenience and ease of administration and dosing schedule;
- prevalence and severity of any side effects;
- price of any future products, if approved, both in absolute terms and relative to alternative treatments;
- the effectiveness of our or any future collaborators' sales and marketing strategies;
- the effect of current and future healthcare laws on any approved products;
- patient access programs that require patients to provide certain information prior to receiving new and refill prescriptions;
- results of any post-approval studies of the product;
- product labeling or product insert requirements of the FDA or other regulatory authorities; and
- requirements for prescribing physicians to complete certain educational programs for prescribing drugs.

Even if approved, any product candidate may fail to achieve market acceptance or generate significant revenue to achieve or sustain profitability, which would harm the Company's business. In addition, our efforts to educate the medical community and third-party payers on the benefits of any product candidate may require significant resources and may never be successful.

Even if approved for marketing by applicable regulatory bodies, we will not be able to create a market for any of our product candidates if we fail to establish marketing, sales, and distribution capabilities, either on our own or through arrangements with third parties.

Our strategy with LYMPHIR (through Citius Oncology) and for our unapproved product candidates is to outsource to third parties all or most aspects of the product development process, as well as much of our marketing, sales, and distribution activities. In order to generate sales of any product candidate that receives regulatory approval, we must either acquire or develop an internal marketing and sales force with technical expertise and with supporting distribution capabilities or make arrangements with third parties to perform these services for us. Currently, we, through Citius Oncology, have developed our sales, marketing and distribution capabilities for LYMPHIR and have contracted with Innovation Partners, a large third-party commercial sales and marketing organization with an existing commercial infrastructure and product launch experience, to assist in our commercialization efforts. In addition, Citius Oncology has entered into distribution agreements with Cardinal Health, Cencora and McKesson Corporation and has contracted with EVERSANA to support the launch and commercialization of LYMPHIR. We do not have any sales, marketing or distribution capabilities with respect to our other product candidates. The acquisition or development of a sales and distribution infrastructure requires substantial resources, which may divert the attention of our management and key personnel and defer our product development efforts. To the extent that we enter into marketing and sales arrangements with other companies for any product candidates, our revenues will depend on the efforts of others. These efforts may not be successful. If we fail to develop and maintain sales, marketing, and distribution channels, or fail to enter into arrangements with third parties or the collaboration is terminated or is otherwise unsuccessful, we will experience delays in product launch and sales and incur increased costs.

Our projections regarding the market opportunity for our LYMPHIR may not be accurate, and the actual market for LYMPHIR may be smaller than we estimate.

Our projections of incidence rate of MF/SS and the people living with CTCL and who have the potential to benefit from treatment with LYMPHIR are based on our beliefs and estimates. These estimates have been derived from a variety of sources, including SEER data from 2001 to 2007, and may prove to be incorrect. The number of patients may turn out to be lower than expected. Additionally, the potentially addressable patient population for LYMPHIR may be limited or may not be amenable to treatment with LYMPHIR and may also be limited by the cost of our treatments for patients, any future increase to such costs, and the reimbursement of those treatment costs by third-party payors. Even if we obtain significant market share for LYMPHIR, because the potential target populations are small, we may never achieve profitability.

Physicians and patients might not accept and use any of our product candidates for which regulatory approval is obtained.

Even with the approval of LYMPHIR, and if the FDA approves one of our other product candidates, physicians and patients might not accept and use it. Acceptance and use of our approved product candidates will depend upon a number of factors, including:

- perceptions by members of the health care community, including physicians, about the safety and effectiveness of any of our product candidates;
- perceptions by members of the health care community, including physicians, about the use of our product candidates versus the then respective standards of care for the disease or problem that we seek to address with our product candidates;
- cost-effectiveness of our product candidates relative to competing products or therapies;
- availability of reimbursement for our product candidates from government or other healthcare payers; and
- effective marketing and distribution efforts by us and/or our licensees and distributors, if any.

If any of our current product candidates are approved, we expect their sales to generate substantially all of our revenues for the foreseeable future, and as a result, the failure of any of these product candidates to find market acceptance would harm our business and would require us to seek additional financing. Prior to the planned distribution of any Citius Oncology shares to our stockholders, we anticipate LYMPHIR will be our only revenue-generating product for the foreseeable future, unless and until we are able to gain approval for another product candidate, namely Mino-Lok.

Our ability to generate product revenues will be diminished if any of our product candidates that may be approved sell for inadequate prices or patients are unable to obtain adequate levels of reimbursement.

Our ability to commercialize our approved product candidates, alone or with collaborators, will depend in part on the extent to which reimbursement will be available from:

- government and health administration authorities;
- private health maintenance organizations (HMOs) and health insurers; and
- other healthcare payers.

Significant uncertainty exists as to the reimbursement status of newly approved healthcare products. Healthcare payers, including Medicare, are challenging the prices charged for medical products and services. Government and other healthcare payers increasingly attempt to contain healthcare costs by limiting both coverage and the level of reimbursement for drugs. Even if our product candidates are approved by the FDA, insurance coverage might not be available, and reimbursement levels might be inadequate, to cover our products. If government and other healthcare payers do not provide adequate coverage and reimbursement levels for our products, once approved, market acceptance of such products could be reduced. We cannot predict whether federal or state legislation will be passed that may impact reimbursement policies nor what the impact of any such legislation would be on the healthcare industry in general or on our business specifically.

We are actively engaged with CMS in order to obtain the necessary coverage to facilitate reimbursement for LYMPHIR. However, we can offer no assurance as to any reimbursement coverage. In February, CMS assigned LYMPHIR a unique, permanent Healthcare Common Procedure Coding System J-code, which is expected to provide coding clarity for physicians and facilities who administer LYMPHIR, thereby facilitating reimbursement. This achievement is a key step in ensuring that LYMPHIR is accessible to patients with commercial and government insurance (VA, DoD, Medicare) coverage.

Health administration authorities in countries other than the U.S. may not provide reimbursement for our products at rates sufficient for us to achieve profitability, or at all. Like the U.S., these countries have considered health care reform proposals and could materially alter their government-sponsored health care programs by reducing reimbursement rates. Any reduction in reimbursement rates under Medicare or foreign health care programs could negatively affect the pricing of our approved product candidates. If we are not able to charge a sufficient amount for our approved product candidates, then our margins and our profitability will be adversely affected.

The FDA and other regulatory agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses.

If we are found to have improperly promoted any off-label use of LYMPHIR or for any product candidates, if approved, or if we are found to have improperly engaged in pre-approval promotion prior to the approval of such product candidates, we may become subject to significant liability. Such enforcement has become more common in the pharmaceutical industry. The FDA and other regulatory agencies strictly regulate the promotional claims that may be made about prescription products, such as LYMPHIR and any product candidates that might be approved. In particular, a product may not be promoted for uses that are not approved by the FDA or such other regulatory agencies as reflected in the product's approved labeling. If the Company receives marketing approval for its product candidates for its proposed indications, physicians may nevertheless use its product for their patients in a manner that is inconsistent with the approved label, if the physicians believe in their professional medical judgment it could be used in such manner. However, if the Company is found to have promoted its product for any off-label uses, the federal government could levy civil, criminal and/or administrative penalties, and seek fines against us. The FDA, Department of Justice or other regulatory authorities could also request that we enter into a consent decree or a corporate integrity agreement, or seek a permanent injunction against us under which specified promotional conduct is monitored, changed or curtailed. If we cannot successfully manage the promotion of LYMPHIR or any product candidates that receive approval, we could become subject to significant liability, which would materially adversely affect our business, financial condition and results of operations.

The markets in which we operate are highly competitive and we might be unable to compete successfully against new entrants or established companies.

Competition in the pharmaceutical and medical products industries is intense and is characterized by costly sales and marketing infrastructures, as well as extensive research efforts and rapid technological progress. We are aware of several pharmaceutical companies also actively engaged in the development of therapies or products for at least some of the same conditions we are targeting. Many of these companies have substantially greater research and development capabilities as well as substantially greater marketing, financial and human resources than we do. In addition, many of these companies have significantly greater experience than us in undertaking pre-clinical testing, clinical trials and other regulatory approval procedures. Our competitors may develop technologies and products that are more effective than those we are researching and developing. Such developments could render our product candidates, if approved, less competitive or possibly obsolete. We are also competing with respect to marketing capabilities and manufacturing efficiency, areas in which we have no current capabilities and in which we have no experience as a company, although our executive officers do have pharmaceutical commercialization and launch experience. We, through Citius Oncology, have contracted with Innovation Partners, a large third-party commercial sales and marketing organization with an existing commercial infrastructure and product launch experience, and with EVERSANA, a large third-party provider of global commercialization services, to assist in our commercial efforts for LYMPHIR. However, our prior experience and our third-party arrangements might not translate into the successful launch of LYMPHIR or any of our product candidates. Mergers, acquisitions, joint ventures and similar events may also significantly increase the competition we face. In addition, new developments, including the development of other drug technologies and methods of preventing the incidence of disease, occur in the pharmaceutical and medical technology industries at a rapid pace. These developments may render our approved products and our product candidates obsolete or noncompetitive. Compared to us, many of our potential competitors have substantially greater as well as access to strategic partners and capital resources.

As a result of these factors, our competitors may obtain regulatory approval of their products more rapidly than we can or may obtain patent protection or other intellectual property rights that limit our ability to develop or commercialize our product candidates. Our competitors might also develop products that are more effective, more useful and less costly than ours and might also be more successful in manufacturing and marketing their products. In addition, our competitors might be more effective than us in commercializing their products and as a result, our business and prospects might be materially harmed.

Healthcare reform measures could hinder or prevent our product candidates' commercial success.

There have been, and the Company expects there will continue to be, a number of legislative and regulatory changes to health care systems in the U.S. and abroad that could impact its ability to sell its products profitably. The U.S. government and other governments have shown significant interest in pursuing healthcare reform. For example, in 2010, the Patient Protection and Affordable Care Act ("ACA") was enacted, which substantially changed the way healthcare is financed by both governmental and private insurers in the U.S. Healthcare reform measures like the ACA may adversely impact the pricing of healthcare products and services in the U.S. or internationally and the amount of reimbursement available from governmental agencies or other third-party payors.

Since its enactment, there have been ongoing efforts to modify the ACA and its implementing regulations. The Company cannot predict what healthcare reform measures may be enacted by the U.S. Congress or implemented by any administration or how such efforts would impact its business. Litigation and legislation over the ACA and other healthcare reform measures are likely to continue, with unpredictable and uncertain results. Further, additional legislative changes to and regulatory changes under or related to the ACA remain possible.

In addition, other legislative changes have been proposed and adopted in the U.S. since the ACA was enacted that impact government health programs. Moreover, payment methodologies may be subject to changes in healthcare legislation and regulatory initiatives. For example, CMS may develop new payment and delivery models, such as bundled payment models. In addition, recently there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several U.S. Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under government payor programs, and review the relationship between pricing and manufacturer patient programs. The Company expects that additional U.S. federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal health care programs and commercial payers will pay for healthcare products and services, which could result in reduced demand for our product candidates, if approved, or additional pricing pressures.

Individual states in the U.S. have also increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. Legally mandated price controls on payment amounts by third party payors or other restrictions could harm our business, financial condition and results of operations. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. Furthermore, there has been increased interest by third party payors and governmental authorities in reference pricing systems and publication of discounts and list prices. These or other reforms could reduce the ultimate demand for our product candidates, if approved, or put pressure on its product pricing.

The Company cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action in the U.S. If the Company or any third parties it may engage are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if the Company or such third parties are not able to maintain regulatory compliance, any approved product candidates may lose any regulatory approval that may have been obtained and we may not achieve or sustain profitability.

We are and will be dependent on third-party contract research organizations to conduct all of our clinical trials.

We are and will be dependent on third-party research organizations to conduct all of our clinical trials with respect to our product candidates, including any candidates that we may develop in the future. If we are unable to obtain any necessary testing services on acceptable terms, we may not complete our product development efforts in a timely or cost-effective manner or at all. If we rely on third parties for human trials, we may lose some control over these activities and become too dependent upon these parties. These third parties may not complete testing activities on schedule or when we so request. We may not be able to secure and maintain suitable research organizations to conduct our human trials. We are responsible for confirming that each of our clinical trials is conducted in accordance with the trial's general plan and protocol. Moreover, the FDA and foreign regulatory agencies require us to comply with regulations and standards, commonly referred to as good clinical practices, for conducting, recording, and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the trial participants are adequately protected. Our reliance on third parties does not relieve us of these responsibilities and requirements. If these third parties do not successfully carry out their contractual duties or regulatory obligations or meet expected deadlines, if the third parties need to be replaced or if the quality or accuracy of the data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements or for other reasons, our preclinical development activities or clinical trials may be extended, delayed, suspended or terminated, and we may not be able to obtain regulatory approval for any of our product candidates.

Any termination, or breach by, or conflict with our strategic partners could harm our business.

If we or any of our current or future collaborators fail to renew or terminate any of our collaboration or license agreements or if either party fails to satisfy its obligations under any of our collaboration or license agreements or complete them in a timely manner, we could have difficulty continuing marketing and sales efforts for LYMPHIR or any other approved product candidate, or completing the development of any of our product candidates and potentially lose significant sources of revenue, which could result in an adverse impact on our operations and financial condition as well as volatility in any future revenue. In addition, our agreements with our collaborators may have provisions that give rise to disputes regarding the rights and obligations of the parties. These and other possible disagreements could lead to termination of the agreement or delays in collaborative research, development, supply, or commercialization of our product candidates, or could require or result in litigation or arbitration. Any such conflicts with our collaborators could reduce our ability to obtain future collaboration agreements and could have a negative impact on our relationship with existing collaborators, adversely affecting our business and revenues. Finally, any of our collaborations may prove to be unsuccessful.

We rely on the significant experience and specialized expertise of our executive management and other key personnel and the loss of any of our executive management or key personnel or our inability to successfully hire their successors could harm our business.

Our performance is substantially dependent on the continued services and on the performance of our executive management and other key personnel, who have extensive experience and specialized expertise in our business. Our Chief Executive Officer, Leonard Mazur, our Vice Chairman, Myron Holubiak, our Chief Financial Officer and Chief Business Officer, Jaime Bartushak, and our Chief Medical Officer and Executive Vice President, Myron Czuczman, in particular have significant experience in the running of pharmaceutical companies and/or drug development itself. This depth of experience is of significant benefit to us, especially given the small size of our management team and our company, including our subsidiaries. The loss of the services of any of Mr. Mazur, Mr. Holubiak, Mr. Bartushak and Dr. Czuczman as well as any other member of our executive management or any key employees, including those at NoveCite or Citius Oncology, could harm our ability to attract capital and develop and commercialize our product candidates. Neither we nor NoveCite nor Citius Oncology has key man life insurance policies.

If we are unable to retain or hire additional qualified personnel, our ability to grow our business might be harmed.

We utilize the services of a clinical management team on a part-time basis to assist us in managing our ongoing Phase 2 and Phase 3 trials and intend to do so for future preclinical and clinical trials. Pursuant to the shared services agreement with Citius Pharma, Citius Oncology utilizes the services of Citius Pharma's management team to assist it in managing the clinical and pre-clinical trials. Pursuant to the amended and restated shared services agreement, Citius Oncology will continue to utilize the services of Citius Pharma employees with expertise in product manufacturing and commercialization for the post-launch support of LYMPHIR. While we believe this will provide us with sufficient staffing for our current and future development efforts, we will need to hire or contract with additional qualified personnel with expertise in preclinical testing, clinical research and testing, government regulation, formulation and manufacturing and sales and marketing in connection with the continued development, regulatory approval and commercialization of our product candidates. We compete for qualified individuals with numerous pharmaceutical and biopharmaceutical companies, universities, and other research institutions.

All but one of Citius Oncology's board members are also directors of Citius Pharma, and the executive officers of Citius Oncology are also employees of Citius Pharma pursuant to the shared services agreement. Citius Oncology expects to rely on these individuals and the other expertise and personnel made available under the shared services agreement for the foreseeable future.

Competition for qualified directors, officers and employees is intense, and we cannot be certain that our retention of these individuals or any search for additional such personnel will be successful. Attracting and retaining qualified personnel will be critical to our success. As a small company with no marketed product and with limited resources, we might not be able to compete with more established entities for the attraction and retention of qualified directors, officers and employees. In addition, we may be unable to attract and retain those qualified officers, directors and members of Board committees required to provide for effective management. If we are unable to attract and retain qualified employees, officers and directors, the management and operation of our business could be adversely affected.

We expect to need to increase the size of our organization to further develop our product candidates, and we may experience difficulties in managing growth.

We will need to manage our anticipated growth and increased operational activity, including as a result of the recent launch by Citius Oncology of LYMPHIR and our continued development of our other product candidates. Our personnel, systems, and facilities currently in place may not be adequate to support this future growth. Our need to effectively execute our growth strategy will require that we:

- maintain and strengthen, as necessary, Citius Oncology's collaborations with third parties for the sales and marketing of LYMPHIR;
- manage our research and development activities and our regulatory trials effectively;
- develop internal sales and marketing capabilities or establish collaborations with third parties with such capabilities for any other product candidates that receive approval;
- commercialize our product candidates that receive approval;
- manage our internal development efforts effectively while complying with our contractual obligations to licensors, licensees, contractors, collaborators and other third parties;
- attract and motivate sufficient numbers of talented employees or consultants; and
- improve our operational, financial and management controls, reporting systems and procedures.

This planned future growth could place a strain on our administrative and operational infrastructure and may require our management to divert a disproportionate amount of its attention away from our day-to-day activities. We may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel, which may result in weaknesses in our infrastructure, and give rise to operational mistakes, loss of business opportunities, loss of employees and consultants and reduced productivity among remaining employees and consultants. We may not be able to make improvements to our management information and control systems in an efficient or timely manner and may discover deficiencies in existing systems and controls. If our management is unable to effectively manage our expected growth, our expenses may increase more than expected, our ability to generate or increase our revenues could be reduced and we may not be able to implement our business strategy. Our future financial performance and our ability to compete effectively will depend, in part, on our ability to effectively manage any future growth.

We are subject to information technology and cyber-security threats which could have an adverse effect on our business and results of operations.

Our business is increasingly dependent on information technology systems, including Internet-based systems, to support our business processes and internal and external communications. We have outsourced significant elements of these systems and our information technology infrastructure and operations to third-party service providers who provide and maintain these systems, maintain proprietary and sensitive information on our behalf, and provide related information technology services that are important to our operations. We and these service providers have taken measures that are designed to ensure the secure and uninterrupted operation of our information technology systems and to protect those systems against cybersecurity threats. For more information on how we manage cybersecurity risk, see *Item 1C -- Cybersecurity* in this Report.

Despite our and our service providers' efforts to protect our information technology systems against cybersecurity threats and other disruptions, we are vulnerable to damage to and disruption of those systems from computer viruses and other malware, natural disasters, terrorism, war, telecommunication and electrical failures, and cyberattacks or cyber intrusions. The risk of a security breach or disruption, particularly through cyberattacks or cyber intrusions by computer hackers, foreign governments, and cyber-terrorists, has increased as the number, intensity, and sophistication of attempted attacks and intrusions from around the world have increased. A security breach or other damage to or disruption of our information technology systems could cause interruptions to our operations, including material disruptions of our product development programs. For example, the loss of data from completed, ongoing, or planned clinical trials could result in delays in our regulatory approval efforts and cause us to incur significant costs to recover or reproduce the data, resulting in lost revenues and delays in further development of our product candidates.

A security breach or other damage to or disruption of our information technology systems could also lead to the loss of trade secrets or other intellectual property, result in the theft of funds or demands for ransom, and lead to the unauthorized exposure of personal information (including sensitive personal information) of our employees, clinical trial patients, customers, and others. We could be required to spend significant financial and other resources to respond to and remedy the damage caused by such an incident, including the costs to recover data or to repair or replace networks and information technology systems, increased cybersecurity protection costs, and increased insurance premiums. If we or our suppliers and/or service providers fail to maintain or protect our information technology systems effectively and in compliance with U.S. and foreign laws, or otherwise to prevent, detect, or control security breaches or other system disruptions, we could also be exposed to government investigations, become subject to lawsuits or other legal proceedings, and experience damage to our reputation, which could have a material adverse effect on our business, prospects, operating results, and financial condition.

We plan to grow and develop our business through acquisitions of or investment in new or complementary businesses, products or technologies, and the failure to manage these acquisitions or investments, or the failure to integrate them with our existing business, could have a material adverse effect on us.

Our business strategy is based on the acquisition of additional product candidates. This is evidenced by our in-licensing of NoveCite in October 2020 and LYMPHIR in September 2021. We might consider opportunities to acquire or invest in other technologies, products and businesses that might enhance our capabilities or complement our current product candidates. Potential and completed acquisitions and strategic investments involve numerous risks, including potential problems or issues associated with the following:

- assimilating the acquired technologies, products, or business operations;
- maintaining uniform standards, procedures, controls, and policies;
- unanticipated costs associated with the acquisition or investment;
- diversion of our management's attention from our preexisting business;
- maintaining or obtaining the necessary regulatory approvals or complying with regulatory standards; and
- adverse effects on existing business operations.

We have no current commitments with respect to any acquisition or investment in other technologies or businesses. We do not know if we will identify other suitable acquisitions, whether we will be able to successfully complete any acquisitions, or whether we will be able to successfully integrate any acquired product, technology or business into our business operations or retain key personnel, suppliers, or collaborators.

Our ability to successfully develop our business through acquisitions will depend on our ability to identify, negotiate, complete, and integrate suitable target businesses or technologies and obtain any necessary financing. These efforts could be expensive and time consuming and might disrupt our ongoing operations. If we are unable to efficiently integrate any acquired business, technology or product into our business operations, our business and financial condition might be adversely affected.

Conflicts of interest may arise from our relationship with Citius Oncology and NoveCite.

As of December 17, 2025, we beneficially owned approximately 77.9% (excluding pre-funded warrants to purchase up to 15,229,358 shares of Citius Oncology common stock in a transaction that closed on December 10, 2025) of the voting power of Citius Oncology (Nasdaq: CTOR) and 75% of the voting power of NoveCite's outstanding common stock and Novellus owns the other 25% of NoveCite. As a result of our partial ownership, our relationship with each of Citius Oncology and NoveCite could give rise to certain conflicts of interest that could have an impact on our, Citius Oncology's and NoveCite's respective research and development programs, business opportunities, and operations generally.

- Even though we utilize different technologies than Citius Oncology or NoveCite, we could find ourselves in competition with either for research scientists, financing and other resources, licensing, manufacturing, and distribution arrangements.

- Each of Citius Oncology and NoveCite will engage for its own business in research and product development programs, investments, and business ventures, and we will not be entitled to participate or to receive an interest in those programs, investments, or business ventures other than to the extent as a stockholder in the subsidiary. Citius Oncology and NoveCite will not be obligated to present any particular research and development, investment, or business opportunity to us, even if the opportunity would be within the scope of our research and development plans or programs, business objectives, or investment policies. These opportunities may include, for example, opportunities to acquire businesses or assets, including but not limited to patents and other intellectual property that could be used by us or by Citius Oncology or NoveCite.

- Each conflict of interest will be resolved by our respective boards of directors in keeping with their fiduciary duties and such policies as they may implement from time to time.

- There is overlap among our board of directors, senior management and research staffs and that of Citius Oncology and NoveCite. All of our directors also serve as directors of Citius Oncology. Two of our directors, Leonard Mazur and Myron Holubiak, also serve as directors of NoveCite. In addition, Myron Holubiak serves as Chief Executive Officer and Jaime Bartushak serves as Chief Financial Officer of each of Citius Pharma, Citius Oncology and NoveCite. These overlapping positions could interfere with the duties owed by such individuals to Citius Pharma.

Risks Related to Our Regulatory and Legal Environment

We might not obtain the necessary U.S. or foreign regulatory approvals to commercialize any current product candidates.

We cannot assure you that we will receive the approvals necessary to commercialize for sale any product candidates we are currently developing or that we may acquire or seek to develop in the future. We will need FDA approval to commercialize our product candidates in the U.S. In order to obtain FDA approval of any product candidate, we must submit to the FDA an NDA or a BLA demonstrating that the product candidate is safe for humans and effective for its intended use. This demonstration requires significant research, pre-clinical studies, and clinical trials. Satisfaction of the FDA's regulatory requirements typically takes many years, depends upon the type, complexity and novelty of the product candidate and requires substantial resources for research, development and testing. We cannot predict whether our research and clinical approaches will result in products that the FDA considers safe for humans and effective for their indicated uses. The FDA has substantial discretion in the product approval process and might require us to conduct additional pre-clinical and clinical testing, perform post-marketing studies or otherwise limit or impose conditions on any additional approvals we obtain. The approval process might also be delayed by changes in government regulation, future legislation or administrative action or changes in FDA policy that occur prior to or during our product candidate's regulatory review. Delays in obtaining regulatory approvals might:

- delay commercialization of, and our ability to derive product revenues from, our product candidates;

- impose costly procedures on us; and

- diminish any competitive advantages that we might otherwise enjoy.

Even if we comply with all FDA requests, the FDA might ultimately reject one or more of our NDAs or BLAs. Even if we are able to obtain regulatory approval for a particular product candidate, the approval might limit the indicated medical uses for the product, limit our ability to promote, sell, and distribute the product, require that we conduct costly post-marketing surveillance, and/or require that we conduct ongoing post-marketing studies. We cannot be sure that we will ever obtain regulatory clearance for any of our product candidates. Failure to obtain FDA approval of one or more of our product candidates could severely undermine our business by leaving us with only one saleable product, LYMPHIR, and therefore with a limited source of revenue, until another product candidate could be developed or obtained and successfully developed, approved and commercialized. Foreign jurisdictions impose similar regulatory approval processes and we will face the same risks if we seek foreign approval for any of our product candidates. There is no guarantee that we will ever be able to successfully develop or acquire any product candidate.

Following any regulatory approval of any product candidate, we will be subject to ongoing regulatory obligations and restrictions, which may result in significant expense and limit our ability to commercialize our other product candidates.

When a product candidate is approved by the FDA or by a foreign regulatory authority, we will be required to comply with extensive regulations for product manufacturing, labeling, packaging, adverse event reporting, storage, distribution, advertising, promotion and record keeping. Regulatory approvals may also be subject to significant limitations on the indicated uses or marketing of the product or to whom and how we may distribute an approved product. Even if U.S. regulatory approval is obtained, the FDA may still impose significant restrictions on a product's indicated uses or marketing or impose ongoing requirements for potentially costly post-approval studies. For example, the label ultimately approved for any of our product candidates, if any, may include restrictions on use. If so, we may be subject to ongoing regulatory obligations and restrictions, which may result in significant expense and limit our ability to commercialize that product candidate. The FDA could also require a registry to track the patients utilizing the product or implement a Risk Evaluation and Mitigation Strategy ("REMS") that could restrict access to the product, which would reduce our revenues and/or increase our costs. Potentially costly post-marketing clinical studies may be required as a condition of approval to further substantiate safety or efficacy, or to investigate specific issues of interest to the regulatory authority. Similar risks apply in foreign jurisdictions.

Manufacturers of pharmaceutical products and their facilities are subject to continual review and periodic inspections by the FDA and other regulatory authorities for compliance with cGMP regulations, which include requirements relating to quality control and quality assurance as well as the corresponding maintenance of records and documentation. Similar regulatory programs exist in foreign jurisdictions. Further, regulatory agencies must approve these manufacturing facilities before they can be used to manufacture an approved product and these facilities are subject to ongoing regulatory inspections. In addition, regulatory agencies subject an approved pharmaceutical product, its manufacturer and the manufacturer's facilities to continual review and inspections. The subsequent discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, may result in restrictions on the marketing of that product, up to and including, withdrawal of the product from the market. If the manufacturing facilities of our suppliers fail to comply with applicable regulatory requirements, it could result in regulatory action and additional costs to us. Failure to comply with applicable FDA and other regulatory requirements may subject us to administrative or judicially imposed sanctions, either before or after product approval, if any.

In addition, the law or regulatory policies governing pharmaceutical products may change. New statutory requirements may be enacted or additional regulations may be enacted that could prevent or delay regulatory approval of our product candidates. CMOs and their vendors or suppliers may also face changes in regulatory requirements from governmental agencies in the U.S. and other countries. We cannot predict the likelihood, nature, extent or effects of government regulation that may arise from future legislation or administrative action, either in the U.S. or elsewhere. If we are not able to maintain regulatory compliance, we might not be permitted to market any future approved products and our business could suffer.

We could be forced to pay substantial damage awards if product liability claims that may be brought against us are successful.

The use of any of our product candidates in pre-clinical and clinical trials, and the sale of any approved products, may expose us to liability claims and financial losses resulting from the use or sale of our product candidates. We have obtained limited product liability insurance coverage for our pre-clinical and clinical trials of $5 million per occurrence and in the aggregate, subject to a deductible of $25,000 per bodily injury and property damage occurrence, and a medical expense per person limit of $25,000. There can be no assurance that our existing insurance coverage will extend to any other product candidates in the future. Any product liability insurance coverage may not be sufficient to satisfy all liabilities resulting from product liability claims. A successful claim may prevent us from obtaining adequate product liability insurance in the future on commercially desirable terms, if at all. Even if a claim is not successful, defending such a claim would be time consuming and expensive, may damage that product's and our reputations in the marketplace, and would likely divert management's attention, any of which could have a material adverse effect on our Company.

Risks Related to Our Intellectual Property

Our business depends on protecting our intellectual property.

Without the intellectual property rights we have already obtained, as well as the further rights we are also pursuing, our competitors would have opportunity to take advantage of our research and development efforts to develop competing products. Our success, competitive position, and future revenues, if any, depend in part on our ability and the abilities of our licensors to obtain and maintain patent protection for our product candidates, methods, processes and other technologies, to preserve our trade secrets, to prevent third parties from infringing on our proprietary rights and to operate without infringing the proprietary rights of third parties. We anticipate filing additional patent applications both in the U.S. and in other countries, as appropriate. However, the patent process is subject to numerous risks and uncertainties, and there can be no assurance that we will be successful in protecting our product candidates by obtaining and defending patents. These risks and uncertainties include the following:

- our patent rights might be challenged, invalidated, or circumvented, or otherwise might not provide any competitive advantage;
- our competitors, many of which have substantially greater resources than we do and many of which might make significant investments in competing technologies, might seek, or might already have obtained, patents that will limit, interfere with, or eliminate our ability to make, use, and sell our product candidates either in the U.S. or in international markets;
- countries other than the U.S. might have less restrictive patent laws than those upheld by U.S. courts, allowing foreign competitors the ability to exploit these laws to create, develop, and market competing products; and
- as a matter of public policy regarding worldwide health concerns, there might be significant pressure on the U.S. government and other international governmental bodies to limit the scope of patent protection both inside and outside the U.S. for product candidates that prove successful.

In addition, the USPTO and patent offices in other jurisdictions have often required that patent applications concerning pharmaceutical and/or biotechnology-related inventions be limited or narrowed substantially to cover only the specific innovations exemplified in the patent application, thereby limiting the scope of protection against competitive challenges. Thus, even if we or our licensors are able to obtain patents, the patents might be substantially narrower than anticipated.

Because the time period from filing a patent application to the issuance, if ever, of the patent is often more than three years and because any regulatory approval and marketing for a pharmaceutical product often occurs several years after the related patent application is filed, the resulting market exclusivity afforded by any patent on our drug candidates and technologies will likely be substantially less than 20 years. For example, the U.S. patent on the original Mino-Lok composition expired in June 2024, and the U.S. patent on the stabilized Mino-Lok composition expires in November 2036. Since we anticipate significant additional time before FDA approval could be obtained, the maximum market exclusivity afforded by the statutory term of the currently issued patents would be less than 10 years. In the U.S., the European Union and some other jurisdictions, patent term extensions are available for certain delays in either patent office proceedings or marketing and regulatory approval processes. However, due to the specific requirements for obtaining these extensions, there is no assurance that our patents will be granted extensions even if we encounter significant delays in patent office proceedings or marketing and regulatory approval.

Additionally, patent law is subject to change and varies among the U.S. and foreign countries. Depending on decisions by the U.S. Congress, the U.S. federal courts, the USPTO or similar authorities in foreign jurisdictions, the laws and regulations governing patents could change in unpredictable ways that may weaken our and our licensors' abilities to obtain new patents or to enforce existing patents that we and our licensors or partners may obtain in the future.

Patent and other intellectual property protection is crucial to the success of our business and prospects, and there is a substantial risk that such protections will prove inadequate. Our business and prospects will be harmed if these protections prove insufficient.

We rely on trade secret protections through confidentiality agreements with our employees and other parties, and the breach of these agreements could adversely affect our business and prospects.

We rely on trade secrets, which we seek to protect, in part, through confidentiality and non-disclosure agreements with our employees, collaborators, suppliers, and other parties. There can be no assurance that these agreements will not be breached, that we would have adequate remedies for any such breach or that our trade secrets will not otherwise become known to or independently developed by our competitors. We might be involved from time to time in litigation to determine the enforceability, scope and validity of our proprietary rights. Any such litigation could result in substantial cost and divert management's attention from our operations.

If we infringe the rights of third parties we might have to forego developing and/or selling any approved products, pay damages, or defend against litigation.

If our product candidates, methods, processes, and other technologies infringe the proprietary rights of other parties, we could incur substantial costs and we might have to:

- obtain licenses, which might not be available on commercially reasonable terms, if at all;
- abandon an infringing product candidate;
- redesign our product candidates or processes to avoid infringement;
- stop using the subject matter claimed in the patents held by others;
- pay damages; and/or
- defend litigation or administrative proceedings which might be costly whether we win or lose, and which could result in a substantial diversion of our financial and management resources.

Any of these events could substantially harm our earnings, financial condition, and operations.

The U.S. government could have "march-in rights" to certain of our intellectual property.

If at any time federal monies are used in support of the research and development activities at MDACC that resulted or in the future result in certain of our issued pending U.S. patent applications, the federal government retains what are referred to as "march-in rights" to patents that are granted on these applications. Our license agreement for Mino-Lok provides that in the event of such governmental funding, our rights are subject to the government's prior rights, if any. In addition, the license agreement provides that we will comply with the requirements of any agreement between MDACC and the governmental funding entity. If applicable, this could require us to grant the U.S. government either a nonexclusive, partially exclusive, or exclusive license to the patented invention in any field of use, upon terms that are reasonable for a particular situation. Circumstances that could trigger march-in rights generally would be set out in the agreement between MDACC and the funding governmental entity and could include, for example, failure to take, within a reasonable time, effective steps to achieve practical application of the invention in a field of use, failure to satisfy the health and safety needs of the public and failure to meet requirements of public use specified by federal regulations. A funding governmental entity could elect to exercise these march-in rights on their own initiative or at the request of a third party; however, the exercise of such march-in rights has been historically rare when the patent holder (or its licensee) is practicing the patent invention although there can be no assurance that such rights would not be exercised. This same risk would apply to any other license into which we enter if the licensor receives government funding for the product candidate that is the subject of the license.

If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition and our business, financial condition and results of operations may be adversely affected.

We have registered a trademark with the USPTO for the marks "LYMPHIR" and "Mino-Lok". These and any other trademarks or trade names we may obtain may be challenged, infringed, diluted, tarnished, circumvented or declared generic or determined to be infringing on other marks. We may not be able to protect our rights to these trademarks and trade names, which we need to build name recognition among potential partners or customers in the markets of interest. At times, competitors or other third parties may adopt similar trade names or trademarks, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement, dilution or tarnishment claims brought by owners of other registered trademarks or trademarks that incorporate variations of our registered or unregistered trademarks or trade names. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively and our business, financial condition and results of operations may be adversely affected. Our efforts to enforce or protect our proprietary rights related to trademarks, trade secrets, domain names, copyrights or other intellectual property may be ineffective and could result in substantial costs and diversion of resources.

Risks Related to the Recently Completed Merger of Citius Oncology

We may be unable to achieve some or all of the benefits that we expect to achieve from the Merger.

The Company believes that separating LYMPHIR into a standalone entity has created two focused standalone public companies that are better positioned to pursue their respective strategic priorities, invest in growth opportunities, and attract new investors. The Company also believes that the Merger will result in significant benefits to our Company and our stockholders as a result of unlocking the value we believe that Citius Oncology will have as a standalone publicly traded company. However, by separating from Citius Pharma, Citius Oncology might be more susceptible to market fluctuations and we may be unable to achieve some or all of the benefits that we expect Citius Oncology to achieve as an independent company in the time we expect, if at all. Further, if the Merger's benefits do not meet the expectations of financial analysts, or due to the other factors discussed in this "*Risk Factors*" section and elsewhere in this report, the market price of both Citius Pharma common stock and Citius Oncology common stock might decline or increase in volatility.

Additionally, as previously announced by the Company, Citius Pharma intends to distribute an undetermined amount of Citius Oncology shares to its stockholders at a yet-to-be-determined date in the future. Following the distribution of any Citius Oncology shares, Citius Pharmaceuticals will be entitled to less of any benefits that flow from the commercialization by Citius Oncology of LYMPHIR or would otherwise be derived from Citius Oncology if it were to remain a majority-owned subsidiary.

A planned distribution by Citius Pharma to its stockholders of shares of Citius Oncology could result in significant tax liability to Citius Pharma and our stockholders.

A planned distribution of Citius Oncology shares to our stockholders would not qualify for non-recognition of gain and loss, and therefore, our stockholders could be subject to tax. Each U.S. holder who received Citius Oncology stock in a distribution would generally be treated as receiving a distribution in an amount equal to the fair market value of Citius Oncology common stock received, which would generally result in (i) a taxable dividend to the stockholder to the extent that stockholder's pro rata share of Citius Pharma's current or accumulated earnings and profits; (ii) a reduction in the stockholder's basis (but not below zero) in Citius Pharma's common stock to the extent the amount received exceeds the stockholder's shares of Citius Pharma's earnings and profits; and (iii) a taxable gain from the exchange of Citius Pharma's stock to the extent the amount received exceeds the sum of the stockholder's share of Citius Pharma's earnings and profits and the stockholder's basis in its Citius Pharma stock.

Citius Pharma will also recognize a taxable gain in an amount up to the fair market value of any distributed Citius Oncology shares in excess of the taxable basis in such distributed shares.

Risks Related to Our Common Stock

Our failure to maintain compliance with Nasdaq's continued listing requirements could result in the delisting of our common stock.

Citius Pharma common stock is currently listed on The Nasdaq Capital Market. In order to maintain this listing, we must satisfy minimum financial and other requirements.

On September 12, 2023, Citius Pharma received a notification letter from 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 (the "Bid Price Rule"). In accordance with Nasdaq Listing Rule 5810(c)(3)(A), a company has a compliance period of 180 calendar days to regain compliance with the Bid Price Rule and may be eligible for a second 180 calendar day extension period for compliance. As the Company did not regain compliance with the Bid Price Rule within the compliance periods, the Company received a delisting determination letter on September 10, 2024. Accordingly, the Company timely requested a hearing before a Nasdaq Hearing Panel ("Panel"). The hearing request automatically stayed any suspension or delisting action pending the hearing and the expiration of any additional extension period granted by the Panel following the hearing. On November 6, 2024, the Company received notification that the Panel, which determined that the Company must be in compliance with the Bid Price Rule by December 3, 2024. On December 18, 2024, following the execution of the Company's reverse stock split, the Company received notification from Nasdaq that it had regained compliance with the Bid Price Rule.

On May 29, 2025, the Company received a second determination letter from Nasdaq notifying the Company that, based upon the closing bid price of the Company's common stock for the prior 33 consecutive business days, the Company was not in compliance with the Bid Price Rule and, pursuant to Nasdaq Listing Rule 5810(c)(3)(A)(iv), the Company was not eligible for any compliance period due to the fact that the Company had effected a reverse stock split during the prior one-year period. The Company timely requested an appeal of Nasdaq's determination, which stayed the suspension and delisting of the Company's common stock pending a the Panel's decision. Prior to the hearing, the Company received written notice of compliance from Nasdaq that for 10 consecutive trading days, from June 20, 2025 to July 3, 2025, the closing bid price of the Company's common stock had been at $1.00 per share or greater, and accordingly, the Company regained compliance with the Bid Price Rule. Nasdaq informed the Company in the compliance notice that it considered this matter closed.

While Citius Pharma intends to maintain compliance in the future, and thus maintain our listing, there can be no assurance that we will be successful and continue to meet all applicable Nasdaq Capital Market requirements in the future.

If Citius Pharma's common stock were to be removed from listing with Nasdaq, it may be subject to the so-called "penny stock" rules. The SEC has adopted regulations that define a "penny stock" to be any equity security that has a market price per share of less than $5.00, subject to certain exceptions, such as any securities listed on a national securities exchange, which is the exception on which we currently rely. For any transaction involving a "penny stock," unless exempt, the rules impose additional sales practice requirements on broker-dealers, subject to certain exceptions. If our common stock were delisted and determined to be a "penny stock," a broker-dealer may find it more difficult to trade our common stock and an investor may find it more difficult to acquire or dispose of our common stock on the secondary market.

If Citius Pharma's common stock is delisted and there is no longer an active trading market for our shares, it may, among other things:

- cause stockholders difficulty in selling Citius Pharma's shares without depressing the market price for the shares or selling the shares at all;
- substantially impair the ability to raise additional funds;
- result in a loss of institutional investor interest and fewer financing opportunities; and/or
- result in potential breaches of representations or covenants of agreements pursuant to which Citius Pharma made representations or covenants relating to compliance with applicable listing requirements. Claims related to any such breaches, with or without merit, could result in costly litigation, significant liabilities and diversion of management's time and attention and could have a material adverse effect on the financial condition, business and results of operations.

A delisting would also reduce the value of Citius Pharma's equity compensation plans, which could negatively impact the ability to retain employees.

The market price of our common stock is highly volatile, and you may lose some or all of your investment.

The market price of our common stock has fluctuated significantly due to a number of factors, some of which are beyond our control, including those factors discussed in this "*Risk Factors"* and *"Risk Factor Summary*" section of this report and many others, such as:

- the Company's cash resources available to successfully commercialize LYMPHIR, including covering the costs of licensing payments, product manufacturing and other third-party goods and services;
- the Company's ability to meet its contractual obligations;
- the ability of the Company to maintain compliance with the Nasdaq continued listing requirements;
- the Company's ability to commercialize its product candidates, if approved and Citius Oncology's ability to successfully commercialize LYMPHIR;
- the level of success and the cost of Company's marketing efforts for LYMPHIR and its other product candidates, if approved;
- the Company's dependence on third parties
- unanticipated serious safety concerns related to the use of its product candidates;
- announcements regarding results of any pre-clinical or clinical trials relating to Company's product candidates;
- adverse regulatory decisions;
- changes in laws or regulations applicable to any product candidates, including but not limited to clinical trial requirements for approvals;
- future issuances of debt or equity securities;

- actual or anticipated fluctuations in the Company's financial condition and operating results, including fluctuations in our quarterly and annual results;
- the Company's inability to establish additional partnerships, the termination of license agreements by our existing partners or announcements by our partners regarding therapeutic candidates competitive with ours;
- the introduction of new technologies or enhancements to existing technology by the Company or others in the industry;
- the recruitment or departure of key scientific or management personnel;
- announcements of significant acquisitions, strategic partnerships, joint ventures or capital commitments by the Company or our competitors;
- the Company's failure to meet the estimates and projections of the investment community or that we may otherwise provide to the public;
- publication of research reports about the Company or our industry, or antibody discovery in particular, or positive or negative recommendations or withdrawal of research coverage by securities analysts;
- changes in the market valuations of similar companies;
- overall performance of the equity markets;
- announcements or actions taken by Citius Oncology, as a majority-owned subsidiary of the Company;
- the planned distribution of shares common stock of Citius Oncology by Citius Pharma;
- sales of shares of common stock by Citius Pharma;
- trading volume of the Company's common stock;
- legal disputes or other developments relating to proprietary rights, including patents, litigation matters and Company's ability to obtain and maintain patent protection of its product candidates, government investigations and the results of any proceedings or lawsuits, including, but not limited to, patent or stockholder litigation;
- significant lawsuits, including patent or stockholder litigation;
- the impact of any natural disasters or public health emergencies;
- general economic, industry and market conditions other events or factors, many of which are beyond the Company's control; and
- changes in accounting standards, policies, guidelines, interpretations or principles.

In addition, in the past, stockholders have initiated Company action lawsuits against biotechnology and biopharmaceutical companies following periods of volatility in the market prices of these companies' stock. Such litigation, if instituted against us, could cause the Company to incur substantial costs and divert our management's attention and resources, which could have a material adverse effect on our business, financial condition and results of operations.

You may experience dilution of your ownership interests because of the future issuance of additional shares of our common stock or securities convertible into common stock.

For the foreseeable future until LYMPHIR generates significant revenue, if at all, we will need to raise capital to finance our operations, including possible acquisitions or strategic transactions. To do so we might be required to issue equity securities, resulting in the dilution of the ownership interests of our present stockholders. We are currently authorized to issue an aggregate of 250,000,000 shares of common stock and 10,000,000 shares of preferred stock. As of September 30, 2025, there were 18,067,744 shares of common stock outstanding, 14,479,372 shares underlying warrants with a weighted average exercise price of $7.41 per share and 839,510 shares underlying options with a weighted average exercise price of $30.09 per share. We may also issue additional shares of common stock or other securities that are convertible into or exercisable for common stock in connection with hiring or retaining employees, or for other business purposes. The future issuance of any such additional shares of common stock or common stock equivalents may create downward pressure on the trading price of our common stock.

Our Certificate of Incorporation allows for our Board to create new series of preferred stock without further approval by our stockholders, which could adversely affect the rights of the holders of the common stock.

Our Board has the authority to issue up to 10,000,000 shares of preferred stock and to fix and determine the relative rights and preferences of any such preferred stock without further stockholder approval. As a result, our Board could authorize the issuance of one or more series of preferred stock that would grant preferential rights to our assets upon liquidation, the right to receive dividend payments before dividends are distributed to the holders of common stock and the right to the redemption of the preferred shares, together with a premium, prior to the redemption of the common stock. In addition, our Board could authorize the issuance of a series of preferred stock that has greater voting power than the common stock or that is convertible into our common stock, which could decrease the relative voting power of the common stock or result in dilution to our existing stockholders. For example, in April 2025, our Board authorized the issuance of Series A preferred stock. Each share of Series A preferred stock carried 1,000,000,000 votes and voted together with the outstanding shares of our common stock as a single class, exclusively with respect to a proposed increase in the authorized shares allowed under our Amended and Restated Articles of Incorporation and were not entitled to vote on any other matter. The Series A preferred stock had no other voting rights, including in respect of any other proposal to stockholders, except as otherwise mandated by applicable law. The Series A preferred stock was not convertible into, or exchangeable for, shares of any other class or series of stock or other securities of the Company. The Series A preferred stock had no rights with respect to any distribution of assets of the Company and was not entitled to receive dividends of any kind. By its terms, the Series A preferred stock was redeemed and retired on June 9, 2025.

We have not paid cash dividends in the past and we do not expect to pay cash dividends in the foreseeable future. Any return on investment may be limited to the capital appreciation, if any, of our common stock.

We have not paid cash dividends on our common stock and we do not anticipate paying cash dividends on our common stock in the foreseeable future. The payment of dividends on our common stock will depend on our earnings, financial condition and other business and economic factors affecting us at such time as the Board may consider relevant. In addition, our ability to pay dividends may be limited by covenants in any future outstanding indebtedness that we may incur. Since we do not intend to pay dividends, a stockholder’s ability to receive a return on such stockholder’s investment will depend on any future appreciation in the market value of the Company’s common stock. There is no guarantee that our common stock will appreciate or even maintain the price at which our stockholders have purchased it.

Provisions in our Amended and Restated Articles of Incorporation, as amended, and under Nevada law could discourage a takeover that stockholders may consider favorable and may lead to entrenchment of management.

Provisions of our articles of incorporation and bylaws may delay or discourage transactions involving an actual or potential change of control or change in our management, including transactions in which stockholders might otherwise receive a premium for their shares, or transactions that our stockholders might otherwise deem to be in their best interests. Therefore, these provisions could adversely affect the price of our common stock. Among other things, these provisions include:

- the authorization of 10,000,000 shares of "blank check" preferred stock, the rights, preferences and privileges of which may be established and shares of which may be issued by our Board of Directors at its discretion from time to time and without stockholder approval;
- limiting the removal of directors by the stockholders;
- allowing for the creation of a staggered Board of Directors;
- eliminating the ability of stockholders to call a special meeting of stockholders; and
- establishing advance notice requirements for nominations for election to the Board of Directors or for proposing matters that can be acted upon at stockholder meetings.

Additionally, Nevada's "combinations with interested stockholders" statutes prohibit certain business "combinations" between certain Nevada corporations and any person deemed to be an "interested stockholder" for two years after such person first becomes an "interested stockholder" unless (i) the corporation's Board of Directors approves the combination (or the transaction by which such person becomes an "interested stockholder") in advance, or (ii) the combination is approved by the Board of Directors and 60% of the corporation's voting power not beneficially owned by the interested stockholder, its affiliates and associates. Furthermore, in the absence of prior approval, certain restrictions may apply even after such two-year period. For purposes of these statutes, an "interested stockholder" is any person who is (x) the beneficial owner, directly or indirectly, of 10% or more of the voting power of the outstanding voting shares of the corporation, or (y) an affiliate or associate of the corporation and at any time within the two previous years was the beneficial owner, directly or indirectly, of 10% or more of the voting power of the then outstanding shares of the corporation. The definition of the term "combination" is sufficiently broad to cover most significant transactions between the corporation and an "interested stockholder". Subject to certain timing requirements set forth in the statutes, a corporation may elect not to be governed by these statutes. We have not included any such provision in our articles of incorporation.

We are not currently subject to Nevada's "acquisition of controlling interest" statutes that contain provisions governing the acquisition of a controlling interest in certain Nevada corporations. If these laws were to apply to us, they might further discourage companies or persons interested in acquiring a significant interest in or control of the Company, regardless of whether such acquisition may be in the interest of our stockholders.

The effect of these statutes may be to potentially discourage parties interested in taking control of the Company from doing so if it cannot obtain the approval of our Board of Directors.

Item 1B. Unresolved Staff Comments

Not applicable.

Item 1C. Cybersecurity

Risk Management and Strategy

The Company has established processes to assess, identify, and manage risks from cybersecurity threats as part of our broader enterprise-wide risk management system and processes, which is overseen by our Board through our Audit Committee, along with our executive management.

Our cybersecurity program focuses on all areas of our business, including cloud-based environments, devices used by employees and contractors, facilities, networks, applications, vendors, disaster recovery, business continuity and controls and safeguards enabled through business processes and tools. We continuously monitor for unauthorized access to our information technology systems and identify potential security threats through various automated detection solutions. To protect the security of our information infrastructure and protect our systems and information from unauthorized access, we draw on the knowledge and insights of an external information technology consultant who acts as our primary IT administrator and employ an array of third-party tools and technologies. As part of its oversight, the Audit Committee also oversees and identifies risks from cybersecurity threats associated with our use of an external information technology consultant, as well cybersecurity threats posed by our engagement of other similar third-party providers.

As of the date of this Annual Report, we have not encountered any risks from cybersecurity threats that have materially affected or are reasonably likely to materially affect the Company, including its business strategy, results of operations, or financial condition. For more information on our cybersecurity related risks, see "*Risk Factors - Risks Related to Our Business and Our Industry"* included elsewhere in this Annual Report on Form 10-K.

Governance

The Board is responsible for overseeing our enterprise risk management program. The Audit Committee of the Board has been designated by the Board to oversee cybersecurity risks and our processes to identify, prioritize, assess, manage, and mitigate those risks. The Audit Committee receives updates on cybersecurity and information technology matters and related risk exposures from our Chief Financial Officer.

The Chief Financial Officer oversees the operation of our cybersecurity program and has over 10 years of executive experience overseeing risk management and internal controls. The Chief Financial Officer is informed about and monitors the prevention, detection, mitigation, and remediation of cybersecurity incidents through the Chief Financial Officer's oversight of the Company's information technology function and supervision of the Company's IT administrator.

Item 2. Properties

We lease our offices at 11 Commerce Drive, First Floor, Cranford, New Jersey 07016. The lease runs until February 28, 2030.

Item 3. Legal Proceedings

We are not involved in any litigation that we believe could have a material adverse effect on our financial position or results of operations. There is no action, suit, proceeding, inquiry, or investigation before or by any court, public board, government agency, self-regulatory organization or body pending or, to the knowledge of our executive officers, threatened against or affecting our Company or our officers or directors in their capacities as such.

In the future, we might from time to time become involved in litigation relating to claims arising from our ordinary course of business.

Item 4. Mine Safety Disclosures

Not applicable.

PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities

The information regarding our equity compensation plans required by this Item is found in Item 12 of this report.

Market Information

Our common stock trades on The Nasdaq Capital Market under the symbol "CTXR."

Holders of Common Stock

Based upon information furnished by our transfer agent, as of December 17, 2025, we had approximately 90 stockholders of record of our common stock. However, because many of the shares of our common stock are held by brokers and other institutions on behalf of stockholders, we believe there are substantially more beneficial holders of our common stock than record holders.

Dividends

We have never paid dividends on our common stock. We intend to follow a policy of retaining earnings, if any, to finance the growth of our business and do not anticipate paying any cash dividends in the foreseeable future. The declaration and payment of future dividends on the common stock will be at the sole discretion of our Board and will depend on our profitability and financial condition, capital requirements, statutory and contractual restrictions, future prospects and other factors deemed relevant by the Board.

Recent Sales of Unregistered Securities

On December 2, 2025, in consideration for the Pagoda Note Amendment (as defined below), we issued to Pagoda Resources, Inc. ("Pagoda") a warrant to purchase 75,000 shares of our common stock. The warrant has a five-year term commencing on the date of issuance and an exercise price equal to the closing price of our common stock on Nasdaq on the date of issuance, which was $1.26 per share.

During the year ended September 30, 2025, we did not issue or sell any unregistered securities not previously disclosed in a Quarterly Report on Form 10-Q or in a Current Report on Form 8-K, except for the following: On July 1, 2025, we issued 20,000 shares of common stock for media, and public and investor relations services and on October 14, 2025, we issued an aggregate of 83,036 shares of common stock for investor relations services. The issuance of the shares was exempt from registration under Section 4(a)(2) of the Securities Act of 1933, as amended.

Issuer Purchases of Equity Securities

We did not make any purchases of our common stock during the three months ended September 30, 2025, which is the fourth quarter of our fiscal year.

Item 6. [Reserved]

Item 7. 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 should be read together with our financial statements and related notes included elsewhere in this annual report on Form 10-K. Management's discussion and analysis contains forward-looking statements, such as statements of our plans, objectives, expectations, and intentions. Any statements that are not statements of historical fact are forward-looking statements. When used, the words "believe," "plan," "intend," "anticipate," "target," "estimate," "expect" and the like, and/or future tense or conditional constructions ("will," "may," "could," "should," etc.), or similar expressions, identify these forward-looking statements. These forward-looking statements are subject to risks and uncertainties including those under "Risk Factors" in Item 1A in this Form 10-K that could cause actual results or events to differ materially from those expressed or implied by the forward-looking statements. Our actual results and the timing of events could differ materially from those anticipated in these forward-looking statements as a result of several factors. We do not undertake any obligation to update forward-looking statements to reflect events or circumstances occurring after the filing date of this report.

Business

We are a biopharmaceutical company dedicated to the development and commercialization of first-in-class critical care products. On September 12, 2014, we acquired Citius Pharmaceuticals, LLC as a wholly-owned subsidiary. Citius Pharmaceuticals, LLC was dissolved on December 29, 2023.

On March 30, 2016, we acquired all of the outstanding stock of Leonard-Meron Biosciences, Inc. 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., of which we own 75% of the issued and outstanding capital stock.

On August 23, 2021, we formed Citius Acquisition Corp., or SpinCo, as a wholly-owned subsidiary in conjunction with the acquisition of LYMPHIR, but Citius Acquisition did not begin operations until April 2022, when Citius Pharma transferred to it the assets related to LYMPHIR, including the related license agreement with Eisai and the related asset purchase agreement with Dr. Reddy's Laboratories SA, a subsidiary of Dr. Reddy's. At this time, Citius Acquisition changed its name to Citius Oncology, Inc. In August 2024, as part of the merger, the new publicly-traded company and majority-owned subsidiary was named Citius Oncology, Inc.

In-process research and development of $19,400,000 represents the 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. 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. In-process research and development of $73,400,000 represents the value of our exclusive license for LYMPHIR (denileukin diftitox), a late-stage oncology immunotherapy for the treatment of 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 in December 2025.

Through September 30, 2025, we have devoted substantially all our efforts to product development, raising capital, building infrastructure through strategic alliances and coordinating activities relating to our proprietary products. We have not yet realized any revenues from our operations.

Reverse Stock Split

Effective November 25, 2024, we executed a reverse stock split of our common stock, at a ratio of 1-for-25. All share amounts have been retroactively adjusted to reflect the split.

Patent and Technology License Agreements

Mino-Lok® – LMB has a patent and technology license agreement with Novel Anti-Infective Therapeutics, Inc. ("NAT") to develop and commercialize Mino-Lok on an exclusive, worldwide sub-licensable basis, as amended. Since May 2014, LMB has paid an annual maintenance fee, which began at $30,000 and has increased over five years to $90,000, where it will remain until the commencement of commercial sales of a product subject to the license. LMB will also pay annual royalties on net sales of licensed products, with royalties ranging from the mid-single digits to the low double 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.

NoveCite – On October 6, 2020, our subsidiary NoveCite entered into a license agreement with Novellus Therapeutics Limited, whereby NoveCite acquired an exclusive, worldwide license, with the right to sublicense, to develop and commercialize a stem cell therapy based on Novellus'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 $5,000,000 to Novellus and issued Novellus 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.

In July 2021, Novellus was acquired by Brooklyn ImmunoTherapeutics. 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.

As part of the Novellus and Brooklyn merger transaction, the 25% non-dilutive position per the subscription agreement between Novellus and NoveCite was removed.

Under the license agreement, NoveCite is obligated to pay Novellus 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 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 an amount equal to a mid-twenties percentage of any sublicensee fees it receives.

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

LYMPHIR – In September 2021, the Company entered into an asset purchase agreement with Dr. Reddy's and a license agreement with Eisai to acquire an exclusive license of E7777 (denileukin diftitox), an oncology immunotherapy for the treatment of CTCL, a rare form of non-Hodgkin lymphoma. Citius Pharma assigned these agreements to SpinCo effective April 1, 2022. We renamed E7777 as I/ONTAK and also obtained the trade name LYMPHIR™ for the product. Denileukin diftitox is referred to in this annual report as E7777, I/ONTAK or LYMPHIR, depending on the period of time and context that is being discussed.

Under the terms of these agreements, Citius Pharma acquired Dr. Reddy's exclusive license of E7777 from Eisai and other related assets owned by Dr. Reddy's (which are now owned by Citius Oncology). The exclusive license includes rights to develop and commercialize E7777 in all markets except for Japan and certain parts of Asia. Eisai retains exclusive development and marketing rights for the agent in Japan, China, Korea, Taiwan, Hong Kong, Macau, Indonesia, Thailand, Malaysia, Brunei, Singapore, India, Pakistan, Sri Lanka, Philippines, Vietnam, Myanmar, Cambodia, Laos, Afghanistan, Bangladesh, Bhutan, Nepal, Mongolia, and Papua New Guinea. Citius Pharma paid Dr. Reddy's a $40 million upfront payment which represents the acquisition date fair value of the in-process research and development acquired. 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. Citius Oncology 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. Citius Oncology will also pay 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. Citius Pharma is a guarantor of Citius Oncology's payment obligations under these agreements.

At the time of the FDA approval for LYMPHIR, a $27.5 million milestone payment became payable to Dr. Reddy's under the terms of the asset purchase agreement for which a balance of $19.75 million remains due as of September 30, 2025. Dr. Reddy's agreed to a partial deferral without penalty of this milestone payment.

Under the license agreement, Eisai was due a $5.9 million milestone payment, upon FDA approval, of which $2.9 million remains payable at September 30, 2025, and additional commercial milestone payments related to the achievement of net product sales thresholds and an aggregate of up to $22 million related to the achievement of net product sales thresholds. Citius Oncology was required to reimburse Eisai for up to $2.65 million of its costs to complete the Phase 3 pivotal clinical trial for LYMPHIR for the CTCL indication and reimburse Eisai for all reasonable costs associated with the preparation of a BLA for LYMPHIR. Eisai was responsible for completing the CTCL clinical trial, and CMC activities through the filing of the BLA for LYMPHIR with the FDA. Citius Oncology is responsible for development costs associated with potential additional indications.

On March 28, 2025, Citius Oncology and Eisai entered into a letter agreement that amended the license agreement to provide for a payment schedule to Eisai for the milestone payment and certain unpaid invoices. Citius Oncology agreed to pay Eisai on or before July 15, 2025, an aggregate amount of $2,535,318 and thereafter on the 15th of each of the next four months to pay Eisai $2.35 million and make a final payment of $2,197,892 to Eisai on or before December 15, 2025, in each case with interest on each obligation from its original due date through the date of actual payment under the letter agreement at the rate of 2% per annum. During the year ended September 30, 2025, Citius Oncology recorded $218,032 in interest expense under the agreement. The parties released each other from any and all claims, losses, damages, costs and expenses that arise from or related to our failure to pay the milestone payment or the other incurred costs under the license agreement except for any claims arising out of a breach of the letter agreement. All other terms of the license agreement remain in full force and effect. During the year ended September 30, 2025 Citius Oncology paid $3 million of the development milestone and the balance of $2.9 million is included in license fee payable at September 30, 2025. On July 21, 2025, Citius Oncology made a payment to Eisai of $1,616,522 for other invoices and accumulated interest associated with the letter agreement.

The term of the license agreement will continue until (i) March 30, 2026, if there has not been a commercial sale of a licensed product in the territory, or (ii) if there has been a commercial sale of a licensed product in the territory by March 30, 2026, the 10-year anniversary of the first commercial sale on a country-by-country basis. We expect the first commercial sale to occur in the first quarter of 2026. 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.

Under the purchase agreement with Dr. Reddy's, we are required to (i) use commercially reasonable efforts to make commercially available products in the CTCL indication, peripheral T-cell lymphoma indication and immuno-oncology indication, (ii) initiate two investigator initiated immuno-oncology trials (both of which have been initiated), (iii) use commercially reasonable efforts to achieve each of the approval milestones, and (iv) to 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; the launch of LYMPHIR in December 2025 satisfied this requirement in the U.S.

Specialty Distribution Agreements

In 2025, the Company executed three service agreements with pharmaceutical wholesalers to provide distribution of its LYMPHIR product to healthcare organizations which include academic centers, community oncology practices, as well as infusion centers.

RESULTS OF OPERATIONS

Year ended September 30, 2025 compared to year ended September 30, 2024

	Year Ended September 30, 2025	Year Ended September 30, 2024
Revenues	$ -	$ -
Operating expenses:		
Research and development	9,156,474	11,906,601
General and administrative	18,532,843	18,249,402
Stock-based compensation – general and administrative	10,836,291	11,839,678
Total operating expenses	38,525,608	41,995,681
Operating loss	(38,525,608)	(41,995,681)
Interest income	110,081	758,000
Interest expense	(267,782)	-
Gain on sale of New Jersey net operating losses	-	2,387,842
Loss before income taxes	(38,683,309)	(38,849,839)
Income tax expense	1,056,960	576,000
Net loss	$ (39,740,269)	$ (39,425,839)

Revenues

We did not generate any revenues for the years ended September 30, 2025 or 2024. Revenue commenced in December 2025.

Research and Development Expenses

For the year ended September 30, 2025, research and development expenses were $9,156,474 as compared to $11,906,601 during the year ended September 30, 2024, a decrease of $2,750,127.

Research and development costs for LYMPHIR were $8,328,588 during the year ended September 30, 2025 as compared to $5,118,977 for the year ended September 30, 2024. The $3,209,611 increase in expenses was primarily due to costs associated with the expense of a drug substance batch needed for the pre-license inspection of the manufacturer.

Research and development costs for Mino-Lok decreased by $3,863,984 to $798,984 for the year ended September 30, 2025 as compared to $4,662,968 for the year ended September 30, 2024, due primarily to decreased costs since the completion of the Phase 3 trial and subsequent shutdown costs. In November 2024, the Company held a Type C meeting with the FDA to discuss the results of the Phase 3 study and to obtain the FDA's view on development plans for Mino-Lok. The FDA provided clear, constructive, and actionable guidance during the discussion, underscoring a pathway to support a future an NDA submission for Mino-Lok.

Research and development costs for Halo-Lido decreased by $493,084 to $14,690 for the year ended September 30, 2025 as compared to $507,774 for the year ended September 30, 2024 due to lower costs since the completion of the Phase 2 study in April 2023. Citius subsequently met with the FDA for an end of Phase 2 meeting to discuss the next steps in the clinical development program.

We expect that research and development expenses will continue to decrease in fiscal 2026 as we continue to focus on the commercialization of LYMPHIR and because we have completed the Phase 3 trial for Mino-Lok.

General and Administrative Expenses

For the year ended September 30, 2025, general and administrative expenses were $18,532,843 as compared to $18,249,402 for the year ended September 30, 2024. General and administrative expenses increased by $283,441 in comparison with the prior period. The primary reason for the increase were higher costs for pre-launch commercial 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 year ended September 30, 2025, stock-based compensation expense was $10,836,291 as compared to $11,839,678 for the year ended September 30, 2024. Stock-based compensation expense includes $2,515,872 for stock options under the Citius Pharma stock plans, $8,116,678 for stock options and $203,741 for restricted stock awards under the Citius Oncology stock plans for the year ended September 30, 2025. Stock-based compensation expense includes $4,293,287 for stock options under the Citius Pharma stock plans, $7,498,817 for stock options under the Citius Oncology stock plans, and $47,574 for stock options under the NoveCite Stock plan for the year ended September 30, 2024. Stock-based compensation expense for the year ended September 30, 2025 decreased by $1,003,387 in comparison to the prior period primarily due to lower costs for the Citius Pharma stock plans.

Other Income (Expense)

Interest income for the year ended September 30, 2025 was $110,081 as compared to interest income of $758,000 for the prior period. The decrease is due to lower average investable balances of the remaining proceeds of our equity offerings in money market accounts.

Interest expense of $267,782 for the year ended September 30, 2025 consists of $218,032 in interest expense under the payment agreement with Eisai and $49,750 in interest expense on the note payable.

Other income for the year ended September 30, 2024 included a gain of $2,387,842 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 $1,056,960 and $576,000 for the years ended September 30, 2025 and 2024, respectively. Deferred income tax expense is related to the amortization for taxable purposes of our in-process research and development asset.

Net Loss

For the year ended September 30, 2025, we incurred a net loss of $39,740,269, compared to a net loss for the year ended September 30, 2024 of $39,425,839. The $314,430 increase in the net loss was primarily due to the increase of $283,441 in general and administrative expenses, the decrease in other income (expense) of $3,303,543 partially offset by lower research and development expense of $2,750,127 and lower stock-based compensation expense of $1,003,387.

LIQUIDITY AND CAPITAL RESOURCES

Liquidity and Working Capital

Citius Pharma has incurred operating losses since inception and incurred net losses of $39,740,269 and $39,425,839 for the years ended September 30, 2025 and 2024, respectively. At September 30, 2025, Citius Pharma had an accumulated deficit of $238,804,129. Citius Pharma's net cash used in operations during the years ended September 30, 2025 and 2024 was $26,552,738 and $28,201,375, respectively.

The Company had working capital of approximately ($16,980,000) at September 30, 2025. At September 30, 2025, Citius Pharma had cash and cash equivalents of approximately $4,252,000 available to fund its operations. The Company's only source of cash flow since inception has been from financing activities.

During the years ended September 30, 2025 and 2024, the Company received net proceeds of $32,329,748 and $13,803,684, respectively from the issuance of equity.

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.

After giving effect to a $6.0 million capital raise by us in October 2025 and an $18.0 million capital raise by Citius Oncology in December 2025, we expect that we will have sufficient funds to continue our operations through March 2026.

Financing Activities

In the quarter ended December 31, 2023, the Company was selected to participate in New Jersey's Technology Business Tax Certificate Transfer (NOL) Program and received $2,387,842 million in non-dilutive capital through the New Jersey Economic Development Authority in March 2024.

On April 30, 2024, Citius Pharma sold 857,143 shares of common stock and warrants to purchase 857,143 shares, at $17.50 per share and accompanying warrant for gross proceeds of $15,000,002. The warrants have an exercise price of $18.75 per share, are exercisable six months after issuance, and expire on October 30, 2029.

During the year ended September 30, 2024, Citius Pharma sold 18,168 shares for gross proceeds of $252,140 under its at the market offering agreement.

On November 15, 2024, Citius Pharma sold 480,000 shares of common stock and warrants to purchase 480,000 shares at $6.25 per share for gross proceeds of $3,000,000. The immediately exercisable warrants have an exercise price of $6.25 per share and expire on November 19, 2029.

On January 7, 2025, Citius Pharma sold 743,496 shares of common stock and warrants to purchase 743,496 shares at $4.035 per share for gross proceeds of $3,000,000. The immediately exercisable warrants have an exercise price of $3.91 per share and expire on January 8, 2030.

On April 1, 2025, Citius Pharma sold 465,000 shares of common stock, and pre-funded warrants to purchase 1,274,131 shares at offering prices of $1.15 per share and $1.1499 per pre-funded warrant for gross proceeds of $1,999,873. The immediately exercisable pre-funded warrants have an exercise price of $0.0001 per share and do not expire. All of the pre-funded warrants were exercised during the year ended September 30, 2025.

On June 11, 2025, Citius Pharma sold 540,000 shares of common stock at $1.22 per share, sold pre-funded warrants to purchase 4,380,000 shares at $1.2199 per share, and issued immediately exercisable two-year warrants to purchase 9,840,000 shares at $1.00 per share. for gross proceeds of $6,001,962. The pre-funded warrants are exercisable immediately at $0.0001 per share and do not expire. During the year ended September 30, 2025 all of the pre-funded warrants were exercised.

On July 17, 2025, Citius Oncology sold 6,818,182 shares of common stock and warrants to purchase 6,818,182 shares at a unit price of $1.32 for gross proceeds of $9,000,000. The immediately exercisable five-year warrants have an exercise price of $1.32 per share.

On September 10, 2025, Citius Oncology sold 5,142,858 shares of common stock and warrants to purchase 5,142,858 shares at a unit price of $1.75 for gross proceeds of $9,000,000. The warrants are exercisable at $1.84 per share beginning on March 10, 2026 and expire on March 10, 2031.

During the year ended September 30, 2025, Citius Pharma sold 2,917,874 shares for gross proceeds of $4,968,618 under its at-the-market offering facility.

On October 21, 2025, Citius Pharma sold 3,973,510 shares of common stock (or pre-funded warrants in lieu thereof) and accompanying warrants to purchase 3,973,510 shares of common stock at a combined per unit price of $1.51 per share for gross proceeds of $6,000,000. The immediately exercisable five-year warrants have an exercise price of $1.40 per share.

We need to obtain substantial additional financing in order to satisfy our outstanding milestone payment obligations, as well as meet minimum purchase commitments under our agreements for the manufacture and supply of our drug product, and cannot be sure that any additional funding will be available on terms favorable to us, or at all. As of September 30, 2025, our outstanding milestone payments and purchase commitments for 2025 include:

- On March 28, 2025, we entered into a letter agreement to pay Eisai on or before July 15, 2025, $2,535,318 and thereafter on the 15th of each of the next four months $2,350,000 and make a final payment of $2,197,892 to Eisai on or before December 15, 2025, in each case with interest on each obligation from its original due date at the rate of 2% per annum. As of September 30, 2025, we owe a balance of $2,900,000 for the milestone approval fee and $6,697,892 for certain other invoices.

- At the time of the FDA approval for LYMPHIR, a $27.5 million milestone payment became payable to Dr. Reddy's of which a balance of $19.75 million remains due as of September 30, 2025. Dr. Reddy's has agreed to a partial deferral without penalty of this milestone payment.

- We entered into an agreement with a contract manufacturing organization for the manufacture and supply of drug substance. Under this agreement, we are obligated to purchase minimum annual quantities of batches at a set price per batch, subject to annual increases. As of September 30, 2025, the total minimum purchase commitment under this agreement was approximately $16.2 million, consisting of payments of $8.5 million and $5.3 million for calendar years 2025 and 2026, respectively and $2.4 million for 2026 pass-throughs and consumable manufacturing components.

- As of September 30, 2025, the Company also has commercial supply agreements with two other vendors for the completion and packaging of finished drug products. Minimum purchase commitments under these two agreements are approximately $4.9 million consisting of purchase commitment obligations of $1.2 million in calendar years 2025 and $1.9 million in 2026 and $1.8 million in 2027.

Based on our cash and cash equivalents at September 30, 2025 and our October 21, 2025 equity sale and the December 2025 equity sale by Citius Oncology, we expect that we will have sufficient funds to continue our operations through March 2026. We will need to raise additional capital in the future to support our operations beyond March 2026. 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

Our discussion and analysis of our financial condition and results of operations is based on our financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities and expenses and related disclosure of contingent assets and liabilities. We review our estimates on an ongoing basis. We base our estimates on historical experience and on various other factors that we believe to be reasonable under the circumstances. Actual results may differ from these estimates. We believe the judgments and estimates required by the following accounting policies to be critical in the preparation of our financial statements.

In-process Research and Development

The Company reviews intangible assets annually to determine if any adverse conditions exist or a change in circumstances has occurred that would indicate impairment or a change in the remaining useful life of any intangible asset. If the carrying value of an asset exceeds its undiscounted cash flows, the Company writes down the carrying value of the intangible asset to its fair value for the period identified. No impairments have occurred since the acquisitions of our intangible assets through September 30, 2025.

The Company capitalizes intangible assets purchased from others for use in research and development activities as In Process Research & Development (IPR&D) when the assets acquired have an alternative future use, the Company anticipates future economic benefit from that use and the assets acquired are not dependent on future development. Milestone payments upon regulatory approval that meet the same criteria are capitalized when the payments are considered recoverable based on expected future cash flows. Amortization of IPR&D over the exclusive regulatory period of the acquired asset commences upon revenue generation.

In-process research and development includes $19,400,000 representing the value of LMB's drug candidate, Mino-Lok, an antibiotic lock solution in Phase 3 clinical development, which if approved, would be 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. In-process research and development also includes $73,400,000 representing the value of Citius Oncology's exclusive license for LYMPHIR (denileukin diftitox), an oncology immunotherapy for the treatment of CTCL, a rare form of non-Hodgkin lymphoma and is expected to be amortized on a straight-line basis over a period of 12 years commencing upon revenue generation. Citius Oncology's In-process research and development consists of $40,000,000 paid to Dr. Reddy's from the asset purchase agreement and approval milestone fees of $27,500,000 to Dr. Reddy's and $5,900,000 to Eisai.

Incremental costs incurred on IPR&D after the acquisition date are expensed as incurred, unless there is an alternative future use.

Goodwill

Goodwill represents the value of LMB's industry relationships and its assembled workforce. Goodwill will not be amortized and will be tested at least annually for impairment.

The Company evaluates the recoverability of goodwill annually or more frequently if events or changes in circumstances indicate that the carrying value of an asset might be impaired, in accordance with Accounting Standard Update ("ASU") 2017-04, *Intangibles – Goodwill and Other (Topic 350): Simplifying the Accounting for Goodwill Impairment*. Goodwill is first qualitatively assessed to determine whether further impairment testing is necessary. Factors that management considers in this assessment include macroeconomic conditions, industry and market considerations, overall financial performance (both current and projected), changes in management and strategy and changes in the composition or carrying amount of net assets. If this qualitative assessment indicates that it is more likely than not that the fair value of a reporting unit is less than its carrying amount, a one-step test is then performed in accordance with ASU 2017-04. Under the simplified model, a goodwill impairment is calculated as the difference between the carrying amount of the reporting unit and its fair value.

For its 2025 goodwill analysis, the Company performed a quantitative assessment as of September 30, 2025. Based on this analysis, management concluded that the estimated fair value of the reporting unit exceeded its carrying amount. Accordingly, no impairment charge was recorded, and goodwill continues to be carried at its current value.

Stock-Based Compensation

The Company recognizes compensation costs resulting from the issuance of stock-based awards to employees and directors as an expense in the consolidated statement of operations over the requisite service period based on the fair value for each stock award on the grant date. The fair value of each option grant is estimated as of the date of grant using the Black-Scholes option pricing model. The Company estimates volatility using the trading activity of its common stock. Because the Company's stock options have characteristics significantly different from those of traded options, and because changes in the input assumptions can materially affect the fair value estimate, the existing model may not necessarily provide a reliable single measure of fair value of the Company's stock options.

The Company recognizes compensation costs resulting from the issuance of stock-based awards to non-employees as an expense in the consolidated statement of operations over the service period based on the measurement of fair value for each stock award and records forfeitures as they occur.

Income Taxes

We follow accounting guidance regarding the recognition, measurement, presentation, and disclosure of uncertain tax positions in the financial statements. Tax positions taken or expected to be taken in the course of preparing our tax returns are required to be evaluated to determine whether the tax positions are "more-likely-than-not" of being sustained by the applicable tax authorities. Tax positions not deemed to meet a more-likely-than-not threshold would be recorded in the financial statements.

We recognize deferred tax assets and liabilities based on differences between the financial reporting and tax basis of assets and liabilities using the enacted tax rates and laws that are expected to be in effect when the differences are expected to reverse. We provide a valuation allowance for deferred tax assets for which we do not consider realization of such assets to be more likely than not.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

Not required.

Item 8. Financial Statements and Supplementary Data

See the financial statements included in this report beginning on page F-1.

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure

None.

Item 9A. Controls and Procedures

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 September 30, 2025, the end of our fiscal year. 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 September 30, 2025, 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.

Management's Annual Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining effective internal control over financial reporting as defined in Rule 13a-15(f) under the Exchange Act. Because of its inherent limitations, internal control over financial reporting is not intended to provide absolute assurance that a misstatement of our financial statements would be prevented or detected. Under the supervision of our Chief Executive Officer and Chief Financial Officer, the Company conducted an evaluation of the effectiveness of our internal control over financial reporting as of September 30, 2025 using the criteria established in Internal Control-*Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission ("COSO") (2013 Framework).

Based on this evaluation, management has concluded that our internal controls were effective and that we maintained effective controls over our financial reporting as of September 30, 2025.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risks that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Changes in Internal Controls over Financial Reporting

There were no changes in our internal controls over financial reporting during the fourth quarter of fiscal 2025 that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Attestation Report of Registered Public Accounting Firm

Our independent registered public accounting firm has not assessed the effectiveness of our internal control over financial reporting and, under SEC rules, will not be required to provide an attestation report on the effectiveness of our internal control over financial reporting so long as we qualify as a "non-accelerated filer".

Item 9B. Other Information.

On December 2, 2025, we approved and entered into an amendment (the "Pagoda Note Amendment") to our existing unsecured promissory note with Pagoda. The original note provided for aggregate principal of $1,000,000, bore interest at a per annum rate of 15.00% compounded monthly (or such lesser rate as the maximum permitted by applicable law), and was scheduled to mature on December 2, 2025. Pursuant to the Pagoda Note Amendment, we extended the maturity date to January 2, 2026. In consideration for the extension, we issued to Pagoda a warrant to purchase 75,000 shares of our common stock. The warrant has a five-year term commencing on the date of issuance and an exercise price equal to the closing price of our common stock on Nasdaq on the date of issuance, which was $1.26 per share.

On December 10, 2025, in connection with a common stock transaction effected by Citius Oncology, we amended the promissory note, dated August 16, 2024, as previously amended on September 10, 2025 (the "Note"), issued by Citius Oncology to us to provide that the maturity of the Note would be the date at which Citius Oncology has closed a series of capital raises that in the aggregate provide gross proceeds of at least $50 million through the issuance of debt or equity securities or the royalty-backed monetization of LYMPHIR. All other terms of the Note remain the same.

On December 23, 2025, we extended the term of the Amended and Restated Employment Agreement between us and Myron Holubiak for an additional 12 months until October 31, 2026, effective as of October 31, 2025.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections.

Not applicable.

PART III

Item 10. Directors, Executive Officers and Corporate Governance

We have adopted a written Code of Ethics and Business Conduct that applies to our directors, officers, and all employees. We intend to disclose any amendments to, or waivers from, our code of ethics and business conduct that are required to be publicly disclosed pursuant to rules of the SEC by filing such amendment or waiver with the SEC. Additionally, we have adopted an insider trading policy to establish guidelines for our employees, officers, directors, and consultants regarding transactions in our securities and the disclosure of material nonpublic information related to our Company, which are reasonably designed to promote compliance with insider trading laws, rules and regulations, and any listing standards applicable to the registrant. Each of these policies can be found in the "Investors - Governance – Governance Documents" section of our website, *www.citiuspharma.com*.

The other information required by this Item concerning our directors and executive officers is incorporated by reference to the section captioned "Proposal No. 1—Election of Directors" and "Corporate Governance" to be contained in our proxy statement related to the 2026 Annual Meeting of Stockholders (the "Proxy Statement"), which information is expected to be filed with the SEC within 120 days of the end of our fiscal year pursuant to General Instruction G(3) of Form 10-K. The information required by this Item concerning compliance with Section 16(a) of the Exchange Act by our directors, executive officers and persons who own more than 10% of our outstanding common stock is incorporated by reference from the section captioned "Section 16(a) Beneficial Ownership Reporting Compliance" to be contained in the Proxy Statement.

Item 11. Executive Compensation

The information required by this Item concerning directors and executive compensation is incorporated by reference from the sections captioned "Corporate Governance", "Director Compensation" and "Executive Compensation", respectively, to be contained in the Proxy Statement.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters

The following table sets forth the indicated information as of September 30, 2025 with respect to our equity compensation plans:

Plan Category	Number of securities to be issued upon exercise of outstanding options, warrants and rights	Weighted-average exercise price of outstanding options, warrants and rights	Number of securities remaining available for future issuance under equity compensation plans
Equity compensation plans approved by security holders			
2014 Stock Incentive Plan	16,910	$ 166.67	—
2018 Omnibus Stock Incentive Plan	67,200	27.20	—
2020 Omnibus Stock Incentive Plan	66,000	27.83	—
2021 Omnibus Stock Incentive Plan	330,000	41.67	—
2023 Omnibus Stock Incentive Plan	359,400	13.99	118,000
Total	839,510	$ 30.09	118,000

Our equity compensation plans consist of the Citius Pharmaceuticals, Inc. 2023 Omnibus Stock Incentive Plan, 2021 Omnibus Stock Incentive Plan, 2020 Omnibus Stock Incentive Plan, 2018 Omnibus Stock Incentive Plan and 2014 Stock Incentive Plan, which were all approved by our stockholders. We do not have any equity compensation plans or arrangements that have not been approved by our stockholders.

We no longer may grant awards under the 2014 Stock Incentive Plan, the 2018 Omnibus Stock Incentive Plan, the 2020 Omnibus Stock Incentive Plan or the 2021 Omnibus Stock Incentive Plan.

The other information required by this Item is incorporated by reference to the information under the section captioned "Security Ownership of Certain Beneficial Owners and Management" to be contained in the Proxy Statement.

Item 13. Certain Relationships and Related Transactions, and Director Independence

The information required by this Item is incorporated by reference to the information under the sections captioned "Corporate Governance", "Certain Relationships and Related Transactions" and "Proposal No. 1—Election of Directors" to be contained in the Proxy Statement.

Item 14. Principal Accountant Fees and Services

The information required by this Item is incorporated by reference to the information under the section captioned "Auditor and Audit Committee Matters" to be contained in the Proxy Statement.

PART IV

Item 15. Exhibits and Financial Statement Schedules

Exhibit Number	Description of Document	Registrant's Form	Dated	Exhibit Number	Filed Herewith
2.1+	Agreement and Plan of Merger, dated as of October 23, 2023, by and among Citius Pharmaceuticals, Inc., Citius Oncology, Inc., TenX Keane Acquisition, and TenX Merger Sub Inc.	8-K	10/24/2023	2.1	
3.1.1	Amended and Restated Articles of Incorporation of Citius Pharmaceuticals, Inc.	8-K	9/18/2014	3.1	
3.1.2	Certificate of Amendment to the Amended and Restated Articles of Incorporation of Citius Pharmaceuticals, Inc., effective September 16, 2016.	8-K	9/21/2016	3.1	
3.1.3	Certificate of Amendment to the Amended and Restated Articles of Incorporation of Citius Pharmaceuticals, Inc., effective June 9, 2017.	8-K	6/8/2017	3.1	
3.1.4	Certificate of Amendment to the Articles of Incorporation of Citius Pharmaceuticals Inc., dated June 21, 2021.	8-K/A	6/22/2021	3.1	
3.1.5	Certificate of Designation of Series A Preferred Stock.	8-K	4/18/2025	3.1	
3.1.6	Certificate of Amendment to the Articles of Incorporation of Citius Pharmaceuticals, Inc., dated June 9, 2025.	8-K	6/9/2025	3.1	
3.1.7	Certificate of Change filed with the Secretary of State of Nevada on November 22, 2024.	8-K	11/26/2024	3.1	
3.2.1	Amended and Restated Bylaws of Citius Pharmaceuticals, Inc.	8-K	2/9/2018	3.1	
3.2.2	Amendment to the Amended and Restated Bylaws of Citius Pharmaceuticals, Inc.	8-K	4/18/2025	3.2	
4.1	Form of Common Stock Purchase Warrant, dated August 13, 2018, as amended August 8, 2023.	10-K	12/29/2023	4.1	
4.2	Form of Pre-Funded Common Stock Purchase Warrant, dated August 13, 2018.	8-K	8/13/2018	4.2	
4.3	Form of Underwriter's Common Stock Purchase Warrant, dated August 13, 2018, as amended August 8, 2023.	10-K	12/29/2023	4.3	
4.4	Form of Investor Warrant issued April 3, 2019.	8-K	4/03/2019	4.1	
4.5	Form of Placement Agent Warrant issued April 3, 2019.	8-K	4/03/2019	4.2	
4.6	Form of Common Stock Purchase Warrant issued September 27, 2019.	8-K	9/27/2019	4.1	
4.7	Form of Underwriters Common Stock Purchase Warrant issued September 27, 2019.	8-K	9/27/2019	4.3	
4.8	Form of Investor Warrant issued on February 19, 2020.	8-K	2/19/2020	4.1	
4.9	Form of Placement Agent Warrant issued on February 19, 2020.	8-K	2/19/2020	4.2	
4.10	Form of Investor Warrant issued May 18, 2020.	8-K	5/18/2020	4.1	
4.11	Form of Placement Agent Warrant issued May 18, 2020.	8-K	5/18/2020	4.2	
4.12	Form of Underwriter Warrant issued August 10, 2020.	8-K	8/10/2020	4.1	
4.13	Form of Investor Warrant issued January 27, 2021.	8-K	1/27/2021	4.1	
4.14	Form of Placement Agent Warrant issued January 27, 2021.	8-K	1/27/2021	4.2	

Exhibit Number	Description of Document	Registrant's Form	Dated	Exhibit Number	Filed Herewith
4.15	Form of Registration Rights Agreement, dated January 24, 2021, by and between Citius Pharmaceuticals, Inc. and the purchasers signatory thereto.	8-K	1/27/2021	4.3	
4.16	Form of Investor Warrant issued February 19, 2021.	8-K	2/19/2021	4.1	
4.17	Form of Placement Agent Warrant issued February 19, 2021	8-K	2/19/2021	4.2	
4.18	Form of Warrant issued May 8, 2023.	8-K	5/8/2023	4.1	
4.19	Form of Placement Agent Warrant issued May 8, 2023.	8-K	5/8/2023	4.2	
4.20	Form of Investor Warrant issued April 30, 2024.	8-K	4/30/2024	4.1	
4.21	Form of Investor Warrant issued November 18, 2024.	8-K	11/18/2024	4.1	
4.22	Form of Investor Warrant issued on January 8, 2025	8-K	1/8/2025	4.1	
4.23	Form of Pre-funded Warrant issued on April 2, 2025	8-K	4/2/2025	4.1	
4.24	Form of Placement Agent Warrant issued on April 2, 2025	8-K	4/2/2025	4.2	
4.25	Form of Investor Warrant issued on June 11, 2025.	8-K	6/12/2025	4.1	
4.26	Form of Pre-Funded Warrant issued on June 11, 2025.	8-K	6/12/2025	4.2	
4.27	Form of Placement Agent Warrant issued on June 11, 2025.	8-K	6/12/2025	4.3	
4.28	Form of Investor Warrant issued on October 21, 2025.	8-K	10/21/2025	4.1	
4.29	Form of Pre-Funded Warrant issued on October 21, 2025.	8-K	10/21/2025	4.2	
4.30	Form of Placement Agent Warrant issued on October 21, 2025.	8-K	10/21/2025	4.3	
4.31	Form of Warrant issued on December 2, 2025.				X
4.32	Description of Common Stock.	10-K	12/27/2025	4.22	
10.1*	Citius Pharmaceuticals, Inc. 2014 Stock Incentive Plan.	10-Q	8/15/2016	10.1	
10.2*	Form of Citius Pharmaceuticals, Inc. 2014 Stock Incentive Plan Nonqualified Stock Option.	10-Q	8/15/2016	10.2	
10.3*	Amended and Restated Employment Agreement between Myron Holubiak and Citius Pharmaceuticals, Inc., executed April 12, 2022, effective May 1, 2022.	10-Q	5/12/2022	10.1	
10.4	Second Amendment to the Patent and Technology License Agreement between Novel Anti-Infective Technologies, LLC and Leonard-Meron Biosciences, Inc., dated March 20, 2017.	10-Q	5/15/2017	10.8	
10.5*	Amended and Restated Employment Agreement between Leonard Mazur and Citius Pharmaceuticals, Inc., dated October 19, 2017.	10-K	12/11/2018	10.23	
10.6*	Employment Agreement between Jaime Bartushak and Citius Pharmaceuticals, Inc., dated November 27, 2017.	8-K	12/1/2017	10.1	
10.7*	Citius Pharmaceuticals, Inc. 2018 Omnibus Stock Incentive Plan	10-Q	2/14/2018	10.2	
10.8	Form of Securities Purchase Agreement between Citius Pharmaceuticals, Inc. and the purchasers named therein, dated March 28, 2018.	8-K	3/29/2018	10.1	
10.9+	Patent and Technology License Agreement, dated January 2, 2019, between the Board of Regents of the University of Texas System on behalf of the University of Texas M. D. Anderson Cancer Center and Citius Pharmaceuticals, Inc.	10-Q	2/14/2019	10.1	
10.10	First Amendment, dated October 15, 2015, to Patent and Technology License Agreement, dated May 14, 2014, between Novel Anti-Infective Technologies, LLC and Leonard-Meron Biosciences, Inc.	10-Q	2/14/2019	10.2	
10.11+	Patent and Technology License Agreement, dated May 14, 2014, between Novel Anti-Infective Technologies, LLC and Leonard-Meron Biosciences, Inc.	10-Q	5/12/2023	10.1	

Exhibit Number	Description of Document	Registrant's Form	Dated	Exhibit Number	Filed Herewith
10.12	Form of Securities Purchase Agreement, dated April 1, 2019, by and between Citius Pharmaceuticals, Inc. and the purchasers named therein.	8-K	4/03/2019	10.1	
10.13*	Citius Pharmaceuticals, Inc. 2020 Omnibus Stock Incentive Plan.	Schedule 14A	12/20/2019	Appendix A	
10.14*	Form of Notice of Stock Option Grant and Stock Option Award Agreement.	10-Q	2/13/2020	10.2	
10.15	Form of Warrant Exercise Agreement, dated February 14, 2020, by and between Citius Pharmaceuticals, Inc. and the investor signatory thereto.	8-K	2/19/2020	10.1	
10.16	Form of Warrant Exercise Agreement, dated February 14, 2020, by and between Citius Pharmaceuticals, Inc. and the investor signatory thereto.	8-K	2/19/2020	10.2	
10.17	Form of Securities Purchase Agreement, dated May 14, 2020, by and between Citius Pharmaceuticals, Inc. and the purchasers signatory thereto.	8-K	5/18/2020	10.1	
10.18*	Employment Agreement, effective as of July 14, 2020, between Citius Pharmaceuticals, Inc. and Myron Czuczman.	10-Q	8/14/2020	10.3	
10.19+	License Agreement, dated October 6, 2020, between NoveCite, Inc. and Novellus Therapeutics, Limited.	10-K	12/16/2020	10.24	
10.20	Form of Securities Purchase Agreement, dated January 24, 2021, by and between Citius Pharmaceuticals, Inc. and the purchasers signatory thereto.	8-K	1/27/2021	10.1	
10.21	Form of Securities Purchase Agreement, dated February 16, 2021, by and between Citius Pharmaceuticals, Inc. and the purchasers signatory thereto.	8-K	2/19/2021	10.1	
10.22*	Citius Pharmaceuticals, Inc. 2021 Omnibus Incentive Stock Plan.	Schedule 14A	4/12/2021	Appendix B	
10.23*	Form of Notice of Stock Option Grant and Stock Option Award Agreement.	10-K	12/15/2021	10.29	
10.24+	Asset Purchase Agreement, dated as of September 1, 2021, between Dr. Reddy's Laboratories S.A. and Citius Pharmaceuticals, Inc.	10-K	12/15/2021	10.30	
10.25+	Amended and Restated License, Development and Commercialization Agreement, dated as of February 26, 2018, between Eisai, Ltd. and Dr. Reddy's Laboratories S.A.	10-K	12/15/2021	10.31	
10.26+	Amendment to Amended and Restated License, Development and Commercialization Agreement, dated as of August 9, 2018, between Eisai, Ltd. and Dr. Reddy's Laboratories S.A.	10-K	12/15/2021	10.32	
10.27+	Amendment No. 2 to Amended and Restated License, Development and Commercialization Agreement, dated as of August 31, 2021, between Eisai, Ltd. and Dr. Reddy's Laboratories S.A.	10-K	12/15/2021	10.33	
10.28*	Citius Pharmaceuticals, Inc. 2023 Omnibus Stock Incentive Plan.	Schedule 14A	12/22/2022	Annex A	
10.29	Form of Securities Purchase Agreement, dated May 3, 2023, by and between Citius Pharmaceuticals, Inc. and the purchasers signatory thereto.	8-K	5/8/2023	10.1	
10.30+	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.	8-K	10/24/2023	10.1	

Exhibit Number	Description of Document	Registrant's Form	Dated	Exhibit Number	Filed Herewith
10.31+	Form of Amended and Restated Registration Rights Agreement.	8-K	10/24/2023	10.2	
10.32+	Form of Amended and Restated Shared Services Agreement.	8-K	10/24/2023	10.3	
10.33+	Form of Securities Purchase Agreement, dated as of April 25, 2024, by and among Citius Pharmaceuticals, Inc. and the investors signatory thereto.	8-K	4/30/2024	10.1	
10.34+	Amended and Restated Shared Services Agreement, dated, August, 9, 2023, between Citius Pharmaceuticals, Inc. and Citius Oncology, Inc.	8-K	8/16/2024	10.1	
10.35+	Amended and Restated Registration Rights Agreement, dated as of August 9, 2024, by and between Citius Oncology, Inc. and the signatories thereto.	8-K	8/16/2024	10.2	
10.36+	Side Letter Agreement, dated August 12, 2024, by and by and among Citius Pharmaceuticals, Inc., Citius Oncology, Inc., TenX Keane Acquisition and TenX Merger Sub, Inc.	8-K	8/16/2024	10.3	
10.37+	Promissory note, dated August 16, 2024, issued to Citius Pharmaceuticals, Inc. by Citius Oncology, Inc.	8-K	8/16/2024	10.4	
10.38	Amendment to Promissory Note, dated September 10, 2025, by and between Citius Oncology, Inc. and Citius Pharmaceuticals, Inc.				X
10.39	Second Amendment to Promissory Note, dated December 10, 2025, by and between Citius Oncology, Inc. and Citius Pharmaceuticals, Inc.				X
10.40	Form of Securities Purchase Agreement, dated as of November 15, 2024, by and among Citius Pharmaceuticals, Inc. and the investors signatory thereto.	8-K	11/18/2024	10.1	
10.41	Form of Securities Purchase Agreement, dated as of January 7, 2025, by and among Citius Pharmaceuticals, Inc. and the investors signatory thereto.	8-K	1/8/2025	10.1	
10.42	Form of Securities Purchase Agreement, dated as of April 1, 2025, by and among Citius Pharmaceuticals, Inc. and the investor signatory thereto.	8-K	4/2/2025	10.1	
10.43	Subscription and Investment Representation Agreement, dated April 17, 2025, by and between Citius Pharmaceuticals, Inc. and Leonard Mazur.	8-K	4/18/2025	10.1	
10.44	Unsecured Promissory Note issued to Pagoda Resources, Inc., dated June 2, 2025.	8-K	6/3/2025	10.1	
10.45	Amendment No. 1 to Unsecured Promissory Note issued to Pagoda Resources, Inc., dated December 2, 2025.				X
10.46	Form of Securities Purchase Agreement, dated as of June 9, 2025, by and among Citius Pharmaceuticals, Inc. and the investor signatory thereto.	8-K	6/12/2025	10.1	
10.47	Form of Securities Purchase Agreement, dated as of October 20, 2025, by and among Citius Pharmaceuticals, Inc. and the investor signatory thereto.	8-K	10/21/2025	10.1	
10.48*	First Amendment to Amended and Restated Employment Agreement by and between Myron Holubiak and Citius Pharmaceuticals, Inc., executed September 25, 2024, effective May 31, 2024.				X
10.49*	Second Amendment to Amended and Restated Employment Agreement by and between Myron Holubiak and Citius Pharmaceuticals, Inc., executed December 23, 2025, effective October 31, 2025.				X
19.1	Insider Trading Policy.	10-K	12/27/2024	19.1	
21	Subsidiaries.	10-K	12/29/2023	21	
23.1	Consent of Independent Registered Public Accounting Firm.	--	--	--	X
31.1	Certification of the Chief Executive Officer pursuant to Exchange Act Rule 13a-14(a).	--	--	--	X
31.2	Certification of the Chief Financial Officer pursuant to Exchange Act Rule 13a-14(a).	--	--	--	X
32.1	Certifications of the Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. 1350, as adopted pursuant to Section 906 of the Sarbanes Oxley Act of 2002.	--	--	--	X
97.1	Compensation Recovery Policy.	10-K/A	1/27/2025	97.1	
EX-101.INS	INLINE XBRL INSTANCE DOCUMENT	--	--	--	X
EX-101.SCH	INLINE XBRL TAXONOMY EXTENSION SCHEMA DOCUMENT	--	--	--	X
EX-101.CAL	INLINE XBRL TAXONOMY EXTENSION CALCULATION LINKBASE	--	--	--	X
EX-101.DEF	INLINE XBRL TAXONOMY EXTENSION DEFINITION LINKBASE	--	--	--	X
EX-101.LAB	INLINE XBRL TAXONOMY EXTENSION LABELS LINKBASE	--	--	--	X
EX-101.PRE	INLINE XBRL TAXONOMY EXTENSION PRESENTATION LINKBASE	--	--	--	X
104	Cover Page Interactive Data File, formatted in Inline Extensible Business Reporting Language (iXBRL).	--	--	--	X

+ Portions of this exhibit have been omitted pursuant to Item 601(b)10 of Regulation S-K or 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 an unredacted copy such exhibit, including any omitted exhibits and schedules, to the SEC upon its request.

* Management contract or compensatory plan.

Item 16. Form 10-K Summary.

Not applicable.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) 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: December 23, 2025

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

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ Leonard Mazur Leonard Mazur	Chief Executive Officer and Director (Principal Executive Officer)	December 23, 2025
/s/ Myron Holubiak Myron Holubiak	Executive Vice Chairman and Director	December 23, 2025
/s/ Jaimie Bartushak Jaime Bartushak	Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	December 23, 2025
/s/ Suren Dutia Suren Dutia	Director	December 23, 2025
/s/ Eugene Holuka Eugene Holuka	Director	December 23, 2025
/s/ Dennis McGrath Dennis McGrath	Director	December 23, 2025
/s/ Robert J. Smith Robert J. Smith	Director	December 23, 2025
/s/ Carol Webb Carol Webb	Director	December 23, 2025

CITIUS PHARMACEUTICALS, INC.
CONSOLIDATED FINANCIAL STATEMENTS

INDEX

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Stockholders and Board of Directors of Citius Pharmaceuticals, Inc.:

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Citius Pharmaceuticals, Inc. (the Company) as of September 30, 2025 and 2024, and the related consolidated statements of operations, changes in stockholders' equity and cash flows for the years then ended, and the related notes to the consolidated financial statements (collectively, the financial statements). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of September 30, 2025 and 2024, and the results of its operations and its cash flows for the years then ended, in conformity with accounting principles generally accepted in the United States of America.

Emphasis of a Matter Regarding Going Concern

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 2 to the financial statements, the Company has suffered recurring losses and has a working capital deficit as of September 30, 2025. These conditions raise substantial doubt about the Company's ability to continue as a going concern. Management's plans in regard to these matters are described in Note 2. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits, we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

Critical Audit Matters

Critical audit matters are matters arising from the current period audit of the consolidated financial statements that were communicated or required to be communicated to the audit committee and that: (1) relate to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective, or complex judgments. We determined that there are no critical audit matters.

/s/ Wolf & Company, P.C.

We have served as the Company's auditor since 2014.

Boston, Massachusetts
December 23, 2025

CITIUS PHARMACEUTICALS, INC.
CONSOLIDATED BALANCE SHEETS
SEPTEMBER 30, 2025 AND 2024

	2025	2024
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 4,252,290	$ 3,251,880
Inventory	22,286,693	8,268,766
Prepaid expenses	1,395,490	2,700,000
Total Current Assets	27,934,473	14,220,646
Operating lease right-of-use asset, net	818,694	246,247
Other Assets:		
Deposits	38,062	38,062
In-process research and development	92,800,000	92,800,000
Goodwill	9,346,796	9,346,796
Total Other Assets	102,184,858	102,184,858
Total Assets	$ 130,938,025	$ 116,651,751
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	$ 13,693,692	$ 4,927,211
License payable	22,650,000	28,400,000
Accrued expenses	4,190,253	17,027
Accrued compensation	3,292,447	2,229,018
Note payable	1,000,000	—
Operating lease liability	88,348	241,547
Total Current Liabilities	44,914,740	35,814,803
Deferred tax liability	7,770,760	6,713,800
Operating lease liability – non current	724,925	21,318
Total Liabilities	53,410,425	42,549,921
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; 250,000,000 and 16,000,000 shares authorized at September 30, 2025 and 2024, respectively; 18,067,744 and 7,247,243 shares issued and outstanding at September 30, 2025 and 2024, respectively	18,068	7,247
Additional paid-in capital	306,336,239	271,440,421
Accumulated deficit	(238,804,129)	(201,370,218)
Total Citius Pharmaceuticals, Inc. Stockholders' Equity	67,550,178	70,077,450
Non-controlling interest	9,977,422	4,024,380
Total Equity	77,527,600	74,101,830
Total Liabilities and Equity	$ 130,938,025	$ 116,651,751

See accompanying report of independent registered public accounting firm and notes to the financial statements.
Reflects a 1-for-25 reverse stock split effective November 25, 2024.

CITIUS PHARMACEUTICALS, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS
FOR THE YEARS ENDED SEPTEMBER 30, 2025 AND 2024

	2025	2024
Revenues	$ —	$ —
Operating Expenses:		
Research and development	9,156,474	11,906,601
General and administrative	18,532,843	18,249,402
Stock-based compensation – general and administrative	10,836,291	11,839,678
Total Operating Expenses	38,525,608	41,995,681
Operating Loss	(38,525,608)	(41,995,681)
Other Income (Expense):		
Interest income	110,081	758,000
Interest expense	(267,782)	—
Gain on sale of New Jersey net operating losses	—	2,387,842
Total Other Income (Expense), Net	(157,701)	3,145,842
Loss before Income Taxes	(38,683,309)	(38,849,839)
Income tax expense	1,056,960	576,000
Net Loss	(39,740,269)	(39,425,839)
Net loss attributable to non-controlling interest	2,306,358	287,000
Deemed dividend on warrant extension	—	(1,047,312)
Net Loss Applicable to Common Stockholders	$ (37,433,911)	(40,186,151)
Net Loss Per Share Applicable to Common Stockholders - Basic and Diluted	$ (3.38)	(5.97)
Weighted Average Common Shares Outstanding		
Basic and diluted	11,065,225	6,726,999

See accompanying report of independent registered public accounting firm and notes to the financial statements.
Reflects a 1-for-25 reverse stock split effective November 25, 2024.

CITIUS PHARMACEUTICALS, INC.
CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY
FOR THE YEARS ENDED SEPTEMBER 30, 2025 AND 2024

	Preferred Stock	Common Stock Shares	Common Stock Amount	Additional Paid-In Capital	Accumulated Deficit	Total Citius Pharmaceuticals, Inc. Stockholders' Equity	Non-Controlling Interest	Total Equity
Balance, September 30, 2023	—	6,354,371	$ 6,354	$253,056,133	$(162,231,379)	$ 90,831,108	$ 600,380	$ 91,431,488
Issuance of common stock for services	—	15,479	15	284,161	—	284,176	—	284,176
Issuance of common stock upon exercise of stock options	—	2,082	2	(2)	—	—	—	—
Sale of common stock, net of costs	—	875,311	876	13,802,808	—	13,803,684	—	13,803,684
Stock-based compensation expense	—	—	—	11,839,678	—	11,839,678	—	11,839,678
Merger, net of transaction costs of $2,358,780	—	—	—	(3,831,357)	—	(3,831,357)	—	(3,831,357)
Minority interest from Merger	—	—	—	(3,711,000)	—	(3,711,000)	3,711,000	—
Net loss	—	—	—	—	(39,425,839)	(39,425,839)	—	(39,425,839)
Net loss attributable to noncontrolling interest	—	—	—	—	287,000	287,000	(287,000)	—
Balance, September 30, 2024	—	7,247,243	7,247	271,440,421	(201,370,218)	70,077,450	4,024,380	74,101,830
November 2024 sale of common stock, net of costs of $425,949	—	480,000	480	2,573,571	—	2,574,051	—	2,574,051
January 2025 sale of common stock, net of costs of $342,833	—	743,496	744	2,656,423	—	2,657,167	—	2,657,167
April 2025 sale of common stock and pre-funded warrants, net of costs of $256,116	—	465,000	465	1,743,292	—	1,743,757	—	1,743,757
June 2025 sale of common stock and pre-funded warrants, net of costs of $571,126	—	540,000	540	5,430,296	—	5,430,836	—	5,430,836
July 2025 sale of common stock by Citius Oncology, net of costs of $1,453,012	—	—	—	3,770,278	—	3,770,278	(3,776,710)	7,546,988
September 2025 sale of common stock by Citius Oncology, net of costs of $1,380,146	—	—	—	4,090,493	—	4,090,493	(3,529,361)	7,619,854
Issuance of common stock for services	—	20,000	20	26,580	—	26,600	—	26,600
Issuance of common stock upon exercise of pre-funded warrants	—	5,654,131	5,654	(5,088)	—	566	—	566
Sales of common stock under at the market offering agreement, net of costs	—	2,917,874	2,918	4,727,011	—	4,729,929	—	4,729,929
Sale of Series A preferred stock	1	—	—	100	—	100	—	100
Redemption of Series A preferred stock	(1)	—	—	(100)	—	(100)	—	(100)
Stock-based compensation expense	—	—	—	9,882,962	—	9,882,962	953,329	10,836,291
Net loss	—	—	—	—	(39,740,269)	(39,740,269)	—	(39,740,269)
Net loss attributable to noncontrolling interest	—	—	—	—	2,306,358	2,306,358	(2,306,358)	—
Balance, September 30, 2025	—	18,067,744	$ 18,068	$306,336,239	$(238,804,129)	$ 67,550,178	$ 9,977,422	$ 77,527,600

See accompanying report of independent registered public accounting firm and notes to the financial statements.
Reflects a 1-for-25 reverse stock split effective November 25, 2024.

CITIUS PHARMACEUTICALS, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS
FOR THE YEARS ENDED SEPTEMBER 30, 2025 AND 2024

	2025	2024
Cash Flows From Operating Activities:		
Net loss	$ (39,740,269)	$ (39,425,839)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	10,836,291	11,839,678
Issuance of common stock for services	26,600	284,176
Amortization of operating lease right-of-use asset	214,250	208,179
Depreciation	—	1,432
Deferred income tax expense	1,056,960	576,000
Changes in operating assets and liabilities:		
Inventory	(12,649,207)	(2,133,871)
Prepaid expenses	(64,210)	(945,389)
Accounts payable	8,766,481	1,999,877
Accrued expenses	4,173,226	(459,273)
Accrued compensation	1,063,429	72,035
Operating lease liability	(236,289)	(218,380)
Net Cash Used In Operating Activities	(26,552,738)	(28,201,375)
Cash Flows From Investing Activities:		
License payment	(5,750,000)	(5,000,000)
Net Cash Used In Investing Activities	(5,750,000)	(5,000,000)
Cash Flows From Financing Activities:		
Proceeds from note payable and advance from employee	1,300,000	—
Repayment of advance from employee	(300,000)	—
Merger, net	—	(3,831,357)
Net proceeds from common stock offerings	32,303,148	13,803,684
Net Cash Provided By Financing Activities	33,303,148	9,972,327
Net Change in Cash and Cash Equivalents	1,000,410	(23,229,048)
Cash and Cash Equivalents – Beginning of Year	3,251,880	26,480,928
Cash and Cash Equivalents – End of Year	$ 4,252,290	$ 3,251,880
Supplemental Disclosures of Cash Flow Information and Non-cash Activities:		
IPR&D Milestones included in License Payable	$ —	$ 28,400,000
Net Prepaid Manufacturing transferred to Inventory	$ 1,368,720	$ 6,134,895
Operating lease right-of-use asset and liability recorded	$ 786,697	$ —
Interest paid	$ 187,389	$ —

See accompanying report of independent registered public accounting firm and notes to the financial statements.

1. NATURE OF OPERATIONS AND BASIS OF PRESENTATION

Business

Citius Pharmaceuticals, Inc. ("Citius Pharma," the "Company," "we," or "us") is a late-stage biopharmaceutical company dedicated to the development and commercialization of 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, we acquired Leonard-Meron Biosciences, Inc. ("LMB") as a wholly-owned subsidiary. We acquired all the outstanding stock of LMB by issuing shares of our common stock. The net assets acquired included identifiable intangible assets of $19,400,000 related to in-process research and development. We recorded goodwill of $9,346,796 for the excess of the purchase price 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. ("Citius Oncology"), as a wholly-owned subsidiary in conjunction with the acquisition of LYMPHIR, which began operations in April 2022. On August 12, 2024, Citius Pharma and Citius Oncology entered into a merger agreement with TenX Keane Acquisition, and its wholly owned subsidiary, TenX Merger Sub Inc ("Merger Sub"), whereby Merger Sub merged with and into Citius Oncology. After the merger and recapitalization (the "Merger"), the newly combined publicly traded company was owned 92.3% by Citius Pharma, and is named Citius Oncology, Inc. (see Note 10).

Since our 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 us or our competitors of research and development stage products, regulatory approval and market acceptance of its products, competition from larger companies, dependence on key personnel, dependence on key suppliers and strategic partners, our ability to obtain additional financing and our compliance with governmental and other regulations.

Basis of Presentation

The accompanying consolidated financial statements include the operations of Citius Pharmaceuticals, Inc., and its wholly-owned subsidiary LMB and its majority-owned subsidiaries NoveCite and Citius Oncology. On August 12, 2024, Citius Oncology, previously a wholly-owned subsidiary, became a majority-owned subsidiary. As of September 30, 2025, Citius Oncology was a 79.1% majority-owned subsidiary.

The operations of NoveCite and Citius Oncology are included in the consolidated results. The portion of equity that is not attributable to the Company, is presented as a non-controlling interest within stockholders' equity. Unless excluded by shareholder agreements, the portion of net loss attributable to non-controlling interests is included in the statement of operations.

All significant inter-company balances and transactions have been eliminated in consolidation.

All share amounts and per share data reflect a 1-for-25 reverse stock split which became effective on November 25, 2024.

2. GOING CONCERN UNCERTAINTY AND MANAGEMENT'S PLAN

The accompanying 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. We experienced negative cash flows from operations of $26,552,738 and $28,201,375, for the years ended September 30, 2025 and 2024, respectively. We had a negative working capital of approximately $17 million at September 30, 2025. We estimate that our available cash resources will be sufficient to fund its operations through March 2026 which raises substantial doubt about our ability to continue as a going concern within one year after the date that the accompanying consolidated financial statements are issued.

We have generated no operating revenue to date and have principally raised capital through the issuance of debt and equity instruments to finance our operations. However, our continued operations beyond March 2026, including our development plans for Mino-Lok, Halo-Lido and NoveCite, will depend on our ability to obtain regulatory approval for Mino-Lok and generate substantial revenue from the sale of LYMPHIR and on our ability to raise additional capital through various potential sources, such as equity and/or debt financings, strategic relationships, or out-licensing of our product candidates. We can provide no assurances on regulatory approval, commercialization, or future sales of LYMPHIR or that financing or strategic relationships will be available on acceptable terms, or at all. If we are unable to raise sufficient capital, find strategic partners or generate substantial revenue from the sale of LYMPHIR, there would be a material adverse effect on our business. Further, we expect in the future to incur additional expenses as we continue to develop our product candidates, including seeking regulatory approval, and protecting our intellectual property. The accompanying financial statements do not include any adjustments that might result from the outcome of the above uncertainty.

3. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

A summary of the significant accounting policies followed by us in the preparation of the consolidated financial statements is as follows:

Use of Estimates

The process of preparing financial statements in conformity with accounting principles generally accepted in the United States of America ("GAAP") requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of financial statements and the reported amounts of revenues and expenses during the reporting period. Estimates having relatively higher significance include the accounting for in-process research and development, goodwill, stock-based compensation and income taxes. Actual results could differ from those estimates and changes in estimates may occur.

Cash and Cash Equivalents

We consider all highly liquid instruments with maturities of less than three months at the time of purchase to be cash equivalents. From time to time, we may have cash balances in financial institutions in excess of insurance limits. We have never experienced any losses related to these balances.

Prepaid Expenses

Prepaid expenses at September 30, 2025 and 2024 consist of $64,210 and $0 in prepaid annual service fees, respectively, and $1,331,280 and $2,700,000 of advance payments made for the preparation of long-lead time drug substance and product costs, respectively, which will be utilized in research and development activities or in the manufacturing of LYMPHIR for sales.

Inventory

Inventory is stated at the lower of actual accumulated costs or net realizable value as of September 30, 2025 and 2024, related to the manufacturing of LYMPHIR commercial products to be sold commencing in 2025. No reserves against inventory were deemed necessary based on an evaluation of the product expiration dating.

	September 30, 2025	September 30, 2024
Finished goods	$ 10,577,876	$ 6,134,895
Work in process	11,708,817	2,133,871
Total	$ 22,286,693	$ 8,268,766

During 2024 and 2025, $6,134,895 and $1,368,720 respectively, of prepaid manufacturing costs were transferred to inventory upon product approval and production commencement at our third-party manufacturers.

Research and Development

Research and development costs, including upfront fees and milestones paid to collaborators who are performing research and development activities under contractual agreements with us, are expensed as incurred. We defer and capitalize our nonrefundable advance payments that are for research and development activities until the related goods are delivered or the related services are performed. When we are reimbursed by a collaboration partner for work we perform, we record the costs incurred as research and development expenses and the related reimbursement as a reduction to research and development expenses in our consolidated statement of operations. Research and development expenses primarily consist of clinical and non-clinical studies, materials and supplies, third-party costs for contracted services, and payments related to external collaborations and other research and development related costs.

In-process Research and Development

We capitalize intangible assets purchased from others for use in research and development activities as In Process Research & Development (IPR&D) when the assets acquired have an alternative future use, we anticipate future economic benefit from that use and the assets acquired are not dependent on future development. Milestone payments upon regulatory approval that meet the same criteria are capitalized when the payments are considered recoverable based on expected future cash flows. Amortization of IPR&D over the exclusive regulatory period of the acquired asset commences upon revenue generation.

In-process research and development includes $19,400,000 representing the value of LMB's drug candidate, Mino-Lok, an antibiotic lock solution in Phase 3 clinical development, which if approved, would be 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. In-process research and development also includes $73,400,000 representing the value of Citius Oncology's exclusive license for LYMPHIR (denileukin diftitox), a late-stage oncology immunotherapy for the treatment of 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. Citius Oncology's In-process research and development consists of $40,000,000 paid to Dr. Reddy's from the asset purchase agreement and approval milestone fees of $27,500,000 to Dr. Reddy's and $5,900,000 to Eisai. Included in the IPR&D is the historical know-how, formula protocols, designs, and procedures that were needed to complete Phase 3. In addition, the contracts acquired in connection with Dr. Reddy's transaction with the clinical research and manufacturing organization are at market rates and could be provided by multiple vendors in the marketplace. Therefore, there is no fair value associated with the contracts acquired.

The Company reviews intangible assets annually to determine if any adverse conditions exist or a change in circumstances has occurred that would indicate impairment or a change in the remaining useful life of any intangible asset. If the carrying value of an asset exceeds its undiscounted cash flows, the Company writes down the carrying value of the intangible asset to its fair value in the period identified. No impairment has occurred since the acquisitions through September 30, 2025.

Goodwill

Goodwill represents the value of LMB's industry relationships and its assembled workforce. Goodwill is not amortized but it is tested at least annually for impairment.

The Company evaluates the recoverability of goodwill annually or more frequently if events or changes in circumstances indicate that the carrying value of an asset might be impaired, in accordance with Accounting Standard Update ("ASU") 2017-04, *Intangibles – Goodwill and Other (Topic 350): Simplifying the Accounting for Goodwill Impairment* issued by the Financial Accounting Standards Bureau ("FASB"). Goodwill is first qualitatively assessed to determine whether further impairment testing is necessary. Factors that management considers in this assessment include macroeconomic conditions, industry and market considerations, overall financial performance (both current and projected), changes in management and strategy and changes in the composition or carrying amount of net assets. If this qualitative assessment indicates that it is more likely than not that the fair value of a reporting unit is less than its carrying amount, a one-step test is then performed in accordance with ASU 2017-04. Under the simplified model, a goodwill impairment is calculated as the difference between the carrying amount of the reporting unit and its fair value.

For its 2025 goodwill analysis, the Company performed a quantitative assessment as of September 30, 2025. Based on this analysis, management concluded that the estimated fair value of the reporting unit exceeded its carrying amount. Accordingly, no impairment charge was recorded, and goodwill continues to be carried at its current value.

Stock-Based Compensation

We recognize compensation costs resulting from the issuance of stock-based awards to employees and directors as an expense in the consolidated statement of operations over the requisite service period based on the fair value for each stock award on the grant date. The fair value of each option grant is estimated as of the date of grant using the Black-Scholes option pricing model. We estimate volatility using the trading activity of our common stock. Because our stock options have characteristics significantly different from those of traded options, and because changes in the input assumptions can materially affect the fair value estimate, the existing model may not necessarily provide a reliable single measure of fair value of our stock options.

We recognize compensation costs resulting from the issuance of stock-based awards to non-employees as an expense in the consolidated statement of operations over the service period based on the measurement of fair value for each stock award and record forfeitures as they occur.

Income Taxes

We follow accounting guidance regarding the recognition, measurement, presentation, and disclosure of uncertain tax positions in the consolidated financial statements. Tax positions taken or expected to be taken in the course of preparing our tax returns are required to be evaluated to determine whether the tax positions are "more-likely-than-not" of being sustained by the applicable tax authorities. Tax positions not deemed to meet a more-likely-than-not threshold would be recorded in the consolidated financial statements. There are no uncertain tax positions that require accrual or disclosure as of September 30, 2025. Any interest or penalties are charged to expense. During the years ended September 30, 2025 and 2024, the Company did not recognize any interest and penalties. Tax years subsequent to September 30, 2021 are subject to examination by federal and state authorities.

The Company recognizes deferred tax assets and liabilities based on differences between the financial reporting and tax basis of assets and liabilities, and operating loss and tax credit carry forwards. Deferred tax assets and liabilities are measured using the enacted tax rates and laws that are expected to be in effect when the differences are expected to reverse. The Company provides a valuation allowance, if necessary, for deferred tax assets for which it does not consider realization of such assets to be "more-likely-than-not." The deferred tax benefit or expense for the period represents the change in the deferred tax asset or liability from the beginning to the end of the period.

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 options and warrants were not included in the calculation of the diluted loss per share because they were anti-dilutive.

Segment Reporting

The Company operates through a single operating and reportable segment which is focused on developing and commercializing innovative targeted oncology therapies. The Company's lead product candidate is LYMPHIR, an engineered IL-2 diphtheria toxin fusion protein, for the treatment of patients with persistent or recurrent CTCL, a rare form of non-Hodgkin lymphoma. LYMPHIR was approved by the FDA in August 2024. The Company manages all business activities on a consolidated basis. The Company's Chief Operating Decision Maker ("CODM") is the Chief Executive Officer.

The accounting policies of the operating segment are as described in Note 3. The CODM evaluates the performance of the operating segment and allocates resources based on amounts as reported on the consolidated statements of operations and cash flows. Segment expenses are presented on the Company's consolidated statements of operations. The operating segment assets are reported on the consolidated balance sheet as total assets.

Concentrations of Credit Risk

We have no significant off-balance-sheet concentration of credit risk such as foreign exchange contracts, option contracts or other hedging arrangements.

Recently Adopted Accounting Standards

Reportable Segment Disclosures

In November 2023, the FASB issued ASU 2023-07, Segment Reporting (Topic 280), Improvements to Reportable Segment Disclosures. The change in the standard improves reportable segment disclosure requirements, primarily through enhanced disclosures about significant segment expenses. The changes improve financial reporting by requiring disclosure of incremental segment information on an annual and interim basis for all public entities to enable investors to develop more decision-useful financial analyses. The guidance will be effective for annual reporting periods beginning after December 15, 2023, and for interim periods beginning after December 15, 2024. Early adoption is permitted. The standard will be applied retrospectively. Since the Company has one reportable segment, adoption of this new standard did not have a material impact on the Company's consolidated financial statements.

Recently Issued Accounting Standards

Income Tax Disclosures

In December 2023, the FASB issued ASU 2023-09, Income Taxes (Topic 740), Improvements to Income Tax Disclosures. The standard enhances the transparency, decision usefulness and effectiveness of income tax disclosures by requiring consistent categories and greater disaggregation of information in the reconciliation of income taxes computed using the enacted statutory income tax rate to the actual income tax provision and effective income tax rate, as well as the disaggregation of income taxes paid (refunded) by jurisdiction. The standard also requires disclosure of income (loss) before provision for income taxes and income tax expense (benefit) in accordance with U.S. Securities and Exchange Commission (SEC) Regulation S-X 210.4-08(h), Rules of General Application – General Notes to Financial Statements: Income Tax Expense, and the removal of disclosures no longer considered cost beneficial or relevant. The guidance will be effective for annual reporting periods beginning after December 15, 2024. Early adoption is permitted. The standard will be applied on a prospective basis, with retrospective application permitted. We are currently evaluating the impact of adoption of the standard on our financial statement disclosures.

Disaggregation of Income Statement Expenses

In November 2024, the FASB issued ASU 2024-03, Income Statement Reporting–Comprehensive Income–Expense Disaggregation Disclosures (Subtopic 220-40), Disaggregation of Income Statement Expenses. The standard update improves the disclosures about a public business entity's expenses by requiring more detailed information about the types of expenses (including purchases of inventory, employee compensation, depreciation and amortization) included within income statement expense captions. The guidance will be effective for annual reporting periods beginning after December 15, 2026, and interim reporting periods beginning after December 15, 2027. Early adoption is permitted. The standard updates are to be applied prospectively with the option for retrospective application. We are currently evaluating the impact of adoption of the standard on ours financial statement disclosures.

4. 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. We recorded an annual maintenance fee expense of $90,000 in both 2025 and 2024.

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- to mid-single digits. After a commercial sale is obtained, LMB must pay minimum aggregate annual royalties of $100,000 in the first commercial year which is prorated for a less than 12-month period, increasing $25,000 per year to a maximum of $150,000 annually. LMB must also pay NAT up to $1,100,000 upon achieving specified regulatory and sales milestones. Finally, LMB must pay NAT a specified percentage of payments received from any sub-licensees.

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

License Agreement with Eterna

On October 6, 2020, NoveCite, entered into a license agreement with Novellus Therapeutics Limited ("Novellus"), whereby NoveCite acquired an exclusive, worldwide license, with the right to sublicense, develop and commercialize a stem cell therapy based on the Novellus'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, which was charged to research and development expense during the year ended September 30, 2021, and issued to Novellus shares of NoveCite's common stock representing 25% of the outstanding equity. We own the other 75% of NoveCite's outstanding equity. Pursuant to the terms of the original stock subscription agreement, if NoveCite issued additional equity, subject to certain exceptions, NoveCite had to maintain Novellus's ownership at 25% by issuing additional shares to Novellus.

In July 2021, Novellus was acquired by Brooklyn ImmunoTherapeutics, Inc. ("Brooklyn"). In this transaction, the NoveCite license was assumed by Brooklyn with all original terms and conditions. The stock subscription agreement was amended to assign to Brooklyn all of Novellus's rights 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").

We are responsible for the operational activities of NoveCite and bear all costs necessary to operate NoveCite. Our 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 we have not allocated any losses to the noncontrolling interest.

Under the license agreement, NoveCite is obligated to pay Eterna up to an aggregate of $51,000,000 in regulatory and developmental milestone payments. NoveCite also must pay a royalty equal to a mid-teens percentage 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 a mid-single digit percentage (within a range of 4% to 8%) 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 Eterna 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 Eterna 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 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 continue on a country-by-country and licensed product-by-licensed product basis until the expiration of the last-to-expire royalty term. Either party may terminate the license agreement upon written notice if the other party is in material default. NoveCite may terminate the license agreement at any time without cause upon 90 days prior written notice.

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, we entered into an asset purchase agreement with Dr. Reddy's Laboratories SA, a subsidiary of Dr. Reddy's Laboratories, Ltd. (collectively, "Dr. Reddy's") and a license agreement with Eisai Co., Ltd. ("Eisai") to acquire an exclusive license of E7777 (denileukin diftitox), an 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 of LYMPHIR for the product. We assigned these agreements to Citius Oncology effective April 1, 2022 and received a BLA approval from the FDA for LYMPHIR in August 2024.

Under the terms of these agreements, we acquired Dr. Reddy's exclusive license for E7777 from Eisai and other related assets (which are now owned by Citius Oncology). The exclusive license rights, through Citius Oncology, include rights to develop and commercialize E7777 in all markets except for Japan and certain parts of Asia. Eisai retains exclusive development and marketing rights for the agent in Japan, China, Korea, Taiwan, Hong Kong, Macau, Indonesia, Thailand, Malaysia, Brunei, Singapore, India, Pakistan, Sri Lanka, Philippines, Vietnam, Myanmar, Cambodia, Laos, Afghanistan, Bangladesh, Bhutan, Nepal, Mongolia, and Papua New Guinea. We paid Dr. Reddy's a $40 million upfront payment, which represents the acquisition date fair value of the in-process research and development acquired. 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. Citius Oncology 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. Citius Oncology 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. Citius Pharma is a guarantor of Citius Oncology's payment obligations under these agreements.

At the time of the FDA approval for LYMPHIR, a $27.5 million milestone became payable to Dr. Reddy's, of which a balance of $19.75 million included in license fee payable, remained due as of September 30, 2025. After discussions, Dr. Reddy's agreed to a partial deferral without penalty of this milestone payment. During the years ended September 30, 2025 and 2024, we paid $2,750,000 and $5,000,000, respectively, against the outstanding milestone fee.

At the time of the FDA approval for LYMPHIR, a $5.9 million milestone became payable to Eisai, of which a balance of $2.9 million included in license fee payable, remained due as of September 30, 2025. During the year ended September 30, 2025, we paid $3,000,000 against the outstanding milestone fee. Eisai is to receive additional commercial milestone payments related to the achievement of net product sales thresholds and an aggregate of up to $22 million related to the achievement of net product sales thresholds. Citius Oncology was o required to reimburse Eisai for up to $2.65 million of its costs to complete the Phase 3 pivotal clinical trial for the CTCL indication and reimburse Eisai for all reasonable costs associated with the preparation of a Biologics License Application ("BLA") for LYMPHIR. Eisai was responsible for completing the CTCL clinical trial, and chemistry, manufacturing, and controls ("CMC") activities through the filing of the BLA with the FDA. The BLA was approved by the FDA on August 8, 2024. We are responsible for development costs associated with potential additional indications.

On March 28, 2025, Citius Oncology and Eisai entered into a letter agreement that amended the license agreement to provide for a payment schedule to Eisai for the milestone payment and certain unpaid invoices. We agreed to pay Eisai on or before July 15, 2025, an aggregate amount of $2,535,318 and thereafter on the 15th of each of the next four months to pay Eisai $2,350,000 and make a final payment of $2,197,892 to Eisai on or before December 15, 2025, in each case with interest on each obligation from its original due date through the date of actual payment under the letter agreement at the rate of 2% per annum. During the year ended September 30, 2025, we recorded $218,032 in interest expense under the agreement. The parties released each other from any and all claims, losses, damages, costs and expenses that arise from or related to our failure to pay the milestone payment or the other incurred costs under the license agreement except for any claims arising out of a breach of the letter agreement. All other terms of the license agreement remain in full force and effect. During the year ended September 30, 2025 we paid $3,000,000 of the development milestone and the balance of $2,900,000 is included in license fee payable at September 30, 2025. On July 21, 2025, we made a payment to Eisai of $1,616,522 for other invoices and accumulated interest associated with the letter agreement.

The term of the license agreement will continue until (i) March 30, 2026, if there has not been a commercial sale of a licensed product in the territory, or (ii) if there has been a first commercial sale of a licensed product in the territory by March 30, 2026, the 10-year anniversary of the first commercial sale on a country-by-country basis. We expect the first commercial sale to occur in the first quarter of 2026. 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.

Under the purchase agreement with Dr. Reddy's, we are required to (i) use commercially reasonable efforts to make commercially available products in the CTCL indication, peripheral T-cell lymphoma indication and immuno-oncology indication, (ii) initiate two investigator initiated immuno-oncology trials (both of which have been initiated), (iii) use commercially reasonable efforts to achieve each of the approval milestones, and (iv) to 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; the launch of LYMPHIR in December 2025 satisfied this requirement in the U.S.

As part of the definitive agreement with Dr. Reddy's, we acquired method of use patents in which LYMPHIR is administered in combination with the programmed cell death protein 1 ("PD-1") pathway inhibitor drug class. PD-1 plays a vital role in inhibiting immune responses and promoting self-tolerance through modulating the activity of T-cells, activating apoptosis of antigen-specific T cells and inhibiting apoptosis of regulatory T cells.

The following patents were acquired and subsequently transferred to Citius Oncology:

US Provisional Application No. 63/070,645, which was filed on August 26, 2020, and subsequently published as US 2022/0062390 A1 on March 3, 2022, entitled Methods of Treating Cancer.

International Patent Application Number: PCT/IB2021/0576733, which was filed with the World Intellectual Property Organization on August 23, 2021, and subsequently published as WO 2022/043863 A1 on March 3, 2022, entitled, Combination for Use in Methods of Treating Cancer.

5. NOTE PAYABLE AND ADVANCE FROM EMPLOYEE

On June 2, 2025, The Company borrowed $1,000,000 from an unrelated lender. The note payable is due in full on December 2, 2025 with interest at 15% compounded monthly. Leonard Mazur (Chairman and Chief Executive Officer of the Company) personally guaranteed repayment of the note. Interest expense for the year ended September 30, 2025 was $49,750.

On May 28, 2025, an employee provided a $300,000 non-interest-bearing advance to the Company. On June 5, 2025, the Company repaid the employee in full.

6. COMMON STOCK, STOCK OPTIONS, RESTRICTED STOCK AWARDS, AND WARRANTS

Authorized Common Stock and Reverse Stock Split

We filed a Certificate of Change with the Secretary of State of the State of Nevada to (i) effect a 1-for-25 reverse stock split of our issued and outstanding shares of common stock, and (ii) decrease the number of total authorized shares of common stock from 400,000,000 shares to 16,000,000 shares. The reverse stock split was intended to regain compliance with the minimum bid price requirement of $1.00 per share of common stock for continued listing on the Nasdaq Capital Market. The reverse stock split became effective on November 25, 2024, and our common stock began trading on a reverse stock split-adjusted basis on the Nasdaq Capital Market on November 26, 2024. All share amounts have been retroactively adjusted to reflect the split.

Series A Preferred Stock and Authorized Common Stock

On April 17, 2025, we entered into an agreement with Leonard Mazur (Chairman and Chief Executive Officer of the Company), pursuant to which we sold one share of Series A Preferred Stock, par value $0.001 per share for $100 to Mr. Mazur. The Series A Preferred Stock was sold in connection with the June 9, 2025 special meeting of the stockholders for the purpose of approving an amendment to our Articles of Incorporation, as amended, to increase the number of shares of our authorized common stock from 16,000,000 to 250,000,000. Our stockholders approved the authorized share increase on June 9, 2025.

On April 17, 2025, we filed a certificate of designation with the Nevada Secretary of State, designating the powers, rights, privileges and restrictions of the Series A Preferred Stock. The certificate provides that each share of Series A Preferred Stock will have 1,000,000,000 votes and will vote together with the outstanding shares of common stock as a single class, exclusively with respect to the authorized share increase proposal and shall not be entitled to vote on any other matter. The Series A Preferred Stock will be voted on the authorized share increase in the same proportion as the aggregate votes cast by holders of common stock “for” and “against” the proposal. The Series A Preferred Stock otherwise has no other voting rights, including in respect of any other proposal. The voting power attributable to the Series A Preferred Stock will be disregarded for purposes of determining whether a quorum is present at the special meeting, and the establishment of a quorum at the special meeting will be determined only with reference to the common stock.

Pursuant to its terms, on June 9, 2025, the outstanding share of Series A Preferred Stock was redeemed automatically for $100 after we published the final results of the stockholder vote on the authorized stock increase.

Common Stock Issued for Services

On October 10, 2023, we issued 4,351 shares of common stock for media, and public and investor relations services and expensed the $76,146 fair value of the common stock issued.

On January 17, 2024, we issued 5,128 shares of common stock for general and business development advisory services and expensed the $98,079 fair value of the common stock issued.

On April 25, 2024, we issued 6,000 shares of common stock for financial, general and business development advisory services and expensed the $109,950 fair value of the common stock issued.

On July 1, 2025, we issued 20,000 shares of common stock for media, and public and investor relations services and expensed the $26,600 fair value of the common stock issued.

Common Stock Offerings

On April 30, 2024, Citius Pharma sold 857,143 shares of common stock and warrants to purchase 857,143 shares of common stock, at a purchase price of $17.50 per share and accompanying warrant for gross proceeds of $15,000,002. The warrants have an exercise price of $18.75 per share, are exercisable six months after issuance, and expire on October 30, 2029. The estimated fair value of the warrants issued to the investors was approximately $11,206,000.

Net proceeds were $13,718,951 after deducting the placement agent fee of $1,050,000, placement agent expenses of $135,000, legal fees of $80,101, and other offering expenses of $15,950. We also issued 60,000 warrants to the placement agent at an exercise price of $21.875 per share, that are exercisable six months from the date of issuance and expire on April 25, 2029. The estimated fair value of the warrants issued to the placement agent was approximately $756,000.

On November 15, 2024, Citius Pharma sold 480,000 shares of common stock and warrants to purchase 480,000 shares of common stock. Gross proceeds were $3,000,000 and net proceeds were $2,574,051 after deducting fees and expenses. The shares and warrants were sold at a combined offering price of $6.25. The immediately exercisable warrants have an exercise price of $6.25 per share and expire on November 19, 2029. The estimated fair value of the warrants issued to the investors was approximately $1,575,000.

We paid the placement agent 7% of the gross proceeds and granted the placement agent immediately exercisable warrants to purchase 33,600 shares of common stock at an exercise price is $7.8125 per share which expire on November 15, 2029. The estimated fair value of the warrants issued to the placement agent was approximately $104,000.

On January 7, 2025, Citius Pharma sold 743,496 shares of common stock and warrants to purchase 743,496 shares of common stock. Gross proceeds were approximately $3,000,000 and net proceeds were $2,657,167 after deducting fees and expenses. The shares and warrants were sold at a combined offering price of $4.035. The immediately exercisable warrants have an exercise price of $3.91 per share and expire on January 8, 2030. The estimated fair value of the warrants issued to the investors was approximately $2,091,000.

We paid the placement agent 7% of the gross proceeds and granted the placement agent immediately exercisable warrants, to purchase 52,045 shares of common stock at $5.0438 per share which expire on January 7, 2030. The estimated fair value of the warrants issued to the placement agent was approximately $138,000.

On April 1, 2025, Citius Pharma sold 465,000 shares of common stock, and pre-funded warrants to purchase 1,274,131 shares of common stock at an offering price of $1.15 and $1.1499. Gross proceeds were $1,999,873 and net proceeds were $1,743,757 after deducting fees and expenses. The immediately exercisable pre-funded warrants have an exercise price of $0.0001 per share and do not expire. All 1,274,131 of the pre-funded warrants were exercised during the year ended September 30, 2025.

We paid the placement agent 7% of the gross proceeds and granted the placement agent warrants to purchase 121,739 shares of common stock at $1.4375 per share which are exercisable commencing on October 2, 2025 and expire on April 1, 2030. The estimated fair value of the warrants issued to the placement agent was approximately $100,000.

On June 11, 2025, Citius Pharma sold 540,000 shares of common stock, and pre-funded warrants to purchase 4,380,000 shares of common stock at offering prices of $1.22 and $1.2199, respectively, along with immediately exercisable two-year warrants to purchase 9,840,000 shares of common stock at $1.00 per share. Gross proceeds were $6,001,962 and net proceeds of the offering were $5,430,836 after deducting fees and expenses. The pre-funded warrants are exercisable immediately at $0.0001 per share and do not expire. During the year ended September 30, 2025 all 4,380,000 of the pre-funded warrants were exercised. The estimated fair value of the 9,840,000 warrants issued to the investors was approximately $4,867,000.

We paid the placement agent a fee of $420,168 and other fees and expenses were $150,958. In addition, we granted placement agent warrants to purchase 344,400 shares of common stock at an exercise price equal to $1.525 per share. The warrants are exercisable six months after issuance and expire after five years. On the expiration date, any warrants outstanding will be exercised via cashless exercise. The estimated fair value of the warrants issued to the placement agent was approximately $222,000.

On July 17, 2025, Citius Oncology sold 6,818,182 shares of common stock and warrants to purchase 6,818,182 shares of common stock. The shares and warrants were sold at a per unit price of $1.32. The immediately exercisable five-year warrants have an exercise price of $1.32 per share. Gross proceeds from the offering were approximately $9.0 million and net proceeds were $7,546,988, after deducting placement agent fees and other offering expenses. The estimated fair value of the warrants issued to the investors was approximately $8,197,000.

Citius Oncology paid the placement agent a fee of 7.0% of the gross proceeds and expenses of $125,000, and issued the placement agent warrants to purchase up to 272,727 shares of common stock at an exercise price of $1.65 per share. The warrants are exercisable commencing on January 17, 2026 and expire on July 17, 2030. Citius Oncology also paid an additional 7.0% fee to a prior placement agent and issued the prior placement agent warrants to purchase up to 477,273 shares of common stock at an exercise price of $1.65 per share. The placement agent warrants are exercisable commencing on August 17, 2025 and expire on July 17, 2030. The estimated fair value of the warrants issued to the placement agents was approximately $905,000.

On September 10, 2025, Citius Oncology sold 5,142,858 shares of common stock and warrants to purchase 5,142,858 shares of common stock. The shares and warrants were sold at a per unit price of $1.75. The warrants are exercisable beginning on March 10, 2026 and expire on March 10, 2031 at an exercise price of $1.84 per share. Gross proceeds from the offering were approximately $9.0 million and net proceeds were $7,619,854, after deducting placement agent fees and other offering expenses. The estimated fair value of the warrants issued to the investors was approximately $6,995,000.

Citius Oncology paid the placement agent a fee of 7.0% of the gross proceeds and expenses of $125,000. Additionally, Citius Oncology issued the placement agent warrants to purchase up to 205,714 shares of common stock at an exercise price of $1.92 per share. The warrants are exercisable commencing on March 10, 2026 and expire on March 10, 2031. We also paid an additional 7.0% fee to a prior placement agent and issued the prior placement agent warrants to purchase up to 360,000 shares of common stock at an exercise price of $2.1875 per share. The placement agent warrants are exercisable commencing on March 10, 2026 and expire on March 10, 2031. The estimated fair value of the warrants issued to the placement agents was approximately $717,000.

Citius Pharma At the Market Offering Agreement

On August 12, 2024, we entered into a sales agreement, to sell, from time to time during the term of the agreement our shares of common stock.

During the year ended September 30, 2024, Citius Pharma sold 18,168 shares for gross proceeds of $252,140. Net proceeds after deducting broker fees and other offering expenses were $84,735.

During the three months ended March 31, 2025, Citius Pharma sold 289,910 shares for gross proceeds of $839,468. Net proceeds after deducting broker fees and other offering expenses were $808,640.

During the three months ended June 30, 2025, Citius Pharma sold 2,185,249 shares for gross proceeds of $3,471,866. Net proceeds after deducting broker fees and other offering expenses were $3,294,446.

During the three months ended September 30, 2025, Citius Pharma sold 442,715 shares for gross proceeds of $657,284. Net proceeds after deducting broker fees and other offering expenses were $626,843.

Citius Pharma Stock Option Plans

Under our 2014 Stock Plan, we reserved 34,667 shares of common stock. As of September 30, 2025, there were options to purchase 16,910 shares outstanding and no shares were available for future grants.

Under our 2018 Stock Plan, we reserved 80,000 shares of common stock. As of September 30, 2025, there were options to purchase 67,200 shares outstanding and no shares were available for future grants.

Under our 2020 Stock Plan, we reserved 124,400 shares of common stock. As of September 30, 2025, there were options to purchase 66,000 shares outstanding and no shares available for future grants.

Under our 2021 Stock Plan, we reserved 349,600 shares of common stock. As of September 30, 2025, options to purchase 330,000 shares were outstanding and no shares reserved for future grants

Under our 2023 Stock Plan, we reserved for issuance 481,400 shares of common stock. As of September 30, 2025, options to purchase 359,400 shares were outstanding, and 118,000 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. Volatility is estimated using the trading activity of our common stock. 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 to employees and directors, 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.

The following assumptions were used in determining the fair value of stock option grants for the years ended September 30, 2025 and 2024:

	2025	2024
Risk-free interest rate	4.17 – 4.31%	4.62 – 4.66%
Expected dividend yield	0.00%	0.00%
Expected term	5.50 – 10 years	5.50 – 10 years
Expected volatility	85%	85 – 86%

A summary of option activity under our plans (excluding the NoveCite and Citius Oncology Stock Plans) is presented below:

	Option Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term	Aggregate Intrinsic Value
Outstanding at September 30, 2024	656,084	$ 36.41	7.26 years	$ 0.00
Granted	185,000	$ 9.50		
Exercised	—			
Forfeited or expired	(1,574)	$ 242.80		
Outstanding at September 30, 2025	839,510	$ 30.09	6.90 years	$ 0.00
Exercisable at September 30, 2025	512,509	$ 39.70	5.88 years	$ 0.00

The weighted average grant date fair value of the options granted during the year ended September 30, 2025 was estimated at $7.15 per share. All these options vest over terms of 12 to 36 months and have a term of 10 years.

At September 30, 2025, unrecognized total compensation cost related to unvested awards under the Citius Pharma stock plans of $1,485,612 is expected to be recognized over a weighted average period of 1.55 years.

NoveCite Stock Plan – Under the NoveCite Stock Plan, we reserved 2,000,000 shares of common stock of NoveCite. As of September 30, 2025, there were options outstanding to purchase 1,911,500 shares and 88,500 shares of common stock available for future grants.

During the year ended September 30, 2021, NoveCite granted options to purchase 2,000,000 shares of common stock to employees at an exercise price of $0.24 per share, 88,500 shares were forfeited, and options to purchase 1,911,500 shares were exercisable as of September 30, 2025. These options vested 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 5.39 years. No options were issued in fiscal years 2025 and 2024. At September 30, 2025, there is no remaining unrecognized total compensation cost related to awards under the plan.

Citius Oncology Stock Plan - Under the 2023 Citius Oncology Stock Plan, we reserved 15,000,000 shares of common stock of Citius Oncology. On August 2, 2024, Citius Oncology reserved 15,000,000 shares under the Citius Oncology 2024 Stock plan The Citius Oncology Stock Plans provide incentives to employees, directors, and consultants through grants of options, SARs, dividend equivalent rights, restricted stock, restricted stock units, or other rights. As of September 30, 2025, options to purchase 18,100,000 shares were outstanding, restricted stock awards of 11,600,000 have not vested and 300,000 shares remain available for future grants.

The following assumptions were used in determining the fair value of the Citius Oncology stock option grants for the year ended September 30, 2025 and 2024:

	2025	2024
Risk-free interest rate	4.08-4.18%	4.66%
Expected dividend yield	0.00	0.00%
Expected term	5.50-6.50 years	6.50 years
Expected volatility	85%	87%

Volatility is estimated using the trading activity of Citius Pharmaceuticals common stock. until such time as Citius Oncology has sufficient history. 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 to employees and directors, all of which qualify as “plain vanilla,” is based on the average of the contractual term (generally 10 years) and the vesting period. For non-employee options, the expected term is the contractual term.

A summary of option activity under the Citius Oncology plan is presented below:

	Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term	Aggregate Intrinsic Value
Outstanding at September 30, 2024	12,750,000	$ 2.15	8.78 years	$ —
Granted	5,750,000	1.07		
Forfeited	(400,000)			
Outstanding at September 30, 2025	18,100,000	$ 1.83	8.21 years	$ 5,386,000
Exercisable at September 30, 2025	9,781,250	$ 2.02	7.94 years	$ 1,136,500

On December 2, 2024, the Board of Directors granted options to purchase 200,000 shares of common stock at an exercise price of $1.02 per share. On December 12, 2024, the Board of Directors granted options to purchase 5,550,000 shares of common stock at an exercise price of $1.07 per share. The weighted average grant date fair value of the options granted during the year ended September 30, 2025 was estimated at $0.80 per share. All these options vest over terms of 12 to 36 months and have a term of 10 years.

At September 30, 2025, unrecognized total compensation cost related to unvested awards of $7,814,682 is expected to be recognized over a weighted average period of 1.23 years.

Citius Oncology Restricted Stock Awards

On September 19, 2025, the Board of Directors granted restricted stock awards of 11,600,000 shares of common stock to employees and directors. The restricted stock awards vest on September 30, 2028. The fair value of the common stock on the date of grant was $20,300,000 ($1.75 per share).

Stock-based compensation expense for restricted stock awards for the year ended September 30, 2025 was $203,741.

At September 30, 2025, unrecognized total compensation cost related to unvested restricted stock awards under the stock plans of $20,096,259 is expected to be recognized over a weighted average period of 2.97 years.

Stock-based compensation expense - under all plans for the years ended September 30, 2025 and 2024 was $10,836,291 (including $8,116,678 for Citius Oncology options and $203,741 for Citius Oncology restricted stock awards) and $11,839,678 (including $47,574 for the NoveCite plan and $7,498,817 for the Citius Oncology plan). respectively.

Citius Pharmaceuticals Warrants

We reserved 14,479,372 shares of common stock for the exercise of outstanding warrants. The following table summarizes the warrants outstanding at September 30, 2025:

	Exercise price	Number	Expiration Dates
August 2018 Offering Investors	28.75	156,863	August 14, 2026
August 2018 Offering Agent	39.84	7,576	August 8, 2026
September 2019 Offering Investors	19.25	111,732	September 27, 2026
September 2019 Offering Underwriter	27.97	7,774	September 27, 2026
May 2020 Offering Investors	25.00	66,824	November 18, 2025
January 2021 Offering Investors	30.78	123,648	July 27, 2026
January 2021 Offering Agent	40.44	14,065	July 27, 2026
February 2021 Offering Investors	42.50	823,211	February 19, 2026
February 2021 Offering Agent	47.03	100,256	February 19, 2026
May 2023 Offering Investors	37.50	500,000	May 8, 2028
May 2023 Offering Agent	37.50	35,000	May 3, 2028
April 2024 Offering Investors	18.75	857,143	October 30, 2029
April 2024 Offering Agent	21.875	60,000	April 25, 2029
November 2024 Offering Investors	6.25	480,000	November 18, 2029
November 2024 Offering Agent	7.8125	33,600	November 15, 2029
January 2025 Offering Investors	3.91	743,496	January 8, 2030
January 2025 Offering Agent	5.0438	52,045	January 7, 2030
April 2025 Offering Agent	1.4375	121,739	April 1, 2030
June 2025 Offering Investor	1.00	9,840,000	June 11, 2027
June 2025 Offering Agent	1.525	344,400	June 11, 2027
		14,479,372	

On April 2, 2024, we extended the term to April 5, 2025, for 51,780 warrants with an exercise price of $35.50 per share and extended the term to April 5, 2025, for 9,605 warrants with an exercise price of $48.28 per share. We recorded a deemed dividend of $321,559 based on the excess of the fair value of the modified warrants over the fair value of the warrants before the modification which increased the net loss attributable to common shareholders for the year ended September 30, 2024.

On August 7, 2024, we extended the term to August 14, 2025, for 156,863 warrants with an exercise price of $28.75 per share and extended the term to August 8, 2025, for 7,576 warrants with an exercise price of $39.84 per share. We recorded a deemed dividend of $375,511 based on the excess of the fair value of the modified warrants over the fair value of the warrants before the modification which increased the net loss attributable to common shareholders for the year ended September 30, 2024.

On September 25, 2024, we extended the term to September 27, 2025, for 111,732 warrants with an exercise price of $19.25 per share and extended the term to September 27, 2025, for 7,774 warrants with an exercise price of $27.97 per share. We recorded a deemed dividend of $350,241 based on the excess of the fair value of the modified warrants over the fair value of the warrants before the modification which increased the net loss attributable to common shareholders for the year ended September 30, 2024.

On August 7, 2025, we extended the term to August 14, 2026 for 156,863 warrants with an exercise price of $28.75 per share and extended the term to August 8, 2026 for 7,577 warrants with an exercise price of $39.84 per share. On August 7, 2025, we also extended the term to September 27, 2026 for 111,732 warrants with an exercise price of $19.25 per share and 7,774 warrants with an exercise price of $27.97 per share. We did not record a deemed dividend for the year ended September 30, 2025, as there was no increase in the fair value of the modified warrants over the fair value of the warrants before the modification.

At September 30, 2025, the weighted average remaining life of the outstanding warrants is 2.02 years, all warrants are exercisable, and the aggregate intrinsic value of the warrants outstanding was $2,361,600.

Citius Oncology Warrants

We have reserved 13,276,754 shares of common stock for the exercise of outstanding warrants. The following table summarizes the warrants outstanding at September 30, 2025:

	Exercise price	Number	Expiration Dates
July 2025 Offering Investors	$ 1.32	6,818,182	July 17, 2030
July 2025 Offering Agent	1.65	272,727	July 17, 2030
July 2025 Prior Offering Agent	1.65	477,273	July 17, 2030
September 2025 Offering Investors	1.84	5,142,858	March 10, 2031
September 2025 Offering Agent	1.92	205,714	March 10, 2031
September 2025 Prior Offering Agent	2.1875	360,000	March 10, 2031
		13,276,754	

At September 30, 2025, the weighted average remaining life of the outstanding warrants is 5.08 years, all warrants are exercisable except for the September 2025 Offering warrants which become exercisable on March 10, 2026, and the aggregate intrinsic value of the warrants outstanding was $6,125,681.

Citius Pharma Common Stock Reserved

A summary of common stock reserved for future issuances by Citius Pharma excluding our subsidiaries as of September 30, 2025 is as follows:

Stock plan options outstanding	839,510
Stock plan shares available for future grants	118,000
Warrants outstanding	14,479,372
Total	15,436,882

Citius Oncology Common Stock Reserved

A summary of common stock reserved for future issuances by Citius Oncology as of September 30, 2025 is as follows:

Stock plan options outstanding	18,100,000
Restricted stock awards	11,600,000
Stock plan shares available for future grants	300,000
Warrants outstanding	13,276,754
Total	43,276,754

7. RELATED PARTY TRANSACTIONS

During the year ended September 30, 2024, Citius Pharma extended warrants held by our Chairman and Executive Vice Chairman (see Note 6) for 51,780 warrants on April 5, 2024, 156,863 warrants on August 7, 2024 and 111,732 warrants on September 25, 2024. During the year ended September 30, 2025, Citius Pharma extended warrants held by our Chairman and Executive Vice Chairman (see Note 6) for 156,863 warrants and 111,732 warrants on August 7, 2025.

See also Note 10 for Merger transaction and transactions consummated with our subsidiary to facilitate the Merger.

Citius Pharma is a party to a Shared Services Agreement with Citius Oncology. Under the terms of the agreement, the Citius Pharma provides all executive, operational, financial, and administrative support to Citius Oncology for a period of up to two (2) years. The quarterly allocated expense to Citius Oncology by Citius Pharma is currently approximately $1,006,000.

8. EMPLOYMENT AGREEMENTS

On October 19, 2017, the Company and its Chairman of the Board, Leonard Mazur, entered into an employment agreement with a three-year term. Upon expiration, the agreement automatically renews for successive periods of one-year unless terminated. Under the terms of the agreement, we are required to pay base compensation plus incentives over the employment term plus severance benefits upon the occurrence of certain events as described in the agreement.

On November 27, 2017, we entered into an employment agreement with Jaime Bartushak to serve as our Chief Financial Officer and Principal Financial Officer.. The agreement requires us to pay base compensation plus incentives over the employment term plus severance benefits upon the occurrence of certain events as described in the agreement.

On April 12, 2022, we entered into an employment agreement with Myron Holubiak to serve as Executive Vice Chairman. Upon expiration, the agreement automatically renews for successive periods of one-year unless terminated. The agreement requires us to pay base compensation plus incentives over the employment term plus severance benefits upon the occurrence of certain events as described in the agreement.

On July 13, 2020, we entered into an employment agreement with Myron Czuczman, M.D. to serve as Executive Vice President, Chief Medical Officer. The agreement requires us to pay base compensation plus incentives over the employment term plus severance benefits upon the occurrence of certain events as described in the agreement.

The Company has employment agreements with certain other employees that require us to pay base compensation plus incentives over the employment term plus severance benefits upon the occurrence of certain events as described in the agreement.

9. COMMITMENTS AND CONTINGENCIES

Operating Lease

Effective July 1, 2019, we entered into a 76-month lease for office space in Cranford, NJ. On February 28, 2025 we extended the lease to February 28, 2030. A right-of-use asset of $786,697 was recognized as a non-cash asset and liability on the amendment date. We pay our 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.

We identified and assessed the following significant assumptions in recognizing our right-of-use assets and corresponding lease liabilities:

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

The elements of lease expense are as follows:

Lease cost	**Year Ended September 30, 2025**	**Year Ended September 30, 2024**
Operating lease cost	$ 269,143	$ 238,823
Variable lease cost	32,692	25,809
Total lease cost	$ 301,835	$ 264,632
Other information		
Weighted-average remaining lease term - operating leases	4.42 Years	1.1 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,	
2026	$ 171,280
2027	232,827
2028	237,686
2029	242,545
2030	102,849
Total lease payments	987,187
Less: interest	(173,914)
Present value of lease liabilities	$ 813,273

Leases	**Classification**	**September 30, 2025**	**September 30, 2024**
Assets			
Lease asset	Operating	$ 818,694	$ 246,247
Total lease assets		$ 818,694	$ 246,247
Liabilities			
Current	Operating	$ 88,348	$ 241,547
Non-current	Operating	724,925	21,318
Total lease liabilities		$ 813,273	$ 262,865

Interest expense on the lease liability was $39,054 and $30,644 for the years ended September 30, 2025 and 2024, respectively. This amount is classified within general & administrative expense.

Commercial Manufacturing Contracts

We entered into an agreement with a Contract Manufacturing Organization for the manufacture and supply of drug substance. The agreement runs through calendar 2026, with an automatic renewal for a subsequent 4-year term. Under this agreement, we are obligated to purchase minimum annual quantities of batches at a set price per batch, subject to annual increases. Additionally, we are required to pay an annual service fee of $250,000. The agreement also includes provisions for potential price increases based on increases in the manufacturer's operating expenses or industry indices, as well as significant termination fees and obligations. As of September 30, 2025, the total minimum purchase commitment under this agreement was approximately $16.2 million consisting of payments of $8.5 million and $5.3 million for 2025 and 2026 respectively and approximately $2.4 million for 2026 pass-throughs and consumable manufacturing components.

As of September 30, 2025, we also have commercial supply agreements with two other vendors for the completion and packaging of finished drug products. Minimum purchase commitments under these two agreements amount to approximately $4.9 million consisting of purchase commitment obligations of $1.2 million in 2025 and $1.9 million in 2026 and $1.8 million in 2027.

Legal Proceedings

We are not involved in any litigation that we believe could have a material adverse effect on our financial position or results of operations. There is no action, suit, proceeding, inquiry, or investigation before or by any court, public board, government agency, self-regulatory organization or body pending or, to the knowledge of our executive officers, threatened against or affecting us or our officers or directors in their capacities as such.

10. MERGER AGRFEEMENT

On October 23, 2023, the Company and its then wholly owned subsidiary 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 TenX Merger Sub Inc., a Delaware corporation and a wholly owned subsidiary of TenX ("Merger Sub").

On August 12, 2024, pursuant to the terms and conditions of the Merger Agreement, Merger Sub merged with and into Citius Oncology, with Citius Oncology surviving as a wholly owned subsidiary of TenX (the "Merger") which was subsequently renamed Citius Oncology Sub. Prior to the closing of the Merger, TenX migrated to and domesticated 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"). As part of the Domestication, TenX changed its name to "Citius Oncology, Inc." (Nasdaq: CTOR). Immediately after the closing of the Merger, Citius Pharma owned approximately 92.3% of the outstanding shares of common stock of Citius Oncology.

The Merger, net amount of $3,831,357 charged to additional paid in capital consists of $395,515 of net liabilities of TenX on the date of the Merger (cash of $163,500 less liabilities of $559,015) plus directly related transaction costs $2,358,780 and the cost of public rights in the amount of $1,077,062.

As part of the Merger, we made capital investments in Citius Oncology through cash contributions of $3,827,944 to fund transactions related to the Merger and by reclassifying to additional paid in capital intercompany receivables of $33,180,961 that were due from Citius Oncology to us. Simultaneously, we advanced an additional $3,800,111 to Citius Oncology under the terms of a non-interest bearing note payable. The note is repayable upon a capital raise by Citius Oncology of at least $10,000,000 through the issuance of debt, equity or royalty financing. The Merger resulted in an initial 92.3% ownership interest by Citius Pharma in Citius Oncology.

11. GAIN ON SALE OF NEW JERSEY NET OPERATING LOSSES

We recognized a gain of $2,387,842 for the year ended September 30, 2024, 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.

12. INCOME TAXES

We recorded deferred income tax expense of $1,056,960 and $576,000 for the years ended September 30, 2025 and 2024 related to the amortization for taxable purposes of its in-process research and development asset.

The income tax expense (benefit) differs from the amount of income tax determined by applying the U.S. federal income tax rate to pretax income for the years ended September 30, 2025 and 2024 due to the following:

	2025	2024
Computed "expected" tax benefit	(21.0)%	(21.0)%
Increase (decrease) in income taxes resulting from:		
State taxes, net of federal benefit	(6.3)	(6.3)
Permanent differences	4.0	5.5
Increase in the valuation reserve	26.0	23.3
	2.7%	1.5%

Deferred income taxes reflect the net tax effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. Significant components of our deferred tax assets and liabilities are as follows:

	September 30, 2025	September 30, 2024
Deferred tax assets:		
Net operating loss carryforward	$ 48,987,000	$ 39,888,000
Stock-based compensation	4,269,000	3,310,000
Capitalized research and development	6,695,000	5,762,000
Other	6,420,000	4,933,000
Valuation allowance on deferred tax assets	(66,147,000)	(53,826,000)
Total deferred tax assets	224,000	67,000
Deferred tax liabilities:		
ROU Asset	(224,000)	(67,000)
In-process research and development	(7,770,760)	(6,713,800)
Total deferred tax liability	(7,994,760)	(6,780,800)
Net deferred tax liability	$ (7,770,760)	$ (6,713,800)

We recorded a valuation allowance against deferred tax assets as the utilization of the net operating loss carry-forward and other deferred tax assets is uncertain. During the years ended September 30, 2025 and 2024, the valuation allowance increased by $12,321,000 and $8,911,000, respectively. The increase in the valuation allowance during the years ended September 30, 2025 and 2024 was primarily due to our net operating loss. At September 30, 2025, we have a federal net operating loss carryforward of approximately $181,000,000. Federal net operating loss carryforwards of approximately $29,000,000 begin expiring in 2034 and carryforwards of approximately $152,000,000 generated in tax years beginning after 2017 may be carried forward indefinitely. Use of federal net operating losses may be limited under Section 382 of the Internal Revenue Code due to changes in ownership.

As of September 30, 2025, we also have estimated federal research and development credits of $5,297,000 to offset future income taxes. The tax credit carryforwards will begin to expire in 2036.

On July 4, 2025, the "One Big Beautiful Bill Act" ("OBBBA") was signed into law in the United States. The OBBBA includes a broad range of tax reform provisions for businesses, including extensions of key Tax Cuts and Jobs Act provisions, modifications to the international tax framework, and restoration of favorable tax treatment for certain business provisions. Certain provisions of the legislation will become effective in 2025, while others are effective in 2026. The OBBBA was enacted during our fourth fiscal quarter of 2025, and we have considered its potential effects and reflected the impact of the OBBBA on our financial position, results of operations, and cash flows. We are in the process of evaluating the impact of these provisions on future periods, but we do not expect the OBBBA to have a material impact on our consolidated financial statements.

We account for uncertain tax positions in accordance with the guidance provided in ASC 740, "Accounting for Income Taxes." This guidance describes a recognition threshold and measurement attribute for the financial statement disclosure of tax positions taken or expected to be taken in a tax return and requires recognition of tax benefits that satisfy a more-likely-than-not threshold. ASC 740 also provides guidance on de-recognition, classification, interest and penalties, accounting in interim periods and disclosure. There have been no reserves for uncertain tax positions recorded by us to date.

13. SUBSEQUENT EVENTS

On October 20, 2025, Citius Pharmaceuticals, Inc. entered into a securities purchase agreement with a certain institutional investor for the issuance and sale, in a registered direct offering by the Company , of 1,460,000 shares of the Company's common stock, par value $0.001 per share , and pre-funded warrants to purchase up to 2,513,510 shares of common stock at an offering price of $1.51 and $1.5099, respectively. The Company also issued to the investor warrants to purchase up to 3,973,510 shares of common stock. The offering closed on October 21, 2025. Gross proceeds were approximately $6.0 million, before deducting placement agent fees and other expenses.

On December 8, 2025, Citius Oncology entered into a securities purchase agreement with a certain institutional investor in a registered direct offering for the purchase and sale of 1,284,404 shares of our common stock at an offering price of $1.09 per share of common stock. In a concurrent private placement, the Company also agreed to sell such institutional investor warrants to purchase up to 1,284,404 shares of common stock, with an exercise price of $1.09 per share of our common stock, which are exercisable upon the requisite stockholder approval, and have a term of five years from the date of the stockholder approval. The aggregate gross proceeds to the Company from the offering were approximately $18.0 million. Net proceeds were approximately $15.2 million, after deducting placement agent fees and other offering expenses payable by the Company.

On December 8, 2025, Citius Oncology also entered into a securities purchase agreement with such institutional investor to issue in a concurrent private placement pre-funded warrants to purchase up to 15,229,358 shares of common stock and 15,229,358 warrants, at a combined price of $1.0899 per pre-funded warrant and accompanying warrant. The pre-funded warrants are exercisable immediately, at an exercise price of $0.0001 per share, and will remain valid and exercisable until all the pre-funded warrants are exercised in full.

In connection with the offering, Citius Oncology agreed to pay the placement agent a cash fee of 7.0% of the aggregate gross proceeds Citius Oncology received in the offering. In addition, the Company granted warrants to the placement agent, or its designees, to purchase up to 1,155,963 shares of common stock. The terms of the placement agent warrants are substantially the same as the terms of the warrants, except that the exercise price is $1.3625 per share and expire five years from the commencement of sales in the offering.

NEITHER THIS SECURITY NOR THE SECURITIES FOR WHICH THIS SECURITY IS EXERCISABLE HAVE BEEN REGISTERED WITH THE SECURITIES AND EXCHANGE COMMISSION OR THE SECURITIES COMMISSION OF ANY STATE IN RELIANCE UPON AN EXEMPTION FROM REGISTRATION UNDER THE SECURITIES ACT OF 1933, AS AMENDED (THE "SECURITIES ACT"), AND, ACCORDINGLY, MAY NOT BE OFFERED OR SOLD EXCEPT PURSUANT TO AN EFFECTIVE REGISTRATION STATEMENT UNDER THE SECURITIES ACT OR PURSUANT TO AN AVAILABLE EXEMPTION FROM, OR IN A TRANSACTION NOT SUBJECT TO, THE REGISTRATION REQUIREMENTS OF THE SECURITIES ACT AND IN ACCORDANCE WITH APPLICABLE STATE SECURITIES LAWS. THIS SECURITY AND THE SECURITIES ISSUABLE UPON EXERCISE OF THIS SECURITY MAY BE PLEDGED IN CONNECTION WITH A BONA FIDE MARGIN ACCOUNT OR OTHER LOAN SECURED BY SUCH SECURITIES.

COMMON STOCK PURCHASE WARRANT

CITIUS PHARMACEUTICALS, INC.

Warrant Shares: 75,000 Initial Exercise Date: December 2, 2025

THIS COMMON STOCK PURCHASE WARRANT (the "Warrant") certifies that, for value received, Pagoda Resources, Inc. or its assigns (the "Holder") is entitled, upon the terms and subject to the limitations on exercise and the conditions hereinafter set forth, at any time on or after the date set forth above (the "Initial Exercise Date") and on or prior to 5:00 p.m. (New York City time) on December 2, 2030 (the "Termination Date") but not thereafter, to subscribe for and purchase from CITIUS PHARMACEUTICALS, INC., a Nevada corporation (the "Company"), up to 75,000 shares of Common Stock (as subject to adjustment hereunder, the "Warrant Shares"). The purchase price of one share of Common Stock under this Warrant shall be equal to the Exercise Price, as defined in Section 2(b).

Section 1. Definitions. In addition to the terms defined elsewhere in this Warrant, the following terms have the meanings indicated in this Section 1:

"Business Day" means any day other than Saturday, Sunday or other day on which commercial banks in The City of New York are authorized or required by law to remain closed; provided, however, for clarification, commercial banks shall not be deemed to be authorized or required by law to remain closed due to "stay at home", "shelter-in-place", "non-essential employee" or any other similar orders or restrictions or the closure of any physical branch locations at the direction of any governmental authority so long as the electronic funds transfer systems (including for wire transfers) of commercial banks in The City of New York are generally open for use by customers on such day.

"Common Stock" means the common stock of the Company, $0.001 par value per share, and any other class of securities into which such securities may hereafter be reclassified or changed.

"Trading Day" means a day on which the Common Stock is traded on a Trading Market.

"Trading Market" means any of the following markets or exchanges on which the Common Stock is listed or quoted for trading on the date in question: the NYSE American, the Nasdaq Capital Market, the Nasdaq Global Market, the Nasdaq Global Select Market, or the New York Stock Exchange (or any successors to any of the foregoing).

"Transfer Agent" means VStock Transfer, with offices located at 18 Lafayette Place, Woodmere, NY 11598, and any successor transfer agent of the Company.

Section 2. Exercise.

a) Exercise of Warrant. Exercise of the purchase rights represented by this Warrant may be made, in whole or in part, at any time or times on or after the Initial Exercise Date and on or before the Termination Date by delivery to the Company of a duly executed PDF copy submitted by e-mail (or e-mail attachment) of the Notice of Exercise in the form annexed hereto (the "Notice of Exercise"). Within the one (1) Trading Day following the date of exercise as aforesaid, the Holder shall deliver the aggregate Exercise Price for the Warrant Shares specified in the applicable Notice of Exercise by wire transfer or cashier's check drawn on a United States bank. No ink-original Notice of Exercise shall be required, nor shall any medallion guarantee (or other type of guarantee or notarization) of any Notice of Exercise be required. Notwithstanding anything herein to the contrary, the Holder shall not be required to physically surrender this Warrant to the Company until the Holder has purchased all of the Warrant Shares available hereunder and the Warrant has been exercised in full, in which case, the Holder shall surrender this Warrant to the Company for cancellation within three (3) Trading Days of the date on which the final Notice of Exercise is delivered to the Company. Partial exercises of this Warrant resulting in purchases of a portion of the total number of Warrant Shares available hereunder shall have the effect of lowering the outstanding number of Warrant Shares purchasable hereunder in an amount equal to the applicable number of Warrant Shares purchased. The Holder and the Company shall maintain records showing the number of Warrant Shares purchased and the date of such purchases. The Company shall deliver any objection to any Notice of Exercise within one (1) Business Day of receipt of such notice. **The Holder and any assignee, by acceptance of this Warrant, acknowledge and agree that, by reason of the provisions of this paragraph, following the purchase of a portion of the Warrant Shares hereunder, the number of Warrant Shares available for purchase hereunder at any given time may be less than the amount stated on the face hereof.**

b) Exercise Price. The exercise price per Warrant Share under this Warrant shall be $1.26, subject to adjustment hereunder (the "Exercise Price").

c) Mechanics of Exercise.

i. Delivery of Warrant Shares Upon Exercise. The Company shall cause the Warrant Shares purchased hereunder to be transmitted by the Transfer Agent to the Holder by crediting the account of the Holder's or its designee's balance account with DTC through its Deposit or Withdrawal at Custodian system ("DWAC") if the Company is then a participant in such system and there is an effective registration statement permitting the issuance of the Warrant Shares to or resale of the Warrant Shares by the Holder, and otherwise by physical delivery of a certificate, registered in the Company's share register in the name of the Holder or its designee, for the number of Warrant Shares to which the Holder is entitled pursuant to such exercise to the address specified by the Holder in the Notice of Exercise. Upon delivery of the Notice of Exercise, the Holder shall be deemed for all corporate purposes to have become the holder of record of the Warrant Shares with respect to which this Warrant has been exercised, irrespective of the date of delivery of the Warrant Shares, provided that payment of the aggregate Exercise Price (other than in the case of a cashless exercise) is received by the Company prior to such delivery.

ii. Delivery of New Warrants Upon Exercise. If this Warrant shall have been exercised in part, the Company shall, at the request of the Holder and upon surrender of this Warrant certificate, at the time of delivery of the Warrant Shares, deliver to the Holder a new Warrant evidencing the rights of the Holder to purchase the unpurchased Warrant Shares called for by this Warrant, which new Warrant shall in all other respects be identical with this Warrant.

iii. No Fractional Shares or Scrip. No fractional shares or scrip representing fractional shares shall be issued upon the exercise of this Warrant. If, upon the exercise of this Warrant, the Holder would be entitled to receive a fractional interest in a Warrant Share, the Company will, upon exercise, round down to the nearest whole number of Warrant Shares to be issued to the Holder.

iv. Charges, Taxes and Expenses. Issuance of Warrant Shares shall be made without charge to the Holder for any issue or transfer tax or other incidental expense in respect of the issuance of such Warrant Shares, all of which taxes and expenses shall be paid by the Company, and such Warrant Shares shall be issued in the name of the Holder or in such name or names as may be directed by the Holder; provided, however, that, in the event that Warrant Shares are to be issued in a name other than the name of the Holder, this Warrant when surrendered for exercise shall be accompanied by the Assignment Form attached hereto duly executed by the Holder and the Company may require, as a condition thereto, the payment of a sum sufficient to reimburse it for any transfer tax incidental thereto. The Company shall pay all Transfer Agent fees required for same-day processing of any Notice of Exercise and all fees to DTC (or another established clearing corporation performing similar functions) required for same-day electronic delivery of the Warrant Shares.

v. Closing of Books. The Company will not close its stockholder books or records in any manner which prevents the timely exercise of this Warrant, pursuant to the terms hereof.

Section 3. Certain Adjustments.

a) Stock Dividends and Splits. If the Company, at any time while this Warrant is outstanding: (i) pays a stock dividend or otherwise makes a distribution or distributions on shares of its Common Stock or any other equity or equity equivalent securities payable in shares of Common Stock (which, for avoidance of doubt, shall not include any shares of Common Stock issued by the Company upon exercise of this Warrant), (ii) subdivides outstanding shares of Common Stock into a larger number of shares, (iii) combines (including by way of reverse stock split) outstanding shares of Common Stock into a smaller number of shares, or (iv) issues by reclassification of shares of Common Stock of the Company, then in each case the Exercise Price shall be multiplied by a fraction of which the numerator shall be the number of shares of Common Stock (excluding treasury shares, if any) outstanding immediately before such event and of which the denominator shall be the number of shares of Common Stock outstanding immediately after such event, and the number of shares issuable upon exercise of this Warrant shall be proportionately adjusted such that the aggregate Exercise Price of this Warrant shall remain unchanged. Any adjustment made pursuant to this Section 3(a) shall become effective immediately after the record date for the determination of stockholders entitled to receive such dividend or distribution and shall become effective immediately after the effective date in the case of a subdivision, combination or re-classification.

b) Calculations. All calculations under this Section 3 shall be made to the nearest cent or the nearest 1/100th of a share, as the case may be. For purposes of this Section 3, the number of shares of Common Stock deemed to be issued and outstanding as of a given date shall be the sum of the number of shares of Common Stock (excluding treasury shares, if any) issued and outstanding.

c) Notice to Holder.

i. Adjustment to Exercise Price. Whenever the Exercise Price is adjusted pursuant to any provision of this Section 3, the Company shall promptly deliver to the Holder by email a notice setting forth the Exercise Price after such adjustment and any resulting adjustment to the number of Warrant Shares and setting forth a brief statement of the facts requiring such adjustment.

ii. Notice to Allow Exercise by Holder. If (A) the Company shall declare a dividend (or any other distribution in whatever form) on the Common Stock, (B) the Company shall declare a special nonrecurring cash dividend on or a redemption of the Common Stock, (C) the Company shall authorize the granting to all holders of the Common Stock rights or warrants to subscribe for or purchase any shares of capital stock of any class or of any rights, or (D) the Company shall authorize the voluntary or involuntary dissolution, liquidation or winding up of the affairs of the Company, then, in each case, the Company shall cause to be delivered by email to the Holder at its last email address as it shall appear upon the Warrant Register (as defined below) of the Company, at least 20 calendar days prior to the applicable record or effective date hereinafter specified, a notice stating (x) the date on which a record is to be taken for the purpose of such dividend, distribution, redemption, rights or warrants, or if a record is not to be taken, the date as of which the holders of the Common Stock of record to be entitled to such dividend, distribution, redemption, rights or warrants are to be determined or (y) the date on which such dissolution or liquidation is expected to become effective; provided that the failure to deliver such notice or any defect therein or in the delivery thereof shall not affect the validity of the corporate action required to be specified in such notice. The Holder shall remain entitled to exercise this Warrant during the period commencing on the date of such notice to the effective date of the event triggering such notice except as may otherwise be expressly set forth herein.

Section 4. Transfer of Warrant.

a) Transferability. Subject to compliance with any applicable securities laws, this Warrant and all rights hereunder (including, without limitation, any registration rights) are transferable, in whole or in part, upon surrender of this Warrant at the principal office of the Company or its designated agent, together with a written assignment of this Warrant substantially in the form attached hereto duly executed by the Holder or its agent or attorney and funds sufficient to pay any transfer taxes payable upon the making of such transfer. Upon such surrender and, if required, such payment, the Company shall execute and deliver a new Warrant or Warrants in the name of the assignee or assignees, as applicable, and in the denomination or denominations specified in such instrument of assignment, and shall issue to the assignor a new Warrant evidencing the portion of this Warrant not so assigned, and this Warrant shall promptly be cancelled. The Warrant, if properly assigned in accordance herewith, may be exercised by a new holder for the purchase of Warrant Shares without having a new Warrant issued.

b) New Warrants. This Warrant may be divided or combined with other Warrants upon presentation hereof at the aforesaid office of the Company, together with a written notice specifying the names and denominations in which new Warrants are to be issued, signed by the Holder or its agent or attorney. Subject to compliance with Section 4(a), as to any transfer which may be involved in such division or combination, the Company shall execute and deliver a new Warrant or Warrants in exchange for the Warrant or Warrants to be divided or combined in accordance with such notice. All Warrants issued on transfers or exchanges shall be dated the initial issuance date of this Warrant and shall be identical with this Warrant except as to the number of Warrant Shares issuable pursuant thereto.

c) Warrant Register. The Company shall register this Warrant, upon records to be maintained by the Company for that purpose (the "Warrant Register"), in the name of the record Holder hereof from time to time. The Company may deem and treat the registered Holder of this Warrant as the absolute owner hereof for the purpose of any exercise hereof or any distribution to the Holder, and for all other purposes, absent actual notice to the contrary.

Section 5. Miscellaneous.

a) No Rights as Stockholder Until Exercise; No Settlement in Cash. This Warrant does not entitle the Holder to any voting rights, dividends or other rights as a stockholder of the Company prior to the exercise hereof as set forth in Section 2(c)(i), except as expressly set forth in Section 3. In no event will the Company be required to net cash settle an exercise of this Warrant.

b) Loss, Theft, Destruction or Mutilation of Warrant. The Company covenants that upon receipt by the Company of evidence reasonably satisfactory to it of the loss, theft, destruction or mutilation of this Warrant or any stock certificate relating to the Warrant Shares, and in case of loss, theft or destruction, of indemnity or security reasonably satisfactory to it (which, in the case of the Warrant, shall not include the posting of any bond), and upon surrender and cancellation of such Warrant or stock certificate, if mutilated, the Company will make and deliver a new Warrant or stock certificate of like tenor and dated as of such cancellation, in lieu of such Warrant or stock certificate.

c) Saturdays, Sundays, Holidays, etc. If the last or appointed day for the taking of any action or the expiration of any right required or granted herein shall not be a Business Day, then such action may be taken or such right may be exercised on the next succeeding Business Day.

d) Authorized Shares.

The Company covenants that, during the period the Warrant is outstanding, it will reserve from its authorized and unissued Common Stock a sufficient number of shares to provide for the issuance of the Warrant Shares upon the exercise of any purchase rights under this Warrant. The Company further covenants that its issuance of this Warrant shall constitute full authority to its officers who are charged with the duty of issuing the necessary Warrant Shares upon the exercise of the purchase rights under this Warrant. The Company will take all such reasonable action as may be necessary to assure that such Warrant Shares may be issued as provided herein without violation of any applicable law or regulation, or of any requirements of the Trading Market upon which the Common Stock may be listed. The Company covenants that all Warrant Shares which may be issued upon the exercise of the purchase rights represented by this Warrant will, upon exercise of the purchase rights represented by this Warrant and payment for such Warrant Shares in accordance herewith, be duly authorized, validly issued, fully paid and nonassessable and free from all taxes, liens and charges created by the Company in respect of the issue thereof (other than taxes in respect of any transfer occurring contemporaneously with such issue).

Except and to the extent as waived or consented to by the Holder, the Company shall not by any action, including, without limitation, amending its certificate of incorporation or through any reorganization, transfer of assets, consolidation, merger, dissolution, issue or sale of securities or any other voluntary action, avoid or seek to avoid the observance or performance of any of the terms of this Warrant, but will at all times in good faith assist in the carrying out of all such terms and in the taking of all such actions as may be necessary or appropriate to protect the rights of Holder as set forth in this Warrant against impairment.

Before taking any action which would result in an adjustment in the number of Warrant Shares for which this Warrant is exercisable or in the Exercise Price, the Company shall obtain all such authorizations or exemptions thereof, or consents thereto, as may be necessary from any public regulatory body or bodies having jurisdiction thereof.

e) Jurisdiction. All questions concerning the construction, validity, enforcement and interpretation of this Warrant shall be governed by and construed and enforced in accordance with the internal laws of the State of Pennsylvania, without regard to the principles of conflict of laws thereof. If either party shall commence an action, suit or proceeding to enforce any provisions of this Warrant, the prevailing party in such action, suit or proceeding shall be reimbursed by the other party for their reasonable attorneys' fees and other costs and expenses incurred with the investigation, preparation and prosecution of such action or proceeding.

f) Restrictions. The Holder acknowledges that the Warrant Shares acquired upon the exercise of this Warrant, if not registered, will have restrictions upon resale imposed by state and federal securities laws.

g) Nonwaiver and Expenses. No course of dealing or any delay or failure to exercise any right hereunder on the part of Holder shall operate as a waiver of such right or otherwise prejudice the Holder's rights, powers or remedies. Without limiting any other provision of this Warrant, if the Company willfully and knowingly fails to comply with any provision of this Warrant, which results in any material damages to the Holder, the Company shall pay to the Holder such amounts as shall be sufficient to cover any costs and expenses, including, but not limited to, reasonable attorneys' fees, excluding those of appellate proceedings, incurred by the Holder in collecting any amounts due pursuant hereto or in otherwise enforcing any of its rights, powers or remedies hereunder.

h) Notices. Any and all notices or other communications or deliveries to be provided by the Holder hereunder including, without limitation, any Notice of Exercise, shall be in writing and delivered personally, by e-mail, or sent by a nationally recognized overnight courier service, addressed to the Company at 11 Commerce Drive, First Floor, Cranford, New Jersey 07016, Attention: **Jamie Bartushak, Chief Financial Officer**, email address: **jbartushak@citiuspharma.com**, or such other email address or address as the Company may specify for such purposes by notice to the Holder. Any and all notices or other communications or deliveries to be provided by the Company hereunder shall be in writing and delivered personally, by email, or sent by a nationally recognized overnight courier service addressed to Holder at the email address or address of Holder appearing on the books of the Company. Any notice or other communication or deliveries hereunder shall be deemed given and effective on the earliest of (i) the time of transmission, if such notice or communication is delivered via facsimile or email at the facsimile number or email address set forth in this Section prior to 5:30 p.m. (New York City time) on any date, (ii) the next Trading Day after the date of transmission, if such notice or communication is delivered via email at the email address set forth in this Section on a day that is not a Trading Day or later than 5:30 p.m. (New York City time) on any Trading Day, (iii) the second Trading Day following the date of mailing, if sent by U.S. nationally recognized overnight courier service, or (iv) upon actual receipt by the party to whom such notice is required to be given.

i) Limitation of Liability. No provision hereof, in the absence of any affirmative action by the Holder to exercise this Warrant to purchase Warrant Shares, and no enumeration herein of the rights or privileges of the Holder, shall give rise to any liability of the Holder for the purchase price of any Common Stock or as a stockholder of the Company, whether such liability is asserted by the Company or by creditors of the Company.

j) Successors and Assigns. Subject to applicable securities laws, this Warrant and the rights and obligations evidenced hereby shall inure to the benefit of and be binding upon the successors and permitted assigns of the Company and the successors and permitted assigns of Holder. The provisions of this Warrant are intended to be for the benefit of Holder or any holder from time to time of this Warrant and shall be enforceable by the Holder or holder of Warrant Shares.

k) Amendment. This Warrant may be modified or amended or the provisions hereof waived with the written consent of the Company and the Holder.

l) Severability. Wherever possible, each provision of this Warrant shall be interpreted in such manner as to be effective and valid under applicable law, but if any provision of this Warrant shall be prohibited by or invalid under applicable law, such provision shall be ineffective to the extent of such prohibition or invalidity, without invalidating the remainder of such provisions or the remaining provisions of this Warrant.

m) Headings. The headings used in this Warrant are for the convenience of reference only and shall not, for any purpose, be deemed a part of this Warrant.

****

(Signature Page Follows)

IN WITNESS WHEREOF, the Company has caused this Warrant to be executed by its officer thereunto duly authorized as of the date first above indicated.

CITIUS PHARMACEUTICALS, INC.

By: /s/ Leonard Mazur
Name: Leonard Mazur
Title: Chief Executive Officer

NOTICE OF EXERCISE

TO: CITIUS PHARMACEUTICALS, INC.

(1) The undersigned hereby elects to purchase _____ Warrant Shares of the Company pursuant to the terms of the attached Warrant (only if exercised in full), and tenders herewith payment of the exercise price in full, together with all applicable transfer taxes, if any.

Payment shall be in the form of lawful money of the United States.

(2) Please issue said Warrant Shares in the name of the undersigned or in such other name as is specified below:

_____

The Warrant Shares shall be delivered to the following DWAC Account Number:

_____

_____

_____

[SIGNATURE OF HOLDER]

Name of Investing Entity: _____

Signature of Authorized Signatory of Investing Entity: _____

Name of Authorized Signatory: _____

Title of Authorized Signatory: _____

Date: _____

ASSIGNMENT FORM

(To assign the foregoing Warrant, execute this form and supply required information. Do not use this form to purchase shares.)

FOR VALUE RECEIVED, the foregoing Warrant and all rights evidenced thereby are hereby assigned to

Name: _____
(Please Print)

Address: _____
(Please Print)

Email Address: _____

Phone Number: _____

Dated: _____ __, _____
Holder's Signature: _____
Holder's Address: _____

Exhibit 10.38

AMENDMENT TO PROMISSORY NOTE

This Amendment to Promissory Note (the "Amendment") is entered into as of the 10th day of September 2025, by and among Citius Oncology, Inc., a Delaware corporation ("Payor"), and Citius Pharmaceutics, Inc., a Nevada corporation ("Payee").

WHEREAS, Payor issued to Payee a promissory note, dated August 16, 2024 (the "Note");

WHEREAS, Section 10 of the Note requires the written consent of Payor and Payee to any amendment to the Note; and

WHEREAS, Payor and Payee desire to amend the Note as provided herein;

NOW, THEREFORE, to facilitate Payor's current financing efforts, which Payee acknowledges is of direct benefit to Payee and its stockholders, and in consideration of these premises and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties hereby agree as follows:

1. Amendment. Section 1 of the Note is hereby amended in its entirety as follows:

(a) Principal. The entire unpaid principal balance of this Note shall be payable on the date at which Payor has closed a series of capital raises that in the aggregate provide gross proceeds of at least $30 million through the issuance of debt or equity securities or the royalty-backed monetization of LYMPHIR™ (the "**Maturity Date**"). The principal balance may be prepaid. Under no circumstances shall any individual, including but not limited to any officer, director, employee or shareholder of the Payor, be obligated personally for any obligations or liabilities of the Payor hereunder.

2. No Further Modifications. Except as modified pursuant to this Amendment, the Notes and their terms remain in full force and effect.

3. Entire Agreement. This Amendment contains the entire understanding of the parties with respect to the subject matter hereof, and there are no representations, warranties, covenants or undertakings, oral or otherwise, that are not expressly set forth herein. No further modification of the Note is valid unless executed in writing with the same formality as this Amendment and by the same parties or their successors or assigns.

4. Counterparts; Facsimile Signatures. This Amendment may be executed in any number of counterparts, each of which shall constitute an original, but which, when taken together, shall constitute by one instrument. One or more counterparts of this Amendment or any exhibit hereto may be delivered via facsimile, with the intention that they shall have the same effect as an original counterpart hereof.

5. Construction. THIS NOTE SHALL BE CONSTRUED AND ENFORCED IN ACCORDANCE WITH THE LAWS OF THE STATE OF DELAWARE, WITHOUT REGARD TO CONFLICT OF LAW PROVISIONS THEREOF.

[Signature pages follow]

IN WITNESS WHEREOF, this Amendment has been executed and delivered by the parties hereto as of the date first written above.

CITIUS ONCOLOGY, INC.

By: /s/ Leonard Mazur
Leonard Mazur
Chairman and Chief Executive Officer

CITIUS PHARMACEUTICALS, INC.

By: /s/ Jaime Bartushak
Jaime Bartushak
Chief Financial Officer

Exhibit 10.39

SECOND AMENDMENT TO PROMISSORY NOTE

This Second Amendment to Promissory Note (the "Amendment") is entered into as of the 10th day of December 2025, by and among Citius Oncology, Inc., a Delaware corporation ("Payor"), and Citius Pharmaceutics, Inc., a Nevada corporation ("Payee").

WHEREAS, Payor issued to Payee a promissory note, dated August 16, 2024, amended September 10, 2025 (the "Note");

WHEREAS, Section 10 of the Note requires the written consent of Payor and Payee to any amendment to the Note; and

WHEREAS, Payor and Payee desire to amend the Note as provided herein;

NOW, THEREFORE, to facilitate Payor's current financing efforts, which Payee acknowledges is of direct benefit to Payee and its stockholders, and in consideration of these premises and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties hereby agree as follows:

1. Amendment. Section 1 of the Note is hereby amended in its entirety as follows:

(a) Principal. The entire unpaid principal balance of this Note shall be payable on the date at which Payor has closed a series of capital raises that in the aggregate provide gross proceeds of at least $50 million through the issuance of debt or equity securities or the royalty-backed monetization of LYMPHIR™ (the "**Maturity Date**"). The principal balance may be prepaid. Under no circumstances shall any individual, including but not limited to any officer, director, employee or shareholder of the Payor, be obligated personally for any obligations or liabilities of the Payor hereunder.

2. No Further Modifications. Except as modified pursuant to this Amendment, the Notes and their terms remain in full force and effect.

3. Entire Agreement. This Amendment contains the entire understanding of the parties with respect to the subject matter hereof, and there are no representations, warranties, covenants or undertakings, oral or otherwise, that are not expressly set forth herein. No further modification of the Note is valid unless executed in writing with the same formality as this Amendment and by the same parties or their successors or assigns.

4. Counterparts; Facsimile Signatures. This Amendment may be executed in any number of counterparts, each of which shall constitute an original, but which, when taken together, shall constitute by one instrument. One or more counterparts of this Amendment or any exhibit hereto may be delivered via facsimile, with the intention that they shall have the same effect as an original counterpart hereof.

5. Construction. THIS NOTE SHALL BE CONSTRUED AND ENFORCED IN ACCORDANCE WITH THE LAWS OF THE STATE OF DELAWARE, WITHOUT REGARD TO CONFLICT OF LAW PROVISIONS THEREOF.

[Signature pages follow]

IN WITNESS WHEREOF, this Amendment has been executed and delivered by the parties hereto as of the date first written above.

CITIUS ONCOLOGY, INC.

By: /s/ Leonard Mazur
Leonard Mazur
Chairman and Chief Executive Officer

CITIUS PHARMACEUTICALS, INC.

By: /s/ Jaime Bartushak
Jaime Bartushak
Chief Financial Officer

Exhibit 10.45

CITIUS PHARMACEUTICALS, INC.

First Amendment to Unsecured Promissory Note

This First Amendment to Unsecured Promissory Note (the "***First Amendment***") is executed effective as of December 2, 2025, by Citius Pharmaceuticals, Inc. (the "***Company***") and Pagoda Resources, Inc. ("***Lender***").

WHEREAS, the Company has issued to Lender an Unsecured Promissory Note in the principal amount of One Million Dollars ($1,000,000.00), dated as of June 2, 2025 (the "***Note***").

WHEREAS, interest on the Note is to accrue at the per annum rate equal to 15.00%, compounded monthly, or such lesser rate as shall be the maximum rate allowable under applicable law.

WHEREAS, all unpaid principal and unpaid accrued interest on the Note shall is due and payable in full on December 2, 2025.

WHEREAS, the Company and Lender now desire to amend the Note as set forth herein.

NOW THEREFORE, the parties hereto, intending to be legally bound, based on the agreement set forth herein and other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, agree to amend the Note as follows:

1. All unpaid principal and unpaid accrued interest on the Note shall be due and payable in full on January 2, 2026.

2. Upon repayment in full of all unpaid principal and unpaid interest, the Company will issue to Lender a warrant to purchase 75,000 shares of the Company's common stock in the form attached hereto as Exhibit A ("the ***Warrant***"). The Warrant will have a five (5) year term, beginning on the date of issuance, and have an exercise price set at fair market value, which will be the closing price of the Company's common stock on Nasdaq on the date of issuance. Lender understands that the Warrant will not be registered under the Securities Act of 1933, as amended (the "***Securities Act***"), by reason of Section 4(a)(2) of the Securities Act. Lender understands that the Warrant will be a "restricted security" under applicable U.S. federal and state securities laws and that, pursuant to these laws, Lender must hold the Warrant and the shares underlying the Warrant indefinitely unless registered with the Securities and Exchange Commission and qualified by state authorities, or an exemption from such registration and qualification requirements is available. Lender acknowledges that the Company has no obligation to register or qualify the Warrant or the shares underlying the Warrant for resale. Lender further acknowledges that if an exemption from registration or qualification is available, it may be conditioned on various requirements including, but not limited to, the time and manner of sale, the holding period for the Warrant, and on requirements relating to the Company which are outside of Lender's control, and which the Company is under no obligation and may not be able to satisfy. Lender represents that it is familiar with Rule 144 under the Securities Act, as presently in effect, and understands the resale limitations imposed thereby and by the Securities Act. Lender hereby confirms, that the Warrant to be acquired by Lender will be acquired for investment for Lender's own account, not as a nominee or agent, and not with a view to the resale or distribution of any part thereof, and that Lender has no present intention of selling, granting any participation in, or otherwise distributing the same. Lender further represents that Lender does not presently have any contract, undertaking, agreement or arrangement with any person or entity to sell, transfer or grant participations to any such person or entity, with respect to the Warrant. The Lender has not been formed for the specific purpose of acquiring the Warrant. Lender is an accredited investor as defined in Rule 501(a) of Regulation D promulgated under the Securities Act. Lender understands that the Warrant will be endorsed with a legend substantially as follows (in addition to any other applicable legends):

THIS WARRANT AND THE SECURITIES UNDERLYING THIS WARRANT HAVE NOT BEEN REGISTERED WITH THE SECURITIES AND EXCHANGE COMMISSION OR THE SECURITIES COMMISSION OF ANY STATE IN RELIANCE UPON AN EXEMPTION FROM REGISTRATION UNDER THE SECURITIES ACT OF 1933, AS AMENDED (THE "SECURITIES ACT"), AND, ACCORDINGLY, MAY NOT BE OFFERED OR SOLD EXCEPT PURSUANT TO AN EFFECTIVE REGISTRATION STATEMENT UNDER THE SECURITIES ACT OR PURSUANT TO AN AVAILABLE EXEMPTION FROM, OR IN A TRANSACTION NOT SUBJECT TO, THE REGISTRATION REQUIREMENTS OF THE SECURITIES ACT AND IN ACCORDANCE WITH APPLICABLE STATE SECURITIES LAWS AS EVIDENCED BY A LEGAL OPINION OF COUNSEL IN A FORM ACCEPTABLE TO THE COMPANY.

3. Except as expressly amended herein, all terms, covenants and conditions of the Note shall remain in full force and affect.

4. The terms of this First Amendment shall be binding upon the successors and permitted assigns of the Company and shall inure to the benefit of the successors and assigns of Lender.

5. This First Amendment shall be construed in accordance with the laws of the Commonwealth of Pennsylvania and the parties submit to the jurisdiction of the courts located in said state.

6. This First Amendment may be executed in any number of counterparts and may be delivered via electronic mail (including .pdf or any electronic signature complying with the U.S. federal ESIGN Act of 2000, e.g., www.docusign.com) or other transmission method, and any counterpart so delivered shall be deemed to have been duly and validly delivered and be valid and effective for all purposes, each of which shall be deemed an original, and all of which together shall constitute one instrument.

[The next page is the signature page]

IN WITNESS WHEREOF, the Company and Lender have executed this First Amendment as of the date first above written.

Citius Pharmaceuticals, Inc.

By: /s/ Leonard Mazur
(Signature)

Name: Leonard Mazur
Title: CEO

Lender

By: /s/ Robert W. Kennedy
(Signature)

Name: Robert W. Kennedy
Title President - Pagoda Resources Inc.

Exhibit 10.48

FIRST AMENDMENT TO
AMENDED AND RESTATED EMPLOYMENT AGREEMENT

This First Amendment to Amended and Restated Employment Agreement (this "**Amendment**") is entered into effective as of September 25, 2024 (the "**Amendment Effective Date**"), by and between Citius Pharmaceuticals, Inc., a Nevada corporation (the "**Company**") and Myron Holubiak ("**Executive**").

WHEREAS, the Company and Executive are parties to that certain Amended and Restated Employment Agreement effective as of May 1, 2022 (the "**Employment Agreement**");

WHEREAS, by its terms, the Employment Agreement was to be in effect for an initial 18-month period, followed by an additional 12-month period, and would terminate at the conclusion of such additional period on October 31, 2024; and

WHEREAS, the Company and Executive now desire to extend the term of the Employment Agreement by 12 additional months, through October 31, 2025.

NOW, THEREFORE, in consideration of the promises and the mutual covenants, conditions and agreements set forth herein and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties hereto, intending to be legally bound, hereby agree as follows:

1. Extension of Term of Employment Agreement. The Company and Executive agree that the "Additional Term" of the Employment Agreement is extended through October 31, 2025, unless sooner terminated as provided in Section 7 of the Employment Agreement.

2. Effect on Remainder of Employment Agreement. Except as expressly set forth in this Amendment, the provisions of the Employment Agreement shall remain in full force and effect, in their entirety, in accordance with their terms.

3. Miscellaneous. This Amendment shall be governed, construed, and interpreted in accordance with the laws of the State of New Jersey, without giving effect to conflicts of laws principles. The parties agree that this Amendment may only be modified in a signed writing executed by both parties. This Amendment shall be binding upon and shall inure to the benefit of the parties hereto and their respective heirs, successors, and assigns. This Amendment may be executed in separate counterparts, each of which is deemed to be an original and all of which taken together constitute one agreement. Counterparts may be delivered via facsimile, electronic mail (including pdf or any electronic signature complying with the U.S. ESIGN Act of 2000, e.g., www.docusign.com) or other transmission method and any counterpart so delivered will be deemed to have been duly and validly delivered and be valid and effective for all purposes.

[Signature Page Immediately Follows]

IN WITNESS WHEREOF, the parties hereto have executed this First Amendment to Amended and Restated Employment Agreement effective as of the Amendment Effective Date.

CITIUS PHARMACEUTICALS, INC.

By: /s/ Leonard Mazur
Name: Leonard Mazur
Title: Chief Executive Officer and Chairman of the Board

EXECUTIVE

/s/ Myron Holubiak

Exhibit 10.49

SECOND AMENDMENT TO
AMENDED AND RESTATED EMPLOYMENT AGREEMENT

This Second Amendment to Amended and Restated Employment Agreement (this "**Amendment**") is entered into by and between Citius Pharmaceuticals, Inc., a Nevada corporation (the "**Company**") and Myron Holubiak ("**Executive**").

WHEREAS, the Company and Executive are parties to that certain Amended and Restated Employment Agreement dated March 30, 2016, as amended and restated effective as of May 1, 2022 (the "**Employment Agreement**");

WHEREAS, by its original terms, the Employment Agreement was to be in effect for an initial 18-month period, followed by an additional 12-month period, and would terminate at the conclusion of such additional period on October 31, 2024;

WHEREAS, the Employment Agreement was subsequently amended to extend the term of the Employment Agreement by 12 additional months, through October 31, 2025; and

WHEREAS, the Company and Executive now desire to extend the term of the Employment Agreement again by 12 additional months, through October 31, 2026.

NOW, THEREFORE, in consideration of the promises and the mutual covenants, conditions and agreements set forth herein and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties hereto, intending to be legally bound, hereby agree as follows:

1. Extension of Term of Employment Agreement. The Company and Executive agree that the "Additional Term" of the Employment Agreement is extended through October 31, 2026, unless sooner terminated as provided in Section 7 of the Employment Agreement.

2. Effective Date of Amendment. The Company and Executive agree that this Amendment is intended to be effective for all purposes as of October 31, 2025 (the "**Amendment Effective Date**"), such that there will be no lapse in the continuing effectiveness of the Employment Agreement.

3. Effect on Remainder of Employment Agreement. Except as expressly set forth in this Amendment, the provisions of the Employment Agreement shall remain in full force and effect, in their entirety, in accordance with their terms.

4. Miscellaneous. This Amendment shall be governed, construed, and interpreted in accordance with the laws of the State of New Jersey, without giving effect to conflicts of laws principles. The parties agree that this Amendment may only be modified in a signed writing executed by both parties. This Amendment shall be binding upon and shall inure to the benefit of the parties hereto and their respective heirs, successors, and assigns. This Amendment may be executed in separate counterparts, each of which is deemed to be an original and all of which taken together constitute one agreement. Counterparts may be delivered via facsimile, electronic mail (including pdf or any electronic signature complying with the U.S. ESIGN Act of 2000, e.g., www.docusign.com) or other transmission method and any counterpart so delivered will be deemed to have been duly and validly delivered and be valid and effective for all purposes.

[Signature Page Immediately Follows]

IN WITNESS WHEREOF, the parties hereto have executed this Second Amendment to Amended and Restated Employment Agreement effective as of the Amendment Effective Date.

CITIUS PHARMACEUTICALS, INC.

By: /s/ Leonard Mazur
Name: Leonard Mazur
Title: Chief Executive Officer and Chairman of the Board

EXECUTIVE

/s/ Myron Holubiak

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the Registration Statements on Form S-8 (No.'s 333-235535, 333-257282, 333-269703 and 333-277315), Form S-1 (No.'s 333-226395, 333-233759, 333-237638 and 333-238975) and on Form S-3 (No.'s 333-221492, 333-248748, 333-253179, 333-252561, 333-255005 and 333-256063, 333-277319) of Citius Pharmaceuticals, Inc. of our report dated December 23, 2025, relating to the consolidated financial statements of Citius Pharmaceuticals, Inc., appearing in the Annual Report on Form 10-K for the year ended September 30, 2025.

/s/ Wolf & Company, P.C.

Wolf & Company, P.C.
Boston, Massachusetts
December 23, 2025

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 Annual Report on Form 10-K 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.

December 23, 2025

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

Exhibit 31.2

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

I, Jaime Bartushak, certify that:

1. I have reviewed this Annual Report on Form 10-K 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.

December 23, 2025

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 Annual Report of Citius Pharmaceuticals, Inc. (the "Company") on Form 10-K for the year ended September 30, 2025 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: December 23, 2025

By: */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)