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, 2022

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

Commission File Number 001-38174

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

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

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

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

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

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

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

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 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 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. ☐

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, 2022) was approximately $240 million.

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:

146,211,130 shares as of December 15, 2022, all of one class of common stock, $0.001 par value.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Company's Proxy Statement for the Annual Meeting of Stockholders expected to be held on February 7, 2023 are incorporated by reference in Part III of this Report.

Citius Pharmaceuticals, Inc.

FORM 10-K
September 30, 2022

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NOTES

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

Mino-Lok® is our registered trademark. All other trade names, trademarks and service marks appearing in this prospectus 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, 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:

- the cost, timing, and results of our pre-clinical and clinical trials;
- our ability to raise funds for general corporate purposes and operations, including our pre-clinical and clinical trials;
- our ability to apply for, obtain and maintain required regulatory approvals for our product candidates;
- the commercial feasibility and success of our technology and our product candidates;
- our ability to recruit qualified management and technical personnel to carry out our operations; and
- the other factors discussed in the "Risk Factors" section and elsewhere in this report.

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

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:

- 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 need to secure additional financing in the near future to complete the development of our current product candidates and support our operations. If we fail to raise additional funds, our operations and business will be significantly adversely affected.

- The COVID-19 pandemic has adversely impacted hospitals and medical facilities where we are currently conducting our Mino-Lok Phase 3 trial and may materially and adversely affect our clinical trial operations in the future, which could increase our operating expenses and the length of time to complete the Mino-Lok Phase 3 trial and any/or other trial and have a material adverse effect on our financial results.

- We cannot assure you that we will receive the approvals necessary to commercialize for sale any product candidates we are currently developing or that we may acquire or seek to develop in the future. Failure to obtain FDA approval of one or more of our product candidates could severely undermine our business by leaving us without saleable products, and therefore without any potential sources of revenues.

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

- If we are unable to file for approval of Mino-Lok or Halo-Lido under Section 505(b)(2) of the Federal Food, Drug and Cosmetic Act, and thereby not be able to use existing, publicly available third-party data regarding components of Mino-Lok or Halo-Lido, or if we are required to generate additional data related to safety and efficacy in order to obtain approval of Mino-Lok or Halo-Lido under Section 505(b)(2), we may be unable to meet our anticipated development and commercialization timelines. Such a development would be costly and time consuming and adversely impact our operations and financial condition.

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

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

- The proposed spinoff of our I/ONTAK asset is dependent on final approval from the Citius Board of Directors, market conditions, regulatory approvals, and SEC filings. Consequently, there can be no assurance regarding the ultimate timing of the proposed transaction or that the transaction will be completed at all.

- Currently, we do not have any sales, marketing, or distribution capabilities. In order to generate sales of any product candidate that receives regulatory approval, we must either acquire or develop an internal marketing and sales force with technical expertise and with supporting distribution capabilities or make arrangements with third parties to perform these services for us.

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

- Our ability to commercialize our product candidates will depend in part on the extent to which reimbursement will be available from government and health administration authorities, private health maintenance organizations and health insurers, and other healthcare payers. Our ability to generate product revenues will be diminished if any of our product candidates that may be approved sell for inadequate prices or patients are unable to obtain adequate levels of reimbursement.

- We are and will be dependent on third-party contract research organizations to conduct all of our clinical trials. If these third parties do not successfully carry out their contractual duties or regulatory obligations or meet expected deadlines, if the third parties need to be replaced or if the quality or accuracy of the data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements or for other reasons, our preclinical development activities or clinical trials may be extended, delayed, suspended or terminated, and we may not be able to obtain regulatory approval for any of our product candidates.

- 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 are currently being manufactured entirely by commercial third-party manufacturers.

- 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.

- We share some directors, officers, and research staff with NoveCite. The dual roles of our employees, officers and directors who also serve in similar roles with NoveCite could create a conflict of interest, which could expose us to claims by our investors and creditors and could harm our results of operations.

- Our future success, competitive position and 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.

- If we fail to meet the continued listing requirements of Nasdaq it could result in a delisting of our common stock. We have twice failed to meet the listing standards, most recently between April 2020 and July 2020, but regained compliance. However, we cannot assure our future compliance with Nasdaq's listing requirements.

- You may experience dilution of your ownership interests because of the future issuance of additional shares of our common stock or securities convertible into common stock. As of September 30, 2022, there were 146,211,130 shares of common stock outstanding, 38,325,489 shares underlying warrants and 9,400,171 shares underlying options.

- Under our Certificate of Incorporation, our Board of Directors 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 of Directors could authorize the issuance of one or more series of preferred stock that would grant preferential rights over our common stock.

PART I

Item 1. Business

Overview

Citius Pharmaceuticals, Inc. (the "Company," "Citius" or "we"), headquartered in Cranford, New Jersey, is a late-stage pharmaceutical company dedicated to the development and commercialization of first-in-class critical care products with a focus on oncology, anti-infectives in adjunct cancer care, unique prescription products and stem cell therapy. Our goal generally is to achieve leading market positions by providing therapeutic products that address unmet medical needs yet have a lower development risk than usually is associated with new chemical entities. New formulations of previously approved drugs with substantial existing safety and efficacy data are a core focus. We seek to reduce development and clinical risks associated with drug development, yet still focus on innovative applications. Our strategy centers on products that have intellectual property and regulatory exclusivity protection, while providing competitive advantages over other existing therapeutic approaches.

The Company was founded as Citius Pharmaceuticals, LLC, a Massachusetts limited liability company, on January 23, 2007. On September 12, 2014, Citius Pharmaceuticals, LLC entered into a Share Exchange and Reorganization Agreement, with Citius (formerly Trail One, Inc.), a publicly traded company incorporated under the laws of the State of Nevada. Citius Pharmaceuticals, LLC became a wholly-owned subsidiary of Citius. On March 30, 2016, Citius acquired Leonard-Meron Biosciences, Inc. ("LMB") as a wholly-owned subsidiary. LMB was a pharmaceutical company focused on the development and commercialization of critical care products with a concentration on anti-infectives. On September 11, 2020, we formed NoveCite, Inc. ("NoveCite"), a Delaware corporation, of which we own 75% of the issued and outstanding capital stock. NoveCite is focused on the development and commercialization of its proprietary mesenchymal stem cells for the treatment of acute respiratory disease syndrome ("ARDS"). On August 23, 2021, we formed Citius Acquisition Corp. ("Citius Acq.") as a wholly-owned subsidiary in conjunction with the acquisition of I/ONTAK, which began operations in April 2022.

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

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

I/ONTAK

Overview

In September 2021, the Company announced that it had entered into a definitive agreement with Dr. Reddy's Laboratories SA, a subsidiary of Dr. Reddy's Laboratories, Ltd. (collectively, "Dr. Reddy's"), to acquire its exclusive license of E7777 (denileukin diftitox), a late-stage oncology immunotherapy for the treatment of CTCL, a rare form of non-Hodgkin lymphoma. E7777, an engineered IL-2-diphtheria toxin fusion protein, is an improved formulation of oncology agent, ONTAK®, which was previously approved by the U.S. Food and Drug Administration ("FDA") for the treatment of patients with persistent or recurrent CTCL. We have renamed E7777 as I/ONTAK although we refer to it as E7777 at times in this report.

Phase 3 Trial

A global, multicenter, open label single arm pivotal clinical trial for the treatment of patients with persistent or recurrent CTCL was initiated in 2013. 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 pivotal trial was divided into two phases, a lead-in phase with 21 subjects that evaluated dose finding, pharmacokinetics and immunogenicity, as well as assessing the Objective Response Rate (the "ORR"). An ORR is defined as a greater than 50% reduction in tumor burden.

The results of the lead-in study were:

- 9 mcg/kg/dose for 5 consecutive days in 21-day cycles which was selected for the main phase of the study based on safety, tolerability, and efficacy data.
- No new safety signals were identified compared to Ontak.
- An ORR of 38.1% in the intent to treat population and 44.4% in the efficacy evaluable populations.

The second phase to the pivotal trial was a 70-patient study administered at the 9 mcg/kg/dose rate for 5 consecutive days in 21-day cycles, The inclusion criteria was identical to the lead-in study and the primary objective was to evaluate the ORR.

According to the trial protocol, the treatment would be considered efficacious and demonstrate clinical benefit if the lower limit of the 2-sided 95% exact confidence interval (CI) of the observed ORR exceeds 25.0%, as determined by the Independent Review Committee (IRC).

The results of the pivotal trial were:

- The IRC determined the study achieved an ORR of 36.2%, 95% confidence interval (25.0%, 48.7%) (25 patients out of 69);
- An Investigator Efficacy Analysis determined that the study achieved an ORR of 42.3%, 95% confidence interval (30.6%, 54.6%) (30 patients out of 71);
- The FDA recently provided additional written comments indicating that their efficacy evaluation will be based on study results showing the lower limit of a 95% confidence interval to exceed a clinically relevant response rate (determined during its review of our BLA) which may be supported with data from the prior ONTAK study that led to ONTAK's initial approval. In our trial, ORR will need to be supported by adequate magnitude of duration of response and an acceptable risk/benefit ratio; and
- Overall rates of adverse events and serious adverse events were consistent with published data of previously approved ONTAK. Most common adverse events included: nausea, fatigue, increased alanine aminotransferase, chills and peripheral oedema, increased aspartate aminotransferase, and infusion related reaction. No new safety concerns were identified.

Selected Preliminary Efficacy Data Table

	Independent (IRC) Stage I-III Primary Efficacy Analysis Set[1] (n=69)	**Investigator Stage I-III Efficacy Analysis Set[2] (n=71)**
Objective Response Rate (ORR) (Complete Response + Partial Response), n (%)	25 (36.2)	30 (42.3)
95% CI	(25.0, 48.7)	(30.6, 54.6)
Duration of Response (months)		
Subjects with Objective Response (n)	25	30
Median observed DOR (months)	6.5	5.7
Range (Min, Max)	(3.0+, 23.5+)	(0.7+, 26.1+)
Time to Response (months)		
Subjects with Objective Response (n)	25	30
Median	1.41	1.41
Clinical Benefit Rate, n (%) (CR + PR + Durable Stable Disease)	**34 (49.3)**	**38 (53.5)**
95% CI	(37.0, 61.6)	(41.3, 65.5)

1. Independent Review Committee assessment of the primary efficacy analysis set which included 69 Stage I – III subjects from the Lead-In Study and the Main Study who received study drug at 9 ug/kg/day dose. This dataset matches the one used for the ONTAK indication.

2. Investigator Efficacy Analysis Set: All subjects with Stage I-III CTCL who received study drug at 9 µg/kg dose in Lead-In and Main Study (n=71)

Investigator Initiated Trials

We believe there is an opportunity in the field of immune-oncology and have undertaken two investigator-initiated trials to evaluate the potential safety and efficacy of E7777 for potential as an immune-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 non-randomized trial which has an estimated enrollment of 30 participants who will be administered E7777 prior to tisagenlecleucel Chimeric Antigen Receptor, (“CAR-T”) therapy. The Phase 1 study consists of two components: dose finding to establish a maximum tolerated dose (“MTD”) of E7777 in combination with CART-T Therapy, and a small extension component to provide an estimate of efficacy at that MTD.

A second Phase 1 Study was initiated in September 2022 at the University of Pittsburg Medical Center, Hillman Cancer Center. This study will be investigating the safety and efficacy of a combined regimen of pembrolizumab with T-regulatory cell depletion and E7777 in patients diagnosed with recurrent or metastatic solid tumors in the second line setting.

Regulatory Development

In the 1990's, 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 with Ligand Pharmaceuticals, Inc. ("Ligand") acquiring the marketing rights in that same year. In 2006, Eisai Co., Ltd. ("Eisai") acquired the commercial rights to Ontak from Ligand.

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

In 2011, there was a commercial supply disruption due to manufacturing issues and a new formulation of denileukin diftitox was developed under the code name E7777. The FDA considered this a new product with a new IND being filed. In ensuing discussions, the FDA agreed to a development plan that included a single arm, open label study to conclude safety and efficacy of E7777 and a 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 Laboratories ("DRL") acquired the global rights to E7777 from Eisai, other than far east countries, with Eisai retaining the rights in those countries.

In June 2016, the first patient was enrolled in the Phase 3 pivotal study for E7777 CTCL in the U.S.

In March 2020, Eisai filed an NDA for E7777 in Japan for both CTCL and PTCL and in March 2021 received approvals in both CTCL and PTCL.

Patient enrollment for the Phase 3 Pivotal study of E7777 was completed in December 2021. In April 2022, we reported that the topline results from the Phase 3 trial were consistent with the prior formulation. Moreover, no new safety signals were identified.

In September 2022, we filed a biologics license application ("BLA") for E7777. In December 2022, we announced that the FDA had accepted the BLA.

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 80–85% of all CTCL. Sézary Syndrome ("SS"), a very rare subtype (~2–5% 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 2001–2007, the estimated incidence rate of MF/SS in the U.S. is 0.5/100,000 or about 2,500–3,000 new cases per year representing about 25% of all T-cell lymphomas.

The Company estimates that there are 30,000 – 40,000 patients living with CTCL in the U.S. with approximately 16,000 – 20,000 having mycosis fungoides. Of those, the Company further estimates that there are 10,000 patients with relapsed or refractory CTCL that require systemic therapy.

The Company also estimates that the addressable U.S. market is approximately $300,000,000 - $400,000,000 for patients with advanced stage relapsed or refractory CTCL.

Proposed Spinoff

In May 2022, we announced that we intend to split the Company's assets into two separate publicly traded entities. We plan to form a new company focused on developing and commercializing I/ONTAK. Our other pipeline assets, including Mino-Lok, would remain at Citius. Citius would continue to trade on the Nasdaq exchange under its current ticker CTXR. The strategic action is intended to optimize organizational resources and investment capital to support the successful execution of each development program. The transactions are expected to be completed in calendar year 2023, subject to the satisfaction of customary conditions, including final approval from the Citius Board of Directors, regulatory approvals, and SEC filings. There can be no assurance regarding the ultimate timing of the proposed transaction or that the transaction will be completed at all.

Mino-Lok®

Overview

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

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

Phase 2b Results

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

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

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

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

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

** 6 Patients had > 1 complication

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

Phase 3 Trial

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

The Mino-Lok Phase 3 Trial was originally planned to enroll 700 patients in 50 participating institutions, all located in the U.S. There were interim analyses at both the 50% and 75% points of the trial as measured by the number of patients treated. As of November 30, 2022, there are 18 active sites in the United States currently enrolling patients including such academic centers as MDACC, Henry Ford Health Center, Georgetown University Medical Center, and others.

In May 2022, the Company selected Biorasi, LLC ("Biorasi"), a global clinical research organization (CRO), to help expand the Company's Phase 3 Mino-Lok trial by implementing additional sites outside the United States. There currently are 17 sites selected in India, making a total of 35 participating Mino-Lok institutions globally.

In September 2019, the Company announced that the FDA agreed to a new primary efficacy endpoint of "time to catheter failure" in comparing Mino-Lok to the antibiotic lock control arm. This change in the trial design reduced the required patient sample size of the trial from 700 subjects to approximately 144 available subjects to achieve the pre-specified 92 catheter failure events needed to conclude the trial. Additionally, the Company submitted a response to the FDA that it would implement this change in the primary endpoint and expected it to result in less than 150 subjects needed in its Phase 3 trial. The new primary endpoints require that the time to catheter failure be at least 38 days for Mino-Lok versus 21 days for the standard of care antibiotic locks.

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

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

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

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

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

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

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

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

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

As of December 21, 2022, the Mino-Lok Phase 3 trial has resulted in:

- 169 patients enrolled to date vs. a planned 144 patients;
- 72 failure events to date vs. a planned 92 failure events; and
- 17 patients currently in treatment or pending study completion data. These may result in future failure events.

Completion of enrollment is expected in 2023.

Fast Track Designation

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

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

Mino-Lok International Study

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

Stability Patent Application for Mino-Lok

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

Market Opportunity

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

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

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

We estimate that the potential market for Mino-Lok in the U.S. to be approximately $500 million to $1 billion as shown in the table below based on a target price of up to $300 per dose of each salvage flush treatment.

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

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

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

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

Halo-Lido

Overview

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

Development of Hemorrhoids Drugs

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

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

Grade I Hemorrhoids not prolapsed but bleeding.

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

Grade III Prolapsed hemorrhoids that require reduction manually.

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

Development Activities to Date

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

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

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

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

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

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

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

In April 2022, we initiated a.multi-center, randomized, dose-ranging, double-blind, parallel group comparison Phase 2b clinical trial. Five cohorts of adults with a clinical diagnosis of symptomatic Goligher's classification Grade II or Grade III hemorrhoids are planned to be dosed. Approximately 60 patients per cohort are expected to be enrolled, for a total of 300 patients.

The key objective of the study is to evaluate the ability of the formulations used in each cohort to provide relief for patients with acute flare ups. The study will evaluate reduction in hemorrhoidal symptoms (including: pain, burning, itching, and swelling) following treatment and is expected to provide the foundation for development of the Phase 3 study.

A Patient Reported Outcome (ePRO) instrument, developed by Citius with FDA guidance, will be used by patients to record and report important safety and efficacy data in real time. The instrument has been adapted for use on an electronic platform and will be loaded on patients' hand-held smart devices. The study will also be used to validate the ePRO. Data readout of the trial is expected in the second half of 2023.

Market Opportunity

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

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

Market Exclusivity

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

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

Mino-Wrap

Overview

On January 2, 2019, we entered into a patent and technology license agreement with the Board of Regents of the University of Texas System on behalf of MDACC, whereby we in-licensed exclusive worldwide rights to the patented technology for any and all uses relating to breast implants, specifically the Mino-Wrap technology. This includes rights to U.S. Patent No. 9,849,217, which was issued on December 16, 2017. We intend to develop Mino-Wrap as a liquefying, gel-based wrap containing minocycline and rifampin for the reduction of infections associated with breast implants following breast reconstructive surgeries. We are required to use commercially reasonable efforts to commercialize Mino-Wrap under several regulatory scenarios and achieve milestones associated with these regulatory options leading to an approval from the FDA. Mino-Wrap will require pre-clinical development prior to any regulatory pathway. In July 2019, we announced that we intend to pursue the FDA's Investigational New Drug ("IND") regulatory pathway for the development of Mino-Wrap. On August 4, 2020, we announced that we had submitted a briefing package to the FDA for a pre-IND consultation on Mino-Wrap.

In December 2020, the Company announced the receipt of a written response and guidance from the FDA Division of Anti-Infective Products to the Company's Pre-IND consultation request for its Mino-Wrap briefing package. The briefing package contained information regarding pre-clinical data and a clinical development plan, along with questions for the FDA regarding safety and efficacy data that would be required to advance Mino-Wrap into clinical trials. The FDA granted a Written Response Only meeting regarding guidance and direction on our Mino-Wrap development plan. The FDA indicated that bio absorption simulation studies may provide information to support the development of Mino-Wrap and made suggestions on what should be provided relative to non-clinical support. The FDA provided guidance on the design of the drug elution studies and agreed that a large animal pharmacology study would be appropriate. They also agreed that a 28-day toxicology study appears appropriate and that microbiology support through existing data is acceptable. We are pursuing these studies and anticipate filing an IND for Mino-Wrap in 2023.

Market Opportunity

Breast cancer is the most frequent cancer in women worldwide, representing 25% of all cancer diagnoses with the exception of non-melanoma skin cancer. In the United States, the overall rate of mastectomies, combining single and double mastectomies, increased 36% from 2005 to 2013. Additionally, the incidence of post-mastectomy breast reconstruction, following breast cancer treatment, has been increasing on an annual basis.

In 2017, the American Society of Plastic Surgeons reported that over 105,000 women in the United States underwent a post-mastectomy breast reconstructive procedure. Approximately 30% of these breast reconstructions occur simultaneously with mastectomy, with most reconstructions occurring weeks later.

The current standard of care in post-mastectomy breast reconstruction is the use of a Tissue Expander ("TE"), which is a temporary implant that is placed below the pectoralis muscle within the mastectomy space. Once a sufficiently large soft tissue envelope has been created, the TE is then replaced by a permanent breast implant. Approximately 80% of the time, a TE is used in breast reconstructions.

The rate of infection following a mastectomy with a TE is 2.4 to 24% with an estimated mean of 12-14%. Once the implant becomes infected, the patient is usually hospitalized requiring approximate two weeks of IV and/or oral antimicrobials. In addition, the TE is removed, leading to a delay of lifesaving chemo-radiation therapy, and a more complex reconstruction in the future.

Currently, preventive measures are used to decrease the rate of TE infections, which include a systemic perioperative antimicrobial agent with the perioperative immersion of the implant or irrigation of the surgical pocket with an antimicrobial solution prior to insertion of the device. This is also administered with immediate postoperative oral antimicrobials.

Based on the in vitro preclinical laboratory work, Mino-Wrap appears to have the characteristics necessary for advancement in the protection of human implants from subsequent infection.

NoveCite

Overview

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

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

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

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

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

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

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

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

Market Opportunity

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

Sales and Marketing

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

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

Intellectual Property

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

I/ONTAK Intellectual Property

On September 3, 2021, we acquired the exclusive license of E7777 (denileukin diftitox), a late-stage oncology immunotherapy for the treatment of CTCL, a rare form of non-Hodgkin lymphoma. E7777, an engineered IL-2-diphtheria toxin fusion protein, is an improved formulation of oncology agent, ONTAK®, which was previously FDA-approved for the treatment of patients with persistent or recurrent CTCL, from Dr. Reddy's. We refer to the agent as I/ONTAK. The exclusive license, which was amended as part of the transaction, is with Eisai and includes rights to develop and commercialize I/ONTAK in all markets except for Japan and certain parts of Asia. Additionally, we have an option on the right to develop and market the product in India.

Under the license agreement, Eisai is to receive a $6 million development milestone payment upon initial approval by the FDA of I/ONTAK for the CTCL indication (which increases to $7 million in the event we have exercised our option to add India to the licensed territory prior to FDA approval) and an aggregate of up to $22 million related to the achievement of net product sales thresholds. We also are required to reimburse Eisai for up to $2.65 million of its costs to complete the ongoing Phase 3 pivotal clinical trial for I/ONTAK for the CTCL indication and reimburse Eisai for all reasonable costs associated with the preparation of a BLA for I/ONTAK.

Pursuant to the terms of the license agreement, Eisai is responsible for completing the current CTCL clinical trial, and chemistry, manufacturing and controls development activities through the production of the BLA, which we filed with the FDA in September 2022, while we are responsible for the costs of correcting any major deficiencies in the BLA as well as the costs of any necessary companion diagnostic or pediatric study. We are responsible for development costs associated with potential additional indications.

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

We are 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.

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. We also must pay on a fiscal quarter basis tiered royalties equal to low double-digit percentages of net product sales. 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.

Also 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 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.

Patents

As part of the definitive agreement with Dr. Reddy's, the Company acquired 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:

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.

Mino-Lok Intellectual Property

In May 2014, our subsidiary LMB entered into a patent and technology license agreement with Novel Anti-Infective Therapeutics, Inc. ("NAT"), who licensed the intellectual property from MDACC, to develop and commercialize Mino-Lok on an exclusive, worldwide (except for South America), sub-licensable basis. LMB incurred a one-time license fee in May 2014. On March 20, 2017, LMB entered into an amendment to the license agreement that expanded the licensed territory to include South America, providing LMB with worldwide rights. We are obligated to pay annual maintenance fees that increase annually until reaching a designated amount, which we must pay until the first sale of product. We also must pay up to an aggregate of approximately $1.1 million in milestone payments, depending on the achievement of various regulatory and commercial milestones. Under the terms of the license agreement, we also must pay a royalty equal to mid-single digit percentages to low-double digit percentages of net sales, depending on the level of sales in that year, and subject to downward adjustment to lower- to mid-single digit percentages in the event there is no valid patent for the product in the country of sale at the time of sale. After the first sale of product, we will owe an annual minimum royalty payment that will increase annually until reaching a designated amount, which we must pay for the duration of the term. We will be responsible for all patent expenses for the term of the agreement although MDACC is responsible for filing, prosecution and maintenance of all patents.

Unless earlier terminated by NAT based on the failure to achieve certain development or commercial milestones, the license agreement remains in effect until the date that all patents licensed under the agreement have expired and all patent applications within the licensed patent rights have been cancelled, withdrawn or expressly abandoned. The license agreement will terminate in the event we breach any of our payment or reporting obligations or NAT breaches any of its obligations under the agreement. NAT will have the right to terminate the agreement if we bring or participate in an action to challenge NAT's ownership of any of the licensed patent rights. We may terminate the license agreement upon 180 days' notice. The license agreement may also be terminated upon our and NAT's mutual consent.

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

Stability Patent Application for Mino-Lok

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

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

Halo-Lido Intellectual Property

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

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

Mino-Wrap Intellectual Property

In January 2019, we entered into a patent and technology license agreement with MDACC to develop and commercialize Mino-Wrap on an exclusive worldwide basis, with no rights to sub-license. We paid a one-time upfront licensing fee upon execution of the agreement. Under the agreement, we are required to use commercially reasonable efforts to commercialize Mino-Wrap under several regulatory scenarios and achieve milestones that are associated with these regulatory options leading to an approval from the FDA. We are obligated to pay annual maintenance fees that increase annually until reaching a designated amount, which we must pay until the first sale of product. We also must pay up to an aggregate of $2.1 million in milestone payments, depending on the achievement of various regulatory and commercial milestones. Under the terms of the license agreement, we also must pay a royalty equal to mid- to upper-single digit percentages of net sales, depending on the level of sales in that year, and subject to downward adjustment to lower- to mid-single digit percentages in the event there is no valid patent for the product in the United States at the time of sale. After the first sale of product, we will owe an annual minimum royalty payment that will increase annually for the duration of the term. We will be responsible for all patent expenses incurred by MDACC for the term of the agreement although MDACC is responsible for filing, prosecution and maintenance of all patents.

The term of the license agreement will end on the later of the expiration of all licensed patents, or the fifteenth anniversary of the agreement. MDACC may terminate the license agreement at any time after four years in any country if we have not commercialized or are not actively attempting to commercialize a product in such country. The license agreement will terminate in the event we breach any of our payment or reporting obligations or MDACC breaches any of its obligations under the agreement. MDACC will have the right to terminate the agreement if we bring or participate in an action to challenge MDACC's ownership of any of the licensed patent rights. We may terminate the license agreement upon 180 days' notice. The license agreement may also be terminated upon our and MDACC's mutual consent.

In December 2017, the USPTO issued U.S. Patent No. 9,849,217, entitled "Antimicrobial Wraps for Medical Implants." This invention overcomes limitations in breast reconstruction utilizing tissue expanders and implants following mastectomies by providing, in certain aspects, biodegradable antimicrobial film that may be wrapped around a medical implant such as a breast implant prior to the insertion into a subject such as a human patient. The scientists and technologists at MDACC have developed a biodegradable covering for a medical implant comprising a highly plasticized gelatin and at least one drug to reduce infection.

On November 18, 2021, MDACC filed a provisional patent application entitled "Antimicrobial Wraps for Medical Implants" in which the manufacturing process of the wrap now incorporates a freeze-drying process to prevent degradation of the active drug.

Citius holds the exclusive worldwide license, which provides access to this patented technology for development and commercialization of Mino-Wrap.

NoveCite Intellectual Property

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

Upon execution of the license agreement, NoveCite paid an upfront payment of $5,000,000 and issued to Licensor shares of NoveCite's common stock representing 25% of NoveCite's currently outstanding equity. We own the other 75% of NoveCite's currently outstanding equity.

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

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

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

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

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

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

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

Competition

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

I/ONTAK Competition

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.

There are limitations in these targeted therapies, which often are discontinued due to toxicity and adverse events as well as a limited duration of response due to resistance over time.

Mino-Lok Competition

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

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

Defencath™ (CorMedix Inc.)

Defencath is a formulation of Taurolidine 1.35%, Citrate 3.5%, and Heparin 1000 units/mL. Neutrolin is an anti-microbial catheter lock solution being developed by CorMedix to prevent CRBSIs and to prevent clotting. In January 2015, the FDA granted Fast Track and QIDP designations for Defencath. In December 2015, CorMedix initiated its Phase 3 clinical trial in hemodialysis patients in the United States. On June 20, 2018, CorMedix announced that it had completed its review and source-verification of the data required for the interim analysis of the Phase 3 LOCK-IT-100 study for Neutrolin. The data was then locked and transferred to the independent biostatistician for un-blinding and analysis, who then provided the results to the Data and Safety Monitoring Board ("DSMB") for its review.

On July 25, 2018, CorMedix announced that the DSMB had completed its review of the interim analysis of the data from the currently ongoing Phase 3 LOCK-IT-100 study for Neutrolin. Because the pre-specified level of statistical significance was reached and efficacy had been demonstrated, the DSMB recommended the study be terminated early. No safety concerns were reported by the DSMB based on the interim analysis.

CorMedix submitted its NDA for Defencath to the FDA, which accepted the NDA in August 2020. The FDA set a target review date of February 28, 2021. In March 2021, CorMedix reported that the FDA, in its Complete Response Letter ("CRL"), informed CorMedix that the FDA could not approve the NDA for DefenCath in its present form. The FDA noted concerns at the third-party manufacturing facility after a review of records requested by the FDA and provided by the contract manufacturer ("CMO"). Additionally, the FDA is requiring a manual extraction study to demonstrate that the labeled volume can be consistently withdrawn from the vials despite an existing in-process control to demonstrate fill volume within specifications. In April 2021, CorMedix and the CMO met with the FDA to discuss proposed resolutions for the deficiencies identified in the CRL and the Post-Application Action Letter ("PAAL") received by the CMO from the FDA for the NDA for DefenCath. There was an agreed upon protocol for the manual extraction study identified in the CRL, which has been successfully completed. Addressing the FDA's concerns regarding the qualification of the filling operation necessitated adjustments in the process and generation of additional data on operating parameters for the manufacture of DefenCath. CorMedix and the CMO determined that additional process qualification is needed with subsequent validation to address these issues. The FDA stated that the review timeline would be determined when the NDA resubmission is received and that it expected all corrections to facility deficiencies to be complete at the time of resubmission so that all corrective actions may be verified during an onsite evaluation of the manufacturing facility in the next review cycle, if the FDA determines it will do an onsite evaluation.

On February 28, 2022, CorMedix resubmitted the NDA for DefenCath to address the CRL issued by the FDA. In parallel, CorMedix's third-party manufacturer submitted responses to the deficiencies identified at the manufacturing facility in the PAAL issued by the FDA concurrently with the CRL. On March 28, 2022, CorMedix announced that the resubmission of the NDA for DefenCath had been accepted for filing by the FDA. The FDA considers the resubmission as a complete, Class 2 response with a six-month review cycle. The CMO has notified us that an onsite inspection by the FDA was conducted that resulted in FORM FDA 483 observations that are being addressed. The CMO submitted responses to the inspectional observations along with a corrective action plan and requested a meeting with the FDA to discuss. CorMedix also has been notified by its supplier of heparin, an active pharmaceutical ingredient, or API, for DefenCath, that an inspection by the FDA for an unrelated API has resulted in a Warning Letter due to deviations from good manufacturing practices for the unrelated API.

On August 8, 2022, CorMedix announced receipt of a second CRL from the FDA regarding our DefenCath NDA. The FDA stated that the DefenCath NDA cannot be approved until deficiencies conveyed to the CMO and the heparin API supplier are resolved to the satisfaction of the FDA. There were no other requirements identified by the FDA for CorMedix prior to resubmission of the NDA. As part of the NDA review process, the FDA also notified CorMedix that although the tradename DefenCath was conditionally approved, the FDA now has identified potential confusion with another pending product name that is also under review. The ultimate acceptability of the proposed tradename is dependent upon which application is approved first. As a precaution, CorMedix has submitted an alternative proprietary name to the FDA which will undergo review.

CorMedix also announced that it had finalized an agreement with Alcami Corporation, or Alcami, a U.S. based contract manufacturer with proven capabilities for manufacturing commercial sterile parenteral drug products. Alcami will function as a manufacturing site for DefenCath for the U.S. market, and CorMedix expects to be able to submit a supplement to its NDA application around the end of the first quarter of 2023 to request approval from FDA for DefenCath manufacturing.

Satisfactory resolution of these issues is required for FDA approval of the DefenCath NDA.

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

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

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

Halo-Lido Competition

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

Mino-Wrap Competition

The primary competition for Mino-Wrap would be the existing standard of care treatment, which includes a systemic perioperative antimicrobial agent with the perioperative immersion of the implant or irrigation of the surgical pocket with an antimicrobial solution prior to insertion of the tissue expander device. This is also administered with immediate postoperative oral antimicrobials.

NoveCite Competition

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

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

Athersys, Inc. is a biotechnology company that focuses on the research and development activities in the field of regenerative medicine. Its clinical development programs are focused on treating neurological conditions, cardiovascular diseases, inflammatory and immune disorders, and pulmonary and other conditions. The company's lead platform product includes MultiStem cell therapy, an allogeneic stem cell product, which has an ongoing Phase 2/3 clinical trial for the treatment of ARDS and has an ongoing clinical trial in Japan for the treatment of RDS. The MultiStem therapy also is in a Phase 3 clinical study for the treatment of patients suffering from neurological damage from an ischemic stroke, as well as in a Phase 2 clinical study for the treatment of patients with acute myocardial infarction, and has completed a Phase 1 clinical study for the treatment of patients suffering from leukemia or various other blood-borne cancers. The company has license and collaboration agreements with Healios K.K. to develop and commercialize MultiStem cell therapy for ischemic stroke, acute respiratory distress syndrome, and ophthalmological indications, as well as for the treatment of liver, kidney, pancreas, and intestinal tissue diseases; and the University of Minnesota to develop MultiStem cell therapy platform.

Pluristem Therapeutics Inc. operates as a bio-therapeutics company in Israel. It focuses on the research, development, clinical trial, and manufacture of placental expanded (PLX) based cell therapeutic products and related technologies for the treatment of various ischemic, inflammatory, and hematologic conditions, as well as autoimmune disorders. A Phase 2 study of PLX cells as a treatment for severe COVID-19 cases complicated by acute respiratory distress syndrome has been initiated in the U.S. as well as in Europe and Israel.

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

Supply and Manufacturing

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

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

If we elect to conduct product development and manufacturing, we will be subject to regulation under various federal and state laws, including the Occupational Safety and Health Act, the Environmental Protection Act, the Toxic Substances Control Act, the Resource Conservation and Recovery Act, the Controlled Substances Act and other present and potential future federal, state or local regulations.

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

Regulation

United States Government Regulation

The research, development, testing, manufacture, labeling, promotion, advertising, distribution and marketing, among other things, of our product candidates are extensively regulated by governmental authorities in the United States and other countries. All of our current product candidates are considered drugs. Consequently, we submitted a BLA to the FDA for I/ONTAK in September 2022 and, depending on the results of our preclinical and clinical trials, we intend to submit an NDA to the FDA for each of Mino-Lok, Halo-Lido, Mino-Wrap and a BLA to the FDA for NoveCite.

In the United States, the FDA regulates drugs under the Federal Food, Drug, and Cosmetic Act and the agency's implementing regulations. If we fail to comply with the applicable United States 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. These sanctions could include the FDA's refusal to approve pending applications, license suspension or revocation, withdrawal of an approval, warning letters, adverse publicity, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, civil penalties or criminal prosecution. Any agency enforcement action could have a material adverse effect on our company and its operations.

Before any one of our drug product candidates may be marketed in the United States, it must be approved by the FDA. The steps required before a drug may be approved for marketing in the United States generally include:

- preclinical laboratory and animal tests, and formulation studies;
- the submission to the FDA of an IND application for human clinical testing that must become effective before human clinical trials may begin;
- adequate and well-controlled human clinical trials to establish the safety and efficacy of the product candidate for each indication for which approval is sought;
- the submission to the FDA of an NDA or a BLA and the FDA's acceptance of the NDA or BLA for filing;
- satisfactory completion of an FDA inspection of the manufacturing facilities at which the product is to be produced to assess compliance with the FDA's current Good Manufacturing Practices ("cGMP"); and
- FDA review and approval of the NDA or BLA.

Foreign Regulation

We 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, we or our collaboration 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 United States law, there are restrictions on the export of products not approved by the FDA, depending on the country involved and the status of the product in that country.

Employees

As of September 30, 2022, we had 21 employees and various consultants providing support. Through our consulting and collaboration arrangements, and including our Scientific Advisory Board, we have access to more than 30 additional professionals, who possess significant expertise in business development, legal, accounting, regulatory affairs, clinical operations, and manufacturing. We also rely upon a network of consultants to support our clinical studies and manufacturing efforts.

Executive Officers of Citius

Leonard Mazur, Chief Executive Officer, Chairman and Secretary – Mr. Mazur, 77, was appointed Chief Executive Officer effective May 1, 2022, and has been a member of the Board since September 2014. Mr. Mazur previously served as Chief Executive Officer, President, and Chief Operating Officer from September 2014 until March 2016.

Myron Holubiak, Executive Vice Chairman and Director – Mr. Holubiak, 75, was appointed Executive Vice Chairman effective May 1, 2022, and has been a member of the Board since October 2015. He previously served as President and Chief Executive Officer from March 2016 through April 2022. He was also the founder and Chief Executive Officer and President of Leonard-Meron Biosciences, Inc., an acquired subsidiary of Citius, from March 2013 until March 2016.

Jaime Bartushak, Chief Business Officer, Chief Financial Officer and Principal Financial Officer – Mr. Bartushak, 55, was appointed as Chief Financial Officer in November 2017. Previously, he was one of the founders and Chief Financial Officer of Leonard-Meron Biosciences, Inc., an acquired subsidiary of Citius.

Myron Czuczman, Chief Medical Officer and Executive Vice President – Dr. Czuczman, 63, was appointed as Chief Medical Officer and Executive Vice President in July 2020. Dr. Czuczman previously served as Vice President, Global Clinical Research and Development, Therapeutic Head of Lymphoma/CLL at Celgene Corporation.

Other Information

We make available, free of charge through our website, our annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and all amendments to those reports as soon as is reasonably practicable after such material is electronically filed with or furnished to the SEC pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). The SEC maintains an Internet site that contains these reports at www.sec.gov.

Our website address is *http://www.citiuspharma.com*. The information contained in, or that can be accessed through, our website is not part of this report.

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 Business and our Industry

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

We were formed in 2007 and since our inception have incurred a net loss in each of our previous operating years. Our ability to become profitable depends upon our ability to obtain marketing approval for and generate revenues from sales of our product candidates. We have been focused on product development, have not received approval for any of our product candidates, and have not generated any revenues to date. We have incurred losses in each period of our operations, and we expect to continue to incur losses for the foreseeable future. These losses are likely to continue to adversely affect our working capital, total assets, and stockholders' equity. The process of developing our product candidates requires significant clinical development, laboratory testing and clinical trials. In addition, commercialization of our product candidates will require that we obtain necessary regulatory approvals and establish sales, marketing, and manufacturing capabilities, either through internal hiring or through contractual relationships with others. We expect to incur substantial losses for the foreseeable future as a result of anticipated increases in our research and development costs, including costs associated with conducting preclinical testing and clinical trials, and regulatory compliance activities. We incurred net losses of $33,640,646 and $23,054,434 for the years ended September 30, 2022 and 2021, respectively. At September 30, 2022, we had stockholders' equity of $102,825,865 and an accumulated deficit of $129,688,467. Our net cash used in operating activities was $28,361,256 and $24,250,414 for the years ended September 30, 2022 and 2021, respectively.

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

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

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

Ability to continue as a going concern.

At September 30, 2022, we estimated that we have sufficient capital to continue our operations through December 2023. You should not rely on our consolidated balance sheet as an indication of the amount of proceeds that would be available to satisfy claims of creditors, and potentially be available for distribution to stockholders, in the event of liquidation.

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

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

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

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

We will need to access the capital markets in the future for additional capital for research and development and for operations. As of the date of this report, we do not anticipate seeking additional capital until sometime in 2023. Traditionally, pharmaceutical companies have funded their research and development expenditures through raising capital in the equity markets. Declines and uncertainties in these markets over the past several years have severely restricted raising new capital and have affected companies' abilities to continue to expand or fund existing research and development efforts. The COVID-19 pandemic could also adversely impact future fundraising activities. If the COVID-19 pandemic and related and/or other economic conditions continue or become worse, our future cost of equity or debt capital and access to the capital markets could be adversely affected. If we are not successful in securing additional financing, we may be required to significantly delay, reduce the scope of or eliminate one or more of our research or development programs, downsize our general and administrative infrastructure, or seek alternative measures to avoid insolvency, including arrangements with collaborative partners or others that may require us to relinquish rights to certain of our technologies or product candidates.

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

We have no approved products. All of our current product candidates are in the pre-clinical or clinical stage. We rely on third parties to conduct the research and development activities for our product candidates. Further, we have no sales or marketing capability at this time. Even if we decide to use collaborative partners to assist us in the commercialization of our product candidates, our product commercialization capabilities are unproven. Our success will depend upon our ability to develop such capabilities on our own or to enter into collaboration agreements on favorable terms and to select an appropriate commercialization strategy for each product candidate that we choose to pursue and that receives approval, whether on our own or in collaboration. If we are not successful in implementing our strategy to commercialize our product candidates, we may never achieve, maintain, or increase profitability. Our ability to successfully commercialize any of our product candidates will depend, among other things, on our ability to:

- successfully complete pre-clinical and clinical trials for our product candidates;
- receive marketing approvals from the FDA and similar foreign regulatory authorities for our product candidates;
- establish commercial manufacturing arrangements with third-party manufacturers for our product candidates;
- produce, through a validated process, sufficiently large quantities of our drug compound(s) to permit successful commercialization of our product candidates;

- build and maintain strong sales, distribution, and marketing capabilities sufficient to launch commercial sales of any approved products or establish collaborations with third parties for such commercialization;

- secure acceptance of any approved products from physicians, health care payers, patients, and the medical community; and

- manage our spending as costs and expenses increase due to clinical trials, regulatory applications and development and commercialization activities.

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

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

We have two late-stage stage product candidates while our other product candidates are clinical stage. As a result, our success is dependent upon our ability to obtain regulatory approval for and commercialize our product candidates and we, as a company, have not demonstrated an ability to perform the functions necessary for the approval or successful commercialization of any 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 and are just beginning to undertake commercialization activities, in each case for I/ONTAK. Despite our progress with I/ONTAK, our operations have been limited primarily to business planning, acquiring our proprietary technology, research and development, recruiting management and technical staff, and raising capital. These operations provide a limited basis for you to assess our ability to successfully commercialize our product candidates and the advisability of investing in our securities.

The COVID-19 pandemic may materially and adversely affect our clinical trial operations and our financial results.

The COVID-19 pandemic has adversely impacted hospitals and medical facilities where we are currently conducting our Mino-Lok phase 3 trial. The full extent to which COVID-19 may impact this trial is not known at this time, but it has slowed the estimated completion date for the trial, which we now expect to be in 2023. This same risk applies to our recently begun Phase 2b trial for Halo-Lido and our planned clinical trials for our other product candidates. The exact duration of the delay and any other impact will depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the duration of the outbreak, the severity of COVID-19, or the effectiveness of actions to contain and treat for COVID-19. The continued spread of COVID-19 also could adversely impact our ability to recruit and retain patients and principal investigators and site staff who, as healthcare providers, may have heightened exposure to COVID-19, which could further negatively impact the Mino-Lok and Halo-Lido trials. In addition, if the FDA elects to delay face-to-face meetings for an extended period of time due to COVID-19, it could have a material adverse effect on our Mino-Lok and Halo-Lido trials and our other product candidates. Any or all of these events could increase our operating expenses and the length of time to complete a trial and have a material adverse effect on our financial results.

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

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

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

We face significant risks in our product candidate development efforts.

Our business depends on the successful development and commercialization of our product candidates. We are not permitted to market any of our product candidates in the United States until we receive approval from the FDA, or in any foreign jurisdiction until we receive the requisite approvals from such jurisdiction. The process of developing new drugs and/or therapeutic products is inherently complex, unpredictable, time-consuming, expensive and uncertain. We must make long-term investments and commit significant resources before knowing whether our development programs will result in products that will receive regulatory approval and achieve market acceptance. Product candidates that appear to be promising at some or all stages of development may not receive approval or reach the market for a number of reasons that may not be predictable based on results and data of the clinical program. Product candidates may be found ineffective or may cause harmful side effects during clinical trials, may take longer to progress through clinical trials than had been anticipated, may not be able to achieve the pre-defined clinical endpoints due to statistical anomalies even though clinical benefit may have been achieved, may fail to receive necessary regulatory approvals, may prove impracticable to manufacture in commercial quantities at reasonable cost and with acceptable quality, or may fail to achieve market acceptance.

We cannot predict whether or when we will obtain regulatory approval to commercialize our product candidates that are under development and we cannot, therefore, predict the timing of any future revenues from these product candidates, if any. The FDA has substantial discretion in the drug approval process, including the ability to delay, limit or deny approval of a product candidate for many reasons. For example, the FDA:

- may not find the data from clinical trials, including from our Phase 3 trial for I/ONTAK, sufficient to support the submission of an NDA or BLA or to obtain marketing approval in the United States, including any findings that the clinical and other benefits of our product candidates outweigh their safety risks;

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

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

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

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

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

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

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

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

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

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

Our goal in generally pursuing late-stage therapeutic product candidates with what we believe is a promising pre-clinical and early clinical stage track record is to avoid the risk of failure at the pre-clinical and early clinical stages. However, there is still significant risk to obtaining regulatory approval and successfully commercializing any late-stage product candidate that we pursue. All of the risks inherent in drug development of initial stage product candidates also apply to late-stage candidates. We cannot assure you that our business strategy will be successful.

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

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

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

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

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

We might not decide to proceed with the proposed spinoff of our I/ONTAK asset.

In May 2022, we announced that we intend to split the Company's assets into two separate publicly traded entities. We plan to form a new company focused on developing and commercializing I/ONTAK. Our other pipeline assets, including Mino-Lok, would remain at Citius. Citius would continue to trade on the Nasdaq exchange under its current ticker CTXR. The strategic action is intended to optimize organizational resources and investment capital to support the successful execution of each development program. The transactions are expected to be completed in calendar year 2023, subject to the satisfaction of customary conditions, including final approval from the Citius Board of Directors, market conditions, regulatory approvals, and SEC filings. However, there can be no assurance regarding the ultimate timing of the proposed transaction or that the transaction will be completed at all.

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

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

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

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

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

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

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

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

We do not own NoveCite, Inc. outright and will share any benefits from the development of its NoveCite product candidate with the other stockholder.

As of November 30, 2022, we owned 75% of the outstanding common stock of NoveCite. As a result, we will only be entitled to a portion of any benefits that flow from the development by NoveCite of its NoveCite product candidate or any other product candidates that it might develop. In the event that NoveCite issues additional equity securities in the future this would likely reduce our percentage ownership, which would further reduce the portion of any benefit that might be derived from the NoveCite drug candidate's successful development, unless we were to increase our investment.

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

We intend to develop NoveCite under the FDA's Coronavirus Treatment Acceleration Program, or CTAP. The CTAP program was designed to accelerate the development of COVID-19 treatments via faster communications and regulatory review protocols. In late April 2020, we made a pre-IND submission to the FDA for this treatment and requested the FDA's feedback to support the most expeditious pathway for clinical development of the therapy. The CTAP program is relatively new and the FDA has broad discretion in administering the CTAP program and therefore we cannot assure you what the FDA might decide. Even though we believe that the response from the FDA was favorable, we did not specifically request guidance on the CTAP program. As a result, we may encounter problems at a later date under the CTAP program, or with the therapy itself, and we may not experience a faster development process, review or approval compared to conventional FDA procedures.

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

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

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

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

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

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

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

Even if we receive regulatory approval to commercialize a product candidate, our ability to generate revenues from any resulting product will be subject to a variety of risks, many of which are out of our control.

Even if one of our product candidates obtains regulatory approval, that product may not gain market acceptance among physicians, patients, healthcare payers or the medical community. The indication may be limited to a subset of the population or we may implement a distribution system and patient access program that is limited. Coverage and reimbursement of our product candidates by third-party payers, including government payers, generally is also necessary for commercial success. 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:

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

If approved, any product candidate may fail to achieve market acceptance or generate significant revenue to achieve or sustain profitability. In addition, our efforts to educate the medical community and third-party payers on the benefits of any product candidate may require significant resources and may never be successful.

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

Our strategy with our product candidates is to outsource to third parties all or most aspects of the product development process, and possibly marketing, sales, and distribution activities. Currently, we do not have any sales, marketing or distribution capabilities. In order to generate sales of any product candidate that receives regulatory approval, we must either acquire or develop an internal marketing and sales force with technical expertise and with supporting distribution capabilities or make arrangements with third parties to perform these services for us. The acquisition or development of a sales and distribution infrastructure would require substantial resources, which may divert the attention of our management and key personnel and defer our product development efforts. To the extent that we enter into marketing and sales arrangements with other companies, our revenues will depend on the efforts of others. These efforts may not be successful. If we fail to develop sales, marketing, and distribution channels, or enter into arrangements for such with third parties, we will experience delays in product launch and sales and incur increased costs.

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

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

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

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

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

If any of our current product candidates are approved, we expect their sales to generate substantially all of our revenues for the foreseeable future, and as a result, the failure of any of these product candidates to find market acceptance would harm our business and would require us to seek additional financing.

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

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

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

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

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 product candidates. If we are not able to charge a sufficient amount for our product candidates, then our margins and our profitability will be adversely affected.

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

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

We rely exclusively on third parties to formulate and manufacture our product candidates.

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 are currently being manufactured entirely by commercial third-party manufacturers. If any product candidate we might develop or acquire in the future receives FDA approval, we will rely on one or more third-party contractors to manufacture our products. If, for any reason, we become unable to rely on our current source or any future source or sources to manufacture our 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 do identify. If we are unable to secure and maintain third-party manufacturing capacity, the development and sales of our product candidates and our financial performance might be materially and adversely affected.

In addition, before any of our collaborators can begin to commercially manufacture our product candidates, each must obtain regulatory approval of the manufacturing facility and process. Manufacturing of drugs for clinical and commercial purposes must comply with the FDA's good manufacturing practice, or cGMP, and applicable non-U.S. regulatory requirements. The cGMP requirements govern quality control and documentation policies and procedures. Complying with cGMP and non-U.S. regulatory requirements will require that we expend time, money, and effort in production, recordkeeping, and quality control to assure that the product meets applicable specifications and other requirements. Our contracted manufacturing facilities must also pass a pre-approval inspection prior to FDA approval. Failure to pass a pre-approval inspection might significantly delay FDA approval of our product candidates. If any of our collaborators fails to comply with these requirements, we would be subject to possible regulatory action which could limit the jurisdictions in which we are permitted to sell our product candidates. 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, production of our product candidates after receipt of FDA approval, if any;

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

- 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 our product candidates for commercialization;

- Currently, the contract manufacturer for our clinical supplies is foreign, 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 than us.

Each of these risks could delay our clinical trials or the approval, if any, of our product candidates by the FDA or any foreign regulatory agency or the commercialization of our product candidates 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.

If we materially breach or default under any of our license agreements, the licensor party to such agreement will have the right to terminate the license agreement, which termination may 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, various diligence, milestone payment, royalty and other obligations on us. For example, under our current license agreements, we are required to use commercially reasonable diligence to develop and commercialize a product and to satisfy specified payment obligations. If we fail to comply with our obligations under our 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 our license agreements exercise such a termination right, we would lose our right to the intellectual property under the respective license agreement, which loss may materially harm our business.

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 completing the development of any of our product candidates and potentially lose significant sources of revenue, which could result in an adverse impact on our operations and financial condition as well as volatility in any future revenue. In addition, our agreements with our collaborators may have provisions that give rise to disputes regarding the rights and obligations of the parties. These and other possible disagreements could lead to termination of the agreement or delays in collaborative research, development, supply, or commercialization of our product candidates, or could require or result in litigation or arbitration. Any such conflicts with our collaborators could reduce our ability to obtain future collaboration agreements and could have a negative impact on our relationship with existing collaborators, adversely affecting our business and revenues. Finally, any of our collaborations may prove to be unsuccessful.

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

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

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

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

Competition for these individuals is intense, and we cannot be certain that our search for such personnel will be successful. Attracting and retaining qualified personnel will be critical to our success. 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 in-licensing of I/ONTAK in September 2021 and the continuing development of I/ONTAK and our other product candidates. Our personnel, systems, and facilities currently in place may not be adequate to support this future growth. Our need to effectively execute our growth strategy will require that we:

- manage our research and development activities 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;
- commercialize our product candidates; and
- improve our operational, financial and management controls, reporting systems and procedures.

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

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

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

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

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

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

Conflicts of interest may arise from our relationship with NoveCite.

As of November 30, 2022, we beneficially owned 75% of the voting power of NoveCite's outstanding common stock; Novellus owns the other 25%. As a result of our partial ownership, our relationship with NoveCite could give rise to certain conflicts of interest that could have an impact on our and NoveCite's respective research and development programs, business opportunities, and operations generally.

- Even though we utilize different technologies than NoveCite, we could find ourselves in competition with it for research scientists, financing and other resources, licensing, manufacturing, and distribution arrangements.
- NoveCite will engage for its own business in research and product development programs, investments, and business ventures, and we will not be entitled to participate or to receive an interest in those programs, investments, or business ventures other than to the extent as a stockholder in NoveCite. NoveCite will not be obligated to present any particular research and development, investment, or business opportunity to us, even if the opportunity would be within the scope of our research and development plans or programs, business objectives, or investment policies. These opportunities may include, for example, opportunities to acquire businesses or assets, including but not limited to patents and other intellectual property that could be used by us or by NoveCite.
- Each conflict of interest will be resolved by our respective boards of directors in keeping with their fiduciary duties and such policies as they may implement from time to time.
- There is overlap among our board of directors, senior management and research staffs and that of NoveCite. Two of our directors, Myron Holubiak and Leonard Mazur, also serve as directors of NoveCite. In addition, Myron Holubiak serves as Chief Executive Officer and Jaime Bartushak serves as Chief Financial Officer of both Citius and NoveCite. These overlapping positions could interfere with the duties owed by such individuals to Citius.

Risks Related to Our Regulatory and Legal Environment

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

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

- delay commercialization of, and our ability to derive product revenues from, our product candidates;
- impose costly procedures on us; and
- diminish any competitive advantages that we might otherwise enjoy.

Even if we comply with all FDA requests, the FDA might ultimately reject one or more of our NDAs or BLAs. Even if we are able to obtain regulatory approval for a particular product candidate, the approval might limit the indicated medical uses for the product, limit our ability to promote, sell, and distribute the product, require that we conduct costly post-marketing surveillance, and/or require that we conduct ongoing post-marketing studies. We cannot be sure that we will ever obtain regulatory clearance for any of our product candidates. Failure to obtain FDA approval of one or more of our product candidates could severely undermine our business by leaving us without saleable products, and therefore without any potential sources of revenues, until another product candidate could be developed or obtained and successfully developed, approved and commercialized. Foreign jurisdictions impose similar regulatory approval processes and we will face the same risks if we seek foreign approval for any of our product candidates. There is no guarantee that we will ever be able to successfully develop or acquire any product candidate.

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

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

Manufacturers of pharmaceutical products and their facilities are subject to continual review and periodic inspections by the FDA and other regulatory authorities for compliance with cGMP regulations, which include requirements relating to quality control and quality assurance as well as the corresponding maintenance of records and documentation. Similar regulatory programs exist in foreign jurisdictions. Further, regulatory agencies must approve these manufacturing facilities before they can be used to manufacture our future approved products, if any, and these facilities are subject to ongoing regulatory inspections. In addition, regulatory agencies subject a 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, either before or after product approval, if any, subject our company to administrative or judicially imposed sanctions.

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

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

The use of any of our product candidates in pre-clinical and clinical trials, and the sale of any approved products, may expose us to liability claims and financial losses resulting from the use or sale of our product candidates. We have obtained limited product liability insurance coverage for our pre-clinical and clinical trials of $5.0 million per occurrence and in the aggregate, subject to a deductible of $25,000 per bodily injury and property damage occurrence, and a medical expense per person limit of $25,000. There can be no assurance that our existing insurance coverage will extend to any other product candidates in the future. Any product liability insurance coverage may not be sufficient to satisfy all liabilities resulting from product liability claims. A successful claim may prevent us from obtaining adequate product liability insurance in the future on commercially desirable terms, if at all. Even if a claim is not successful, defending such a claim would be time consuming and expensive, may damage that product's and our reputations in the marketplace, and would likely divert management's attention, any of which could have a material adverse effect on our Company.

Risks Related to Our Intellectual Property

Our business depends on protecting our intellectual property.

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

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

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

Because the time period from filing a patent application to the issuance, if ever, of the patent is often more than three years and because any regulatory approval and marketing for a pharmaceutical product often occurs several years after the related patent application is filed, the resulting market exclusivity afforded by any patent on our drug candidates and technologies will likely be substantially less than 20 years. For example, the U.S. patent on the original Mino-Lok composition expires in June 2024, and the U.S. patent on the stabilized Mino-Lok composition expires in November 2036. Since we anticipate significant additional time before FDA approval could be obtained, the maximum market exclusivity afforded by the statutory term of the currently issued patents would be less than 17 years. In the United States, 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 United States Congress, the U.S. federal courts, the USPTO or similar authorities in foreign jurisdictions, the laws and regulations governing patents could change in unpredictable ways that may weaken our and our licensors' abilities to obtain new patents or to enforce existing patents that we and our licensors or partners may obtain in the future.

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

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

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

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

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

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

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

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

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

Risks Related to Our Securities

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

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

If our common stock were no longer listed on The Nasdaq Capital 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 our 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.

We have twice failed to meet the listing standards, between October 2019 and January 2020 and between April 2020 and July 2020, because the closing bid price for our common stock had fallen below $1.00 per share for 30 consecutive business days, as a result of which we did not comply with the $1.00 minimum bid price requirement for continued listing on The Nasdaq Capital Market under Rule 5550(a)(2) of the Nasdaq Listing Rules. Pursuant to Nasdaq Marketplace Rule 5810(c)(3)(A). In each instance, we regained compliance within the time period allowed by Nasdaq.

In the event of a future delisting, we would take actions to restore our compliance with Nasdaq's 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 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 our common stock and an investor may find it more difficult to acquire or dispose of our common stock in the secondary market.

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

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

For the foreseeable future, to finance our operations, including possible acquisitions or strategic transactions, we expect to issue equity securities, resulting in the dilution of the ownership interests of our present stockholders. We are currently authorized to issue an aggregate of 400,000,000 shares of common stock and 10,000,000 shares of preferred stock. As of September 30, 2022, there were 146,211,130 shares of common stock outstanding, 38,325,489 shares underlying warrants with a weighted average exercise price of $1.57 per share and 9,400,171 shares underlying options with a weighted average exercise price of $2.07 per share. We may also issue additional shares of our common stock or other securities that are convertible into or exercisable for common stock in connection with hiring or retaining employees, or for other business purposes. The future issuance of any such additional shares of common stock or common stock equivalents may create downward pressure on the trading price of our common stock or publicly traded warrants.

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

Our Board of Directors 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 of Directors 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 of Directors could authorize the issuance of a series of preferred stock that has greater voting power than the common stock or that is convertible into our common stock, which could decrease the relative voting power of the common stock or result in dilution to our existing stockholders.

Item 1B. Unresolved Staff Comments

Not applicable.

Item 2. Properties

We lease our offices at 11 Commerce Drive, First Floor, Cranford, New Jersey 07016. The lease runs until October 31, 2025.

Item 3. Legal Proceedings

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

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

Item 4. Mine Safety Disclosures

Not applicable.

PART II

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

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

Market Information

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

Holders of Common Stock

As December 15, 2022, we had approximately 95 stockholders of record of our common stock.

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 sole discretion of our Board of Directors and will depend on our profitability and financial condition, capital requirements, statutory and contractual restrictions, future prospects and other factors deemed relevant by the Board.

Recent Sales of Unregistered Securities

On September 13, 2022, we issued 81,5000 shares of our common stock to a consultant for media relations, public relations, and investor relations services pursuant to the agreed upon compensation terms in the consulting agreement with the entity. The issuance of the shares was exempt from registration under Section 4(a)(2) of the Securities Act.

Issuer Purchases of Equity Securities

We did not make any purchases of our common stock during the three months ended September 30, 2022, 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.

Historical Background

We are a late-stage biopharmaceutical company dedicated to the development and commercialization of first-in-class critical care products with a focus on oncology, anti-infectives in adjunct cancer care, unique prescription products and stem cell therapies. On September 12, 2014, we acquired Citius Pharmaceuticals, LLC as a wholly-owned subsidiary.

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

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

On August 23, 2021, we formed Citius Acquisition Corp., a wholly owned subsidiary, which began operations in April 2022.

In-process research and development of $19,400,000 represents the value of LMB's leading drug candidate (Mino-Lok), which is an antibiotic solution used to treat catheter-related bloodstream infections and is expected to be amortized on a straight-line basis over a period of eight years commencing upon revenue generation. Goodwill of $9,346,796 represents the value of LMB's industry relationships and its assembled workforce. Goodwill will not be amortized but will be tested at least annually for impairment. In-process research and development of $40,000,000 represents the value of our September 2021 acquisition of an exclusive license for E7777 (denileukin diftitox), a late-stage oncology immunotherapy for the treatment of CTCL, a rare form of non-Hodgkin lymphoma and is expected to be amortized on a straight-line basis over a period of twelve years commencing upon revenue generation.

Through September 30, 2022, we have devoted substantially all our efforts to product development, raising capital, building infrastructure through strategic alliances and coordinating activities relating to our proprietary products. We have not yet realized any revenues from our operations.

Patent and Technology License Agreements

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

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

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

NoveCite – On October 6, 2020, our subsidiary NoveCite entered into a license agreement with Novellus Therapeutics Limited ("Licensor"), whereby NoveCite acquired an exclusive, worldwide license, with the right to sublicense, to develop and commercialize a stem cell therapy based on the Licensor's patented technology for the treatment of acute pneumonitis of any etiology in which inflammation is a major agent in humans. Upon execution of the license agreement, NoveCite paid an upfront payment of $5,000,000 to Licensor and issued to Licensor shares of Novecite's common stock representing 25% of NoveCite's currently outstanding equity. We own the other 75% of NoveCite's currently outstanding equity.

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

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

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

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

I/ONTAK/E7777 - In September 2021 the Company announced that it had entered into a definitive agreement with Dr. Reddy's to acquire its exclusive license of E7777 (denileukin diftitox), a late-stage oncology immunotherapy for the treatment of CTCL, a rare form of non-Hodgkin lymphoma.

Under the terms of this agreement, Citius acquired Dr. Reddy's exclusive license of E7777 from Eisai and other related assets owned by Dr. Reddy's. Citius's exclusive license rights include rights to develop and commercialize E7777 in all markets except for Japan and certain parts of Asia. Additionally, Citius has an option on the right to develop and market the product in India. Eisai retains exclusive development and marketing rights for the agent in Japan and Asia. Dr. Reddy's received a $40 million upfront payment and 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. Eisai is to receive a $6 million development milestone payment upon initial approval and additional commercial milestone payments related to the achievement of net product sales thresholds. Eisai will be responsible for completing the current CTCL clinical trial, and chemistry, manufacturing, and controls (CMC) activities through the filing of a BLA for E7777 with the FDA. Citius will be responsible for development costs associated with potential additional indications.

Results of Operations for Year Ended September 30, 2022 compared to Year Ended September 30, 2021

	Year Ended September 30, 2022	Year Ended September 30, 2021
Revenues	$ —	$ —
Operating expenses:		
Research and development	17,655,482	12,240,503
General and administrative	11,754,609	9,836,412
Stock-based compensation – general and administrative	3,905,954	1,454,979
Total operating expenses	33,316,045	23,531,894
Operating loss	(33,316,045)	(23,531,894)
Interest income	251,399	261,825
Gain on forgiveness of note payable - Paycheck Protection Program and accrued interest	—	166,557
Other income	—	59,917
Interest expense	—	(10,839)
Loss before income taxes	(33,064,646)	(23,054,434)
Income tax expense	576,000	—
Net loss	$ (33,640,646)	$ (23,054,434)

Revenues

We did not generate any revenues for the years ended September 30, 2022 and 2021.

Research and Development Expenses

For the year ended September 30, 2022, research and development expenses were $17,655,482 as compared to $12,240,503 for the year ended September 30, 2021, an increase of $5,414,979.

Research and development costs for Mino-Lok® increased by $723,405 to $4,250,655 for the year ended September 30, 2022 as compared to $3,527,250 for the year ended September 30, 2021 driven primarily by an increase in the costs associated with the addition of the global CRO, Biorasi, and the opening of international sites, primarily in India, for the Phase 3 Mino-Lok trial.

Research and development costs for our Halo-Lido product candidate increased by $1,835,175 to $2,697,348 for the year ended September 30, 2022 as compared to $862,173 for the year ended September 30, 2021 due to an increase in costs associated with the initiation of the Phase 2 study for the year ended September 30, 2022.

Research and development costs for our Mino-Wrap product candidate increased by $70,909 to $236,416 for the year ended September 30, 2022, as compared to $165,507 during the year ended September 30, 2021, due to increased formulation work.

During the year ended September 30, 2022, research and development costs for our proposed novel cellular therapy for acute respiratory distress syndrome (ARDS) were $1,777,288 as compared to $6,946,365 for the year ended September 30, 2021. The decrease of $5,169,077 was primarily related to the $5,000,000 license fee paid to Novellus in the year ended September 30, 2021.

We also incurred $8,693,775 in research and development expenses for our E7777 product candidate during the year ended September 30, 2022 as compared to $739,208 during the year ended September 30, 2021. The increase of $7,954,567 was primarily due to costs associated with the completion of the Phase 3 trial, as well as the preparation and submission of the Biologics License Application to the FDA, which we filed in September 2022.

We expect that research and development expenses will continue to increase in fiscal 2023 as we continue to focus on the commercialization of E7777, our Phase 3 trial for Mino-Lok, our Phase 2b trial for Halo-Lido, and accelerate our research and development efforts related to Mino-Wrap and ARDS.

General and Administrative Expenses

For the year ended September 30, 2022, general and administrative expenses were $11,754,609 as compared to $9,836,412 for the year ended September 30, 2021, an increase of $1,918,197. The primary reason for the increase was additional compensation costs for new employees, as well as increased investor relations expense. General and administrative expenses consist primarily of compensation costs, consulting fees incurred for financing activities and corporate development services, and investor relations expenses.

Stock-based Compensation Expense

For the year ended September 30, 2022, stock-based compensation expense was $3,905,954 as compared to $1,454,979 for the year ended September 30, 2021. Stock-based compensation expense includes options granted to directors, employees, and consultants. For the years ended September 30, 2022 and 2021, stock-based compensation expense includes $133,332 and $83,555, respectively, for the NoveCite stock option plan that was adopted in November 2020. Stock-based compensation expense increased by $2,450,975 in comparison to the prior year due to new grants made by Citius and the increase in expense for the NoveCite stock plan. In fiscal year 2022, we granted options to our new employees and additional options to other employees, our directors, and consultants. At September 30, 2022, unrecognized total compensation cost related to unvested options for Citius common stock of $5,317,681 is expected to be recognized over a weighted average period of 1.9 years and unrecognized total compensation cost related to unvested options for NoveCite common stock of $183,111 is expected to be recognized over a weighted average period of 1.5 years.

Other Income (Expense)

During the year ended September 30, 2022, the Company earned $251,399 of interest income compared to $261,825 of interest income during the year ended September 30, 2021. The decrease was due to lower balances of investable funds offset by an increase in interest rates. We have invested the remaining balance of the 2021 equity offerings and common stock warrant exercises proceeds in money market accounts.

The Company recorded a gain of $166,557 during the year ended September 30, 2021 for the principal and accrued interest on the Paycheck Protection Program loan that was forgiven on July 28, 2021.

Other income for the year ended September 30, 2021 consists of accrued interest of $59,917 on notes payable – related parties that was forgiven in June 2021.

There was no interest expense for the year ended September 30, 2022 as compared to $10,839 for the year ended September 30, 2021. Interest expense was for the notes payable to related parties that were acquired in the acquisition of LMB and the COVID-19 related Small Business Administration ("SBA") Paycheck Protection Program loan received on April 15, 2020. The notes payable to related parties were paid in full in June 2021 and therefore were not outstanding at September 30, 2021 or 2022.

Income Taxes

The Company recorded deferred income tax expense of $576,000 for the year ended September 30, 2022 related to the amortization for taxable purposes of its in-process research and development asset. There was no provision for income taxes for the year ended September 30, 2021 due to the Company's operating losses and the valuation reserve on deferred tax assets.

Net Loss

For the year ended September 30, 2022, we incurred a net loss of $33,640,646 compared to a net loss of $23,054,434 for the year ended September 30, 2021. The $10,586,212 increase in the net loss was primarily due to the $5,414,979 increase in research and development expenses, the $1,918,197 increase in general and administrative expenses, and the $2,450,975 increase in stock-based compensation expense.

LIQUIDITY AND CAPITAL RESOURCES

Liquidity and Working Capital

Citius has incurred operating losses since inception and incurred net losses of $33,640,646 and $23,054,434 for the years ended September 30, 2022 and 2021, respectively. At September 30, 2022, Citius had an accumulated deficit of $129,688,467. Citius' net cash used in operations during the years ended September 30, 2022 and 2021 was $28,361,256 and $24,250,414, respectively.

As a result of our common stock offerings and common stock warrant exercises in fiscal year 2021, the Company had working capital of approximately $40,000,000 at September 30, 2022. We expect that we will have sufficient funds to continue our operations through December 2023. At September 30, 2022, Citius had cash and cash equivalents of $41,711,690 available to fund its operations. The Company's only source of cash flow since inception has been from financing activities. During the year ended September 30, 2021, the Company received net proceeds of $120,643,020, from the issuance of equity. Our primary uses of operating cash were for in-licensing of intellectual property, product development and commercialization activities, employee compensation, consulting fees, legal and accounting fees, insurance, and investor relations expenses.

Financing Activities

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

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

During the year ended September 30, 2021, we received $31,130,134 in proceeds from the exercise of common stock warrants and $82,634 in proceeds from the exercise of common stock options.

Based on our cash and cash equivalents at September 30, 2022, we expect that we will have sufficient funds to continue our operations through December 2023. Additionally, in November 2022, the Company was selected to participate in New Jersey's Technology Business Tax Certificate Transfer (NOL) Program and will receive $3.6 million in non-dilutive capital through the New Jersey Economic Development Authority; the Company expects to receive these funds by late 2022 or early 2023. We may need to raise additional capital in the future to support our operations beyond December 2023. There is no assurance, however, that we will be successful in raising the needed capital or that the proceeds will be received in an amount or in a timely manner to support our operations.

While the COVID-19 pandemic has adversely impacted the progress of our clinical trials and operations, as of the date of this report, the Company has been able to access the capital markets and successfully complete financing transactions. However, we cannot be certain that any future impact of COVID-19 on our operations will not negatively impact our ability to raise capital.

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.

Research and Development

Research and development costs, including upfront fees and milestones paid to collaborators who are performing research and development activities under contractual agreement 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 Goodwill

In-process research and development of $19,400,000 represents the value of LMB's leading drug candidate, Mino-Lok, an antibiotic lock solution in Phase 3 clinical development, which if approved, would be used to treat catheter-related bloodstream infections, and is expected to be amortized on a straight-line basis over a period of eight years commencing upon revenue generation. In-process research and development of $40,000,000 represents the value of our September 2021 acquisition of an exclusive license for E7777 (denileukin diftitox), a late-stage oncology immunotherapy for the treatment of CTCL, a rare form of non-Hodgkin lymphoma and is expected to be amortized on a straight-line basis over a period of twelve years commencing upon revenue generation.

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

The Company reviews intangible assets annually to determine if any adverse conditions exist or a change in circumstances has occurred that would indicate impairment or a change in the remaining useful life of any intangible asset. If the carrying value of an asset exceeds its undiscounted cash flows, the Company writes down the carrying value of the intangible asset to its fair value for the period identified. No impairments have occurred since the acquisitions of our intangible assets through September 30, 2022.

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

The Company performed a qualitative assessment for its 2022 analysis of goodwill. Based on this assessment, management does not believe that it is more likely than not that the carrying value of the reporting unit exceeds its fair value. Accordingly, no further testing was performed as management believes that there are no impairment issues with respect to goodwill as of September 30, 2022.

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

CITIUS PHARMACEUTICALS, INC.
CONSOLIDATED FINANCIAL STATEMENTS

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Citius Pharmaceuticals, Inc. (the "Company") as of September 30, 2022 and 2021, and the related consolidated statements of operations, changes in stockholders' equity and cash flows for the years then ended, and the related notes to the consolidated financial statements (collectively, the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of September 30, 2022 and 2021, 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.

Basis for Opinion

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

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

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

Critical Audit Matters

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

/s/ Wolf & Company, P.C.

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

Boston, Massachusetts
December 22, 2022

CITIUS PHARMACEUTICALS, INC.
CONSOLIDATED BALANCE SHEETS
SEPTEMBER 30, 2022 AND 2021

	2022	2021
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 41,711,690	$ 70,072,946
Prepaid expenses	2,852,580	2,741,404
Total Current Assets	44,564,270	72,814,350
Property and equipment, net	4,100	7,023
Operating lease right-of-use asset, net	646,074	822,828
Other Assets:		
Deposits	38,062	38,062
In-process research and development	59,400,000	59,400,000
Goodwill	9,346,796	9,346,796
Total Other Assets	68,784,858	68,784,858
Total Assets	$ 113,999,302	$ 142,429,059
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	$ 1,165,378	$ 1,277,095
Accrued expenses	1,405,394	621,960
Accrued compensation	1,762,251	1,906,000
Operating lease liability	196,989	177,237
Total Current Liabilities	4,530,012	3,982,292
Deferred tax liability	5,561,800	4,985,800
Operating lease liability – non current	481,245	678,234
Total Liabilities	10,573,057	9,646,326
Commitments and Contingencies		
Stockholders' Equity:		
Preferred stock - $0.001 par value; 10,000,000 shares authorized; no shares issued and outstanding	—	—
Common stock - $0.001 par value; 400,000,000 shares authorized; 146,211,130 and 145,979,429 shares issued and outstanding at September 30, 2022 and 2021, respectively	146,211	145,979
Additional paid-in capital	232,368,121	228,084,195
Accumulated deficit	(129,688,467)	(96,047,821)
Total Citius Pharmaceuticals, Inc. Stockholders' Equity	102,825,865	132,182,353
Non-controlling interest	600,380	600,380
Total Equity	103,426,245	132,782,733
Total Liabilities and Equity	$ 113,999,302	$ 142,429,059

The accompanying notes are an integral part of these consolidated financial statements.

CITIUS PHARMACEUTICALS, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS
FOR THE YEARS ENDED SEPTEMBER 30, 2022 AND 2021

	2022	2021
Revenues	$ —	$ —
Operating Expenses:		
Research and development	17,655,482	12,240,503
General and administrative	11,754,609	9,836,412
Stock-based compensation – general and administrative	3,905,954	1,454,979
Total Operating Expenses	33,316,045	23,531,894
Operating Loss	(33,316,045)	(23,531,894)
Other Income (Expense):		
Interest income	251,399	261,825
Gain on forgiveness of note payable - Paycheck Protection Program and accrued interest	—	166,557
Other income	—	59,917
Interest expense	—	(10,839)
Total Other Income, Net	251,399	477,460
Loss before Income Taxes	(33,064,646)	(23,054,434)
Income tax expense	576,000	—
Net Loss	(33,640,646)	(23,054,434)
Deemed dividend on warrant extension	—	1,450,876
Net Loss Applicable to Common Stockholders	$ (33,640,646)	(24,505,310)
Net Loss Per Share Applicable to Common Stockholders - Basic and Diluted	$ (0.23)	(0.23)
Weighted Average Common Shares Outstanding		
Basic and diluted	146,082,399	108,599,080

The accompanying notes are an integral part of these consolidated financial statements.

CITIUS PHARMACEUTICALS, INC.
CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY
FOR THE YEARS ENDED SEPTEMBER 30, 2022 AND 2021

	Preferred Stock	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total Citius Pharmaceuticals, Inc. Shareholder's Equity	Non-Controlling Interest	Total Equity
		Shares	Amount					
Balance, October 1, 2020	$ —	55,576,996	$ 55,577	$ 104,208,958	$ (70,593,867)	$ 33,670,668	$ —	$ 33,670,668
Issuance of NoveCite common stock	—	—	—	1,799,640	(2,399,520)	(599,880)	600,380	500
Issuance of common stock in private placement offering, net of costs of $1,549,602	—	15,455,960	15,456	18,434,954	—	18,450,410	—	18,450,410
Issuance of common stock in registered direct offering, net of costs of $5,520,160	—	50,830,566	50,830	70,929,012	—	70,979,842	—	70,979,842
Issuance of common stock upon exercise of warrants	—	23,995,907	23,996	31,106,138	—	31,130,134	—	31,130,134
Issuance of common stock for services	—	50,000	50	67,950	—	68,000	—	68,000
Issuance of common stock upon exercise of stock options	—	70,000	70	82,564	—	82,634	—	82,634
Stock-based compensation expense	—	—	—	1,454,979	—	1,454,979	—	1,454,979
Net loss	—	—	—	—	(23,054,434)	(23,054,434)	—	(23,054,434)
Balance, September 30, 2021	—	145,979,429	145,979	228,084,195	(96,047,821)	132,182,353	600,380	132,782,733
Issuance of common stock for services	—	231,701	232	377,972	—	378,204	—	378,204
Stock-based compensation expense	—	—	—	3,905,954	—	3,905,954	—	3,905,954
Net loss	—	—	—	—	(33,640,646)	(33,640,646)	—	(33,640,646)
Balance, September 30, 2022	$ —	146,211,130	$ 146,211	$ 232,368,121	$ (129,688,467)	$ 102,825,865	$ 600,380	$ 103,426,245

The accompanying notes are an integral part of these consolidated financial statements.

CITIUS PHARMACEUTICALS, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS
FOR THE YEARS ENDED SEPTEMBER 30, 2022 AND 2021

	2022	2021
Cash Flows From Operating Activities:		
Net loss	$ (33,640,646)	$ (23,054,434)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	3,905,954	1,454,979
Issuance of common stock for services	378,204	68,000
Amortization of operating lease right-of-use asset	176,754	163,376
Depreciation	2,923	1,492
Deferred income tax expense	576,000	—
Gain from forgiveness of notes payable – paycheck protection program and accrued interest	—	(166,557)
Changes in operating assets and liabilities:		
Prepaid expenses	(111,176)	(2,619,167)
Deposits	—	19,031
Accounts payable	(111,717)	(579,140)
Accrued expenses	783,434	457,920
Accrued compensation	(143,749)	251,081
Accrued interest	—	(87,996)
Operating lease liability	(177,237)	(158,999)
Net Cash Used In Operating Activities	(28,361,256)	(24,250,414)
Cash Flows From Investing Activities:		
Purchase of property and equipment	—	(6,938)
Purchase of in-process research and development	—	(40,000,000)
Net Cash Used In Investing Activities	—	(40,006,938)
Cash Flows From Financing Activities:		
Principal paid on notes payable – related parties	—	(172,970)
Proceeds from sale of NoveCite, Inc. common stock	—	500
Proceeds from common stock warrant exercises	—	31,130,134
Proceeds from common stock option exercises	—	82,634
Net proceeds from private placement	—	18,450,410
Net proceeds from registered direct offerings	—	70,979,842
Net Cash Provided By Financing Activities	—	120,470,550
Net Change in Cash and Cash Equivalents	(28,361,256)	56,213,198
Cash and Cash Equivalents – Beginning of Year	70,072,946	13,859,748
Cash and Cash Equivalents – End of Year	$ 41,711,690	$ 70,072,946

The accompanying notes are an integral part of these consolidated financial statements.

CITIUS PHARMACEUTICALS, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
FOR THE YEARS ENDED SEPTEMBER 30, 2022 AND 2021

1. NATURE OF OPERATIONS AND BASIS OF PRESENTATION

Business

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

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

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

On August 23, 2021, we formed Citius Acquisition Corp. ("Citius Acq."), a wholly-owned subsidiary in conjunction with the acquisition of I/ONTAK, which began operations in April 2022.

In-process research and development ("IPR&D) consists of i) $19,400,000 acquisition value of LMB's leading drug candidate (Mino-Lok), which is an antibiotic solution used to treat catheter-related bloodstream infections and is expected to be amortized on a straight-line basis over a period of eight years commencing upon revenue generation, and ii) $40,000,000 acquisition value of the exclusive license for E7777 (denileukin diftitox), a late-stage oncology immunotherapy for the treatment of CTCL, a rare form of non-Hodgkin lymphoma and is expected to be amortized on a straight-line basis over a period of twelve years commencing upon revenue generation. Goodwill of $9,346,796 represents the value of LMB's industry relationships and its assembled workforce. Goodwill will not be amortized but will be tested at least annually for impairment.

Since its inception, the Company has devoted substantially all its efforts to business planning, research and development, recruiting management and technical staff, and raising capital. Citius is subject to a number of risks common to companies in the pharmaceutical industry including, but not limited to, risks related to the development by Citius or its competitors of research and development stage products, market acceptance of its products, competition from larger companies, dependence on key personnel, dependence on key suppliers and strategic partners, the Company's ability to obtain additional financing and the Company's compliance with governmental and other regulations.

Basis of Presentation

The accompanying consolidated financial statements include the operations of Citius Pharmaceuticals, Inc., and its wholly-owned subsidiaries, Citius Pharmaceuticals, LLC, LMB and Citius Acq., and its majority-owned subsidiary NoveCite. NoveCite, was inactive until October 2020. Citius Acq. began operations in April 2022. All significant inter-company balances and transactions have been eliminated in consolidation.

2. LIQUIDITY AND MANAGEMENT'S PLAN

The accompanying consolidated financial statements have been prepared on a going concern basis, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. The Company experienced negative cash flows from operations of $28,361,256 and $24,250,414, for the years ended September 30, 2022 and 2021, respectively. The Company had working capital of approximately $40 million at September 30, 2022. The Company estimates that its available cash resources will be sufficient to fund its operations through December 2023.

The Company has generated no operating revenue to date and has principally raised capital through the issuance of debt and equity instruments to finance its operations. However, the Company's continued operations beyond December 2023, including its development plans for E7777, Mino-Lok, Mino-Wrap, Halo-Lido and NoveCite, will depend on its ability to obtain regulatory approval to market E7777 and/or Mino-Lok and generate substantial revenue from the sale of E7777 and/or Mino-Lok and on its ability to raise additional capital through various potential sources, such as equity and/or debt financings, strategic relationships, or out-licensing of its product candidates. However, the Company can provide no assurances on regulatory approval, commercialization, or future sales of E7777 and/or Mino-Lok or that financing or strategic relationships will be available on acceptable terms, or at all. If the Company is unable to raise sufficient capital, find strategic partners or generate substantial revenue from the sale of Mino-Lok, there would be a material adverse effect on its business. Further, the Company expects in the future to incur additional expenses as it continues to develop its product candidates, including seeking regulatory approval, and protecting its intellectual property.

3. PATENT AND TECHNOLOGY LICENSE AGREEMENTS

Patent and Technology License Agreement – Mino-Lok

LMB has a patent and technology license agreement with Novel Anti-Infective Therapeutics, Inc. ("NAT") to develop and commercialize Mino-Lok® on an exclusive, worldwide sub licensable basis, as amended. LMB pays an annual maintenance fee each June until commercial sales of a product subject to the license commence. The Company recorded an annual maintenance fee expense of $90,000 in 2022 and 2021.

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

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

Patent and Technology License Agreement – Mino-Wrap

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

Under the license agreement, we paid a nonrefundable upfront payment of $125,000 which was recorded as research and development expense during the year ended September 30, 2019. We paid annual maintenance fees of $60,000 and $45,000 in January 2022 and 2021, respectively. The annual maintenance fee increases by $15,000 per year up to a maximum of $90,000 and ceases on the first sale of product. We also must pay up to an aggregate of $2.1 million in milestone payments, contingent on the achievement of various regulatory and commercial milestones. Under the terms of the license agreement, we also must pay a royalty of mid- to upper-single digit percentages of net sales, depending on the amount of annual sales, and subject to downward adjustment to lower- to mid-single digit percentages in the event there is no valid patent for the product in the United States at the time of sale. After the first sale of product, we will owe an annual minimum royalty payment of $100,000 that will increase annually by $25,000 for the duration of the term. We will be responsible for all patent expenses incurred by Licensor for the term of the agreement although Licensor is responsible for filing, prosecution, and maintenance of all patents. The agreement expires on the later of the expiration of the patents or January 2, 2034.

License Agreement with Novellus

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

Our Board Chairman Leonard Mazur, who is also our largest stockholder, was a director and significant shareholder of Novellus at this time and until the acquisition of Novellus by Brooklyn ImmunoTherapeutics, Inc. ("Brooklyn") in July 2021. As required by our Code of Ethics, the Audit Committee of our Board of Directors approved the entry into the option agreement with Novellus, as did the disinterested members of our Board of Directors.

On October 6, 2020, our subsidiary, NoveCite, exercised the option and signed an exclusive license agreement with Novellus. Upon execution of the agreement, we paid $5,000,000 to Novellus, which was charged to research and development expense during the year ended September 30, 2021, and issued Novellus shares of NoveCite's common stock representing 25% of the outstanding equity. We own the other 75% of NoveCite's outstanding equity. Pursuant to the terms of the original stock subscription agreement between Novellus and NoveCite, if NoveCite issued additional equity, subject to certain exceptions, NoveCite had to maintain Novellus's ownership at 25% by issuing additional shares to Novellus.

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

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

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

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

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

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

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

License Agreement with Eisai

In September 2021, the Company entered into a definitive agreement with Dr. Reddy's Laboratories SA, a subsidiary of Dr. Reddy's Laboratories, Ltd. (collectively, "Dr. Reddy's") to acquire its exclusive license of E7777 (denileukin diftitox), a late-stage oncology immunotherapy for the treatment of CTCL, a rare form of non-Hodgkin lymphoma.

Under the terms of this agreement, Citius acquired Dr. Reddy's exclusive license of E7777 from Eisai Co., Ltd. ("Eisai") and other related assets owned by Dr. Reddy's. Citius's exclusive license include rights to develop and commercialize E7777 in all markets except for Japan and certain parts of Asia. Additionally, Citius retained an option on the right to develop and market the product in India. Eisai retains exclusive development and marketing rights for the agent in Japan and Asia. Citius paid $40 million upfront payment which represents the acquisition date fair value of the in-process research and development acquired from Dr. Reddy's. Dr. Reddy's is entitled to up to $40 million in development milestone payments related to CTCL approvals in the U.S. and other markets, up to $70 million in development milestones for additional indications, as well as commercial milestone payments and low double-digit tiered royalties on net product sales, 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. The royalties will end on the earlier of (i) the 15-year anniversary of the first commercial sale of the latest indication that received regulatory approval in the applicable country and (ii) the date on which a biosimilar product results in the reduction of net sales in the applicable product by 50% in two consecutive quarters, as compared to the four quarters prior to the first commercial sale of the biosimilar product. We will also pay to Dr. Reddy's an amount equal to a low-thirties percentage of any sublicense upfront consideration or milestone payments (or the like) received by us and the greater of (i) a low-thirties percentage of any sublicensee sales-based royalties or (ii) a mid-single digit percentage of such licensee's net sales.

Under the license agreement, Eisai is to receive a $6.0 million development milestone payment upon initial approval and additional commercial milestone payments related to the achievement of net product sales thresholds (which increases to $7 million in the event we have exercised our option to add India to the licensed territory prior to FDA approval) and an aggregate of up to $22 million related to the achievement of net product sales thresholds. We also are required to reimburse Eisai for up to $2.65 million of its costs to complete the ongoing Phase 3 pivotal clinical trial for I/ONTAK for the CTCL indication and reimburse Eisai for all reasonable costs associated with the preparation of a BLA for I/ONTAK. Eisai will be responsible for completing the current CTCL clinical trial, and chemistry, manufacturing, and controls (CMC) activities through the filing of a BLA for E7777 with the FDA. Citius will be responsible for development costs associated with potential additional indications.

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

Also under the 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) 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.

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

Cash and Cash Equivalents

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

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 the Company, are expensed as incurred. The Company defers and capitalizes its nonrefundable advance payments that are for research and development activities until the related goods are delivered or the related services are performed. When the Company is reimbursed by a collaboration partner for work the Company performs, it records the costs incurred as research and development expenses and the related reimbursement as a reduction to research and development expenses in its consolidated statement of operations. Research and development expenses primarily consist of clinical and non-clinical studies, materials and supplies, third-party costs for contracted services, and payments related to external collaborations and other research and development related costs.

In-process Research and Development and Goodwill

In-process research and development of $19,400,000 represents the value of LMB's leading drug candidate (Mino-Lok), which is an antibiotic solution used to treat catheter-related bloodstream infections and is expected to be amortized on a straight-line basis over a period of eight years commencing upon revenue generation.

In-process research and development of $40,000,000 represents the value of our September 2021 acquisition of an exclusive license for E7777 (denileukin diftitox), a late-stage oncology immunotherapy for the treatment of CTCL, a rare form of non-Hodgkin lymphoma and is expected to be amortized on a straight-line basis over a period of twelve years commencing upon revenue generation. Included in the IPR&D is the historical know-how, formula protocols, designs, and procedures expected to be needed to complete Phase 3. In addition, the contracts acquired in connection with Dr. Reddy's transaction with the clinical research and manufacturing organization are at market rates and could be provided by multiple vendors in the marketplace. Therefore, there is no fair value associated with the contracts acquired.

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

The Company reviews intangible assets annually to determine if any adverse conditions exist or a change in circumstances has occurred that would indicate impairment or a change in the remaining useful life of any intangible asset. If the carrying value of an asset exceeds its undiscounted cash flows, the Company writes down the carrying value of the intangible asset to its fair value in the period identified. No impairment has occurred since the acquisitions through September 30, 2022.

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

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

The Company performed a qualitative assessment for its 2022 analysis of goodwill. Based on this assessment, management does not believe that it is more likely than not that the carrying value of the reporting unit exceeds its fair value. Accordingly, no further testing was performed as management believes that there are no impairment issues with respect to goodwill as of September 30, 2022.

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, 2022.

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

Stock-Based Compensation

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

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

Income Taxes

The Company follows accounting guidance regarding the recognition, measurement, presentation, and disclosure of uncertain tax positions in the consolidated financial statements. Tax positions taken or expected to be taken in the course of preparing the Company's tax returns are required to be evaluated to determine whether the tax positions are "more-likely-than-not" of being sustained by the applicable tax authorities. Tax positions not deemed to meet a more-likely-than-not threshold would be recorded in the consolidated financial statements. There are no uncertain tax positions that require accrual or disclosure as of September 30, 2022. Any interest or penalties are charged to expense. During the years ended September 30, 2022 and 2021, the Company did not recognize any interest and penalties. Tax years subsequent to September 30, 2018 are subject to examination by federal and state authorities.

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

Basic and Diluted Net Loss per Common Share

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

Segment Reporting

The Company currently operates as a single segment.

Concentrations of Credit Risk

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

Recently Issued Accounting Standards

In August 2020, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2020-06, *Debt — Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging — Contracts in Entity's Own Equity (Subtopic 815-40): Accounting for Convertible Instruments and Contracts in an Entity's Own Equity*, which, among other things, provides guidance on how to account for contracts on an entity's own equity. This ASU eliminates the beneficial conversion and cash conversion accounting models for convertible instruments. It also amends the accounting for certain contracts in an entity's own equity that are currently accounted for as derivatives because of specific settlement provisions. In addition, this ASU modifies how particular convertible instruments and certain contracts that may be settled in cash or shares impact the diluted EPS computation. The amendments in this ASU are effective for public companies for fiscal years beginning after December 15, 2021, including interim periods within those fiscal years. Early adoption is permitted, but no earlier than fiscal years beginning after December 15, 2020. The Company is currently evaluating the impact of ASU 2020-06 on its consolidated financial statements.

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

5. NOTES PAYABLE

Notes Payable – Related Parties

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

In June 2021, we repaid the $172,970 principal balance of these notes and paid accrued interest of $38,917. Accrued interest of $59,917 was forgiven and has been recorded as other income during the year ended September 30, 2021.

Interest expense on notes payable – related parties for the year ended September 30, 2021 was $9,606.

Paycheck Protection Program

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

Interest expense on the PPP loan was $1,233 for the year ended September 30, 2021.

On July 28, 2021, the Small Business Administration gave full forgiveness of the PPP loan. The Company recorded a gain from debt extinguishment of $166,557 consisting of the principal balance and related accrued interest expense.

6. COMMON STOCK, STOCK OPTIONS AND WARRANTS

Common Stock Issued for Services

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

On November 2, 2021, the Company issued 50,201 shares of common stock for investor relations services and expensed the $95,884 fair value of the common stock issued.

On March 21, 2022, the Company issued 100,000 shares of common stock for media, public and investor relations services and expensed the $178,000 fair value of the common stock issued.

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

Common Stock Offerings

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

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

Stock Option Plans

Pursuant to its 2014 Stock Incentive Plan, we reserved 866,667 shares of common stock for issuance to employees, directors and consultants. As of September 30, 2022, there were options to purchase 855,171 shares outstanding, options to purchase 4,829 shares were exercised, options to purchase 6,667 shares expired, and no shares were available for future grants.

On February 7, 2018, our stockholders approved the 2018 Omnibus Stock Incentive Plan and we reserved 2,000,000 shares of common stock for issuance to employees, directors, and consultants. As of September 30, 2022, there were options to purchase 1,820,000 shares outstanding, options to purchase 70,000 shares were exercised and the remaining 110,000 shares were transferred to the 2020 Omnibus Stock Incentive Plan (“2020 Plan”).

On February 10, 2020, our stockholders approved the 2020 Plan and we reserved 3,110,000 common shares. As of September 30, 2022, there were options to purchase 1,870,000 shares outstanding and the remaining 1,240,000 shares were transferred to the 2021 Omnibus Stock Incentive Plan (“2021 Stock Plan”).

On May 24, 2021, our stockholders approved the 2021 Stock Plan and we reserved 8,740,000 shares. The 2021 Stock Plan provides incentives to employees, directors, and consultants through options, SARs, dividend equivalent rights, restricted stock, restricted stock units, or other rights. As of September 30, 2022, options to purchase 4,855,000 shares were outstanding and there were 3,885,000 shares available for future grants.

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

The following assumptions were used in determining the fair value of stock option grants for the years ended September 30, 2022 and 2021:

	2022	2021
Risk-free interest rate	1.05 – 2.94%	0.32 – 0.89%
Expected dividend yield	0.00%	0.00%
Expected term	6.50 – 10 years	6.50 – 10 years
Expected volatility	94 – 110%	111 – 112%

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

	Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term	Aggregate Intrinsic Value
Outstanding at September 30, 2021	5,755,171	$ 2.13	8.02 years	$ 3,589,392
Granted	3,645,000	1.97		
Outstanding at September 30, 2022	9,400,171	$ 2.07	7.81 years	$ 869,509
Exercisable at September 30, 2022	4,140,116	$ 2.42	6.58 years	$ 595,405

The weighted average grant date fair value of the options granted during the year ended September 30, 2021 was estimated at $1.34 per share. All these options vest over terms of 12 to 36 months and have a term of 10 years.

The weighted average grant date fair value of the options granted during the year ended September 30, 2022 was estimated at $1.67 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 the years ended September 30, 2022 and 2021 was $3,905,954 (including $133,332 for the NoveCite Stock Plan) and $1,454,979 (including $83,555 for the NoveCite Stock Plan), respectively.

At September 30, 2022, unrecognized total compensation cost related to unvested awards under the Citius stock plans of $5,317,681 is expected to be recognized over a weighted average period of 1.92 years.

On November 5, 2020, the stockholders of NoveCite, approved NoveCite's Stock Plan and under which 2,000,000 common shares of NoveCite were reserved. The NoveCite Stock Plan provides incentives to employees, directors, and consultants through grants of options, SARs, dividend equivalent rights, restricted stock, restricted stock units, or other rights. As of September 30, 2022, there were options outstanding to purchase 2,000,000 common shares of NoveCite and no common shares of NoveCite available for future grants.

During the year ended September 30, 2021, NoveCite granted options to purchase 2,000,000 common shares to employees at a weighted average exercise price of $0.24 per share, of which 1,084,444 are exercisable as of September 30, 2022. The weighted average grant date fair value of the options granted during the year ended September 30, 2021 was estimated at $0.20 per share. All these options vest over 36 months and have a term of 10 years. The weighted average remaining contractual term of options outstanding under the NoveCite Stock Plan is 8.39 years. At September 30, 2022, unrecognized total compensation cost related to unvested awards under the NoveCite Stock Plan of $183,111 is expected to be recognized over a weighted average period of 1.45 years.

Warrants

The Company has reserved 38,325,489 shares of common stock for the exercise of outstanding warrants. The following table summarizes the warrants outstanding at September 30, 2022:

	Exercise price	Number	Expiration Dates
December 2017 Registered Direct/Private Placement Investors	$ 4.63	640,180	June 19, 2023
December 2017 Registered Direct/Private Placement Agent	5.87	89,625	December 19, 2022
March 2018 Registered Direct/Private Placement Investors	2.86	218,972	October 2, 2023
March 2018 Registered Direct/Private Placement Agent	3.73	46,866	March 28, 2023
August 2018 Offering Investors	1.15	3,921,569	August 14, 2023
August 2018 Offering Agent	1.59	189,412	August 8, 2023
April 2019 Registered Direct/Private Placement Investors	1.42	1,294,498	April 5, 2024
April 2019 Registered Direct/Private Placement Agent	1.93	240,130	April 5, 2024
September 2019 Offering Investors	0.77	2,793,297	September 27, 2024
September 2019 Offering Underwriter	1.12	194,358	September 27, 2024
February 2020 Exercise Agreement Placement Agent	1.28	138,886	August 19, 2025
May 2020 Registered Direct Offering Investors	1.00	1,670,588	November 18, 2025
May 2020 Registered Direct Offering Placement Agent	1.33	155,647	May 14, 2025
August 2020 Underwriter	1.31	201,967	August 10, 2025
January 2021 Registered Direct Offering Investors	1.23	3,091,192	July 27, 2026
January 2021 Registered Direct Offering Agent	1.62	351,623	July 27, 2026
February 2021 Offering Investors	1.70	20,580,283	February 19, 2026
February 2021 Offering Agent	1.88	2,506,396	February 19, 2026
		38,325,489	

In April 2021, we extended the term by three years to April 5, 2024 for 1,294,498 warrants for common stock with an exercise price of $1.42 per share and 240,130 warrants with an exercise price of $1.93 per share. We recorded a deemed dividend of $1,450,876 based on the excess of the fair value of the modified warrants over the fair value of the warrants before the modification, the effect of which was an increase in the net loss attributable to common shareholders in the statement of operations for the year ended September 30, 2021.

During the year ended September 30, 2021, we received $31,130,134 in proceeds from the exercise of common stock warrants.

At September 30, 2022, the weighted average remaining life of the outstanding warrants is 2.89 years, all warrants are exercisable, and the aggregate intrinsic value for the warrants outstanding was $1,832,879.

Common Stock Reserved

A summary of common stock reserved for future issuances as of September 30, 2022 is as follows:

Stock plan options outstanding	9,400,171
Stock plan shares available for future grants	3,885,000
Warrants outstanding	38,325,489
Total	51,610,660

7. RELATED PARTY TRANSACTIONS

The Company had outstanding debt due to Leonard Mazur (Chairman of the Board) and Myron Holubiak (Chief Executive Officer) (see Note 5).

Mr. Mazur was a director and significant shareholder of Novellus, Inc. until July 2021. On October 6, 2020, the Company, through its subsidiary NoveCite, entered into an exclusive agreement with Novellus to develop cellular therapies (see Note 3).

In April 2021, we extended the term by three years for 1,294,498 warrants held by our Chairman and our Chief Executive Officer (see Note 6).

8. EMPLOYMENT AGREEMENTS

Employment Agreements

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

On April 12, 2022, the Company entered into an 18-month employment agreement with Myron Holubiak to serve as Executive Vice Chairman. Upon expiration, the agreement automatically renews for successive periods of one-year unless terminated pursuant to its terms. The agreement requires the Company to pay base compensation plus incentives over the employment term plus severance benefits upon the occurrence of certain events as described in the agreement.

On July 13, 2020, Citius entered into an employment agreement with Myron Czuczman, M.D. to serve as Executive Vice President, Chief Medical Officer. The agreement requires the Company to pay base compensation plus incentives over the employment term plus severance benefits upon the occurrence of certain events as described in the agreement. Dr. Czuczman was granted an option to purchase 500,000 shares of common stock.

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

9. COMMITMENTS AND CONTINGENCIES

Operating Lease

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

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

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

The elements of lease expense are as follows:

Lease cost	**Year Ended September 30, 2022**	**Year Ended September 30, 2021**
Operating lease cost	$ 238,822	$ 238,824
Variable lease cost	772	194
Total lease cost	$ 239,594	$ 239,018
Other information		
Weighted-average remaining lease term - operating leases	3.1 Years	4.1 Years
Weighted-average discount rate - operating leases	8.0%	8.0%

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

Year Ending September 30,	
2023	$ 244,165
2024	249,024
2025	253,883
2026	21,460
Total lease payments	768,532
Less: interest	(90,298)
Present value of lease liabilities	$ 678,234

Leases	Classification	September 30, 2022	September 30, 2021
Assets			
Lease asset	Operating	$ 646,074	$ 822,828
Total lease assets		$ 646,074	$ 822,828
Liabilities			
Current	Operating	$ 196,989	$ 177,237
Non-current	Operating	481,245	678,234
Total lease liabilities		$ 678,234	$ 855,471

Interest expense on the lease liability was $62,068 and $75,448 for the years ended September 30, 2022 and 2021, respectively.

Legal Proceedings

The Company is not involved in any litigation that it believes could have a material adverse effect on its 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 the Company's executive officers, threatened against or affecting the Company or its officers or directors in their capacities as such.

10. INCOME TAXES

The Company recorded deferred income tax expense of $576,000 for the year ended September 30, 2022 related to the amortization for taxable purposes of its in-process research and development asset. There was no provision for income taxes for the year ended September 30, 2021 due to the Company's operating losses and the valuation reserve on deferred tax assets.

The income tax expense (benefit) differs from the amount of income tax determined by applying the U.S. federal income tax rate to pretax income for the years ended September 30, 2022 and 2021 due to the following:

	2022	2021
Computed "expected" tax benefit	(21.0)%	(21.0)%
Increase (decrease) in income taxes resulting from:		
State taxes, net of federal benefit	(6.3)%	(6.3)%
Permanent differences	1.8%	0.7%
Increase in the valuation reserve	27.2%	26.6%
	1.7%	0.0%

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, 2022	September 30, 2021
Deferred tax assets:		
Net operating loss carryforward	$ 34,673,000	$ 25,508,000
Stock-based compensation	1,569,000	1,105,000
Other	3,689,000	2,564,000
Valuation allowance on deferred tax assets	(39,931,000)	(29,177,000)
Total deferred tax assets	—	—
Deferred tax liabilities:		
In-process research and development	(5,561,800)	(4,985,800)
Total deferred tax liability	(5,561,800)	(4,985,800)
Net deferred tax liability	$ (5,561,800)	$ (4,985,800)

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, 2022 and 2021, the valuation allowance increased by $10,754,000 and $12,257,000, respectively. The increase in the valuation allowance during the years ended September 30, 2022 and 2021 was primarily due to the Company's net operating loss. At September 30, 2022, the Company has a federal net operating loss carryforward of approximately $121,000,000. Federal net operating loss carryforwards of approximately $35,000,000 begin expiring in 2034 and carryforwards of approximately $86,000,000 generated in tax years beginning after 2017 may be carried forward indefinitely.

As of September 30, 2022, the Company also has estimated federal research and development credits of $3,208,000 to offset future income taxes. The tax credit carryforwards will begin to expire in 2036.

The Company accounts 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.

11. SUBSEQUENT EVENTS

In November 2022, the Company was selected to participate in New Jersey's Technology Business Tax Certificate Transfer (NOL) Program, more commonly known as the Net Operating Loss (NOL) Program, and will receive $3.6 million in non-dilutive capital through the New Jersey Economic Development Authority (NJEDA). The Company expects to receive the funds by late 2022 or early 2023.

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, 2022, 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, 2022, 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, 2022 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, 2022.

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 2022 that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

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

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. This code of ethics and business conduct can be found in the "Investors - Corporate Governance" section of our website, *www.citiuspharma.com*.

The other information required by this Item concerning our directors and executive officers is incorporated by reference to the section captioned "Proposal No. 1—Election of Directors" and "Corporate Governance" to be contained in our proxy statement related to the 2023 Annual Meeting of Stockholders (the "Proxy Statement"), which information is expected to be filed with the SEC within 120 days of the end of our fiscal year pursuant to General Instruction G(3) of Form 10-K. The information required by this Item concerning compliance with Section 16(a) of the Exchange Act by our directors, executive officers and persons who own more than 10% of our outstanding common stock is incorporated by reference from the section captioned "Section 16(a) Beneficial Ownership Reporting Compliance" to be contained in the Proxy Statement.

Item 11. Executive Compensation

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

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

The following table sets forth the indicated information as of September 30, 2022 with respect to our equity compensation plans:

Plan Category	Number of securities to be issued upon exercise of outstanding options, warrants and rights	Weighted-average exercise price of outstanding options, warrants and rights	Number of securities remaining available for future issuance under equity compensation plans
Equity compensation plans approved by security holders			
2014 Stock Incentive Plan	855,171	$ 6.65	—
2018 Omnibus Stock Incentive Plan	1,820,000	1.08	—
2020 Omnibus Stock Incentive Plan	1,870,000	1.13	—
2021 Omnibus Stock Incentive Plan	4,855,000	1.99	3,885,000
Total	9,400,171	$ 2.07	3,885,000

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

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

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

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

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

Item 14. Principal Accountant Fees and Services

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

PART IV

Item 15. Exhibits and Financial Statement Schedules

Exhibit Number	Description of Document	Registrant's Form	Dated	Exhibit Number	Filed Herewith
3.1	Amended and Restated Articles of Incorporation of Citius Pharmaceuticals, Inc.	8-K	9/18/2014	3.1	
3.2	Certificate of Amendment to the Amended and Restated Articles of Incorporation of Citius Pharmaceuticals, Inc., effective September 16, 2016.	8-K	9/21/2016	3.1	
3.3	Certificate of Amendment to the Amended and Restated Articles of Incorporation of Citius Pharmaceuticals, Inc., effective June 9, 2017.	8-K	6/8/2017	3.1	
3.4	Certificate of Amendment to the Articles of Incorporation of Citius Pharmaceuticals Inc., dated June 21, 2021.	8-K/A	6/22/2021	3.1	
3.5	Amended and Restated Bylaws of Citius Pharmaceuticals, Inc.	8-K	2/9/2018	3.1	
4.1	Form of Registration Rights Agreement between the Purchasers named therein and Citius Pharmaceuticals Holdings, Inc., dated September 12, 2014.	8-K	9/18/2014	10.2	
4.2	Form of Investor Warrant, dated September 12, 2014.	8-K	9/18/2014	10.3	
4.3	Form of Representative's Warrant, dated August 3, 2017.	8-K	8/4/2017	4.2	
4.4	Form of Investor Warrant, dated December 15, 2017.	8-K	12/19/2017	4.1	
4.5	Form of Placement Agent Warrant, dated December 15, 2017.	8-K	12/19/2017	4.2	
4.6	Form of Investor Warrant, dated March 28, 2018.	8-K	3/29/2018	4.1	
4.7	Form of Placement Agent Warrant, dated March 28, 2018.	8-K	3/29/2018	4.2	
4.8	Form of Common Stock Purchase Warrant, dated August 13, 2018.	8-K	8/13/2018	4.1	
4.9	Form of Pre-Funded Common Stock Purchase Warrant, dated August 13, 2018.	8-K	8/13/2018	4.2	
4.10	Form of Underwriter's Common Stock Purchase Warrant, dated August 13, 2018.	8-K	8/13/2018	4.3	
4.11	Form of Investor Warrant issued April 3, 2019.	8-K	4/03/2019	4.1	
4.12	Form of Placement Agent Warrant issued April 3, 2019.	8-K	4/03/2019	4.2	
4.13	Form of Common Stock Purchase Warrant issued September 27, 2019.	8-K	9/27/2019	4.1	
4.14	Form of Underwriters Common Stock Purchase Warrant issued September 27, 2019.	8-K	9/27/2019	4.3	
4.15	Form of Investor Warrant issued on February 19, 2020.	8-K	2/19/2020	4.1	
4.16	Form of Placement Agent Warrant issued on February 19, 2020.	8-K	2/19/2020	4.2	
4.17	Form of Investor Warrant issued May 18, 2020.	8-K	5/18/2020	4.1	
4.18	Form of Placement Agent Warrant issued May 18, 2020.	8-K	5/18/2020	4.2	
4.19	Form of Underwriter Warrant issued August 10, 2020.	8-K	8/10/2020	4.1	
4.20	Form of Investor Warrant issued January 27, 2021.	8-K	1/27/2021	4.1	
4.21	Form of Placement Agent Warrant issued January 27, 2021.	8-K	1/27/2021	4.2	

Exhibit Number	Description of Document	Registrant's Form	Dated	Exhibit Number	Filed Herewith
4.22	Form of Registration Rights Agreement, dated January 24, 2021, by and between Citius Pharmaceuticals, Inc. and the purchasers signatory thereto.	8-K	1/27/2021	4.3	
4.23	Form of Investor Warrant issued February 19, 2021.	8-K	2/19/2021	4.1	
4.24	Form of Placement Agent Warrant issued February 19, 2021	8-K	2/19/2021	4.2	
4.25	Description of Common Stock				X
10.1	Citius Pharmaceuticals, Inc. 2014 Stock Incentive Plan.	10-Q	8/15/2016	10.1	
10.2	Form of Citius Pharmaceuticals, Inc. 2014 Stock Incentive Plan Nonqualified Stock Option.	10-Q	8/15/2016	10.2	
10.3	Amended and Restated Employment Agreement between Myron Holubiak and Citius Pharmaceuticals, Inc., executed April 12, 2022, effective May 1, 2022.	10-Q	5/12/2022	10.1	
10.4	Second Amendment to the Patent and Technology License Agreement between Novel Anti-Infective Technologies, LLC and Leonard-Meron Biosciences, Inc., dated March 20, 2017.	10-Q	5/15/2017	10.8	
10.5	Future Advance Convertible Promissory Note between Leonard Mazur and Citius Pharmaceuticals, Inc., dated May 10, 2017.	10-Q	5/15/2017	10.1	
10.6	Amended and Restated Demand Convertible Promissory Note between Leonard Mazur and Citius Pharmaceuticals, Inc., dated May 10, 2017.	10-Q	5/15/2017	10.3	
10.7	Amended and Restated Employment Agreement between Leonard Mazur and Citius Pharmaceuticals, Inc., dated October 19, 2017.	10-K	12/11/2018	10.23	
10.8	Employment Agreement between Jaime Bartushak and Citius Pharmaceuticals, Inc., dated November 27, 2017.	8-K	12/1/2017	10.1	
10.9	Form of Securities Purchase Agreement between Citius Pharmaceuticals, Inc. and the purchasers named therein, dated December 15, 2017.	8-K	12/19/2017	10.1	
10.10	Citius Pharmaceuticals, Inc. 2018 Omnibus Stock Incentive Plan	10-Q	2/14/2018	10.2	
10.11	Form of Securities Purchase Agreement between Citius Pharmaceuticals, Inc. and the purchasers named therein, dated March 28, 2018.	8-K	3/29/2018	10.1	
10.12+	Patent and Technology License Agreement, dated January 2, 2019, between the Board of Regents of the University of Texas System on behalf of the University of Texas M. D. Anderson Cancer Center and Citius Pharmaceuticals, Inc.	10-Q	2/14/2019	10.1	
10.13	First Amendment, dated October 15, 2015, to Patent and Technology License Agreement, dated May 14, 2014, between Novel Anti-Infective Technologies, LLC and Leonard-Meron Biosciences, Inc.	10-Q	2/14/2019	10.2	
10.14+	Patent and Technology License Agreement, dated May 14, 2014, between Novel Anti-Infective Technologies, LLC and Leonard-Meron Biosciences, Inc.	10-Q	2/14/2019	10.3	

Exhibit Number	Description of Document	Registrant's Form	Dated	Exhibit Number	Filed Herewith
10.15	Form of Securities Purchase Agreement, dated April 1, 2019, by and between Citius Pharmaceuticals, Inc. and the purchasers named therein.	8-K	4/03/2019	10.1	
10.16	Citius Pharmaceuticals, Inc. 2020 Omnibus Stock Incentive Plan.	Schedule 14A	12/20/2019	Appendix A	
10.17	Form of Notice of Stock Option Grant and Stock Option Award Agreement.	10-Q	2/13/2020	10.2	
10.18	Form of Warrant Exercise Agreement, dated February 14, 2020, by and between Citius Pharmaceuticals, Inc. and the investor signatory thereto.	8-K	2/19/2020	10.1	
10.19	Form of Warrant Exercise Agreement, dated February 14, 2020, by and between Citius Pharmaceuticals, Inc. and the investor signatory thereto.	8-K	2/19/2020	10.2	
10.20	Form of Securities Purchase Agreement, dated May 14, 2020, by and between Citius Pharmaceuticals, Inc. and the purchasers signatory thereto.	8-K	5/18/2020	10.1	
10.21	Engagement letter, dated February 14, 2020, between Citius Pharmaceuticals, Inc. and the purchasers signatory thereto.	8-K	5/18/2020	10.2	
10.22	Employment Agreement, effective as of July 14, 2020, between Citius Pharmaceuticals, Inc. and Myron Czuczman.	10-Q	8/14/2020	10.3	
10.23	License Agreement, dated October 6, 2020, between NoveCite, Inc. and Novellus Therapeutics, Limited.+	10-K	12/16/2020	10.24	
10.24	Form of Securities Purchase Agreement, dated January 24, 2021, by and between Citius Pharmaceuticals, Inc. and the purchasers signatory thereto.	8-K	1/27/2021	10.1	
10.25	Engagement letter, dated January 23, 2021, between Citius Pharmaceuticals, Inc. and H. C. Wainwright & Co., LLC	8-K	1/27/2021	10.2	
10.26	Form of Securities Purchase Agreement, dated February 16, 2021, by and between Citius Pharmaceuticals, Inc. and the purchasers signatory thereto.	8-K	2/19/2021	10.1	
10.27	Citius Pharmaceuticals, Inc. 2021 Omnibus Incentive Stock Plan.	Schedule 14A	4/12/2021	Appendix B	
10.28	Form of Notice of Stock Option Grant and Stock Option Award Agreement.	Form 10-K	12/15/2021	10.29	
10.29+	Asset Purchase Agreement, dated as of September 1, 2021, between Dr. Reddy's Laboratories S.A. and Citius Pharmaceuticals, Inc.	Form 10-K	12/15/2021	10.30	
10.30+	Amended and Restated License, Development and Commercialization Agreement, dated as of February 26, 2018, between Eisai, Ltd. and Dr. Reddy's Laboratories S.A.	Form 10-K	12/15/2021	10.31	
10.31+	Amendment to Amended and Restated License, Development and Commercialization Agreement, dated as of August 9, 2018, between Eisai, Ltd. and Dr. Reddy's Laboratories S.A.	Form 10-K	12/15/2021	10.32	
10.32+	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.	Form 10-K	12/15/2021	10.33	
21	Subsidiaries.	Form 10-K	12/15/2021	21	

Exhibit Number	Description of Document	Registrant's Form	Dated	Exhibit Number	Filed Herewith
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
EX-101.INS	XBRL INSTANCE DOCUMENT	--	--	--	X
EX-101.SCH	XBRL TAXONOMY EXTENSION SCHEMA DOCUMENT	--	--	--	X
EX-101.CAL	XBRL TAXONOMY EXTENSION CALCULATION LINKBASE	--	--	--	X
EX-101.DEF	XBRL TAXONOMY EXTENSION DEFINITION LINKBASE	--	--	--	X
EX-101.LAB	XBRL TAXONOMY EXTENSION LABELS LINKBASE	--	--	--	X
EX-101.PRE	XBRL TAXONOMY EXTENSION PRESENTATION LINKBASE	--	--	--	X

+ Portions of this exhibit have been omitted pursuant to Item 601(b)10 of Regulation S-K.

Item 16. Form 10-K Summary.

Not applicable.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

CITIUS PHARMACEUTICALS, INC.

Date: December 22, 2022

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

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

Signature	Title	Date
/s/ Leonard Mazur Leonard Mazur	Chief Executive Officer and Director (Principal Executive Officer)	December 22, 2022
/s/ Myron Holubiak Myron Holubiak	Executive Vice Chairman and Director	December 22, 2022
/s/ Jaimie Bartushak Jaime Bartushak	Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	December 22, 2022
/s/ Suren Dutia Suren Dutia	Director	December 22, 2022
/s/ Carol Webb Carol Webb	Director	December 22, 2022
/s/ William Kane William Kane	Director	December 22, 2022
/s/ Howard Safir Howard Safir	Director	December 22, 2022
/s/ Eugene Holuka Eugene Holuka	Director	December 22, 2022

Exhibit 4.25

Description of Registrant's Securities Registered Under Section 12 of the Securities Exchange Act of 1934

The following description summarizes the material terms of our common stock as of the date of this prospectus. Because it is only a summary, it does not contain all the information that may be important to you. For a complete description of our capital stock, you should refer to our articles of incorporation and our bylaws, and to the provisions of applicable Nevada law.

General

Our authorized capital stock consists of 400,000,000 shares of common stock, par value $0.001, of which 146,211,130 shares were issued and outstanding as of September 30, 2022, and 10,000,000 shares of preferred stock, none of which are issued and outstanding.

Our preferred stock and/or common stock may be issued from time to time without prior approval by our stockholders. Our preferred stock and/or common stock may be issued for such consideration as may be fixed from time to time by our Board of Directors. At September 30, 2022, we had no preferred stock issued or outstanding.

Common Stock

We are authorized to issue 400,000,000 shares of common stock, $0.001 par value. The holders of a majority of the shares entitled to vote, present in person or represented by proxy shall constitute a quorum at all meetings of our stockholders. Our common stock does not provide preemptive, subscription or conversion rights and there are no redemption or sinking fund provisions or rights. Our common stockholders are not entitled to cumulative voting for election of the Board of Directors.

Holders of common stock are entitled to receive ratably such dividends as may be declared by the Board of Directors out of funds legally available therefor as well as any distributions to the security holders. We have never paid cash dividends on our common stock, and do not expect to pay such dividends in the foreseeable future.

In the event of a liquidation, dissolution or winding up of our company, holders of common stock are entitled to share ratably in all of our assets remaining after payment of liabilities.

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the Registration Statements on Form S-1 (No.'s 333-224386, 333-226395, 333-230919, 333-233759, 333-237638 and 333-238975) and on Form S-3 (No's. 333-248748, 333-252561, 333-253179, 333-255005 and 333-256063) of Citius Pharmaceuticals, Inc. of our report dated December 22, 2022, relating to the consolidated financial statements of Citius Pharmaceuticals, Inc., appearing in the Annual Report on Form 10-K for the year ended September 30, 2022.

/s/ Wolf & Company, P.C.

Wolf & Company, P.C.
Boston, Massachusetts
December 22, 2022

Exhibit 31.1

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

I, Leonard Mazur, certify that:

1. I have reviewed this Annual Report on Form 10-K of Citius Pharmaceuticals, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

December 22, 2022

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

Exhibit 31.2

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

I, Jaime Bartushak, certify that:

1. I have reviewed this Annual Report on Form 10-K of Citius Pharmaceuticals, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

December 22, 2022

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

Exhibit 32.1

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

In connection with the Annual Report of Citius Pharmaceuticals, Inc. (the "Company") on Form 10-K for the year ended September 30, 2021 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), Leonard Mazur, Chief Executive Officer of the Company, and Jaime Bartushak, Chief Financial Officer of the Company, each hereby certifies, pursuant to 18 U.S.C. section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to his knowledge:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: December 22, 2022

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

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