**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 001-41534**

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

| **Delaware** | **99-4362660** |
|---|---|
| (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 $0.0001 per share** | **CTOR** | **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 $5,097,850.

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:

84,797,846 shares as of December 23, 2025, all of one class of common stock, $0.0001 par value.

## DOCUMENTS INCORPORATED BY REFERENCE

None.

**Citius Oncology, 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," "Citius Oncology" "we," "us" and "our" refer to Citius Oncology, Inc. and its wholly-owned subsidiary Citius Oncology Sub Inc., "Citius Oncology Sub", taken as a whole.

LYMPHIR™ (denileukin diftitox) is our registered trademark. 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;
- our ability to successfully commercialize LYMPHIR, including covering the costs of licensing payments, product manufacturing and other third-party goods and services;
- the ability of LYMPHIR or any of our future product candidates to impact the quality of life of our target patient populations;
- the estimated markets for LYMPHIR or any of our future product candidates and the acceptance thereof by any market;
- our ability to recognize the anticipated benefits of the August 2024 reverse merger (the "Merger") whereby we became a standalone publicly-traded company and majority-owned subsidiary of Citius Pharmaceuticals, Inc. ("Citius Pharma"), which may not be realized fully, if at all, or may take longer to realize than expected;
- our ability to procure cGMP commercial-scale supply;
- 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 Company's ability to manage and grow our business and execution of our business and growth strategies;
- 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.
- We 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 required to make 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 any future product candidate.
- LYMPHIR may not gain market acceptance among physicians, patients, healthcare payers or the medical community and may not generate significant revenue.
- We will not be able to create a market for LYMPHIR or any future product candidate if we fail to successfully establish marketing, sales, and distribution capabilities.
- Our projections regarding the market opportunity for LYMPHIR may not be accurate.
- Our ability to generate product revenues will be diminished if LYMPHIR, or any of our future product candidates that may be approved, sells for inadequate prices or patients are unable to obtain adequate levels of reimbursement.
- The markets in which we operate are highly competitive and we might be unable to compete successfully.
- Healthcare reform could hinder the commercial success of LYMPHIR or any future 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.
- We remain subject to ongoing regulatory obligations and restrictions, which may result in significant expense and limit our ability to commercialize LYMPHIR and any future approved products.
- We could be forced to pay substantial damage awards if product liability claims that may be brought against us are successful.
- We might not obtain the necessary U.S. or foreign regulatory approvals to commercialize any future product candidates.
- 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 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.
- Future sales of a substantial number of shares of our common stock may cause the price of our common stock to decline.
- Failure to meet Nasdaq standards could result in a suspension or delisting of the common stock, adversely affecting the ability of a broker-dealer to trade, and an investor to acquire or dispose, our common stock.
- As a controlled company under Nasdaq standards, we may rely on exemptions from certain governance requirements, limiting the protections afforded to our stockholders compared to those of other companies.
- Provisions in our Certificate of Incorporation, Bylaws and under Delaware 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.
- Conflicts of interest may arise from our relationship with Citius Pharma.
- Citius Pharma currently performs or supports many of our important corporate functions, which would be difficult to replace if Citius Pharma were to cease providing and we are obligated to pay to Citius Pharma the fees for services under the A&R Shared Services Agreement (as defined herein) and must repay the principal due on a promissory note issued in August 2024.
- Our financial statements may not necessarily be indicative of the conditions that would have existed if we had been operated as an unaffiliated company of Citius Pharma.

## PART I

### Item 1. Business

#### Business Overview

The Company, headquartered in Cranford, New Jersey, is a biopharmaceutical company focused on developing and commercializing innovative targeted oncology therapies. The Company's strategy centers on achieving a market leading position by advancing innovative therapies with reduced development and clinical risks, and competitive advantages supported by intellectual property and regulatory exclusivity protection. This includes new formulations of previously approved drugs with substantial existing safety and efficacy data or expanded indications for approved therapies.

The Company's lead product 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 U.S. Food and Drug Administration (the "FDA") in August 2024 and was launched in December 2025. The Company believes there is an attractive and growing market for LYMPHIR, estimated to exceed $400 million, that is underserved by existing treatments. See below for more detailed information on LYMPHIR.

The Company intends to commercialize our products independently in the U.S., and partner to market products outside of the U.S. The Company has established a small, targeted oncology sales force, initially for LYMPHIR, focused on key geographies and stakeholders, primarily major cancer centers. This commercialization strategy is anticipated to result in a combination of direct sales revenue, and royalty income, as well as incremental operating expenses and greater working capital requirements.

#### Citius Oncology and the Merger

On August 23, 2021, Citius Pharma 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 the Company. 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 11, 2025).

Since SpinCo's 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, Citius Pharma 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.

| | **LYMPHIR** |
|---|---|
| Efficacy Results of E7777-G000-302 | 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 (%) | LYMPHIR N=69 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[j] | 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, Citius Pharma 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 the Company 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, Citius Pharma 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.

***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, the Company believes 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.

***Sales and Marketing***

The Company does not currently have our own commercial infrastructure and has finalized its initial sales and marketing capability by contracting with a large third-party commercial sales and marketing organization with an existing commercial infrastructure and product launch experience to assist in our commercial efforts. Through this third-party organization, the Company 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 our market share. We 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, we have entered into distribution agreements with Cardinal Health, Cencora and McKesson Corporation. In addition, we have 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, we announced that we are 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, we have 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.

***Supply and Manufacturing***

The Company does not currently have, nor do we intend to establish, our own manufacturing facilities. We have secured supply agreements for LYMPHIR with third-party cGMP facilities who are in compliance with current good manufacturing practices as generally accepted by the FDA. The Company is confident that all drug substance and drug product materials meet or will meet specifications as agreed with the FDA.

The Company also believes our contract manufacturers have sufficient capacity to support demand for LYMPHIR and any future clinical phase and approved products as our business grows.

In addition to our supply agreements with third-party manufacturers, the Company has contracted with other proven suppliers for, testing, labeling, packaging, and distribution of LYMPHIR.

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.

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 successfully commercialize LYMPHIR could be delayed or terminated.

***LYMPHIR License Agreement***

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, the Company acquired SpinCo as our wholly owned subsidiary. 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, 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 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. The initial commercial orders for LYMPHIR were placed and filled in 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 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*

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

Under the terms of the asset purchase agreement with Dr. Reddy's, the Company 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. The Company 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. The Company 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 the Company 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 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 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 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 the Company 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.

**Regulation**

***U.S. Government Regulation***

The research, development, testing, manufacture, labeling, promotion, advertising, distribution, and marketing, among other things, of LYMPHIR and other potential future 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. The Company 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***

The Company has no employees. Through our consulting and collaboration arrangements, including the A&R Shared Services Agreement with Citius Pharma, we have access to more than 30 professionals (including our executive officers), who possess significant expertise in business development, legal, accounting, regulatory affairs, clinical operations, and manufacturing. The Company also relies upon a network of consultants to support our clinical studies and manufacturing efforts.

**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 Citius Pharma in October 2025 and the $18.0 million raised by us 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 equity instruments and funding through Citius Pharma to finance its operations. However, the Company's continued operations beyond March 2026 including, its continued commercialization of LYMPHIR, will depend on its ability to successfully launch LYMPHIR and generate substantial revenue from the sale of LYMPHIR and on its ability to raise additional capital through various potential sources, such as equity and/or debt financings, or strategic relationships. However, the Company can provide no assurances on the commercialization or future sales of LYMPHIR, 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, 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 any future 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, which 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 and advance development of LYMPHIR for other indications. Furthermore, following the Merger, we have additional costs associated with operating as a public company and require 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 $3.9 million, and we had an accumulated deficit of approximately $64 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 timing of the repayment of amounts owed to Citius Pharma, including fees for services under the A&R Shared Services Agreement, and the principal due on the promissory note issued to Citius Pharma in August 2024;
- 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;
- its need to implement additional internal systems and infrastructure, including financial and reporting systems;
- 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 August 2021 and began operations in April 2022 when Citius Pharma transferred the assets related to LYMPHIR to us, including the license agreement with Eisai and the asset purchase agreement with of Dr. Reddy's. Our ability to become profitable depends upon our ability to generate revenues from sales of LYMPHIR, and any future product candidates, if any, resulting from our ongoing research with LYMPHIR for other possible indications. We have been focused on product development and have 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 product candidates requires significant clinical development, laboratory testing and clinical trials. In addition, commercialization of LYMPHIR and any future approved product candidates requires that we establish sales, marketing, and manufacturing capabilities, through internal hiring and contractual relationships with others. We expect to incur substantial losses for the foreseeable future as a result of the ongoing commercial launch of LYMPHIR, increases in our research and development costs, including costs associated with conducting preclinical testing and clinical trials for any other potential products, and regulatory compliance activities. We incurred a net loss of $24.7 million for the year ended September 30, 2025. At September 30, 2025, the Company had stockholders' equity of $44.9 million and an accumulated deficit of $64 million. The Company has received significant funding from Citius Pharma. Citius Pharma funded the Company with net cash used for our operating activities of approximately $8.9 million for the year ended September 30, 2025.

As of September 30, 2025, we have outstanding commitments totaling $38.4 million due to third-party suppliers and manufacturers, primarily related to the development and commercialization of LYMPHIR, and an aggregate of $22.7 million due under our license agreements, 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.

In addition, in connection with the closing of the Merger, Citius Pharma made a loan to the Company. The loan is evidenced by an unsecured promissory note issued by the Company, dated August 16, 2024, as amended September 10, 2025, in the principal amount of $3,800,111 to Citius Pharma. The promissory note bears no interest and is repayable in full upon the date at which the Company 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™. Through December 10, 2025, the Company has raised $18 million in capital raises and the likelihood of raising an additional $12 million to trigger the repayment obligation is uncertain at this time.

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

- commercializing LYMPHIR and any future product candidates that receive regulatory approval;
- obtaining medical insurance coverage for LYMPHIR and any future product candidates;
- manufacturing commercial quantities of LYMPHIR and any future product candidates at acceptable cost levels;
- establishing a favorable competitive position for LYMPHIR and any future product candidates;
- receiving regulatory approvals for any future product candidates; and
- developing and testing future product candidates.

Many of these factors will depend on circumstances beyond the Company's control.

***Our ongoing exploration 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 continue to evaluate strategic paths to provide the resources necessary to successfully commercialize LYMPHIR 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 entering into or completing potential transactions within the anticipated timing or at all.

***In the event we 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 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 Delaware 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

***We have one approved product and have an unproven business strategy and may never achieve successful commercialization of LYMPHIR or any future product candidates or achieve or maintain profitability.***

We have one approved product. Any future product candidates, if any, resulting from our ongoing research with LYMPHIR for other possible indications are and would be in the pre-clinical stage. We have invested a significant portion of our efforts and financial resources to bring LYMPHIR to market. 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 have a limited operating history upon which to evaluate our ability to successfully commercialize LYMPHIR and any future product candidate.***

We have one approved product candidate, LYMPHIR, while future product candidates, if any, resulting from our ongoing research with LYMPHIR for other possible indications, are and would be in the pre-clinical stage. As a result, our success is dependent upon our ability to commercialize LYMPHIR, which was launched in December 2025, and we, as a company, have not demonstrated an ability to perform the functions necessary for the approval or successful commercialization of any current or future product candidates. 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 for LYMPHIR) and we are undertaking commercialization activities for the first time for LYMPHIR. We 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. We have distribution agreements with three national companies and an agreement with EVERSANA to support the launch and commercialization of LYMPHIR. Our success will depend upon our third-party sales and marketing infrastructure. If we are not successful in implementing our strategy to commercialize our product candidates, we may never achieve, maintain, or increase profitability.

Despite our progress with LYMPHIR, our operations have been limited primarily to business planning, research and development, and raising capital. These operations provide a limited basis for you to assess our ability to successfully commercialize our current or future product candidates and the advisability of investing in the securities.

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

Under the terms of the License Agreement with Eisai, we were 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, we are 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, 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, (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, 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.

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 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 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 became subject to payments of an aggregate of $33.4 million under the license and asset purchase agreements covering LYMPHIR through Eisai and Dr. Reddy's separately. Pending further discussions with Dr. Reddy's, Dr. Reddy's agreed to a partial deferral without penalty of a milestone payment by us, 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.

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 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 future product candidate approved by the FDA;

- Our third-party manufacturers might be unable to formulate and manufacture LYMPHIR and any future 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 future product candidates by the FDA or any foreign regulatory agency or the successful commercialization of LYMPHIR 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.

***We face significant risks in our commercialization efforts of LYMPHIR and development of any future product candidate.***

Our business depends on the successful commercialization of LYMPHIR. We are not permitted to market any product candidate 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. We received approval from the FDA for LYMPHIR in August 2024. 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 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.

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 $38.4 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 our future product candidates, if any, for many reasons. For example, the FDA:

- may not find the data from clinical trials sufficient to support the submission of a BLA for our future product candidates or to obtain marketing approval in the U.S., including any findings that the clinical and other benefits of our future product candidates outweigh their safety risks;
- could determine that the information provided by us is inadequate, contained clinical deficiencies or otherwise failed to demonstrate the safety and effectiveness of any of our future product candidates for any indication;
- may disagree with the trial design or our interpretation of data from preclinical studies or clinical trials, or may change the requirements for approval even after the FDA has reviewed and commented on the design for the trials;
- may identify deficiencies in the manufacturing processes or facilities of third-party manufacturers with which we enter into agreements for the manufacture of our future product candidates;
- may approve our future 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 the FDA approval policies or adopt new regulations that could adversely impact our future product candidate development programs; or
- may not approve the labeling claims that we believe are necessary or desirable for the successful commercialization of our future product candidates, or may require labeling claims that impair the potential market acceptance of our future product candidates.

These same risks are generally applicable to the regulatory process in foreign countries. Any failure to obtain regulatory approval of our future product candidates, if any, 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.

***LYMPHIR may not gain market acceptance among physicians, patients, healthcare payers or the medical community and may not generate significant revenue.***

LYMPHIR may not gain market acceptance among physicians, patients, healthcare payers or the medical community. Coverage and reimbursement of our product candidates by third-party payers, including government payers, generally is also necessary for commercial success. We believe that the degree of market acceptance and our ability to generate revenues from any approved product candidate or acquired approved product will depend on a number of factors, including:

- strength of sales, marketing and distribution support;
- perceptions by members of the health care community, including physicians, about the safety and effectiveness of LYMPHIR;
- perceptions by members of the health care community, including physicians, about the use of LYMPHIR versus the respective standards of care or other alternatives for the disease or problem that we seek to address with LYMPHIR;
- results of any post-approval studies of the product;
- 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;
- product labeling or product insert requirements of the FDA or other regulatory authorities;
- 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;
- patient access programs that require patients to provide certain information prior to receiving new and refill prescriptions; and
- requirements for prescribing physicians to complete certain educational programs for prescribing drugs.

We expect sales of LYMPHIR to generate substantially all of our revenues for the foreseeable future, and as a result, the failure of LYMPHIR to find market acceptance would harm our business and would require us to seek additional financing. In addition, our efforts to educate the medical community and third-party payers on the benefits of LYMPHIR may require significant resources and may never be successful. These risks also apply to any future approved product candidate.

***We will not be able to create a market for LYMPHIR or any future product candidate if we fail to establish marketing, sales, and distribution capabilities.***

Our strategy with LYMPHIR 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. We have developed our sales, marketing and distribution capabilities 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 for LYMPHIR. In addition, we have entered into distribution agreements with Cardinal Health, Cencora and McKesson Corporation and have contracted with EVERSANA to support the launch and commercialization of LYMPHIR. The development and maintenance of a sales and distribution infrastructure requires substantial resources, which may divert the attention of management and key personnel and defer our product development efforts. Contracting with third-party commercial sales and marketing organizations means that our revenues will depend on the efforts of others. These efforts may not be successful. If 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.

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

Our ability to commercialize our approved product candidates, namely LYMPHIR, 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 LYMPHIR, or any of our future product candidates that may be 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 an approved product candidate, 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 we receive marketing approval for our product candidates for the proposed indications, physicians may nevertheless use the 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 we are found to have promoted a 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 who commercially market products for the same condition or conditions we are targeting for LYMPHIR. There may also be companies who are actively engaged in the development of therapies or products for at least some of these same conditions. 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 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 future 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 LYMPHIR or any of our product candidates obsolete or noncompetitive. Compared to us, many of our potential competitors have substantially greater capital resources, as well as greater access to strategic partners.

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 our products 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 LYMPHIR's commercial success, or any of our future product candidates that may be approved.***

There have been, and we expect 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 our ability to sell our 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. We 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. We expect 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 LYMPHIR and any other 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 LYMPHIR and any other product candidates, if approved, or put pressure on our product pricing.

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

***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 and the development and commercialization of any future product candidate 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, the 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 LYMPHIR and any future product candidate, or could require or result in litigation or arbitration. Any such conflicts with the 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.

Under the license agreement for the intellectual property for LYMPHIR, 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. By breaching any of our covenants, including failure to make timely payments, we risk the loss of the license, which would have a material adverse effect on our business.

***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.***

The Company's performance is substantially dependent on the continued services and on the performance of our executive management and other key personnel through the A&R Shared Services Agreement with Citius Pharma, all who have extensive experience and specialized expertise in our business. Our Chief Executive Officer, Leonard Mazur, our Secretary and Director, Myron Holubiak, our Chief Financial Officer and Chief Business Officer, Jaime Bartushak, and our Chief Medical Officer, 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 company. The loss of the services of any of Mr. Mazur, Mr. Holubiak, Mr. Bartushak or Dr. Czuczman, as well as any other member of our executive management or any key employees could harm our ability to attract capital, commercialize LYMPHIR and develop any future product candidates. We do not have 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.***

Pursuant to the A&R Shared Services Agreement entered into in connection with the closing of the Merger, we utilize the services of the Citius Pharma clinical management team on a part-time basis to assist us in managing the clinical and pre-clinical trials and intend to do so for future pre-clinical and clinical trials. Pursuant to the A&R Shared Services Agreement, we also utilize the services of Citius Pharma employees with expertise in product manufacturing and commercialization for the post-launch support of LYMPHIR. While we believe these arrangements 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 current and future product candidates. We compete for qualified individuals with numerous pharmaceutical and biopharmaceutical companies, universities, and other research institutions.

Except for one director, our current Board members are also directors of Citius Pharma, and our executive officers also are employees of Citius Pharma and serve as the Company's executive officers under the A&R Shared Services Agreement. We expect to rely on the A&R Shared Services Agreement and these individuals 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 commercialization of LYMPHIR and of any future 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:

- successfully commercialize LYMPHIR and any future product candidates;
- maintain and strengthen, as necessary, our collaborations with third parties for the sales and marketing of LYMPHIR;
- manage our research and development activities for future product candidates and our regulatory trials effectively;

- attract and motivate sufficient numbers of talented employees or consultants;
- manage our internal development efforts effectively while complying with our contractual obligations to licensors, licensees, contractors, collaborators and other third parties;
- develop internal sales and marketing capabilities or establish collaborations with third parties with such capabilities; 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 our 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.

***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.***

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 future product candidates, if any, 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 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.

If any of our future 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 potential 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 the stock price would likely decrease significantly.

**Risks Related to Our Regulatory and Legal Environment**

***Following the regulatory approval of LYMPHIR, we remain subject to ongoing regulatory obligations and restrictions, which may result in significant expense and limit our ability to commercialize LYMPHIR and any future approved products.***

Following the approval by the FDA of LYMPHIR in August 2024, we remain required to comply with extensive regulations for product manufacturing, labeling, packaging, adverse event reporting, storage, distribution, advertising, promotion and record keeping. Such regulatory approval is also subject to significant limitations on the indicated uses or marketing of the products or to whom and how we may distribute the approved product.

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 future 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, namely LYMPHIR. 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. We intend to obtain similar product liability insurance coverage for LYMPHIR. 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 us.

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

We cannot assure you that we will receive the approvals necessary to commercialize for sale any future product candidates that we might acquire or seek to develop in the future. We will need FDA approval to commercialize any future 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 the 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 a future product candidate's regulatory review. Delays in obtaining regulatory approvals might:

- delay commercialization of, and our ability to derive product revenues from, any future 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 the NDAs or BLAs. Even if we are able to obtain regulatory approval for a particular future 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. 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, or REMS, which 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. We cannot be sure that we will ever obtain regulatory clearance for any additional product candidates. 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 any additional product candidate.

## 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 expect to pursue, 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 U.S. Patent and Trademark Office ("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 drug candidates and technologies will likely be substantially less than 20 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.

***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 mark "LYMPHIR." This 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 Our Common Stock

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

Following the Merger, 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 Company's ability to commercialize LYMPHIR or any future product candidates, if approved;
- the level of success and the cost of our marketing efforts for LYMPHIR and any future product candidates;
- unanticipated serious safety concerns related to the use of LYMPHIR or any other product candidate;
- announcements regarding results of any pre-clinical or clinical trials relating to our future product candidates;
- adverse regulatory decisions;
- changes in laws or regulations applicable to LYMPHIR or any future product candidates, including but not limited to clinical trial requirements for approvals and post-approval requirements;
- the Company's dependence on third parties and on Citius Pharma under the A&R Shared Services Agreement;
- 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 technologies by us 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 us, the indications we seek to treat or our industry, or oncology research 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 Pharma as the Company's majority stockholder;
- sales (or distributions) of our common stock by Citius Pharma, or our other stockholders in the future;
- trading volume of our common stock;

- legal disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain and maintain patent protection for LYMPHIR or any future 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.

***Future sales of a substantial number of shares of our common stock may cause the price of our common stock to decline.***

Subject to certain exceptions, the amended and restated registration rights agreement entered into in connection with the Merger (the "A&R Registration Rights Agreement") provides for certain restrictions on transfer with respect to the securities of the Company, including shares held by 10XYZ Holdings, LP, the sponsor of TenX, and securities held by certain directors and officers of the Company and Citius Pharma. Such restrictions expired February 9, 2025, subject to certain exceptions. Following the expiration of the lock-up period, such equity holders are not restricted from selling or distributing shares of common stock held by them, other than by applicable securities laws.

Further, because we are not expected to generate revenue in the near future, we will need to continue to raise capital through one or more equity financings in order to continue commercializing LYMPHIR and developing our other product candidates. As such, sales of a substantial number of shares of common stock and/or securities convertible into common stock in the public market could occur at any time. These sales, or the perception in the market that the holders of a large number of shares intend to sell shares, could reduce the market price of the common stock.

***You may experience dilution of your ownership interests because of the future issuance of additional shares of 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. The Company is currently authorized to issue an aggregate of 400,000,000 shares of common stock and 10,000,000 shares of preferred stock, of which 84,797,846 shares are outstanding as of December 23, 2025. 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 the common stock.

***Substantial sales of our common stock may occur in connection with the potential distribution of shares by Citius Pharma, which could cause our stock price to decline.***

Citius Pharma has stated its intention to effect a pro rata distribution of an undetermined amount of the common stock it holds in Citius Oncology to Citius Pharma stockholders at a yet-to-be determined date in the future. As of December 10, 2025, approximately 79% of our outstanding shares of common stock are owned by Citius Pharma. The timeline and details with respect to such distribution have not been announced. Stockholders receiving shares of our common stock in such distribution may be able to sell those shares immediately in the public market. Although we have no actual knowledge of any plan or intention of any significant Citius Pharma stockholder to sell our common stock following the potential distribution, it is likely that some Citius Pharma stockholders, possibly including some of its larger stockholders, would sell their shares of our common stock received in the potential distribution if we do not fit their investment objectives or in order to cover the related tax liability. The sales of significant amounts of our common stock or the perception in the market that this will occur may decrease the market price of our common stock and increase the volatility of our common stock.

***If we fail to meet the Nasdaq continued listing requirements, it could result in a suspension or delisting of the common stock.***

The common stock is listed for trading on The Nasdaq Capital Market, and the continued listing of the common stock on The Nasdaq Capital Market is subject to compliance with a number of listing standards. These listing standards include the requirement of maintaining a minimum level of stockholders' equity and maintaining a minimum stock price of $1.00. The failure to meet any listing standard would subject Company to potential loss of listing.

If the common stock were no longer listed on The Nasdaq Capital Market or any other Nasdaq market, investors might only be able to trade on one of the over-the-counter markets, including the OTC Bulletin Board® or in the Pink Sheets® (a quotation medium operated by Pink Sheets LLC). This would impair the liquidity of the common stock, not only in the number of shares that could be bought and sold at a given price, which might be depressed by the relative illiquidity, but also through delays in the timing of transactions and reduction in media coverage. In addition, we could face significant material adverse consequences, including:

- a limited availability of market quotations for our securities;
- a limited amount of news and analyst coverage for us; and
- a decreased ability to issue additional securities or obtain additional financing in the future.

In the event of a future delisting, we intend to take actions to restore our compliance with Nasdaq's continued listing requirements, but we can provide no assurance that any such action taken by us would allow our common stock to become listed again, stabilize the market price or improve the liquidity of our common stock, prevent our common stock from dropping below the Nasdaq minimum bid price requirement or prevent future non-compliance with Nasdaq's continued listing requirements.

***If our common stock were delisted and determined to be a "penny stock," a broker-dealer may find it more difficult to trade the common stock and an investor may find it more difficult to acquire or dispose of the common stock in the secondary market.***

If our common stock were removed from listing with The Nasdaq Capital Market, we 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 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 the common stock were delisted and determined to be a "penny stock," a broker-dealer may find it more difficult to trade the common stock and an investor may find it more difficult to acquire or dispose of the common stock on the secondary market.

***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 common stock, which could decrease the relative voting power of the common stock or result in dilution to our existing stockholders.

***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 our 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.

***Our operating results may fluctuate significantly.***

We expect our operating results to be subject to quarterly, and possibly annual, fluctuations. Our net loss and other operating results will be affected by numerous factors, including:

- results of the launch and commercialization of LYMPHIR;
- variations in the level of expenses related to the commercialization of LYMPHIR and any other aspects of Company's development programs;
- the level of demand for LYMPHIR and the extent of our market penetration; and
- regulatory developments affecting LYMPHIR or any future product candidates, including post-approval matters.

If our quarterly or annual operating results fall below the expectations of investors or securities analysts, the price of our common stock could decline substantially. Furthermore, any quarterly or annual fluctuations in our operating results may, in turn, cause the price of our common stock to fluctuate substantially.

***If securities or industry analysts do not publish research or reports about our business, or if they issue an adverse opinion regarding our common stock, our stock price and trading volume could decline.***

The trading market for common stock may be influenced by the research and reports that industry or securities analysts publish about us or our business. We currently have research coverage by three securities and industry analysts. If any of the analysts who cover us issue an adverse opinion regarding us, our business model, our intellectual property or our stock performance, or if our commercialization efforts for LYMPHIR, or any clinical trials and operating results fail to meet the expectations of analysts, our stock price would likely decline. If one or more of these analysts cease coverage of us or fail to publish reports on us regularly, we could lose visibility in the financial markets, which in turn could cause our stock price or trading volume to decline.

***We are a controlled company within the meaning of the Nasdaq continued listing requirements and, as a result, will qualify for, and may rely on, exemptions from certain corporate governance requirements. Our stockholders may not have the same protection afforded to stockholders of companies that are subject to such governance requirements.***

Citius Pharma controls approximately 79% of the voting power of the outstanding shares of common stock as of December 10, 2025. As a result, the Company is a "controlled company" within the meaning of the corporate governance standards of Nasdaq. Under these corporate governance standards, a company of which more than 50% of the voting power for the election of directors is held by an individual, group or another company is a "controlled company" and may elect not to comply with certain corporate governance requirements. For example, controlled companies:

- are not required to have a board that is composed of a majority of "independent directors" as defined under the Nasdaq continued listing requirements;
- not required to have a compensation committee that is composed entirely of independent directors or have a written charter addressing the committee's purpose and responsibilities; and
- are not required to have director nominations be made, or recommended to the full board of directors, by its independent directors or by a nominating and corporate governance committee that is composed entirely of independent directors, and to adopt a written charter or a board resolution addressing the nominations process.

While we do not currently rely on these exemptions, we may opt to utilize these exemptions in the future as long as we remain a controlled company. Accordingly, our stockholders may not have the same protections afforded to stockholders of companies that are subject to all of the corporate governance requirements of Nasdaq.

***Volatility in our share price could subject us to securities litigation.***

In the past, securities litigation has often been brought against a company following a decline in the market price of its securities. If we face such litigation, it could result in substantial costs and a diversion of management's attention and resources, which could harm our business.

***Provisions in our Certificate of Incorporation, Bylaws and under Delaware law could discourage a takeover that stockholders may consider favorable and may lead to entrenchment of management.***

Our Certificate of Incorporation and Bylaws contain provisions that could significantly reduce the value of our shares to a potential acquiror or delay or prevent changes in control or changes in our management without the consent of the Board. The provisions in our governance documents include the following:

- a classified board of directors divided into three classes, with only one class of directors being elected in each year and each class serving a three-year term, which may delay the ability of stockholders to change the membership of a majority of the Board;
- no cumulative voting in the election of directors, which limits the ability of minority stockholders to elect director candidates;
- in the event that Citius Pharma ceases to beneficially own more than 50% of the voting power of the then-outstanding shares of stock entitled to vote generally in the election of directors (the "Trigger Event,"), the approval of at least 66-2/3% of the shares entitled to vote will be required to remove a director for cause, and the prohibition on removal of directors without cause;
- the ability of the Board to authorize the issuance of shares of preferred stock and to determine the price and other terms of those shares, including preferences and voting rights, without stockholder approval, which could be used to significantly dilute the ownership of a hostile acquiror;

- the ability of the Board to alter our Bylaws without obtaining stockholder approval;

- upon the occurrence of the Trigger Event, the required approval of at least 66-2/3% of the shares entitled to vote to adopt, amend or repeal the Bylaws or repeal the provisions of our Certificate of Incorporation regarding the election and removal of directors;

- upon the occurrence of the Trigger Event, a prohibition on stockholder action by written consent, which forces stockholder action to be taken at an annual or special meeting of our stockholders;

- upon the occurrence of the Trigger Event, the requirement that a special meeting of stockholders may be called only by the Board, the chair of the Board, the chief executive officer, which may delay the ability of our stockholders to force consideration of a proposal or to take action, including the removal of directors;

- advance notice procedures that stockholders must comply with in order to nominate candidates to the Board or to propose matters to be acted upon at a stockholders' meeting, which may discourage or deter a potential acquiror from conducting a solicitation of proxies to elect the acquiror's own slate of directors or otherwise attempting to obtain control of us; and

- upon the occurrence of the Trigger Event, we also become subject to the anti-takeover provisions contained in Section 203 of the General Corporation Law of the State of Delaware ("DGCL"). Under Section 203, a corporation may not, in general, engage in a business combination with any holder of 15% or more of our capital stock unless the holder has held the stock for three years or, among other exceptions, the Board has approved the transaction.

***The Certificate of Incorporation provides that the Court of Chancery of the State of Delaware will be the exclusive forum for substantially all disputes between the Company and our stockholders and that the federal district courts shall be the exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act of 1933, as amended (the "Securities Act"), which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees or the underwriters or any offering giving rise to such claim.***

The Certificate of Incorporation provides that the Court of Chancery of the State of Delaware is the exclusive forum for any derivative action or proceeding brought on our behalf, any action asserting a breach of fiduciary duty, any action asserting a claim against us arising pursuant to the DGCL, the Certificate of Incorporation or the Bylaws, or any action asserting a claim against us that is governed by the internal affairs doctrine; provided that this provision would not apply to suits brought to enforce a duty or liability created by the Securities Exchange Act of 1934, as amended (the "Exchange Act"). In addition, the Certificate of Incorporation provides that, unless we consent in writing to the selection of an alternative forum, the U.S. federal district courts shall, to the fullest extent permitted by law, be the exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act. For the avoidance of doubt, this provision is intended to benefit and may be enforced by us, our officers and directors, the underwriters to any offering giving rise to such complaint, and any other professional entity whose profession gives authority to a statement made by that person or entity and who has prepared or certified any part of the documents underlying the offering. We note, however, that there is uncertainty as to whether a court would enforce this provision and that investors cannot waive compliance with the federal securities laws and the rules and regulations thereunder. Section 22 of the Securities Act creates concurrent jurisdiction for state and federal courts over all suits brought to enforce any duty or liability created by the Securities Act or the rules and regulations thereunder. These choice of forum provisions may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors and officers, which may discourage such lawsuits against us and our directors and officers or could result in increased costs for our stockholders to bring a claim in the chosen forum. If a court were to find the choice of forum provisions in the Certificate of Incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could adversely affect our business and financial condition.

***We are an emerging growth company and a smaller reporting company, and we cannot be certain if the reduced reporting requirements applicable to emerging growth companies and smaller reporting companies will make our shares less attractive to investors.***

We are an emerging growth company, as defined in the JOBS Act. For as long as we continue to be an emerging growth company, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not "emerging growth companies," including exemption from compliance with the auditor attestation requirements under Section 404 of the Sarbanes-Oxley Act of 2002, reduced disclosure obligations regarding executive compensation and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. We will remain an emerging growth company until the earliest of: (a) the fifth anniversary of the closing of TenX's initial public offering, which was consummated on October 18, 2022, (b) the end of the fiscal year in which our total gross revenues exceed $1.235 billion, (c) the date one we qualify as a large accelerated filer as that term is defined by Rule 12b-2 of the Exchange Act, or (d) the date on which we have issued more than $1.0 billion in non-convertible debt during the prior three-year period.

In addition, under the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards until such time as those standards apply to private companies. We have elected to use this extended transition period for complying with new or revised accounting standards and, therefore, we will not be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

We are also a smaller reporting company as defined in the Exchange Act. Even after we no longer qualify as an emerging growth company, we may still qualify as a "smaller reporting company," which would allow us to take advantage of many of the same exemptions from disclosure requirements including exemption from compliance with the auditor attestation requirements of Section 404 and reduced disclosure obligations regarding executive compensation in our registration statements, periodic reports and proxy statements. We will be able to take advantage of these scaled disclosures for so long as our common stock held by non-affiliates is less than $250 million measured on the last business day of our second fiscal quarter, or our annual revenue is less than $100 million during the most recently completed fiscal year and our common stock held by non-affiliates is less than $700 million measured on the last business day of our second fiscal quarter.

We cannot predict if investors will find our common stock less attractive because we may rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and its market price may be more volatile.

***If our estimates or judgments relating to our critical accounting policies prove to be incorrect or financial reporting standards or interpretations change, the Company's results of operations could be adversely affected.***

The preparation of financial statements in conformity with accounting principles generally accepted in the U.S. ("GAAP") requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. We will base our estimates on historical experience, known trends and events, and various other factors that we believe to be reasonable under the circumstances, as provided in "*The Company Management's Discussion and Analysis of Financial Condition and Results of Operations - Critical Accounting Policies and Estimates*." The results of these estimates form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Significant assumptions and estimates used in preparing our financial statements include the treatment of research and development costs and in-process research and development. Our results of operations may be adversely affected if our assumptions change or if actual circumstances differ from those in our assumptions, which could cause our results of operations to fall below the expectations of securities analysts and investors, resulting in a decline in the trading price of our common stock.

Additionally, we will regularly monitor our compliance with applicable financial reporting standards and review new pronouncements and drafts thereof that are relevant to us. As a result of new standards, changes to existing standards and changes in their interpretation, we might be required to change our accounting policies, alter our operational policies, and implement new or enhance existing systems so that they reflect new or amended financial reporting standards, or we may be required to restate our published financial statements. Such changes to existing standards or changes in their interpretation may have an adverse effect on our reputation, business, financial position, and profit.

***Conflicts of interest may arise from our relationship with Citius Pharma.***

Except for one director, all of our directors, executive officers and employees will also be directors and employees of Citius Pharma; the employees are all available pursuant to the A&R Shared Services Agreement. As a result of this arrangement, our relationship with Citius Pharma could give rise to certain conflicts of interest that could have an impact on our research and development programs, business opportunities, and operations generally.

Even though we are developing different technologies in different fields than Citius Pharma, we could be in competition with Citius Pharma for research scientists, financing and other resources, licensing, manufacturing, and distribution arrangements. Citius Pharma 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. Citius Pharma 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 Pharma. Each conflict of interest will be resolved by the respective boards of directors in keeping with their fiduciary duties and such policies as they may implement from time to time.

***Certain of our directors and officers may have actual or potential conflicts of interest because of their positions with Citius Pharma.***

Suren Dutia, Myron Holubiak, Dr. Eugene Holuka, Leonard Mazur, Dennis McGrath, Robert Smith, and Carol Webb serve on the Board. Mr. Mazur, Jaime Bartushak and Dr. Czuczman, continue to serve as our executive officers. All of these individuals continue in their director and/or management positions with Citius Pharma.

In addition, such directors and officers own shares of Citius Pharma common stock, and warrants and/or options to purchase shares of Citius Pharma common stock. Their position at Citius Pharma and the ownership of Citius Pharma equity or equity awards creates, or may create the appearance of, conflicts of interest when these directors and officers are faced with decisions that could have different implications for Citius Pharma than the decisions have for the Company. For example, potential conflicts of interest could arise in connection with the resolution of any dispute that may arise between Citius Pharma and the Company regarding the terms of the A&R Shared Services Agreement governing the services provided by Citius Pharma to the Company and the relationship between the companies. Potential conflicts of interest may also arise if the Company enters into commercial arrangements with Citius Pharma in the future. As a result of these actual or apparent conflicts, the Company might be precluded from pursuing certain growth initiatives.

***Citius Pharma currently performs or supports many of our important corporate functions, which would be difficult to replace if Citius Pharma were to cease providing and we are obligated to pay to Citius Pharma the fees for services under the A&R Shared Services Agreement and must repay the principal due on a promissory note issued in August 2024.***

Citius Pharma provides all of our operational functions, systems and infrastructure pursuant to the A&R Shared Services Agreement. We may not be able to replace these services or enter into appropriate third-party agreements on terms and conditions, including cost, comparable to those that we receive from Citius Pharma under the A&R Shared Services Agreement. Additionally, after that agreement terminates, we may be unable to sustain the services at the same levels or obtain the same benefits as when we were receiving such services and benefits from Citius Pharma. When we begin to operate these functions separately, if we do not have our own adequate systems and business functions in place, or are unable to obtain them from other providers, we may not be able to operate our business effectively or at comparable costs, and our profitability may decline. In addition, we have historically received informal support from Citius Pharma, which may not be addressed in the agreements with Citius Pharma. The level of this informal support is expected to diminish over time.

The loss of some or all of these services would be difficult for the Company to replace quickly if at all. Such a loss would be expected to have a material adverse effect on the Company’s operations at least in the near term.

In addition, we owe Citius Pharma for fees for each of the services set forth in the A&R Shared Services Agreement and we reimburse Citius Pharma for all reasonable out-of-pocket costs and expenses that it incurs in connection with providing the services.

In connection with the closing of the Merger, Citius Pharma made a loan to the Company. The loan is evidenced by an unsecured promissory note issued by the Company, dated August 16, 2024, as amended September 10, 2025, in the principal amount of $3,800,111 to Citius Pharma. The promissory note bears no interest and is repayable in full upon the date at which the Company 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™. To date the Company has raised $36 million in capital raises and the likelihood of raising an additional $14 million to trigger the repayment obligation is uncertain at this time.

These costs we owe for services rendered by Citius Pharma to the Company and under the terms of the promissory note could have a material adverse effect on the Company's operations and revenues.

***Our financial statements may not necessarily be indicative of the conditions that would have existed if we had been operated as an unaffiliated company of Citius Pharma.***

Citius Pharma provides all of our operational functions, systems and infrastructure pursuant to the A&R Shared Services Agreement. Our financial statements reflect charges for these services on an allocation basis. As a result, our historical financial statements may not be reflective of conditions that would have existed or what our results of operations would have been had we been a stand-alone public company and no longer a majority-owned subsidiary of Citius Pharma. We may incur additional internal costs to implement certain new systems, including infrastructure and an enterprise resource planning system, while our legacy systems are currently being fully supported by Citius Pharma.

We may also need to make investments or hire additional employees to operate without the same access to Citius Pharma' existing operational and administrative infrastructure. These initiatives may be costly to implement. Due to the scope and complexity of the underlying projects relative to these efforts, the amount of total costs could be materially higher than what is currently estimated, and the timing of the incurrence of these costs is subject to change.

These potential costs could have a material adverse effect on the Company's operations and revenues.

***We are controlled by Citius Pharma, whose interests may differ from those of public stockholders.***

Citius Pharma holds approximately 79% of the voting power of us as of December 10, 2025, which means that Citius Pharma controls the vote of all matters submitted to a vote of the Company's stockholders. This control enables Citius Pharma to control the election of the members of the Board and all other corporate decisions. In particular, for so long as Citius Pharma continues to own a majority of the common stock, Citius Pharma will be able to cause or prevent a change of control of our Company or a change in the composition of the Board and could preclude any unsolicited acquisition of our Company.

Pursuant to the A&R Registration Rights Agreement and the Certificate of Incorporation, Citius Pharma has certain rights, and the ability to take certain actions, which are not otherwise available to all stockholders. For example, the A&R Registration Rights Agreement provides Citius Pharma the right, subject to certain conditions, to demand that the Company file a registration statement or request that its shares of common stock be covered by a registration statement that the Company is otherwise filing. In addition, until such time as Citius Pharma first ceases to own greater than 50% of the outstanding voting power of the common stock, the Certificate of Incorporation will effectively provide Citius Pharma with the ability to fill vacancies on the Board, remove directors (with or without cause), act by written consent of the stockholders, call a special meeting of the Company stockholders, amend the Certificate of Incorporation and the Bylaws (subject to approval of the Board). The directors so elected will have the authority, subject to the terms of any indebtedness and applicable rules and regulations, to issue additional stock, implement stock repurchase programs, declare dividends and make other decisions.

Even when Citius Pharma ceases to control a majority of the total voting power of the Company, for so long as Citius Pharma continues to own a significant percentage of the common stock, Citius Pharma will still be able to significantly influence the composition of the Board and the approval of actions requiring stockholder approval. Accordingly, for such period of time, Citius Pharma will have significant influence with respect to the Company's management, business plans and policies. Because of the significant ownership position held by Citius Pharma, and our classified Board structure, new investors may not be able to effect a change in the Company's business or management. The concentration of ownership and availability of the foregoing rights could deprive stockholders of an opportunity to receive a premium for their shares of common stock as part of a sale of the Company and ultimately might affect the market price of the common stock.

Furthermore, the interests of Citius Pharma may not be aligned with those of other stockholders and this could lead to actions that may not be in the best interests of other stockholders. For example, Citius Pharma may have different tax positions or strategic plans for the Company, which could influence its decisions regarding whether and when the Company should dispose of assets, issue equity or incur indebtedness. Additionally, Citius Pharma's significant ownership in the Company may discourage someone from making a significant equity investment in us or could discourage transactions involving a change in control.

In addition, in the ordinary course of its pharmaceutical business activities, Citius Pharma may engage in fields or activities where its interests conflict with our interests or those of our other stockholders, such as investing in or advising businesses that directly or indirectly compete with certain portions of the Company's business or those businesses that are suppliers or customers of us. The Certificate of Incorporation provides that, to the fullest extent permitted by law, none of Citius Pharma nor its affiliates or any person or entity who, while a stockholder, director, officer or agent of us or any of our affiliates, is a director, officer, principal, partner, member, manager, employee, agent and/or other representative of Citius Pharma and its affiliates (each an "Identified Person") will have any duty to refrain from (i) engaging in a corporate opportunity in the same or similar business activities or lines of business in which we or our affiliates are engaged or that are deemed to be competing with us or any of our affiliates or (ii) otherwise investing in or providing services to any person that competes with us or our affiliates engaging, directly or indirectly, in the same or similar business activities or lines of business in which we operate. In addition, to the fullest extent permitted by law, no Identified Person will have any obligation to offer us or our affiliates the right to participate in any corporate opportunity in the same or similar business activities or lines of business in which we or our affiliates are engaged or that are deemed to be competing with us or any of our affiliates. This means that Citius Pharma may pursue acquisition opportunities that may be complementary to our business and, as a result, those acquisition opportunities may not be available to us. In addition, Citius Pharma may have an interest in pursuing acquisitions, divestitures and other transactions that, in its judgment, could enhance its investment, even though such transactions might involve risks to our stockholders or may not prove beneficial.

**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 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**

Included in the A&R Shared Service Agreement is rent for our portion of the occupancy of offices at 11 Commerce Drive, First Floor, Cranford, New Jersey 07016. The lease is held by Citius Pharma and 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 "CTOR."

**Holders of Common Stock**

Based upon information furnished by our transfer agent, as of December 17, 2025, we had approximately 5 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**

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.

**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***

Citius Oncology is a specialty biopharmaceutical company focused on developing and commercializing innovative targeted oncology therapies. We are commercializing LYMPHIR (denileukin diftitox), an oncology immunotherapy for the treatment of CTCL, a rare form of non-Hodgkin lymphoma. LYMPHIR was approved by the FDA in August 2024 and commercially launched in the U.S. in December 2025.

We were incorporated in the Cayman Islands on March 1, 2021, for the purpose of effecting a merger, capital stock exchange, asset acquisition, stock purchase, reorganization or similar business combination with one or more businesses. In August 2024, we reincorporated in Delaware and completed the Merger whereby we acquired SpinCo as a wholly owned subsidiary and changed our name to Citius Oncology, Inc. SpinCo began operations in April 2022.

Since inception, we have devoted substantially all of our efforts to business planning, research and development, recruiting management and technical staff and commercially launching LYMPHIR. We are subject to a number of risks common to companies in the pharmaceutical industry including, but not limited to, our ability to obtain additional financing, risks related to the development by us or our competitors of research and development stage products, market acceptance of our approved products, competition from larger companies, dependence on key personnel, dependence on key suppliers and strategic partners, and our compliance with governmental and other regulations.

***License Agreement with Eisai***

In September 2021, Citius Pharma entered into an asset purchase agreement with Dr. Reddy's and a license agreement with Eisai to acquire an exclusive license 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 us effective April 1, 2022. Citius Pharma 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. 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. We also must pay on a fiscal quarter basis tiered royalties equal to low double-digit percentages of net product sales (within a range of 10% to 15%). The royalties will end on the earlier of (i) the 15-year anniversary of the first commercial sale of the latest indication that received regulatory approval in the applicable country and (ii) the date on which a biosimilar product results in the reduction of net sales in the applicable product by 50% in two consecutive quarters, as compared to the four quarters prior to the first commercial sale of the biosimilar product. We will also pay 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 our 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. We were also required to reimburse Eisai for up to $2.65 million of its costs to complete the Phase 3 pivotal clinical trial for LYMPHIR for the CTCL indication and reimburse Eisai for all reasonable costs associated with the preparation of a BLA for LYMPHIR. Eisai was responsible for completing the CTCL clinical trial, and CMC activities through the filing of the BLA for LYMPHIR with the FDA. 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 $2,535,318 and thereafter on the 15$^{th}$ 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 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 with the year ended September 30, 2024**

| | Year Ended September 30, 2025 | Year Ended September 30, 2024 |
|---|---|---|
| Revenues | $ — | $ — |
| Operating expenses: | | |
| Research and development | 6,418,334 | 4,925,001 |
| General and administrative | 8,783,997 | 8,148,929 |
| Stock-based compensation – general and administrative | 8,320,419 | 7,498,817 |
| Total operating expenses | 23,522,750 | 20,572,747 |
| Operating loss | (23,522,750) | (20,572,747) |
| Interest income | 36,373 | — |
| Interest expense | (218,032) | — |
| Loss before income taxes | (23,704,409) | (20,572,747) |
| Income tax expense | 1,056,960 | 576,000 |
| Net loss | $ (24,761,369) | $ (21,148,747) |

**Revenues**

We did not generate any revenues for the years ended September 30, 2025 and 2024.

**Research and Development Expenses**

For the year ended September 30, 2025, research and development expenses were $6,418,334 as compared to $4,925,001 for the year ended September 30, 2024, an increase of $1,493,333 primarily related to costs associated with the expense of a drug substance batch needed for the pre-license inspection of the manufacturer.

**General and Administrative Expenses**

For the year ended September 30, 2025, general and administrative expenses were $8,783,997 as compared to $8,148,929 for the year ended September 30, 2024, an increase of $635,068. The primary reason for the increase was the efforts associated with the pre-commercial and commercial launch activities of LYMPHIR associated with market research, marketing, distribution and drug product reimbursement from health plans and payers.

**Stock-based Compensation Expense**

For the year ended September 30, 2025, stock-based compensation expense was $8,320,419 as compared to $7,498,817 for the year ended September 30, 2024. The primary reasons for the $821,602 increase in stock-based compensation expense were the new options granted in December 2024 and the restricted stock awards granted in September 2025.

**Other Income (Expense)**

Interest income for the year ended September 30, 2025 was $36,373 as we invested some of the proceeds from our July 2025 and September 2025 equity offerings in a money market account. There was no interest income for the year ended September 30, 2024.

Interest expense of $218,032 for the year ended September 30, 2025 consists of $218,032 in interest under the payment agreement with Eisai.

**Income Taxes**

We recorded deferred income tax expense of $1,056,960 in the year ended September 30, 2025 as compared to $576,000 in the year ended September 30, 2024 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 $24,761,369 compared to a net loss of $21,148,747 for the year ended September 30, 2024. The $3,612,622 increase in the net loss was primarily due to the increases of $1,493,333 in research and development, $635,068 in general and administrative expenses and the increase in stock-based compensation expense of $821,602.

**LIQUIDITY AND CAPITAL RESOURCES**

**Liquidity and Working Capital**

We have incurred operating losses since inception and incurred a net loss of $24,761,369 for the year ended September 30, 2025. At September 30, 2025, we had an accumulated deficit of $64,039,956. We have had no revenue and have historically relied on funding from Citius Pharma to finance our operations. At September 30, 2025, we had $3,924,908 in cash and a negative working capital of approximately $21.9 million.

During the year ended September 30, 2025, Citius Oncology received aggregate net proceeds of approximately $15 million from equity offerings in July 2025 and September 2025 and Citius Pharma received net proceeds of approximately $32 million from their equity offerings and $1 million from the issuance of a note payable.

Additionally, 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 for gross proceeds of approximately $6 million. 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, $2,535,318 and thereafter on the 15$^{th}$ of each of the next four months $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 at the rate of 2% per annum. As of September 30, 2025, we owe a balance of $2.9 million 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.

We plan to continue to rely on funding from Citius Pharma, to raise capital through equity financings from outside investors, and to generate revenue from the future sales of LYMPHIR. We also have retained Jefferies LLC as our exclusive financial advisor in evaluating strategic alternatives aimed at maximizing shareholder value. There is no assurance, however, that Citius Pharma will have the resources to continue funding us, that we will be successful in raising the needed capital and, if funding is available, that it will be available on terms acceptable to us or that we will find strategic partners or generate substantial revenue from the sale of LYMPHIR.

After giving effect to the Citius Pharma equity offerings during the year ended September 30, 2025, our equity offerings during the year ended September 30, 2025, Citius Pharma's October equity offering, and our December 2025 equity offering, we expect that we and Citius Pharma collectively 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, including to successfully commercialize of LYMPHIR. 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.

**Investing Activities**

During the year ended September 30, 2025, we paid $3 million to Eisai in connection with partial milestone payments and paid $2.75 million in connection with partial milestone payments to Dr. Reddy's.

During the year ended September 30, 2024, the Company paid $5 million in connection with a partial milestone payment due under its asset purchase agreement with Dr. Reddy's.

**Financing Activities**

In connection with closing of the Merger on August 12, 2024, Citius Pharma, made a contribution to our capital in the amount of $33,180,961 representing the balance of the due to/due from related party account on the date of the Merger. Citius Pharma also made cash contributions to our capital, pursuant to the terms of the Merger Agreement, in the amount of $3,827,944.

Also in connection with the closing of the Merger, Citius Pharma made a loan to the Company, evidenced by an unsecured promissory note issued by the Company to Citius Pharma, dated August 16, 2024, as amended September 10, 2025, in the principal amount of $3,800,111. The promissory note bears no interest and is repayable in full upon the date at which the Company 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™. To date the Company has raised $18 million in capital raises and the likelihood of raising an additional $12 million to trigger the repayment obligation is uncertain at this time.

On July 17, 2025, we sold 6,818,182 shares of common stock and warrants to purchase 6,818,182 shares of common stock, at a combined per unit price of $1.32. The immediately exercisable five-year warrants have an exercise price of $1.32 per share. Net proceeds were approximately $7.4 million, after deducting placement agent fees and other expenses.

On September 10, 2025, we sold 5,142,858 shares of common stock and warrants to purchase 5,142,858 shares of common stock, at a combined per unit price of $1.75. The warrants have an exercise price of $1.84 per share, are exercisable six months after the date of issuance for one share of common stock and will expire five and a half years following the date of issuance. Gross proceeds were approximately $7.5 million, after deducting placement agent fees and other expenses.

**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 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 of $73.4 million represents the value of our September 2021 acquisition of an 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. In-process research and development consists of $40 million paid to Dr. Reddy’s from the asset purchase agreement and approval milestone fees of $27.5 million to Dr. Reddy’s and $5.9 million to Eisai.

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

We review 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, we write 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.

***Stock-Based Compensation***

We recognize compensation costs resulting from the issuance of stock-based awards to employees and directors as an expense in our 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 using the Black-Scholes option pricing model. Volatility is estimated using the trading activity of Citius Pharma common stock until such time as we have sufficient history. 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 measure of the fair value of our 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 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.**

None.

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

Not applicable.

## PART III

### Item 10. Directors, Executive Officers and Corporate Governance

The following table sets forth information as of the date of this report with respect to the individuals who serve as the directors and executive officers of Company, including their positions, and is followed by a biography of each such individual.

| Name | Age | Title |
|---|---|---|
| Leonard Mazur | 80 | Chairman and Chief Executive Officer and Director |
| Myron Holubiak | 78 | Secretary and Director |
| Suren Dutia | 83 | Director |
| Dr. Eugene Holuka | 66 | Director |
| Dennis M. McGrath | 68 | Director |
| Robert Smith | 65 | Director |
| Joel Mayersohn | 67 | Director |
| Carol Webb | 79 | Director |
| Jaime Bartushak | 58 | Chief Financial Officer and Treasurer |
| Dr. Myron S. Czuczman | 66 | Chief Medical Officer |

***Leonard Mazur***

Leonard Mazur is the Chairman and Chief Executive Officer of the Company, a position he has held since August 12, 2024. Prior thereto, he served as the Chief Executive Officer of Citius Oncology Sub, Inc., beginning on April 1, 2022. Mr. Mazur also serves as the Executive Chairman and Secretary of Citius Pharma (Nasdaq: CTXR) and has been a member of the board of directors of Citius Pharma since September 2014. In May 2022, Mr. Mazur became the Chief Executive Officer of Citius Pharma. He also serves as the Secretary of Citius Pharma's majority-owned subsidiary, NoveCite, Inc. ("NoveCite"), and provides other guidance to Citius Pharma and NoveCite. Since August 2021, Mr. Mazur has served on the board of directors of Hillstream BioPharma, Inc. (Nasdaq: HILS), a pre-clinical biotechnology company developing novel therapeutic candidates targeting ferroptosis, an emerging new anti-cancer mechanism resulting in iron mediated cell death for treatment resistant cancers. Mr. Mazur is the co-founder and Vice Chairman of Akrimax Pharmaceuticals, LLC ("Akrimax"), a privately held pharmaceutical company specializing in producing cardiovascular and general pharmaceutical products. Akrimax was founded in September 2008 and has successfully launched prescription drugs while acquiring drugs from major pharmaceutical companies. From January 2005 to May 2012, Mr. Mazur co-founded and served as the Chief Operating Officer of Triax Pharmaceuticals LLC ("Triax"), a specialty pharmaceutical company producing prescription dermatological drugs. Prior to joining Triax, he was the founder and, from 1995 to 2005, Chief Executive Officer of Genesis Pharmaceutical, Inc. ("Genesis"), a dermatological products company that marketed its products through dermatologists' offices as well as co-promoting products for major pharmaceutical companies. In 2003, Mr. Mazur successfully sold Genesis to Pierre Fabre, a leading pharmaceutical company. Mr. Mazur has extensive sales, marketing and business development experience from his tenures at Medicis Pharmaceutical Corporation as Executive Vice President, ICN Pharmaceuticals, Inc. as Vice President, Sales & Marketing, Knoll Pharma (a division of BASF), and Cooper Laboratories, Inc. Mr. Mazur is a member of the Board of Trustees of Manor College, is a recipient of the Ellis Island Medal of Honor and was previously the Chairman of the board of directors of Leonard-Meron Biosciences, Inc. ("LMB"), the Company's wholly-owned subsidiary. Mr. Mazur received both his B.A. and M.B.A. from Temple University and has served in the U.S. Marine Corps Reserves.

The Board believes that Mr. Mazur is qualified to serve as a director because of his entrepreneurial experience and marketing knowledge in the pharmaceutical industry.

***Myron Holubiak***

Myron Holubiak is the current Secretary of the Company and a member of the Board, a position he has held since August 12, 2024. Prior thereto, he served as Secretary and a director of Citius Oncology Sub, Inc., beginning on April 1, 2022. Mr. Holubiak is also the Executive Vice Chairman of Citius Pharma, a position he has held since May 2022. He has also served as a member of the board of directors of Citius Pharma since October 2015. From October 2015 through April 2022, Mr. Holubiak served as Citius Pharma's President and Chief Executive Officer. Mr. Holubiak also serves as the acting Chief Executive Officer of our majority-owned subsidiary, NoveCite. Mr. Holubiak has extensive experience in managing and advising large and emerging pharmaceutical and life sciences companies. Mr. Holubiak was the President of Roche Laboratories, Inc. ("Roche"), a major research-based pharmaceutical company, from December 1998 to August 2001. Prior to that, he held sales and marketing positions at Roche during his 19-year tenure. From September 2002 to July 2016, Mr. Holubiak served on the board of directors and for the last two years was the Chairman of the board of directors of BioScrip, Inc. ("BioScrip") (Nasdaq: BIOS). BioScrip is a leading national provider of infusion and home care management solutions. Since July 2010, Mr. Holubiak has served as a member of the board of directors of Assembly Biosciences, Inc. ("Assembly") (Nasdaq: ASMB) and its predecessor Ventrus Biosciences, Inc. Assembly is a biopharmaceutical company developing innovative, small molecule therapeutics for hepatitis B virus (HBV), hepatitis delta virus (HDV) and herpes virus infections. Additionally, Mr. Holubiak serves as a director for bioAffinity Technologies Inc., a privately held company. In March 2013, Mr. Holubiak founded LMB, the Company's wholly-owned subsidiary, and he served as the Chief Executive Officer and President of LMB until March 2016. In addition, Mr. Holubiak was also a trustee of the Academy of Managed Care Pharmacy Foundation from April 2013 to April 2015. Mr. Holubiak received a B.S. in Molecular Biology and Biophysics from the University of Pittsburgh; he received advanced business training from the Harvard Business School and the University of London; and advanced training in health economics from the University of York's Centre for Health Economics.

The Board believes that Mr. Holubiak is qualified to serve as a director because of his industry knowledge and experience managing both large and small pharmaceutical companies.

***Suren Dutia***

Suren Dutia has been a member of the Board since August 12, 2024. Mr. Dutia has also been a member of the board of directors of Citius Pharma since October 2015. In addition to his role as an outside independent director of Citius Pharma, Mr. Dutia has been serving as director of Flint Rehab and Vahan Inc, since 2016. Mr. Dutia has been involved in fostering entrepreneurship for more than 20 years and served as Senior Fellow of the Ewing Mario Kauffman Foundation from March 2011 to December 2016 and Senior Fellow of Skandalaris Center for Entrepreneurship and Innovation at Washington University, St. Louis from 2010 to 2013. He has served as a member of the advisory board of Center for Digital Transformation, University of California, Irvine since May 2012. From February 2006 to May 2010, Mr. Dutia served as the Chief Executive Officer of TiE, a non-profit organization involved in fostering entrepreneurship globally. From February 2011 to May 2013, Mr. Dutia served as a director of LifeProof and from July 2000 to December 2011, he served as a director of Anvita Health. From 1989 to 1998, Mr. Dutia served as the Chief Executive Officer and Chairman of the board of directors of Xscribe Corporation. Prior to his positions with Xscribe Corporation, Mr. Dutia held several positions with Dynatech Corporation, and, in addition, he was the President of a medical instruments company. Mr. Dutia received his B.S. and M.S. degrees in chemical engineering and B.A. in political science from Washington University, St. Louis. In addition, he obtained an M.B.A. from the University of Dallas.

The Board believes that Mr. Dutia is qualified to serve as a director because of his financial management background, his involvement with start-up companies and his management skills.

***Dr. Eugene Holuka***

Dr. Eugene Holuka has been a member of the Board since August 12, 2024. Dr. Holuka has also been a member of the board of directors of Citius Pharma since June 2016. Dr. Holuka is an internist and has practiced in internal medicine for almost 35 years. He is presently an attending physician at the Staten Island University Hospital where he has practiced since 1991. Dr. Holuka has also served as an Adjunct Clinical Assistant Professor at the Touro College of Osteopathic Medicine since 2011 and currently serves as an associate professor at the Zucker School of Medicine at Hofstra University. From April 2014 until the acquisition of LMB by the Company in March 2016, he was a member of the LMB Scientific Advisory Board. Dr. Holuka received the Ellis Island Medal of Honor in 2000 and has served on the NECO Committee Board since 2005. He was an Executive Committee Member on the Forum's Children Foundation from 2000 until 2008.

The Board believes that Dr. Holuka is qualified to serve as a director because of his extensive experience in the healthcare industry.

***Dennis M. McGrath***

Dennis M. McGrath has been a member of the Board since August 12, 2024. Mr. McGrath has also been a member of the board of directors of Citius Pharma since February 2023. He has served as the President of PAVmed, Inc. (Nasdaq: PAVM), a diversified commercial-stage medical technology company since March 2019 (having served as Executive Vice President from March 2017 to March 2019) and as PAVmed's Chief Financial Officer since March 2017. Mr. McGrath has also served as the Chief Financial Officer of Lucid, PAVmed's majority owned subsidiary since the consummation of Lucid's initial public offering. Previously, from 2000 to 2017 Mr. McGrath served in several senior level positions of PhotoMedex, Inc. (formerly, Nasdaq: PHMD), a global manufacturer and distributor of medical device equipment and services, including from 2011 to 2017 as director, President, and Chief Financial Officer. Prior to PhotoMedex's reverse merger with Radiancy, Inc in December 2011, he also served as a board member and Chief Executive Officer from 2009 to 2011 and served as Vice President of Finance and Chief Financial Officer from 2000 to 2009. He received honors as a P.A.C.T. (Philadelphia Alliance for Capital and Technology) finalist for the 2011 Investment Deal of the Year, award winner for the SmartCEO Magazine 2012 CEO of the Year for Turnaround Company, and finalist for the Ernst & Young 2013 Entrepreneur of the Year. He has extensive experience in mergers and acquisitions, both domestically and internationally, particularly involving public company acquisitions, including Surgical Laser Technologies, Inc, (formerly, Nasdaq: SLTI), ProCyte Corporation (formerly, Nasdaq: PRCY), LCA Vision, Inc. (formerly, Nasdaq: LCAV) and Think New Ideas, Inc. (formerly, Nasdaq: THNK). Prior to PhotoMedex, he served in several senior level positions of AnswerThink Consulting Group, Inc. (then, Nasdaq: ANSR, now, The Hackett Group, Nasdaq: HCKT), a business consulting and technology integration company, including from 1999 to 2000 as Chief Operating Officer of the Internet Practice, the largest division of AnswerThink Consulting Group, Inc., while concurrently during the merger of the companies, serving as the acting Chief Financial Officer of Think New Ideas, Inc. (then, Nasdaq: THNK, now, Nasdaq: HCKT), an interactive marketing services and business solutions company. Mr. McGrath also served from 1996 until 1999 as Chief Financial Officer, Executive Vice President and director of TriSpan, Inc., an internet commerce solutions and technology consulting company, which was acquired by AnswerThink Consulting Group, Inc. in 1999. During his tenure at Arthur Andersen & Co., where he began his career, he became a Certified Public Accountant in 1981 and he holds a B.S., maxima cum laude, in accounting from LaSalle University. In addition, he serves as the audit and compensation committee chair and a director of several medical device companies, including DarioHealth Corp. (Nasdaq: DRIO), and LIV Process, formerly BioVector, Inc. Previously from 2014 to 2024, Mr. McGrath served as a director and audit chair of Cagent Vascular, Inc., and from 2007 to 2009, Mr. McGrath served as a director of Embrella Cardiovascular, Inc. (sold to Edwards Lifesciences Corporation, NYSE: EW). He also serves on the Board of Visitors for Taylor University and on Board of Trustees of Manor College.

The Board believes that Mr. McGrath is qualified to serve as a director because of his background of his extensive business experience and board service with public companies.

***Robert Smith***

Robert J. Smith has been a member of the Board since August 12, 2024. Mr. Smith has also been a member of the board of directors of Citius Pharma since March 2024. Mr. Smith is an accomplished biopharmaceutical executive who has driven commercial, financial, and operational success at leading pharmaceutical companies, including Pfizer Inc. (NYSE: PFE) and Wyeth Pharmaceuticals (formerly NYSE: WYE), for more than 35 years. Mr. Smith's extensive industry expertise has been honed by decades of executive leadership roles in business development, mergers and acquisitions, corporate and commercial strategy, and research and development. For the past eight years (May 2016 to January 2024), Mr. Smith served as Senior Vice President, Global Gene Therapy Business of Pfizer and was responsible for managing and leading gene therapy and rare disease early commercial development activities in partnership with the rare disease research unit. During his tenure at Pfizer, Mr. Smith also served as Senior Vice President, Business Development and Alliance Management (October 2009 to January 2024) and led its worldwide research and development organization and the business development and strategy teams for Pfizer's global animal health, Capsugel, a former subsidiary of Pfizer, consumer healthcare and nutrition business units, as well as the alliance management function supporting all of Pfizer's global biopharmaceutical business units and the worldwide research and development organization. Mr. Smith joined Pfizer from Wyeth Pharmaceuticals in 2009, following Pfizer's acquisition of Wyeth, where he was Senior Vice President, Mergers and Acquisitions (April 2008 to October 2009) responsible for leading and managing Wyeth's global mergers and acquisitions group. Prior to that, in his role at Wyeth as Senior Vice President of Global Licensing, he completed a wide variety of transactions in support of Wyeth's commercial and research and development divisions. Mr. Smith has served as a member of the board of directors of private companies AM Pharma B.V. (observer), Bamboo Therapeutics Inc. (January 2016 to August 2016), and Ignite Immunotherapeutics Inc. (December 2016 to October 2019), as well as Iterum Therapeutics Limited (observer) (Nasdaq: ITRM). Mr. Smith also serves or has served as a member of Life Sciences PA - the Pennsylvania Biotechnology Association, Bio NJ - the New Jersey State Biotechnology Association (since 2021), the Duke Margolis Value Based Agreements Advisory Board, the Alliance for Regenerative Medicine (ARM) (since 2018) and the Foundation for Cell and Gene Medicine (FCGM) (since 2019). He is a member of the Executive Committees of the ARM and FCGM Board of Directors and serves as the Chairman of the ARM Board's Governance and Operations Committee. Mr. Smith is also a member of the Business Advisory Board of Ocugen, Inc., the Investment Advisory Committee for Venture Investors LLC, Madison, Wisconsin, and the Cell and Gene Therapy Scientific Advisory Board of the Focused Ultrasound Foundation based in Charlottesville, Virginia. Mr. Smith obtained a B.S. in Neuroscience from the University of Rochester and an M.B.A. in Finance and Corporate Accounting from the William E. Simon Graduate School of Business Administration at the University of Rochester, Rochester, New York.

The Board believes that Mr. Smith is qualified to serve as a director because of his extensive background with public companies and his business experience.

***Joel Mayersohn***

Joel Mayersohn has served as a director of the Company since October 2022. Mr. Mayersohn is a member at Dickinson Wright, where he specializes in corporate, securities and business law. He advises a diversified client base in private placements, public offerings, mergers and acquisitions, financing transactions and general securities law matters. He also has experience in venture capital, bridge loans and pipe financings. He is a member of the Florida and New York Bars and received his J.D. and B.A. from The State University of New York at Buffalo.

The Board believes that Mr. Mayersohn is well qualified to serve as a director due to his extensive experience in corporate and finance legal matters.

***Carol Webb***

Carol Webb has been a member of the Board since August 12, 2024. Ms. Webb served as a director of Leonard-Meron Biosciences, Inc. ("LMB"), a wholly owned subsidiary of Citius Pharma, beginning March 17, 2014 and, upon LMB's acquisition by the Citius Pharma in March 2016, and has since been a member of the board of directors of Citius Pharma. From 2000 to 2005, she served as Company Group Chairman of Johnson & Johnson. From 1987 to 2000, she served in various capacities at Ortho Biotech, including President, Vice President, Executive Director, Product Management and Senior Product Director. From 1972 to 1983, Ms. Webb worked in various positions at Roche Laboratories, including Sales Representative, Sales Trainer, Product Manager and Manager of Public Policy. Ms. Webb received her B.S. in Biology from Bowling Green State University.

The Board believes that Ms. Webb is qualified to serve as a director because she brings over 40 years of pharmaceutical sales, marketing and business development experience to our Board.

***Jaime Bartushak***

From April 1, 2014 until November 2017, Mr. Bartushak served as Chief Financial Officer of Leonard-Meron Biosciences, Inc. ("LMB"), a wholly-owned subsidiary of Citius Pharma. In November 2017, he became the Chief Financial Officer of Citius Pharma upon the acquisition of LMB by Citius Pharma. In November 2022, he was appointed Chief Business Officer of Citius Pharma. Mr. Bartushak became our Chief Financial Officer in August 2024. Mr. Bartushak is an experienced finance professional for early-stage pharmaceutical companies, and has over 20 years of corporate finance, business development, restructuring, and strategic planning experience. Mr. Bartushak was one of the founders of LMB in 2014 and was instrumental in its startup as well as in obtaining initial investment capital. In 2014, prior to his work at LMB, Mr. Bartushak helped lead the sale of PreCision Dermatology, Inc. to Valeant Pharmaceuticals International, Inc.

***Myron S. Czuczman, M.D.***

Dr. Czuczman joined Citius Pharma as Chief Medical Officer in July 2020. He became our Chief Medical Officer in August 2024. Prior to his employment with Citius Pharma, Dr. Czuczman was Vice President, Global Clinical Research and Development, Therapeutic Area Head of Lymphoma/CLL at Celgene Corporation, a position he held from June 2015 to January 2020. Prior to working in the pharmaceutical industry, Dr. Czuczman practiced medicine for over two decades at Roswell Park Cancer Institute, an NCI-designated comprehensive cancer center in Buffalo, NY, where he served as chief of the Lymphoma/Myeloma Service and head of the Lymphoma Translational Research Laboratory. In addition to his extensive publications record, membership and leadership roles on national and international research organizations, and consulting and advisory to dozens of pharma companies, Dr. Czuczman also attained the positions of tenured Professor of Medicine at the State University of New York at Buffalo School of Medicine and Biomedical Sciences and Professor of Oncology at Roswell Park Comprehensive Cancer Center. Dr. Czuczman received his medical degree from the Pennsylvania State University College of Medicine after graduating magna cum laude in Biochemistry from the University of Pittsburgh. He completed his Internal Medicine residency training at Weill Cornell North Shore University/MSKCC Program, followed by Medical Oncology/Hematology fellowship training at Memorial Sloan-Kettering Cancer Center in New York City.

**Family Relationships**

There are no family relationships among our executive officers and directors.

**Code of Ethics**

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. Both can be found in the *Resources-Governance-Governance Documents* section of our website, *www.citiusonc.com*.

**Audit and Risk Committee**

Our Audit and Risk Committee currently consists of Messrs. McGrath (Chair), Dutia and Mr. Smith. Each of Messrs. McGrath, Dutia and Smith satisfies the independence requirements of Rule 5605(a)(2) of the Nasdaq Listing Rules and SEC Rule 10A-3. Our Audit and Risk Committee is responsible for, among other things:

- appointing, terminating, compensating, and overseeing the work of any accounting firm engaged to prepare or issue an audit report or other audit, review or attestation services;
- reviewing and approving, in advance, all audit and non-audit services to be performed by the independent auditor, taking into consideration whether the independent auditor's provision of non-audit services to us is compatible with maintaining the independent auditor's independence;
- reviewing and discussing the adequacy and effectiveness of our accounting and financial reporting processes and controls and the audits of our financial statements;
- establishing and overseeing procedures for the receipt, retention, and treatment of complaints received by us regarding accounting, internal accounting controls or auditing matters, including procedures for the confidential, anonymous submission by our employees regarding questionable accounting or auditing matters;
- monitoring and evaluating the independent auditor's qualifications, performance, and independence on an ongoing basis; and
- reviewing and approving related-party transactions for potential conflict of interest situations on an ongoing basis.

Our Board has affirmatively determined that Messrs. McGrath and Dutia are designated as the "audit committee financial experts." The designation does not impose on Messrs. McGrath and Dutia any duties, obligations or liabilities that are greater than those generally imposed on members of our audit committee and our Board.

**Delinquent Section 16(A) Reports**

Section 16(a) of the Exchange Act requires our directors, executive officers and holders of more than 10% of our common stock to file with the SEC initial reports of ownership and reports of changes in the ownership of our common stock and other equity securities. Such persons are required to furnish us copies of all Section 16(a) filings. Based solely upon a review of the copies of the forms furnished to us, we believe that our officers, directors and holders of more than 10% of our common stock complied with all applicable filing requirements during the fiscal year ended September 30, 2025, except for Joel Mayersohn who filed a Form 4 on August 7, 2025 that was due on July 30, 2025 to report a distribution in kind to limited partners of 10XYZ Holdings, which was the Sponsor of TenX Keane Acquisition ("TenX"), the legacy entity of Citius Oncology, Inc. on July 28, 2025.

**Item 11. Executive Compensation**

## EXECUTIVE COMPENSATION

Our Named Executive Officers (as identified below) also are employees of Citius Pharma. The services of Citius Pharma's employees as our Named Executive Officers are provided to us pursuant to an amended and restated shared services agreement with Citius Pharma. For the fiscal years ended September 30, 2025 and 2024, pursuant to the shared services agreement, Citius Pharma allocated a portion of the salary and non-equity incentive compensation paid during each of those fiscal years to the services provided to us by its employees acting as our Named Executive Officers. No benefits provided by Citius Pharma are allocated to any of our Named Executive Officers.

### Executive Compensation Objectives

We seek to achieve the following broad goals in our executive compensation programs and decisions regarding individual compensation:

- Attract and retain executives critical to our overall success.
- Reward executives for contributions to achieving strategic goals that enhance stockholder value.
- Foster and maintain a company culture of ownership, creativity and innovation.
- Motivate our executive officers to achieve critical long- and short-term development, product and financial milestones set by the Board in consultation with management.

### Named Executive Officers

Our "Named Executive Officers" for the year ended September 30, 2025 consist of Mr. Mazur, our Chief Executive Officer, and Mr. Holubiak, our Secretary, and Dr. Czuczman, our Chief Medical Officer, who were the two most highly compensated executive officers other than Mr. Mazur serving as executive officers as of September 30, 2025.

### General Compensation Process

The Compensation Committee is responsible for determining the elements and levels of compensation for our Named Executive Officers. In doing so, the Compensation Committee reviews our corporate performance against financial and corporate achievement measures, assesses individual performance and evaluates recommendations of the Chief Executive Officer regarding compensation for other Named Executive Officers. Deliberations of the Compensation Committee may occur within a meeting of the full Board at which all members of the Compensation Committee are in attendance and the Board may take action in such meetings upon the advice of the Compensation Committee Chair and/or its members.

To assist in its deliberations regarding executive compensation, the Compensation Committee may engage the services of an independent executive compensation advisor. The Company would anticipate that the Compensation Committee may work with such independent executive compensation advisor to develop a peer group of companies within the biotechnology and pharmaceuticals industries.

### Components of Compensation

The key components of our executive compensation package are cash compensation (salary) and long-term equity incentive awards. These components are administered with the goal of providing total compensation that recognizes meaningful differences in individual performance, is competitive, varies the opportunity based on individual and corporate performance, and is valued by our Named Executive Officers.

*Base Salary*

It is the Compensation Committee's objective to set a competitive rate of annual base salary for each Named Executive Officer. The Compensation Committee believes competitive base salaries are necessary to attract and retain top quality executives, since it is common practice for public companies to provide their named executive officers with a guaranteed annual component of compensation that is not subject to performance risk. The Compensation Committee, on its own or with outside consultants may establish salary ranges for our Named Executive Officers, with minimum to maximum opportunities that cover the normal range of market variability. The actual base salary for each Named Executive Officer is then derived from those salary ranges based on his responsibility, tenure and past performance and market comparability. Annual base salaries for the Named Executive Officers are reviewed and approved by the Compensation Committee. Changes in base salary are based on the scope of an individual's current job responsibilities, individual performance in the previous performance year, target pay position relative to the peer group, and our salary budget guidelines. The Compensation Committee reviews established goals and objectives and determines an individual's achievement of those goals and objectives and considers the recommendations provided by the Chief Executive Officer to assist it in determining appropriate salaries for the Named Executive Officers other than the Chief Executive Officer.

The base salary information for our Named Executive Officers for the fiscal years ended September 30, 2025 and 2024 is set forth in the Summary Compensation Table below.

*Long-Term Incentive Equity Awards*

We believe that long-term corporate success is achieved with an ownership culture that encourages high performance by our employees through the use of stock-based awards. The Plans were each established to provide our employees, including our Named Executive Officers, with incentives to help align employees' interests with the interests of our stockholders. The Compensation Committee believes that the use of stock-based awards offers the best approach to achieving our compensation goals of incentivizing long-term performance. We have historically elected to use stock options as the primary long-term equity incentive vehicle; however, the Compensation Committee has the ability under our stock plans to grant restricted stock and other equity awards as part of our long-term incentive program, although no such awards have been granted to date. We have selected the Black-Scholes method of valuation for stock-based compensation. The Compensation Committee generally oversees the administration of our stock plans.

*Stock Options*

Our 2024 Omnibus Stock Incentive Plan (the "2024 Plan") authorizes us to grant options to purchase shares of common stock to our employees, directors and consultants. Our 2023 Omnibus Stock Incentive Plan (the "2023 Plan") authorizes us to grant the same. Upon the adoption of the 2024 Plan, we ceased granting awards under the 2023 Plan.

The Compensation Committee reviews and approves stock option awards to Named Executive Officers based upon a review of competitive compensation data, an assessment of individual performance, a review of each Named Executive Officer's existing long-term incentives, and retention considerations. Periodic stock option grants are made at the discretion of the Compensation Committee to eligible employees and, in appropriate circumstances, after consideration of any recommendations of our Chief Executive Officer.

Stock options granted to employees have an exercise price equal to the fair market value of our common stock on the day of grant, typically vest over a time or upon the achievement of certain performance-based milestones and are based upon continued employment, and generally expire 10 years after the date of grant. The fair value of the options granted to the Named Executive Officers and reflected in the Summary Compensation Table is determined in accordance with the Black-Scholes method of valuation for share-based compensation. Incentive stock options also include certain other terms necessary to ensure compliance with the Code.

We expect to continue to use stock options as a long-term incentive vehicle because:

- Stock options align the interests of our Named Executive Officers with those of our stockholders, supporting a pay-for performance culture, foster employee stock ownership, and focus the management team on increasing value for our stockholders.

- Stock options are performance-based. All of the value received by the recipient of a stock option is based on the growth of the stock price. In addition, stock options can be issued with vesting based on the achievement of specified milestones although we have not used such performance-based vesting to date.

- Stock options help provide balance to the overall executive compensation program as base salary and annual bonuses focus on short-term compensation, while stock options focus on long-term compensation.

- The vesting period of stock options over time encourages executive retention and is designed to increase stockholder value. In determining the number of stock options to be granted to our Named Executive Officers, we take into account the individual's position, scope of responsibility, ability to affect profits and stockholder value and the individual's historic and recent performance and the value of stock options in relation to other elements of the individual Named Executive Officer's total compensation.

**Policies and Practices Related to the Grant of Certain Equity Awards Close in Time to the Release of Material Nonpublic Information**

While we do not have a formal written policy in place with regard to the timing of awards of options or similar awards in relation to the disclosure of material nonpublic information, our equity awards are generally granted on fixed dates determined in advance. On limited occasions, our Compensation Committee or Board may grant equity awards outside of our annual grant cycle for new hires, promotions, recognition, retention or other purposes.

The Committee approves all equity award grants on or before the grant date and does not grant equity awards in anticipation of the release of material nonpublic information. Similarly, the Committee does not time the release of material nonpublic information based on equity award grant dates.

**Executive Benefits and Perquisites**

Our Named Executive Officers are not currently parties to employment agreements. We will consider entering into employment agreements as necessary and advisable. In addition, consistent with our compensation philosophy, we intend to establish benefits for our Named Executive Officers, including medical, dental and life insurance and the ability to contribute to a 401(k) plan. We would expect these benefits to be comparable to benefit levels for comparable companies.

**Pension Benefits**

We do not maintain any qualified or non-qualified defined benefit plans. As a result, none of our Named Executive Officers participate in or have account balances in qualified or non-qualified defined benefit plans sponsored by us. Our Compensation Committee or Board may elect to adopt qualified or non-qualified benefit plans in the future if it determines that doing so is in our best interests.

**Nonqualified Deferred Compensation**

None of our Named Executive Officers participate in or have account balances in nonqualified defined contribution plans or other non-qualified deferred compensation plans maintained by us. Our Compensation Committee or Board may elect to provide our officers and other employees with non-qualified defined contribution or other non-qualified deferred compensation benefits in the future if it determines that doing so is in our best interests.

**Summary Compensation Table**

The following table sets forth information regarding compensation paid to our Named Executive Officers for the years ended September 30, 2025 and 2024.

| Name & Position | Fiscal Year | Salary (1) | Bonus | Stock Award (2) | Option Awards (2) | All Other Compensation | Total |
|---|---|---|---|---|---|---|---|
| **Leonard Mazur** | 2025 | $ 166,250 | $ -- | $ 2,975,000 | $ 647,723 | $ -- | $ 3,788,973 |
| Chief Executive Officer and Executive Chairman | 2024 | $ 166,250 | $ -- | -- | $ 2,035,000 | $ -- | $ 2,201,250 |
| **Myron Holubiak** | 2025 | $ 450,000 | $ -- | $ 1,487,500 | $ 242,896 | $ -- | $ 2,180,396 |
| Executive Vice Chairman | 2024 | $ 450,000 | $ -- | -- | $ 825,000 | $ -- | $ 1,275,000 |
| **Myron Czuczman** | 2025 | $ 225,000 | $ -- | $ 1,443,750 | $ 323,862 | $ -- | $ 1,992,612 |
| Chief Medical Officer | 2024 | $ 225,000 | $ -- | -- | $ 770,000 | $ -- | $ 995,000 |

(1) The salary represents that portion of the total salary received by the Named Executive Officer from Citius Pharma that has been allocated to Citius Oncology pursuant to the Shared Services Agreement.

(2) The dollar amount set forth in the table above represents the aggregate grant date fair value for all restricted stock awards or option awards, as applicable, granted to the executive officer with respect to the fiscal year in accordance with *FASB ASC Topic 718*. These amounts do not reflect the actual economic value that will be realized by the named executive officer upon the vesting of the restricted stock awards or stock options, the exercise of the stock options, or the sale of the common stock underlying such restricted stock awards or stock options.

**Outstanding Equity Awards at Fiscal Year-End 2025**

The following table contains certain information concerning unexercised options for our executive officers as of September 30, 2025.

| | Option Awards | | | | Stock Awards | |
|---|---|---|---|---|---|---|
| Name | Number of Securities Underlying Unexercised Options Exercisable | Number of Securities Underlying Unexercised Options Unexercisable | Option Exercise Price | Option Expiration Date | Number of shares or units of stock that have not vested | Market value of shares or units of stock that have not vested |
| **Leonard Mazur** | 2,466,667 | 1,233,333[(1)] | $ 2.15 | 07/05/2033 | - | - |
| Chief Executive Officer and Chairman | 266,667 | 533,333[(2)] | $ 1.07 | 12/12/2034 | - | - |
| | - | - | - | - | 1,700,000[(3)] | $ 3,451,000[(4)] |
| **Myron Holubiak** | 1,000,000 | 500,000[(1)] | $ 2.15 | 07/05/2033 | - | - |
| Executive Vice Chairman | 100,000 | 200,000[(2)] | $ 1.07 | 12/12/2034 | - | - |
| | - | - | - | - | 850,000[(3)] | $ 1,725,500[(4)] |
| **Myron Czuczman** | 933,333 | 466,667 | $ 2.15 | 07/05/2033 | - | - |
| Chief Medical Officer | 133,333 | 266,667 | $ 1.07 | 12/12/2024 | - | - |
| | - | - | - | - | 825,000[(3)] | $ 1,674,750[(4)] |

(1) This option, originally issued by Citius Oncology Sub, Inc., vests over three years, beginning July 5, 2023, with 1/36th every month for the first year, and the 1/3 each on the second and third anniversary of July 5, 2023, provided that grantee provides continuous service to the Company or a related entity as of each such vesting date. The option was assumed by Citius Oncology, Inc. in the Merger, which closed August 12, 2024.

(2) The options will vest in three substantially equal installments on the first, second and third anniversaries of December 12, 2024, provided that grantee provides continuous service to the Company or a related entity as of each such vesting date.

(3) The shares will vest in total on the third anniversary of September 19, 2025, subject to the grantee's continuous service to the Company or a related entity as of each such vesting date.

(4) Amounts are calculated based on multiplying the number of shares shown in the table by the per share closing price of our common stock on September 30, 2025, which was $2.03.

**Option Repricing**

We did not engage in any repricing or other modifications to any of our executive officers' outstanding options during the year ended September 30, 2025.

**Director Compensation**

***Director Compensation for the Fiscal Year ended September 30, 2025***

The Board has not yet approved a compensation plan for non-employee directors. To assist in its deliberations regarding non-employee compensation, the Compensation Committee may engage the services of an independent compensation advisor. The Company would anticipate that the Compensation Committee may work with such independent compensation advisor to develop a peer group of companies within the biotechnology and pharmaceuticals industries.

Also, as part of the non-employee director compensation plan, we anticipate that non-employee directors would be entitled to receive stock options as part of their annual compensation. In December 2024, our non-employee directors were awarded stock option awards and in September 2025, our non-employee directors were awarded restricted stock awards, each for their service as non-employee directors.

Director compensation for the year ended September 30, 2025 was as follows:

| Name | Fees Earned or Paid in Cash (1) | Stock Awards (1) | Option Awards (1) | All Other Compensation | Total |
|---|---|---|---|---|---|
| Suren Dutia (2) | $ - | $ 525,000 | $ 95,813 | - | $ 620,813 |
| Dr. Eugene Holuka (2) | $ - | $ 525,000 | $ 95,813 | - | $ 620,813 |
| Joel Mayersohn (2) | $ 10,000 | $ 525,000 | $ 191,626 | - | $ 726,626 |
| Dennis McGrath (2) | $ - | $ 525,000 | $ 95,813 | - | $ 620,813 |
| Robert Smith (2) | $ - | $ 525,000 | $ 95,813 | - | $ 620,813 |
| Carol Webb (2) | $ - | $ 525,000 | $ 95,813 | - | $ 620,813 |

(1) The dollar amount set forth in the table above represents the aggregate grant date fair value for all restricted stock awards or option awards, as applicable, granted to the director with respect to the fiscal year in accordance with *FASB ASC Topic 718*. These amounts do not reflect the actual economic value that will be realized by the director upon the vesting of the restricted stock awards or stock options, the exercise of the stock options, or the sale of the common stock underlying such restricted stock awards or stock options.

(2) At September 30, 2025, the non-employee directors held the following options to purchase shares of Citius Oncology common stock: Mr. Dutia, 275,000; Dr. Holuka 275,000; Mr. Mayersohn 250,000; Mr. McGrath; 275,000; Mr. Smith 125,000; and Ms. Webb 275,000.
.

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

**SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT**

The following table shows the amount of our common stock beneficially owned as of December 10, 2025 by (i) each person or group as those terms are used in Section 13(d)(3) of the Exchange Act believed by us to beneficially own more than 5% of our common stock, (ii) each of our current directors, (iii) each of our Named Executive Officers and (iv) all of our directors and executive officers as a group. Except as otherwise noted, each person named in the table has sole voting and investment power with respect to all shares shown as beneficially owned by them, subject to applicable community property laws.

| Name and Address of Beneficial Owner[1] | Number of Shares of Common Stock Beneficially Owned[2] | Percentage of Shares of Common Stock Beneficially Owned[3] |
|---|---|---|
| ***Executive Officers and Directors*** | | |
| Leonard Mazur[4] | 2,733,333 | 3.12% |
| Myron Holubiak[4] | 1,100,000 | 1.28% |
| Suren Dutia[4] | 275,000 | * |
| Dr. Eugene Holuka[4] | 275,000 | * |
| Dennis M. McGrath[4] | 275,000 | * |
| Robert Smith[4] | 125,000 | * |
| Joel Mayersohn[5] | 271,000 | * |
| Carol Webb[4] | 150,000 | * |
| Myron Czuczman[4] | 275,000 | 1.24% |
| ***All directors and executive officers as a group (10 people)[6]*** | **7,462,895** | **8.09%** |
| | | |
| ***5% Holders*** | | |
| Citius Pharmaceuticals, Inc. | 66,049,615 | 77.9% |

(1) The business address of each of the following entities or individuals is c/o of the Company, 11 Commerce Drive, 1st Floor, Cranford, New Jersey 07016.

(2) Beneficial ownership is determined in accordance with the rules of the SEC and generally includes voting or investment power with respect to securities. Shares of common stock subject to options or warrants currently exercisable or convertible, or exercisable or convertible within 60 days of December 10, 2025, are deemed outstanding for computing the percentage of the person holding such option or warrant but are not deemed outstanding for computing the percentage of any other person.

(3) Percentage based on 84,797,846 shares of common stock issued and outstanding as of December 10, 2025.

(4) Consists entirely of shares of common stock that the director or officer has the right to acquire pursuant to outstanding options that are exercisable within 60 days of December 10, 2025.

(5) Consists of: (i) 21,228 shares of common stock acquired by Mr. Mayersohn through a distribution in kind to limited partners of 10XYZ Holdings, which was the Sponsor of TenX Keane Acquisition, the legacy entity of Citius Oncology, Inc., and (ii) 250,000 shares of common stock Mr. Mayersohn has the right to acquire pursuant to outstanding options that are exercisable within 60 days of December 10, 2025.

(6) Consists of: (i) 21,228 shares of common stock, and (ii) 7,441,667 shares of common stock the directors and executive officers have the right to acquire pursuant to outstanding options that are exercisable within 60 days of December 10, 2025.

**SECURITIES AUTHORIZED FOR ISSUANCE UNDER EQUITY COMPENSATION PLANS**

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** | | | |
| 2023 Omnibus Stock Inventive Plan | 18,100,000 | $ 1.82 | |
| 2024 Omnibus Stock Incentive Plan | 11,600,000 | $ - | 300,000 |
| **Total** | 29,700,000 | | 300,000 |

Our equity compensation plan consists of the 2023 Plan which was approved by shareholders of Citius Oncology, Inc. on April 29, 2023, and the 2024 Plan, which was approved by the securityholders of TenX on August 2, 2024, in anticipation of the Merger. The 2024 Plan was subsequently amended on October 27, 2025. We do not have any equity compensation plans or arrangements that have not been approved by stockholders.

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”.

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

Other than as set forth below, there were no transactions since October 1, 2023, to which the Company was or is a party in which:

- the amount involved exceeded or exceeds the lesser of (i) $120,000 and (ii) one percent of the average of our total assets at year-end for the last two completed fiscal years; and

- any of our directors or executive officers, any holder of 5% of our capital stock or any member of their immediate family had or will have a direct or indirect material interest.

***Agreements with Citius Pharma***

The Company and Citius Pharma operate separately, although Citius Pharma continues to control the Company. In connection with the Merger, Citius Pharma and Citius Oncology entered into various agreements to establish the framework for the Company’s relationship with Citius Pharma, including the A&R Shared Services Agreement.

***A&R Shared Services Agreement***

In connection with the Merger, the Company and Citius Pharma entered into an A&R Shared Services Agreement, pursuant to which Citius Pharma and its affiliates provide to the Company the services set forth in the therein, which services are of the type that Citius Pharma provided to the Company prior to the Merger, including services relating to information technology, facilities, accounting and finance, business development, investor relations, human resources, and other corporate and administrative functions, as well as certain scientific services. The fees for each of the services are set forth in the A&R Shared Services Agreement as an aggregate quarterly fee of approximately $940,000, and the Company reimburses Citius Pharma for all reasonable out-of-pocket costs and expenses that it incurs in connection with providing the services. The A&R Shared Services Agreement will terminate on the earlier of (i) mutual agreement of the parties or (ii) two years from the Merger; provided that the agreement automatically extends for additional one-year periods unless the Company or Citius Pharma provides at least 30 days prior written notice of its desire not to automatically extend the term.

***Promissory Note between the Company and Citius Pharma***

In connection with the closing of the Merger, Citius Pharma contributed $10 million in cash to the Company, comprised of $3,800,111 in working capital of the Company, funding $6,199,889 of transaction expenses of the parties to the Merger Agreement, and $1,077,026 for the purchase of TenX Rights prior to the Closing of the transaction (which converted into 422,353 shares of common stock at closing). Such capital contribution is evidenced by an unsecured promissory note (the "Note") issued by the Company, dated August 16, 2024, in the principal amount of $3,800,111 to Citius Pharma. The Note bears no interest and prior to September 10, 2025, was repayable in full upon a financing of at least $10 million by the Company, per the terms of the Note. On September 10, 2025, the Note was amended to be repayable in full at the date on which the Company 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™. On December 10, 2025, the Note was amended to provide that the maturity of the Note would be the date at which the Company has closed a series of capital raises that in the aggregate provide gross proceeds of at least $50 million.

**Procedures for Review and Approval of Transactions with Related Persons**

Pursuant to the Audit and Risk Committee charter, the Audit and Risk Committee is responsible for reviewing and approving all related party transactions as defined under Item 404 of Regulation S-K, after reviewing each such transaction for potential conflicts of interests and other improprieties. Our policies and procedures for review and approval of transactions with related persons are in writing in our Code of Ethics and Business Conduct available under the *Resources-Governance-Governance Documents* section of our website at *www.citiusonc.com*.

**Board of Directors Independence**

After review of all relevant transactions or relationships between each nominee for director, or any of his or her family members, and the Company, its senior management and Wolf & Company, P.C., its independent registered public accounting firm, the Board has determined that all directors of the Company are independent within the meaning of the applicable Nasdaq listing standards, except Leonard Mazur, the Chief Executive Officer and Chairman, Myron Holubiak, the Secretary, and Joel Mayersohn.

Because Citius Pharma continues to control a majority of the voting power of the outstanding shares of Company common stock, the Company qualifies as a "controlled company" within the meaning of the corporate governance standards of the Nasdaq. Under these rules, a listed company of which more than 50% of the voting power is held by an individual, group or another company is a "controlled company" and may elect not to comply with certain corporate governance requirements, including the requirements that (i) a majority of the Board consist of "independent directors" as defined under Nasdaq listing rules, (ii) we have a compensation committee composed entirely of independent directors and (iii) we have a nominating/corporate governance committee composed entirely of independent directors.

The Company does not intend to rely on these exemptions but may opt to utilize these exemptions in the future as long as it remains a controlled company. Accordingly, Company stockholders may not have the same protections afforded to stockholders of companies that are subject to all of the corporate governance requirements of Nasdaq.

If the Company ceases to be a "controlled company" in the future, it will be required to comply with the Nasdaq Listing Rules, which may require replacing a number of its directors and may require development of certain other governance-related policies and practices. These and any other actions necessary to achieve compliance with such rules may increase the Company's legal and administrative costs, will make some activities more difficult, time-consuming, and costly and may also place additional strain on the Company's personnel, systems and resources.

**Item 14. Principal Accountant Fees and Services**

**AUDITOR AND AUDIT COMMITTEE MATTERS**

**Report of the Audit and Risk Committee**

The Audit and Risk Committee has reviewed and discussed with management our audited financial statements for the fiscal year ended September 30, 2025, which were audited by Wolf & Company, P.C. ("Wolf"), an independent registered public accounting firm. The Audit and Risk Committee discussed with Wolf the matters required to be discussed by the applicable requirements of the Public Company Accounting Oversight Board ("PCAOB") and the Commission. The Audit and Risk Committee received the written disclosures and letter from the independent registered public accounting firm required by applicable requirements of the PCAOB regarding the independent registered public accounting firm's communications with the Audit and Risk Committee concerning independence, and discussed with the independent registered public accounting firm the independent registered public accounting firm's independence. The Audit and Risk Committee also considered whether the provision of services other than the audit of our financial statements for the fiscal year ended September 30, 2025 were compatible with maintaining the independence of Wolf.

Based on the review and discussions referred to in the foregoing paragraph, the Audit and Risk Committee recommended to the Board that the audited financial statements be included in the Original Filing.

Our Audit and Risk Committee is currently composed of the following three directors: Mr. McGrath (Chair), Mr. Dutia, and Mr. Smith. All are independent directors as defined in Rules 5605(a)(2) and 5605(c)(2) of the Nasdaq Listing Rules and Section 10A-3 of the Exchange Act. The Board has determined that Messrs. McGrath and Dutia are each an "audit committee financial expert" as such term is defined in Item 407(d)(5)(ii) of Regulation S-K promulgated by the SEC. Our Audit and Risk Committee operates under a written charter adopted by the Board, a copy of which is available under *Governance-Governance Documents* section of our website at *www.citiusonc.com.*

Wolf has served as our auditor since we began operations in April 2022 and audited our consolidated financial statements for the years ended September 30, 2023 through September 30, 2025.

THE AUDIT AND RISK COMMITTEE
Dennis McGrath, Chair
Suren Dutia
Robert Smith

**Fees Paid to the Independent Registered Public Accounting Firm**

***Audit Fees***

The aggregate audit fees billed for professional services rendered by our auditor, Wolf, an independent registered public accounting firm, for the audit of our financial statements as of and for the years ended September 30, 2025 and 2024, our filings with the SEC and other audit fees were $271,250 and $157,080, respectively.

***Audit Related Fees***

The aggregate audit related fees billed for professional services by Wolf for the years ended September 30, 2025 and 2024 were $205,250 and $229,900, respectively.

***Tax Fees***

There were no tax fees billed for professional services by Wolf for the years ended September 30, 2025 and 2024. Tax fees are for the preparation of federal and state income tax returns.

***All Other Fees***

No other fees were billed by or paid to Wolf during the years ended September 30, 2025 and 2024.

**Pre-Approval Policies and Procedures of Audit and Non-Audit Services of Independent Registered Public Accounting Firm**

All fees reported above under the headings Audit Fees, Audit Related Fees, Tax Fees and All Other Fees were approved by the Audit and Risk Committee before the respective services were rendered, which concluded that the provision of such services was compatible with the maintenance of the independence of Wolf in the conduct of its auditing functions.

## 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 and Reorganization, dated as of October 23, 2023, by and among Citius Pharmaceuticals, Inc., Citius Oncology, Inc., TenX Keane Acquisition and TenX Merger Sub, Inc. | 8-K | 10/24/2023 | 2.1 | |
| 3.1.1 | Certificate of Incorporation of Citius Oncology, Inc. | 8-K | 08/16/2024 | 3.1 | |
| 3.1.2 | Certificate of Amendment to the Certificate of Incorporation of Citius Oncology, Inc., filed with the Secretary of State of the State of Delaware on April 7, 2025. | 10-Q | 08/12/2025 | 3.2 | |
| 3.2 | Bylaws of Citius Oncology, Inc. | 8-K | 08/16/2024 | 3.2 | |
| 4.1 | Specimen Common Stock Certificate of Citius Oncology, Inc. | S-4 | 07/11/2024 | 4.5 | |
| 4.2 | Warrant Agency Agreement, dated as of July 17, 2025, by and between Citius Oncology, Inc. and Equiniti Trust Company, LLC. | 8-K | 07/18/2025 | 4.1 | |
| 4.3 | Form of Common Warrant. | 8-K | 07/18/2025 | 4.2 | |
| 4.4 | Form of Placement Agent Warrant. | 8-K | 07/18/2025 | 4.3 | |
| 4.5 | Form of Common Warrant. | 8-K | 09/10/2025 | 4.1 | |
| 4.6 | Form of Placement Agent Warrant. | 8-K | 09/10/2025 | 4.2 | |
| 4.7 | Form of Common Warrant. | 8-K | 12/10/2025 | 4.1 | |
| 4.8 | Form of Pre-funded Warrant. | 8-K | 12/10/2025 | 4.2 | |
| 4.9 | Form of Placement Agent Warrant. | 8-K | 12/10/2025 | 4.3 | |
| 4.10 | Description of Common Stock. | 10-K | 12/27/2024 | 4.2 | |
| 10.1 | Amended and Restated Registration Rights Agreement, dated as of August 12, 2024 by and between Citius Oncology, Inc. and the signatories thereto. | 8-K | 08/16/2024 | 10.1 | |
| 10.2 | Amended and Restated Shared Services Agreement, dated as of August 12, 2024, by and among Citius Oncology, Inc. and Citius Pharmaceuticals, Inc. | 8-K | 08/16/2024 | 10.2 | |
| 10.3† | 2023 Omnibus Stock Incentive Plan. | 10-K | 12/27/2024 | 10.3 | |
| 10.4.1† | 2024 Omnibus Stock Incentive Plan. | 8-K | 08/5/2024 | 10.5 | |
| 10.4.2† | Amendment to the Citius Oncology, Inc. 2024 Omnibus Stock Incentive Plan. | 8-K | 09/19/2025 | 10.1 | |
| 10.5* | Asset Purchase Agreement, dated as of September 1, 2021, between Dr. Reddy's Laboratories S.A. and Citius Pharmaceuticals, Inc. | S-4 | 11/13/2023 | 10.15 | |
| 10.6.1* | Amended and Restated License, Development and Commercialization Agreement, dated as of February 26, 2018, between Eisai, Ltd. and Dr. Reddy's Laboratories S.A. | S-4 | 11/13/2023 | 10.16 | |
| 10.6.2* | Amendment No. 1 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. | S-4 | 11/13/2023 | 10.17 | |
| 10.6.3* | 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. | S-4 | 11/13/2023 | 10.18 | |
| 10.7 | 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 | 08/16/2024 | 10.8 | |
| 10.8 | Promissory Note, dated July 18, 2023, issued by TenX Keane Acquisition to 10XYZ Holdings LP. | 8-K | 07/18/2023 | 10.1 | |

| | | | | | |
|---|---|---|---|---|---|
| 10.9 | Promissory Note, dated October 18, 2023, issued by TenX Keane Acquisition to 10XYZ Holdings LP. | 8-K | 10/18/2023 | 10.1 | |
| 10.10.1 | Promissory Note, dated August 16, 2024, by and between Citius Oncology, Inc. and Citius Pharmaceuticals, Inc. | 8-K | 08/16/2024 | 10.9 | |
| 10.10.2 | Amendment to Promissory Note, dated September 10, 2025, by and between Citius Oncology, Inc. and Citius Pharmaceuticals, Inc. | 8-K | 09/10/2025 | 10.3 | |
| 10.10.3 | Second Amendment to Promissory Note, dated December 10, 2025, by and between Citius Oncology, Inc. and Citius Pharmaceuticals, Inc. | 8-K | 12/10/2025 | 10.5 | |
| 10.11 | Placement Agency Agreement, dated as of July 16, 2025, by and between Citius Oncology, Inc. and Maxim Group LLC. | 8-K | 07/18/2025 | 10.1 | |
| 10.12 | Securities Purchase Agreement, dated as of July 16, 2025, by and between Citius Oncology, Inc. and the purchasers named therein. | 8-K | 07/18/2025 | 10.2 | |
| 10.13 | Placement Agency Agreement, dated as of September 9, 2025, by and between Citius Oncology, Inc. and Maxim Group LLC. | 8-K | 09/10/2025 | 10.1 | |
| 10.14 | Form of Securities Purchase Agreement, dated as of September 9, 2025, by and between Citius Oncology, Inc. and the purchaser signatory thereto. | 8-K | 09/10/2025 | 10.2 | |
| 10.15 | Form of Registered Direct Securities Purchase Agreement, dated as of December 9, 2025, by and between Citius Oncology, Inc. and the purchaser signatory thereto. | 8-K | 12/10/2025 | 10.1 | |
| 10.16 | Form of PIPE Securities Purchase Agreement, dated as of December 9, 2025, by and between Citius Oncology, Inc. and the purchaser signatory thereto. | 8-K | 12/10/2025 | 10.2 | |
| 10.17 | Form of Registration Rights Agreement, dated as of December 9, 2025, by and between Citius Oncology, Inc. and the purchaser signatory thereto. | 8-K | 12/10/2025 | 10.3 | |
| 10.18 | Form of Warrant Amendment Agreement, dated as of December 9, 2025, by and between Citius Oncology, Inc. and the purchaser signatory thereto. | 8-K | 12/10/2025 | 10.4 | |
| 19.1 | Insider Trading Policy. | 10-K | 12/27/2024 | 19.1 | |
| 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 | Policy Relating to Recovery of Erroneously Awarded Compensation | 10-K | 04/16/2024 | 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 CALCULATION 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 Oncology agrees to furnish supplementally an unredacted copy such exhibit, including any omitted exhibits and schedules, to the SEC upon its request.

† Indicates 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 ONCOLOGY, 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<br>Leonard Mazur | Chief Executive Officer and Director<br>(Principal Executive Officer) | December 23, 2025 |
| /s/ Myron Holubiak<br>Myron Holubiak | Secretary and Director | December 23, 2025 |
| /s/ Jaimie Bartushak<br>Jaime Bartushak | Chief Financial Officer and Treasurer<br>(Principal Financial Officer and Principal Accounting Officer) | December 23, 2025 |
| /s/ Suren Dutia<br>Suren Dutia | Director | December 23, 2025 |
| /s/ Eugene Holuka<br>Eugene Holuka | Director | December 23, 2025 |
| /s/ Joel Mayersohn<br>Joel Mayersohn | Director | December 23, 2025 |
| /s/ Dennis McGrath<br>Dennis McGrath | Director | December 23, 2025 |
| /s/ Robert Smith<br>Robert Smith | Director | December 23, 2025 |
| /s/ Carol Webb<br>Carol Webb | Director | December 23, 2025 |

**CITIUS ONCOLOGY, INC.**
**CONSOLIDATED FINANCIAL STATEMENTS**

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## Report of Independent Registered Public Accounting Firm

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

***Opinion on the Financial Statements***

We have audited the accompanying consolidated balance sheets of Citius Oncology, Inc. and its subsidiaries (the Company) as of September 30, 2025 and 2024, 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. The Company is a majority-owned subsidiary of Citius Pharmaceuticals, Inc. Citius Pharmaceuticals, Inc. funds the majority of the Company's operations; therefore, the Company is economically dependent on the continued financial support of Citius Pharmaceuticals, Inc. This raises substantial doubt about the Company's ability to continue as a going concern. Management's plans in regard to these matters also 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 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.

/s/ Wolf & Company, P.C.

We have served as the Company's auditor since 2022.

Boston, Massachusetts
December 23, 2025

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

| | 2025 | 2024 |
|---|---|---|
| **Current Assets:** | | |
| Cash and cash equivalents | $ 3,924,908 | $ 112 |
| Inventory | 22,286,693 | 8,268,766 |
| Prepaid expenses | 1,331,280 | 2,700,000 |
| **Total Current Assets** | 27,542,881 | 10,968,878 |
| | | |
| **Other Assets:** | | |
| In-process research and development | 73,400,000 | 73,400,000 |
| **Total Other Assets** | 73,400,000 | 73,400,000 |
| | | |
| **Total Assets** | $ 100,942,881 | $ 84,368,878 |
| **LIABILITIES AND STOCKHOLDERS' EQUITY** | | |
| **Current Liabilities:** | | |
| Accounts payable | $ 13,234,684 | $ 3,711,622 |
| License payable | 22,650,000 | 28,400,000 |
| Accrued expenses | 4,093,124 | — |
| Due to related party | 9,513,771 | 588,806 |
| **Total Current Liabilities** | 49,491,579 | 32,700,429 |
| | | |
| Deferred tax liability | 2,784,960 | 1,728,000 |
| Note payable to related party | 3,800,111 | 3,800,111 |
| **Total Liabilities** | 56,076,650 | 38,228,540 |
| **Stockholders' Equity:** | | |
| Preferred stock - $0.0001 par value; 10,000,000 shares authorized: no shares issued and outstanding | — | — |
| Common stock - $0.0001 par value; 400,000,000 and 100,000,000 shares authorized at September 30, 2025 and 2024, respectively; 83,513,442 and 71,552,402 shares issued and outstanding at September 30, 2025 and 2024, respectively | 8,351 | 7,155 |
| Additional paid-in capital | 108,897,836 | 85,411,771 |
| Accumulated deficit | (64,039,956) | (39,278,587) |
| **Total Stockholders' Equity** | 44,866,231 | 46,140,339 |
| **Total Liabilities and Stockholders' Equity** | $ 100,942,881 | $ 84,368,878 |

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

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

| | 2025 | 2024 |
|---|---|---|
| **Revenues** | $ — | $ — |
| **Operating Expenses:** | | |
| Research and development | 6,418,334 | 4,925,001 |
| General and administrative | 8,783,997 | 8,148,929 |
| Stock-based compensation – general and administrative | 8,320,419 | 7,498,817 |
| **Total Operating Expenses** | 23,522,750 | 20,572,747 |
| | | |
| **Operating loss** | (23,522,750) | (20,572,747) |
| | | |
| **Other Income (Expense)** | | |
| Interest income | 36,373 | — |
| Interest expense | (218,032) | — |
| **Total Other Income (Expense), Net** | (181,659) | — |
| | | |
| **Loss before Income Taxes** | (23,704,409) | (20,572,747) |
| Income tax expense | 1,056,960 | 576,000 |
| | | |
| **Net Loss** | $ (24,761,369) | $ (21,148,747) |
| | | |
| **Net Loss Per Share – Basic and Diluted** | $ (0.34) | $ (0.31) |
| | | |
| **Weighted Average Common Shares Outstanding – Basic and Diluted** | 73,267,969 | 68,053,607 |

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

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

| | Preferred Stock | | Common Stock | | Additional Paid-In | Accumulated | Total Stockholders' |
|---|---|---|---|---|---|---|---|
| | Shares | Amount | Shares | Amount | Capital | Deficit | Equity |
| **Balance, September 30, 2023** | - | $ - | 67,500,000 | $ 6,750 | $ 43,658,750 | $ (18,129,840) | $ 25,535,660 |
| Capital contributions by parent | - | - | - | - | 37,008,905 | - | 37,008,905 |
| Stock-based compensation expense | - | - | - | - | 7,498,817 | - | 7,498,817 |
| Merger, net of transaction costs of $2,358,780 | - | - | 4,052,402 | 405 | (2,754,701) | - | (2,754,296) |
| Net loss | - | - | - | - | - | (21,148,747) | (21,148,747) |
| Balance, September 30, 2024 | - | - | 71,552,402 | 7,155 | 85,411,771 | (39,278,587) | 46,140,339 |
| Issuance of common stock in July 2025 registered direct offering, net of costs of $1,453,012 | - | - | 6,818,182 | 682 | 7,546,306 | - | 7,546,988 |
| Issuance of common stock in September 2025 registered direct offering, net of costs of $1,380,146 | - | - | 5,142,858 | 514 | 7,619,340 | - | 7,619,854 |
| Stock-based compensation expense | - | - | - | - | 8,320,419 | - | 8,320,419 |
| Net loss | - | - | - | - | - | (24,761,369) | (24,761,369) |
| **Balance, September 30, 2025** | - | $ - | 83,513,442 | $ 8,351 | $108,897,836 | $ (64,039,956) | $ 44,866,231 |

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

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

| | 2025 | 2024 |
|---|---|---|
| **Cash Flows From Operating Activities:** | | |
| Net loss | $ (24,761,369) | $ (21,148,747) |
| Adjustments to reconcile net loss to net cash (used in) provided by operating activities: | | |
| Stock-based compensation expense | 8,320,419 | 7,498,817 |
| Deferred income tax expense | 1,056,960 | 576,000 |
| Changes in operating assets and liabilities: | | |
| Inventory | (12,649,207) | (2,133,871) |
| Prepaid expenses | - | (1,100,000) |
| Accounts payable | 9,523,062 | 2,422,577 |
| Accrued expenses | 4,093,124 | (259,071) |
| Due to related party | 8,924,965 | 14,270,648 |
| **Net Cash (Used in) Provided By Operating Activities** | (5,492,046) | 126,353 |
| | | |
| **Cash Flows From Investing Activities:** | | |
| License payments | (5,750,000) | (5,000,000) |
| **Net Cash Used In Investing Activities** | (5,750,000) | (5,000,000) |
| | | |
| **Cash Flows From Financing Activities:** | | |
| Net proceeds from issuance of common stock | 15,166,842 | - |
| Cash contributed by parent | - | 3,827,944 |
| Merger, net | - | (2,754,296) |
| Proceeds from issuance of note payable to related party | - | 3,800,111 |
| **Net Cash Provided By Financing Activities** | 15,166,842 | 4,873,759 |
| **Net Change in Cash and Cash Equivalents** | 3,924,796 | 112 |
| **Cash and Cash Equivalents – Beginning of Year** | 112 | - |
| **Cash and Cash Equivalents – End of Year** | $ 3,924,908 | $ 112 |
| **Supplemental Disclosures of Cash Flow Information and Non-cash Activities:** | | |
| IPR&D Milestones included in License Payable | $ - | $ 28,400,000 |
| Capital Contribution of due to related party by parent | $ - | $ 33,180,961 |
| Net Prepaid Manufacturing transferred to Inventory | $ 1,368,720 | $ 6,134,895 |
| 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 Oncology, Inc. ("Citius Oncology," the "Company" "we" or "us") is a specialty pharmaceutical company dedicated to the development and commercialization of critical care products targeting unmet needs with a focus on oncology products. We have developed E7777 (denileukin diftitox), an approved oncology immunotherapy for the treatment of cutaneous T-cell lymphoma ("CTCL"), a rare form of non-Hodgkin lymphoma. We have obtained the trade name of LYMPHIR for E7777.

Since our inception, the Company has devoted substantially all of its efforts to business planning, research and development, and recruiting management and technical staff. 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 the Company or its competitors of research and development stage products, market acceptance of any of its products approved for marketing, 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.

Since our inception, Citius Pharmaceuticals, Inc. ("Citius Pharma") (Nasdaq: CTXR) has funded and continues to partially fund the Company. Citius Pharma and the Company 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 the Company.

***Merger***

On August 23, 2021, Citius Pharma formed Citius Acquisition Corp. ("SpinCo") as a wholly-owned subsidiary in conjunction with the acquisition of LYMPHIR, which began operations in April 2022, when Citius Pharma transferred the assets related to LYMPHIR to SpinCo, including the related license agreement and asset purchase agreement (see Note 4).

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 (the "Merger") which was subsequently renamed Citius Oncology Sub, Inc. Prior to 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% of our outstanding shares of common stock. As of September 30, 2025, Citius Pharma owned approximately 79% of our outstanding shares of common stock.

While the Merger Sub was the legal acquirer of the Company, for accounting purposes, the Company was deemed to be the accounting acquirer. Accordingly, for accounting purposes, the Merger was treated as the equivalent of the Company issuing stock for the assets and liabilities of the Merger Sub, accompanied by a recapitalization. Total shares outstanding of the Company after the Merger and recapitalization increased to 71,552,402. The net assets of the merged entities are stated at historical cost, with no goodwill or other intangible assets recorded. Additionally, the historical financial statements of the Company became the historical financial statements of the Registrant.

The Merger, net amount of $2,753,795 charged to additional paid in capital consists of $395,015 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 of $2,358,780.

As part of the Merger, Citius Pharma made capital investments in the Company 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 the Company to Citius Pharma. Simultaneously, Citius Pharma advanced an additional $3,800,111 to the Company under the terms of a note payable (see Note 6).

***Basis of Presentation***

The accompanying consolidated financial statements include the operations of Citius Oncology, Inc., and its wholly-owned subsidiary, Citius Oncology Sub, Inc., which was formed in connection with Merger. The accompanying consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP").

**2. GOING CONCERN UNCERTAINTY AND MANAGEMENT'S PLAN**

The accompanying 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 had a net loss of $24,761,369 and $21,148,747 for the years ended September 30, 2025 and 2024, respectively. We have no revenue and have relied on funding from Citius Pharma to finance our operations. At September 30, 2025, we had $3,924,908 in cash and a negative working capital of $21,948,698. Citius Pharma and Citius Oncology have sufficient capital to fund Citius Oncology 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 financial statements are issued.

During the three months ended September 30, 2025, we raised net proceeds of $15,166,842 from the sale of common stock.

We plan to continue to rely on funding from Citius Pharma, to raise capital through equity financings from outside investors and to generate revenue from the future sales of LYMPHIR. Both the Company and Citius Pharma are actively engaged in capital raising efforts to extend the cash runway. We retained Jeffries LLC as our exclusive financial advisor in evaluating strategic alternatives aimed at maximizing shareholder value. There is no assurance, however, that Citius Pharma will have the resources to continue funding us, that we will be successful in raising the needed capital and, if funding is available, that it will be available on terms acceptable to us, or that the we will find strategic partners, or generate substantial revenue from the sale of LYMPHIR. 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 the Company in the preparation of the consolidated financial statements is as follows:

***Use of Estimates***

The process of preparing financial statements in conformity U.S. 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, 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 $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, which were available for sale commencing in December 2025. No reserves against inventory were deemed necessary based on an evaluation of the product expiration dating.

| | 2025 | 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 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 and License Payable***

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 of $73,400,000 consists of an initial $40,000,000 payment to Dr. Reddy's Laboratories ("DRL") in September 2021, and $27,500,000 and $5,900,000 for approval milestone amounts payable to DRL and Eisai, respectively, that became due during 2024. Of these amounts $22,650,000 and $28,400,000 are included in license payable at September 30, 2025 and 2024, respectively. The value of our September 2021 acquisition of an exclusive license for LYMPHIR (denileukin diftitox), an oncology immunotherapy for the treatment of CTCL, a rare form of non-Hodgkin lymphoma, is expected to be amortized on a straight-line basis over a period of twelve years, (the FDA exclusivity period), commencing upon revenue generation which is expected to commence in December 2025. Included in the IPR&D is the historical know-how, formula protocols, designs, and procedures which were used in the completion of the 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.

We review our 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, we write 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.

***Patents and Trademarks***

Certain costs of outside legal counsel related to obtaining trademarks for the Company are capitalized. Patent costs are amortized over the legal life of the patents, generally twenty years, starting at the patent issuance date. There are no capitalized patents and trademarks as of September 30, 2025.

The costs of unsuccessful and abandoned applications are expensed when abandoned. The costs of maintaining existing patents are expensed as incurred.

***Stock-Based Compensation***

We recognize compensation costs resulting from the issuance of stock-based awards to employees and directors as an expense in the statements 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. 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 statements 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 file consolidated income tax returns with Citius Pharma. 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. 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, we did not recognize any interest and penalties. We are subject to examination by federal and state tax authorities for all tax years since inception.

We recognize 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. We provide a valuation allowance, if necessary, for deferred tax assets for which we do 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 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 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. The Company is currently evaluating the impact of adoption of the standard on its 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 expense 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 update on our financial statement disclosures.

**4. PATENT AND TECHNOLOGY LICENSE AGREEMENTS**

In September 2021, Citius Pharma entered into an asset purchase agreement with Dr. Reddy's Laboratories SA, a subsidiary of Dr. Reddy's Laboratories, Ltd. (collectively, "Dr. Reddy's") and a license agreement with Eisai Co., Ltd. ("Eisai") to acquire an exclusive license 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 us effective April 1, 2022. Citius Pharma renamed E7777 as I/ONTAK and also obtained the trade name of LYMPHIR™ for the product. Denileukin diftitox is referred to 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 for E7777 from Eisai and other related assets owned by Dr. Reddy's. The exclusive license includes rights to develop and commercialize E7777 in all markets except for Japan and certain parts of Asia. 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 a $40,000,000 upfront payment which represents the acquisition date fair value of the in-process research and development acquired from Dr. Reddy's. Dr. Reddy's is entitled to up to $40,000,000 in development milestone payments related to CTCL approvals in the U.S. and other markets, up to $70,000,000 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 $300,000,000 for commercial sales milestones. We also must pay on a fiscal quarter basis tiered royalties equal to low double-digit percentages of net product sales (within a range of 10% to 15%). The royalties will end on the earlier of (i) the 15-year anniversary of the first commercial sale of the latest indication that received regulatory approval in the applicable country and (ii) the date on which a biosimilar product results in the reduction of net sales in the applicable product by 50% in two consecutive quarters, as compared to the four quarters prior to the first commercial sale of the biosimilar product. We will also pay to Dr. Reddy's an amount equal to a low-thirties percentage of any sublicense upfront consideration or milestone payments (or the like) received by us and the greater of (i) a low-thirties percentage of any sublicensee sales-based royalties or (ii) a mid-single digit percentage of such licensee's net sales. Citius Pharma is a guarantor of our obligations under these agreements.

At the time of the FDA approval for LYMPHIR, a $27,500,000 milestone payment became payable to Dr. Reddy's under the terms of the asset purchase agreement for which a balance of $19,750,000 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 $5,900,000 milestone payment upon FDA approval, of which $2,900,000 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 $22,000,000 related to the achievement of net product sales thresholds. Citius Pharma was also required to reimburse Eisai for up to $2,650,000 of its costs to complete the Phase 3 pivotal clinical trial for LYMPHIR for the CTCL indication and reimburse Eisai for all reasonable costs associated with the preparation of a Biologics License Application, (the "BLA") for LYMPHIR. Eisai was responsible for completing the CTCL clinical trial, and chemistry, manufacturing and controls (CMC) activities through the filing of a BLA for LYMPHIR 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 $2,535,318 and thereafter on the 15$^{th}$ 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 $10,000,000. 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, Citius Pharma 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 us:

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

***Authorized Capital Stock***

The certificate of incorporation adopted on August 5, 2024, in connection with the Merger, authorized 110,000,000 shares, of which 100,000,000 shares are common stock with a par value of $0.0001, and 10,000,000 shares are preferred stock with a par value of $0.0001. On April 7, 2025, pursuant to Board and stockholder approval, we amended our certificate of incorporation to increase the authorized shares of common stock from 100,000,000 shares to 400,000,000 shares.

***Common Stock Offerings***

On July 17, 2025, we completed an offering of 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.

We paid the placement agent a fee of 7.0% of the gross proceeds and expenses of $125,000. Additionally, we 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. We also paid an additional 7.0% fee to a prior placement agent and issued to 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, we completed an offering of 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.

We paid the placement agent a fee of 7.0% of the gross proceeds and expenses of $125,000. Additionally, we 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.

***Stock Plans***

Under the Citius Oncology 2023 Stock Plan, adopted on April 29, 2023, we reserved 15,000,000 common shares for issuance. Under the Citius Oncology 2024 Stock Plan, adopted on August 2, 2024, we reserved 15,000,000 common shares for issuance. The 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.

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 Citius Pharma common stock until such time as we have 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.

The following assumptions were used in determining the fair value of 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% |

A summary of option activity under the 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) | 1.75 | | |
| 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 common shares at an exercise price of $1.02 per share. On December 12, 2024, the Board of Directors granted options to purchase 5,550,000 common shares 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.

Stock-based compensation expense for stock options for the years ended September 30, 2025 and 2024 was $8,116,678 and $7,498,817, respectively.

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

***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 19, 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.

**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.

***Common Stock Reserved***

A summary of common stock reserved for future issuances by the Company 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 |

**6. RELATED PARTY TRANSACTIONS**

Our officers and directors also serve as officers of Citius Pharma. As of September 30, 2025, we do not have any employees. The Company and Citius Pharma have entered into the A&R Shared Services Agreement and under the terms of the agreement, Citius Pharma provides management and scientific services to us. During the year ended September 30, 2025, Citius Pharma charged us $2,201,742 for reimbursement of general and administrative payroll, $1,920,000 for reimbursement of research and development payroll, and $114,185 for the use of shared office space. During the year ended September 30, 2024, Citius Pharma charged us $1,846,202 for reimbursement of general and administrative payroll, $1,963,630 for reimbursement of research and development payroll, and $121,570 for the use of shared office space.

We have had limited cash, therefore most of our expenditures have been paid by Citius Pharma and reflected in the due to related party account. At September 30, 2025 and 2024, the net amount due to Citius Pharma was $9,513,771 and $588,806, respectively.

In connection with closing of the Merger, Citius Pharma made a contribution to our capital in the amount of $33,180,961 representing the balance of the due to/due from related party account on the date of the Merger. Citius Pharma also made cash contributions to our capital, pursuant to the terms of the Merger Agreement, in the amount of $3,827,944.

Also, in connection with the Merger, Citius Pharma advanced cash to the Company for a non-interest bearing, unsecured promissory note issued by the Company, dated August 16, 2024, as amended September 10, 2025, in the principal amount of $3,800,111. The note is repayable in full upon a financing of at least $30,000,000 by the Company, per the terms of the promissory note. Management does not anticipate such repayment within the next twelve months. As a result, this note payable is classified as non-current on the balance sheet.

**7. INCOME TAXES**

We file consolidated income tax returns with Citius Pharma. 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 our in-process research and development asset.

The income tax expense 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 | (21.00)% | (21.00)% |
| Increase (decrease) in income taxes resulting from: | | |
| State taxes, net of federal benefit | (7.11) | (7.11) |
| Permanent differences | 6.34 | 6.11 |
| Increase in the valuation reserve | 26.23 | 24.80 |
| | 4.46% | 2.80% |

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 the Company's deferred tax assets and liabilities are as follows:

| | September 30, 2025 | September 30, 2024 |
|---|---|---|
| Deferred tax assets: | | |
| Net operating loss carryforward | $ 12,720,000 | $ 7,530,000 |
| Capitalized research and development expense | 3,189,000 | 2,080,000 |
| Stock-based compensation | 1,928,000 | 1,091,000 |
| Research tax credit | 1,581,000 | 1,035,000 |
| Valuation allowance on deferred tax assets | (19,418,000) | (11,736,000) |
| Total deferred tax assets | - | - |
| Deferred tax liabilities: | | |
| In-process research and development | (2,784,960) | (1,728,000) |
| Total deferred tax liability | (2,784,960) | (1,728,000) |
| Net deferred tax liability | $ (2,784,960) | $ (1,728,000) |

The Company has recorded a valuation allowance against deferred tax assets as the utilization of the net operating loss carryforward and other deferred tax assets is uncertain. During the years ended September 30, 2025 and 2024, the valuation allowance increased by $7,682,000 and $4,928,000, respectively. The increase in the valuation allowance during the years ended September 30, 2025 and 2024 was primarily due to the Company's net operating losses and capitalized research and development expenses. At September 30, 2025, the Company has a federal net operating loss carryforward of approximately $47,153,000. Federal net operating loss carryforwards 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, the Company also has estimated federal research and development credits of $1,581,000 to offset future income taxes. The tax credit carryforwards will begin to expire in 2042.

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 the Company to date.

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.

## 8. COMMITMENTS AND CONTINGENCIES

***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 approximately $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 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 approximately $1.2 million in 2025, $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 the Company or its officers or directors in their capacities as such.

**9. SUBSEQUENT EVENTS**

On October 27, 2025, we held our 2025 annual meeting of stockholders. At the meeting, our stockholders approved an amendment to the Company's 2024 Omnibus Stock Incentive Plan increasing the number of shares of our common stock authorized for issuance under the plan from 15,000,000 to 30,000,000 shares.

On December 8, 2025, the Company entered into a securities purchase agreement (the "RD 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 (the "Shares"). 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 (the "Common Warrants"), with an exercise price of $1.09 per share of our common stock, which are exercisable upon Stockholder Approval (as defined in the Common Warrant), and have a term of five years from the date of 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, the Company also entered into a securities purchase agreement (the "PIPE Purchase Agreement", together with the RD Purchase Agreement, the "Purchase Agreements") 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 (the "Pre-funded Warrants") and 15,229,358 Common Warrants, at a combined price of $1.0899 per Pre-funded Warrant and accompanying Common 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, the Company agreed to pay the placement agent a cash fee of 7.0% of the aggregate gross proceeds the Company received in the offering. In addition, the Company granted placement agent warrants to the placement agent, or its designees, to purchase up to 1,155,963 shares of common stock (the "Placement Agent Warrants"). The terms of the Placement Agent Warrants are substantially the same as the terms of the Common Warrants, except that the exercise price is $1.3625 per share and expire five years from the commencement of sales in the offering.