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, 2020

☐ 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**
Warrants to purchase Common Stock	**CTXRW**	**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, 2020) was approximately $15.5 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:

55,576,996 shares as of November 30, 2020, 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 9, 2021 are incorporated by reference in Part III of this Report.

Citius Pharmaceuticals, Inc.

FORM 10-K
September 30, 2020

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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 as of September 30, 2020, Citius Pharmaceuticals, LLC, Leonard-Meron Biosciences, Inc., and 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:

- our ability to raise funds for general corporate purposes and operations, including our pre-clinical and clinical trials;
- the cost, timing and results of 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 trial and have a material adverse effect on our financial results.

- 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 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.

- 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 and officers with NoveCite. The dual roles of our 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.

- 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.

- 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 and certain warrants. 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, 2020, there were 55,576,996 shares of common stock outstanding, 26,831,989 shares underlying warrants and 3,390,171 shares underlying options.

- As of November 30, 2020, our executive officers and directors beneficially owned approximately 34.0% of our outstanding shares of common stock. Such concentrated control of our company may adversely affect the price of our common stock. If you acquire common stock, you may have no effective voice in the management of our company.

- We have paid no dividends on our common stock to date and we do not anticipate that any dividends will be paid to holders of our common stock in the foreseeable future. The lack of a dividend can further affect the market value of our stock and could significantly affect the value of any investment in our company.

- 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., headquartered in Cranford, New Jersey, is a specialty pharmaceutical company dedicated to the development and commercialization of critical care products targeting important medical needs with a focus on anti-infective products in adjunct cancer care, unique prescription products and, recently, mesenchymal 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 Pharmaceuticals, Inc. (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 Pharmaceuticals, Inc. ("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").

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 four proprietary products: Mino-Lok, an antibiotic lock solution used to treat patients with catheter-related bloodstream infections by salvaging the infected catheter; Mino-Wrap, a liquifying gel-based wrap for reduction of tissue expander infections following breast reconstructive surgeries; Halo-Lido, a corticosteroid-lidocaine topical formulation that is intended to provide anti-inflammatory and anesthetic relief to persons suffering from hemorrhoids; and NoveCite, in-licensed in October 2020, 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.

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 U.S. Food and Drug Administration ("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 will be interim analyses at both the 50% and 75% points of the trial as measured by the number of patients treated. As of November 15, 2020, there are 29 active sites currently enrolling patients including such academic centers as MDACC, Henry Ford Health Center, Georgetown University Medical Center, and others. There are two additional medical centers in startup mode. There are no other remaining sites in feasibility.

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 will 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. It is further assumed 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 is expected to be completed by March 2021.

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.

Fast Track Designation

In October 2017, the Company received official notice from 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 FDA to discuss the drug's development plan and ensure collection of appropriate data needed to support drug approval;
- More frequent written correspondence from 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 FDA, rather than waiting until every section of the application is completed before the entire application can be reviewed.

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." 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.

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.

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.

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, we reported the FDA response to the briefing package and commented that the FDA was in general agreement with our planned pre-clinical program and gave further guidance on our clinical plans.

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, has 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 reconstruction occurs 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 with 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.

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 suggest the possibility of a benefit for the combination product formulation.

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.

In addition to the safety and dose-ranging information, 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 believes that we can continue to develop this assessment tool as well as other patient reported outcome endpoints for use in the next trials and in the pivotal trial.

Information was also obtained about the formulation of the drug and the vehicle. As a result of this study, we believe 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.

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 are able to help us develop patient reported outcome evaluation tools. These tools 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 slidocaine 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. We anticipate beginning a Phase 2b clinical study in the first quarter of 2021.

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

NoveCite

Overview

In October 2020, we, through our recently formed 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 will be focused on developing cellular therapies. Specifically, we will seek to develop and commercialize the NoveCite mesenchymal stem cells ("NC-*i*MSCs") to treat acute respiratory conditions with a near term focus on ARDS associated with COVID-19.

NC-*i*MSCs are the next generation mesenchymal stem cell therapy. They are believed 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). 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 emergency authorization program.

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 the COVID 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.

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.

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

Halo-Lido Intellectual Property

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

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

NoveCite Intellectual Property

In October 2020, we, through our subsidiary NoveCite, Inc., entered into a license agreement with Novellus Therapeutics Limited ("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. Pursuant to the terms of the stock subscription agreement between Novellus and NoveCite, if NoveCite issues additional equity, subject to certain exceptions, prior to its initial public offering or a change of control (as defined in the license agreement), NoveCite must maintain Novellus's ownership at 25% by issuing to Novellus additional shares.

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) 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.

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.

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").

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 has 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.

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.

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.

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.

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.

Halo-Lido Competition

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

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 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 Phase2 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.

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.

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 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 rather than medical devices. Consequently, we intend to submit an NDA to the FDA for each of Mino-Lok, Halo-Lido, Mino-Wrap and 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 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 and the FDA's acceptance of the NDA 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.

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.

International sales of medical devices manufactured in the U.S. that are not approved by the FDA for use in the U.S., or are banned or deviate from lawful performance standards, are subject to FDA export requirements. Exported devices are subject to the regulatory requirements of each country to which the device is exported. Some countries do not have medical device regulations, but in most foreign countries, medical devices are regulated. Frequently, regulatory approval may first be obtained in a foreign country prior to application in the U.S. to take advantage of differing regulatory requirements. Most countries outside of the U.S. require that product approvals be recertified on a regular basis, generally every five years. The recertification process requires that we evaluate any device changes and any new regulations or standards relevant to the device and conduct appropriate testing to document continued compliance. Where recertification applications are required, they must be approved in order to continue selling those products in those countries.

In the European Union, in order for a product to be marketed and sold, it is required to comply with the Medical Devices Directive and obtain CE Mark certification. The CE Mark certification encompasses an extensive review of the applicant's quality management system which is inspected by a notified body's auditor as part of a stage 1 and 2 International Organization for Standardization ("ISO") 13485:2016 audit, in accordance with worldwide recognized ISO standards and applicable European Medical Devices Directives for quality management systems for medical device manufacturers. Once the quality management system and design dossier has been successfully audited by a notified body and reviewed and approved by a competent authority, a CE certificate for the medical device will be issued. Applicants are also required to comply with other foreign regulations such as the requirement to obtain Ministry of Health, Labor and Welfare approval before a new product can be launched in Japan. The time required to obtain these foreign approvals to market our products may vary from U.S. approvals, and requirements for these approvals may differ from those required by the FDA.

Medical device laws and regulations are in effect in many of the countries in which we may do business outside the United States. These laws and regulations range from comprehensive device approval requirements for our medical device product to requests for product data or certifications. The number and scope of these requirements are increasing. We may not be able to obtain regulatory approvals in such countries and may be required to incur significant costs in obtaining or maintaining its foreign regulatory approvals. In addition, the export of certain of our products which have not yet been cleared for domestic commercial distribution may be subject to FDA export restrictions. Any failure to obtain product approvals in a timely fashion or to comply with state or foreign medical device laws and regulations may have a serious adverse effect on our business, financial condition or results of operations.

Employees

As of September 30, 2020, we had ten 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

Myron Holubiak, President, Chief Executive Officer and Director – Mr. Holubiak, 73, was appointed President, Chief Executive Officer and Director in March 2016. He previously served as a Director of Citius since October 2015 and was the founder and Chief Executive Officer and President of Leonard-Meron Biosciences, Inc., an acquired subsidiary of Citius, from March 2013 until March 2016.

Leonard Mazur, Executive Chairman and Secretary – Mr. Mazur, 75, 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.

Jaime Bartushak, Chief Financial Officer and Principal Financial Officer – Mr. Bartushak, 53, 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, 61 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 $17,548,085 and $15,562,144 for the years ended September 30, 2020 and 2019, respectively. At September 30, 2020, we had stockholders' equity of $33,670,668 and an accumulated deficit of $70,593,867. Our net cash used in operating activities was $16,930,658 and $12,437,751 for the years ended September 30, 2020 and 2019, 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;
- 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 our 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.

There is substantial doubt about our ability to continue as a going concern.

At September 30, 2020, we estimated that we have sufficient capital to continue our operations through March 2021. 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.

Our audited consolidated financial statements included in this report have been prepared assuming that we will continue as a going concern and do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets, or the amounts and classification of liabilities that may result if we do not continue as a going concern. We have concluded that substantial doubt about our ability to continue as a going concern exists and our auditors have made reference to this in their audit report on our audited consolidated financial statements for the year ended September 30, 2020.

We need to secure additional financing in the near 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. We have received gross proceeds of approximately $70.5 million from our public and private placement offerings through September 30, 2020. Additionally, in connection with the acquisition of LMB our Executive Chairman, Leonard Mazur, made an equity investment of $3.0 million in March 2016. Mr. Mazur has also loaned us $4,710,000 pursuant to convertible promissory notes. On August 8, 2017, these notes and accrued interest of $76,240 were converted into 1,547,067 shares of common stock at a price of $3.09 per share as part of an underwritten public offering which closed on the same date.

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 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. 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 turmoil in the financial markets due to 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, 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 are a clinical stage company and 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 not successfully completed any late stage clinical trials nor undertaken any commercialization activities. 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 the second half of 2021. This same risk applies to 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 trial. 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 trial and our other product candidates. Any or all of these events could increase our operating expenses and the length of time to complete the 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 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:

- could determine that we cannot rely on Section 505(b)(2) for Mino-Lok or Halo-Lido or any future product candidates;
- 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 not find the data from clinical trials sufficient to support the submission of an NDA 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;
- 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;
- 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 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 generate any revenues, continue our operations and clinical studies, or become profitable. Our reputation in the industry and in the investment community would likely be significantly damaged. Further, it might not be possible for us to raise funds in the public or private markets, and our stock price would likely decrease significantly.

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

Our current plans for filing NDAs 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 which 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, 2020, 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, unless we were to increase our investment, which would further reduce the portion of any benefit that might be derived from the NoveCite drug candidate's successful development.

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 recently created 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 has only recently begun 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; 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 have 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 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:

- research and development resources, including personnel and technology;
- regulatory resources, experience and expertise;
- product candidate development and clinical trial resources and experience;
- product sourcing, sales and marketing resources and experience;
- experience and expertise in exploitation of intellectual property rights; and
- 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. Proposals to modify the current health care system in the U.S. to improve access to health care and control its costs are continually being considered by the federal and state governments. In March 2010, the U.S. Congress passed landmark healthcare legislation. Portions of this legislation have been repealed in recent years and members of the U.S. Congress and some state legislatures continue to seek to overturn at least some remaining portions of the legislation and we expect they will continue to review and assess this legislation and possibly alternative health care reform proposals. We cannot predict what impact on federal reimbursement policies this legislation will have in general or on our business specifically. We cannot predict whether new proposals will be made or adopted, when they may be adopted or what impact they may have on us if they are adopted.

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 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 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, our 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 effect 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 complete 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 license agreements. Currently, we are a party to two in-license agreements with MDACC, one for Mino-Lok (sub-licensed from the entity holding the license from MDACC) and one for Mino-Wrap. We recently entered into an in-license agreement with Novellus through our subsidiary NoveCite. Additionally, we expect to enter into additional license agreements in the future. 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 or licensees could harm our business.

If we or any of our current or future collaborators or licensees fail to renew or terminate any of our collaborations or licensing arrangements 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 and licensees 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 or license agreements may prove to be unsuccessful.

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. 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, as we are currently engaged in for NoveCite;

- 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 NoveCite, 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.

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 President and Chief Executive Officer, Myron Holubiak, our Executive Chairman, Leonard Mazur, 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. Holubiak, Mr. Mazur, 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 NoveCite in October 2020. 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.

Conflicts of interest may arise from our relationship with NoveCite.

As of November 30, 2020, we beneficially owned 75% of the voting power of NoveCite's outstanding common stock; Novellus owns the other 25%. Our Board Chairman Leonard Mazur, who is also our largest stockholder, is a director and significant shareholder of Novellus. As a result of our partial ownership and Mr. Mazur's relationship to Novellus, 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 and senior management 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.

The dual roles of our officers and directors who also serve in similar roles with NoveCite could create a conflict of interest and will require careful monitoring.

We share some directors and officers with NoveCite. This could create conflicts of interest between the two companies in the future. In the future, situations may arise under the operation of both companies that may create a conflict of interest. We will have to be diligent to ensure that any such situation is resolved by independent parties. In particular, NoveCite is free to pursue opportunities which could potentially be of interest to us, and they are not required to notify us prior to pursuing such opportunities. Any such conflict of interest or pursuit by NoveCite of a corporate opportunity independent of us could expose us to claims by our investors and creditors and could harm our results of operations.

Risks Related to Our Regulatory and Legal Environment

We are subject to extensive and costly government regulation.

Our product candidates are and any approved products will be subject to extensive and rigorous domestic government regulation including regulation by the FDA, the Centers for Medicare and Medicaid Services, other divisions of the U.S. Department of Health and Human Services, the U.S. Department of Justice, state and local governments, and their respective foreign equivalents. The FDA regulates the research, development, preclinical and clinical testing, manufacture, safety, effectiveness, record keeping, reporting, labeling, storage, approval, advertising, promotion, sale, distribution, import, and export of pharmaceutical products. If our product candidates are to be marketed abroad, they will also be subject to extensive regulation by foreign governments, whether or not they have obtained FDA approval. Such foreign regulation might be equally or more demanding than corresponding U.S. regulation. Government regulation substantially increases the cost and risk of researching, developing, manufacturing, and selling our product candidates. The regulatory review and approval process, which includes preclinical testing and clinical trials of each product candidate, is lengthy, expensive, and uncertain. We or our collaborators must obtain and maintain regulatory authorization to conduct clinical trials and approval for each product candidate we intend to market, and the manufacturing facilities used for the product candidates must be inspected and meet legal requirements. Securing regulatory approval requires submitting extensive preclinical and clinical data and other supporting information for each proposed product candidate in order to establish the product's safety and efficacy for each intended use. The development and approval process might take many years, requires substantial resources, and might never lead to the approval of a product candidate. Further, the FDA or any foreign regulatory authority could change its established regulations that govern the drug development and approval process, which could negatively impact the ongoing or future regulatory review of our product candidates, including the anticipated timeline and cost of development and approval. 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. Material changes to an approved product, such as, for example, manufacturing changes or revised labeling, might require further regulatory review and approval. Once obtained, any approvals might be withdrawn, including, for example, if there is a later discovery of previously unknown problems with the product, such as a previously unknown safety issue.

If we, our collaborators or our contract manufacturers fail to comply with applicable regulatory requirements at any stage during the regulatory process, such noncompliance could result in, among other things: suspension or cessation of clinical trials; delays in the approval of applications or supplements to approved applications; refusal of a regulatory authority, including the FDA, to review pending market approval applications or supplements to approved applications; warning letters; fines; import and export restrictions; product recalls or seizures; injunctions; total or partial suspension of production; civil penalties; withdrawals of previously approved marketing applications or licenses; recommendations by the FDA or other regulatory authorities against governmental contracts; and/or criminal prosecutions.

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 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. 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, including:

- issuance of Form 483 notices, warning letters and adverse publicity by the FDA or other regulatory agencies;
- imposition of fines and other civil penalties due to product liability or other issues;
- injunctions, suspensions or revocations of regulatory approvals;
- suspension of any ongoing pre-clinical and clinical trials;
- total or partial suspension of manufacturing;
- delays in commercialization;
- refusal by the FDA to approve pending applications or supplements to approved applications filed by us or our collaborators;
- refusals to permit medical products to be imported into or exported from the U.S.;
- restrictions on operations, including costly new manufacturing requirements;
- product recalls or seizures; and
- criminal prosecutions.

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.

Even if we receive regulatory approval to commercialize our product candidates, post-approval marketing and promotion of products is highly regulated by the FDA, and marketing campaigns which violate FDA standards may result in adverse consequences including regulatory enforcement action by the FDA as well as follow-on actions filed by consumers and other end-payers, which could result in substantial fines, sanctions and damage awards against us, any of which could harm our business.

Post-approval marketing and promotion of products, standards and regulations for direct-to-consumer advertising, dissemination of off-label product information, industry-sponsored scientific and educational activities and promotional activities are heavily scrutinized and regulated by the FDA. Products may only be marketed for approved indications and in accordance with provisions of the FDA approved labels. Failure to comply with such requirements may result in adverse publicity, warning letters issued by the FDA, and civil or criminal penalties.

In the event the FDA discovers post-approval violations, we could face penalties in the future including the FDA's issuance of a cease and desist order, impounding of our products, and civil or criminal penalties. As a follow-on to such governmental enforcement activities, consumers and other end-payers of the product may initiate action against us claiming, among other things, fraudulent misrepresentation, unfair competition, violation of various state consumer protection statues and unjust enrichment. If the plaintiffs in such follow-on actions are successful, we could be subject to various damages, including compensatory damages, treble damages, punitive damages, restitution, disgorgement, prejudgment and post-judgment interest on any monetary award, and the reimbursement of the plaintiff's legal fees and costs, any of which could have an adverse effect on our revenue, business, financial condition and prospects.

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.

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.

Changes in patent law or patent jurisprudence could diminish the value of patents in general, thereby impairing our ability to protect our product candidates.

The United States has enacted and is expected to continue to implement wide-ranging patent reform legislation. Further, United States Supreme Court rulings have either narrowed the scope of patent protection available in certain circumstances or weakened the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the scope and value of patents, once obtained.

In September 2011, the Leahy-Smith America Invents Act, also known as the America Invents Act, or AIA, was signed into law. The AIA includes a number of significant changes to U.S. patent law, including provisions that affect the way patent applications will be prosecuted and may also affect patent litigation. The USPTO is currently developing regulations and procedures to govern administration of the AIA, and many of the substantive changes to patent law associated with the AIA. It is not clear what other, if any, impact(s) the AIA will have on the operation of our business. Moreover, the AIA and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have an adverse effect on our business. One important change introduced by the AIA is that, as of March 16, 2013, the United States transitioned to a "first-to-file" system for deciding which party should be granted a patent when two or more patent applications are filed by different parties claiming the same invention. A third party who files a patent application with the USPTO after such date but prior to our filing may therefore be awarded a patent covering an invention of ours even if we were the first to invent. All of our U.S. patent applications were filed after March 16, 2013. This "first-inventor-to-file" system will require us both to remain cognizant, going forward, of the timing between invention and filing of a patent application.

Among some of the other changes introduced by the AIA are those that (i) limit where a patentee may file a patent infringement suit and (ii) provide opportunities for third parties to challenge any issued patent in the USPTO. Such changes apply to all of our U.S. patents. Because of a lower evidentiary standard in USPTO proceedings, as compared to the evidentiary standard applied in U.S. federal courts, necessary to invalidate a patent claim, a third party could potentially present evidence in a USPTO proceeding sufficient for the USPTO to find a claim invalid, notwithstanding that the same evidence would be insufficient to invalidate a claim first presented in a district court action. Accordingly, a third party may attempt opportunistically to use USPTO procedures to invalidate our patent claims.

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 we and our licensors or partners may obtain in the future.

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 and certain warrants.

Our common stock and certain outstanding warrants are 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, most recently between April 2020 and July 2020. In October 2019, we received a notice from Nasdaq that we failed to comply with the $1.00 minimum bid price requirement. We regained compliance on January 31, 2020. On April 1, 2020, we received written notice from The Nasdaq Stock Market indicating that, because the closing bid price for the Company's common stock has fallen below $1.00 per share for 30 consecutive business days, we no longer complied 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), we had been provided a compliance period of 180 calendar days, which ran until September 28, 2020, to regain compliance with the minimum bid price requirement. The date to regain compliance was extended by Nasdaq in response to the COVID-19 pandemic and its impact on the capital markets and listed companies' stock prices. As a result of the extension, to regain compliance, the closing bid price of our common stock had to meet or exceed $1.00 per share for a minimum of 10 consecutive business days prior to December 14, 2020. On July 10, 2020, we regained compliance.

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.

If we fail to maintain an effective system of internal controls, we may not be able to accurately report our financial results or detect fraud. Consequently, stockholders could lose confidence in our financial reporting and this may decrease the trading price of our common stock.

We are subject to the reporting requirements of the Securities Exchange Act of 1934, as amended, or the Exchange Act, the Sarbanes-Oxley Act of 2002, or SOX, and Nasdaq rules and regulations. SOX requires, among other things, that we maintain effective disclosure controls and procedures and internal control over financial reporting. We perform system and process evaluation and testing of our internal controls over financial reporting to allow management to report on the effectiveness of our internal controls over financial reporting in our Annual Report on Form 10-K filing for each year, as required by Section 404 of SOX. We previously had identified material weaknesses in our internal control over financial reporting related to ineffective separation of duties due to our limited finance staff, our reliance on consultants to assist with the financial reporting function and a lack of documented policies and procedures, which weaknesses were reported in fiscal 2016 and 2017 (and prior to that by our predecessor company). We remediated these material weaknesses as of September 30, 2018 and management determined that our internal controls over financial reporting were effective as of that date. While we are committed to continuing to improve our internal control processes, and although we will continue to diligently and vigorously review our internal controls over financial reporting, we cannot be certain that, in the future, a material weakness or significant deficiency will not exist or otherwise be discovered. If that were to happen, it could harm our operating results and cause stockholders to lose confidence in our reported financial information. Any such loss of confidence would have a negative effect on the trading price of our securities.

A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system's objectives will be satisfied. Internal control over financial reporting and disclosure controls and procedures are designed to give a reasonable assurance that they are effective to achieve their objectives. We cannot provide absolute assurance that all of our possible future control issues will be detected. These inherent limitations include the possibility that judgments in our decision making can be faulty, and that isolated breakdowns can occur because of simple human error or mistake. The design of our system of controls is based in part upon assumptions about the likelihood of future events, and there can be no assurance that any design will succeed absolutely in achieving our stated goals under all potential future or unforeseeable conditions. Because of the inherent limitations in a cost-effective control system, misstatements due to error could occur and not be detected. This and any future failures could cause investors to lose confidence in our reported financial information, which could have a negative impact on our financial condition and stock price.

The price of our securities may become volatile, which could lead to losses by stockholders and costly securities litigation.

The trading price of our securities is likely to be highly volatile and could fluctuate in response to factors such as:

- the cost, timing, completion and/or results of our clinical trials;
- our common stock being delisted from The Nasdaq Capital Market;
- sales of our common stock or other securities in the open market or in public offerings or in private placements;
- regulatory actions regarding our product candidates or any approved products;
- additions or departures of key personnel;
- announcements of developments by us or our competitors;
- announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures or capital commitments;
- actual or anticipated variations in our operating results;
- adoption of new accounting standards affecting our industry; and
- other events or factors, many of which are beyond our control.

The stock market is subject to significant price and volume fluctuations. In the past, following periods of volatility in the market price of a company's securities, securities class action litigation has often been initiated against such a company. Any such litigation initiated against us, whether or not successful, could result in substantial costs and diversion of our management's attention and resources, which could harm our business and financial condition.

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 200,000,000 shares of common stock and 10,000,000 shares of preferred stock. As of September 30, 2020, there were 55,576,996 shares of common stock outstanding, 26,831,989 shares underlying warrants with a weighted average exercise price of $1.546 per share and 3,390,171 shares underlying options with a weighted average exercise price of $2.513 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.

The common stock is controlled by insiders.

As of November 30, 2020, our executive officers and directors beneficially owned approximately 34.0% of our outstanding shares of common stock. Such concentrated control of our company may adversely affect the price of our common stock. If you acquire common stock, you may have no effective voice in the management of our company. Sales by our directors and executive officers or their affiliates, along with any other market transactions, could adversely affect the market price of our common stock.

We do not intend to pay dividends for the foreseeable future.

We have paid no dividends on our common stock to date and we do not anticipate that any dividends will be paid to holders of our common stock in the foreseeable future. While our future dividend policy will be based on the operating results and capital needs of our business, we currently anticipate that any future earnings will be retained to finance our future expansion and for the implementation of our business plan. The lack of a dividend can further affect the market value of our stock and could significantly affect the value of any investment in our company.

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, 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 and certain warrants to purchase common stock trade on The Nasdaq Capital Market under the symbol "CTXR" and "CTXRW," respectively.

Holders of Common Stock

As November 30, 2020, 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

None.

Issuer Purchases of Equity Securities

We did not make any purchases of our common stock during the three months ended September 30, 2020, which is the fourth quarter of our fiscal year.

Item 6. Selected Financial Data

Not required.

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 specialty pharmaceutical company dedicated to the development and commercialization of critical care products targeting unmet needs with a focus on anti-infectives, cancer care and unique prescription products. 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 its 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.

In-process research and development represents the value of LMB's leading drug candidate, which is an antibiotic solution used to treat catheter-related bloodstream infections. Goodwill represents the value of LMB's industry relationships and its assembled workforce. In-process research and development is expected to be amortized on a straight-line basis over a period of eight years commencing upon revenue generation. Goodwill will not be amortized, but will be tested at least annually for impairment.

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

Through September 30, 2020, we have devoted substantially all of 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 its 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. Pursuant to the terms of the stock subscription agreement between Novellus and NoveCite, if NoveCite issues additional equity, subject to certain exceptions, NoveCite must maintain Novellus's ownership at 25% by issuing additional shares to Novellus.

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.

Results of Operations for Year Ended September 30, 2020 compared to Year Ended September 30, 2019

	Year Ended September 30, 2020	Year Ended September 30, 2019
Revenues	$ -	$ -
Operating expenses:		
Research and development	8,812,810	8,596,898
General and administrative	8,094,614	6,285,480
Stock-based compensation – general and administrative	803,261	715,983
Total operating expenses	17,710,685	15,598,361
Operating loss	(17,710,685)	(15,598,361)
Interest income	68,066	52,660
Other income	110,207	-
Interest expense	(15,673)	(16,443)
Net loss	$ (17,548,085)	$ (15,562,144)

Revenues

We did not generate any revenues for the years ended September 30, 2020 and 2019.

Research and Development Expenses

For the year ended September 30, 2020, research and development expenses were $8,812,810 as compared to $8,596,898 for the year ended September 30, 2019, an increase of $215,912. Research and development costs for Mino-Lok® decreased by $941,266 to $6,207,018 for the year ended September 30, 2020 as compared to $7,148,284 for the year ended September 30, 2019. Research and development costs for our Halo-Lido product candidate increased by $322,429 to $1,646,043 for the year ended September 30, 2020 as compared to $1,323,614 for the year ended September 30, 2019. Research and development costs for our Mino-Wrap product candidate decreased by $11,483 to $113,517 for the year ended September 30, 2020 as compared to $125,000 during the year ended September 30, 2019. During the year ended September 30, 2020, research and development costs for our new proposed novel cellular therapy for acute respiratory distress syndrome (ARDS) were $846,232.

We expect that research and development expenses will continue to increase in fiscal 2021 as we continue to focus on our Phase 3 trial for Mino-Lok®, progress the Halo-Lido product candidate, and accelerate our research and development efforts related to ARDS and Mino-Wrap. We are actively seeking to raise additional capital in order to fund our research and development efforts.

General and Administrative Expenses

For the year ended September 30, 2020, general and administrative expenses were $8,094,614 as compared to $6,285,480 for the year ended September 30, 2019 an increase of $1,809,134. General and administrative expenses consist primarily of compensation costs, consulting fees incurred for financing activities and corporate development services, and investor relations expenses. Compensation expense increased primarily due to the hiring of our new Chief Medical Officer in July 2020. During the year ended September 30, 2020, the Company issued $528,770 in common stock for investor relations and other consulting services, and incurred additional legal and business advisory expenses.

Stock-based Compensation Expense

For the year ended September 30, 2020, stock-based compensation expense was $803,261 as compared to $715,983 for the year ended September 30, 2019. Stock-based compensation expense increased by $87,278 in comparison to the prior period as we granted an option to our new Chief Medical Officer and additional options to consultants, directors and employees. At September 30, 2020, unrecognized total compensation cost related to unvested options of $1,166,073 is expected to be recognized over a weighted average period of 1.90 years.

Other Income (Expense)

During the year ended September 30, 2020, the Company earned $68,066 of interest income compared to $52,660 of interest income during the year ended September 30, 2019. We have temporarily invested some of the proceeds of our recent equity offerings. During the year ended September 30, 2020, the Company recorded as other income a $110,207 refund received from the FDA for 2016 product and establishment fees. The fees previously paid by the Company exceeded the costs of the FDA's review of the associated applications.

Interest expense for the year ended September 30, 2020 was $15,673 as compared to $16,443 for the year ended September 30, 2019. Interest expense for both years is primarily for the notes payable to related parties that were acquired in the acquisition of LMB. During the year ended September 30, 2020, we also accrued $741 in interest expense on the COVID-related Small Business Administration ("SBA") paycheck protection program loan received on April 15, 2020.

Net Loss

For the year ended September 30, 2020, we incurred a net loss of $17,548,085 compared to a net loss of $15,562,144 for the year ended September 30, 2019. The $1,985,941 increase in the net loss was primarily due to the $1,809,134 increase in general and administrative expenses.

LIQUIDITY AND CAPITAL RESOURCES

Going Concern Uncertainty and Working Capital

Citius has incurred losses of $17,548,085 and $15,562,144 for the years ended September 30, 2020 and 2019, respectively. At September 30, 2020, Citius had an accumulated deficit of $70,593,867. Citius' net cash used in operations during the years ended September 30, 2020 and 2019 was $16,930,658 and $12,437,751, respectively.

The independent registered public accounting firm report on our September 30, 2020 consolidated financial statements contains an emphasis of a matter regarding substantial doubt about our ability to continue as a going concern and that the consolidated financial statements have been prepared assuming we will continue as a going concern and do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets, or the amounts and classification of liabilities that may result if we do not continue as a going concern.

As of September 30, 2020, Citius had working capital of $9,884,852. Our limited working capital was attributable to the operating losses incurred by the Company since inception offset by our capital raising activities. At September 30, 2020, Citius had cash and cash equivalents of $13,859,748 available to fund its operations. The Company's only source of cash flow since inception has been from financing activities. During the years ended September 30, 2020 and 2019, the Company received net proceeds of $22,733,850 and $11,147,552, respectively, from the issuance of equity. We also received $164,583 from the COVID-related SBA paycheck protection program loan received on April 15, 2020. Our primary uses of operating cash were for product development and commercialization activities, regulatory expenses, employee compensation, consulting fees, legal and accounting fees, and insurance expense.

Financing Activities

In December 2019, 1,060,615 of the September 2019 Offering Pre-Funded Unit Warrants were exercised at $0.0001 per share for net proceeds of $106.

In January 2020, investors who participated in the September 2019 Offering exercised 1,315,715 warrants at $0.77 per share resulting in net proceeds of $1,013,101 to the Company.

On February 14, 2020, the Company entered into a warrant exercise agreement for 3,712,218 shares of common stock having an exercise price of $0.77 and 2,586,455 shares of common stock at a reduced exercise price of $1.02. The offering closed on February 19, 2020 and net proceeds were $5,013,930 after placement agent fees and offering expenses.

On May 18, 2020, the Company closed a registered direct offering for the sale of 7,058,824 shares of common stock at $1.0625 per share for gross proceeds of $7,500,001. The Company also agreed to issue 3,529,412 unregistered immediately exercisable warrants to the investors with an exercise price of $1.00 per share and a term of five and one-half years. Net proceeds from the offering were $6,877,100.

On June 26, 2020, 1,129,412 of the May 2020 Registered Direct Offering Investor Warrants were exercised at $1.00 per share for net proceeds of $1,129,412.

On August 10, 2020, the Company closed an underwritten public offering of 9,159,524 shares of common stock at $1.05 per share for gross proceeds of $9,617,500. The Company paid the underwriter a fee of 7% of the gross proceeds totaling $673,225 and issued the underwriter 641,166 immediately exercisable warrants with an exercise price of $1.3125 per share and a term of five years. The Company also reimbursed the placement agent for $135,000 in expenses and incurred $109,074 in other expenses. Net proceeds from the offering were $8,700,201.

We expect that we will have sufficient capital to continue our operations through March 2021. We plan to raise additional capital in the future to support our operations. There is no assurance, however, that we will be successful in raising the needed capital or that proceeds, if any, will be sufficient enough or received in a timely manner to fully 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 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 assist in the treatment of catheter related bloodstream infections and is expected to be amortized on a straight-line basis over eight years 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 impairment has occurred since the acquisition through September 30, 2020.

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 2020 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, 2020.

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, 2020 and 2019, 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, 2020 and 2019, and the results of its operations and its cash flows for the years then ended, in conformity with accounting principles generally accepted in the United States of America.

Emphasis of Matter – Ability to Continue as a Going Concern

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

Basis for Opinion

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

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

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

/s/ Wolf & Company, P.C.

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

Boston, Massachusetts
December 16, 2020

CITIUS PHARMACEUTICALS, INC.
CONSOLIDATED BALANCE SHEETS
SEPTEMBER 30, 2020 AND 2019

	2020	2019 (as restated)
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 13,859,748	$ 7,893,804
Prepaid expenses	122,237	48,111
Total Current Assets	13,981,985	7,941,915
Property and equipment, net	1,577	590
Operating lease right-of-use asset, net	986,204	—
Other Assets:		
Deposits	57,093	57,093
In-process research and development	19,400,000	19,400,000
Goodwill	9,346,796	9,346,796
Total Other Assets	28,803,889	28,803,889
Total Assets	$ 43,773,655	$ 36,746,394
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	$ 1,856,235	$ 2,713,542
Accrued expenses	164,040	246,225
Accrued compensation	1,654,919	1,400,688
Accrued interest	89,970	74,297
Notes payable – related parties	172,970	172,970
Operating lease liability	158,999	—
Total Current Liabilities	4,097,133	4,607,722
Note payable – paycheck protection program	164,583	—
Deferred tax liability	4,985,800	4,985,800
Operating lease liability – non current	855,471	—
Total Liabilities	10,102,987	9,593,522
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; 200,000,000 shares authorized; 55,576,996 and 28,930,493 shares issued and outstanding at September 30, 2020 and 2019, respectively	55,577	28,930
Additional paid-in capital	104,208,958	80,169,724
Accumulated deficit	(70,593,867)	(53,045,782)
Total Stockholders' Equity	33,670,668	27,152,872
Total Liabilities and Stockholders' Equity	$ 43,773,655	$ 36,746,394

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

CITIUS PHARMACEUTICALS, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS
FOR THE YEARS ENDED SEPTEMBER 30, 2020 AND 2019

	2020	2019
Revenues	$ —	$ —
Operating Expenses:		
Research and development	8,812,810	8,596,898
General and administrative	8,094,614	6,285,480
Stock-based compensation – general and administrative	803,261	715,983
Total Operating Expenses	17,710,685	15,598,361
Operating Loss	(17,710,685)	(15,598,361)
Other Income (Expense):		
Interest income	68,066	52,660
Other income	110,207	—
Interest expense	(15,673)	(16,443)
Total Other Income, Net	162,600	36,217
Loss before Income Taxes	(17,548,085)	(15,562,144)
Income tax benefit	—	—
Net Loss	$ (17,548,085)	$ (15,562,144)
Net Loss Per Share - Basic and Diluted	$ (0.45)	$ (0.77)
Weighted Average Common Shares Outstanding		
Basic and diluted	39,165,248	20,161,854

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

CITIUS PHARMACEUTICALS, INC.
CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY
FOR THE YEARS ENDED SEPTEMBER 30, 2020 AND 2019

	Preferred Stock	Common Stock Shares	Common Stock Amount	Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Equity
Balance, October 1, 2018, as previously reported	$ —	16,198,791	$ 16,199	$ 68,107,323	$ (40,257,838)	$ 27,865,684
Restatement (see Note 1)	—	—	—	—	2,774,200	2,774,200
Balance, October 1, 2018, as restated	—	16,198,791	16,199	68,107,323	(37,483,638)	30,639,884
Issuance of common stock in registered direct offering, net of costs of $466,000	—	3,430,421	3,430	4,830,571	—	4,834,001
Issuance of common stock in underwritten offering, net of costs of $710,342	—	6,760,615	6,761	6,283,574	—	6,290,335
Issuance of common stock upon exercise of warrants	—	2,321,569	2,321	20,895	—	23,216
Issuance of common stock for services	—	219,097	219	211,378	—	211,597
Stock-based compensation expense				715,983	—	715,983
Net loss	—	—	—	—	(15,562,144)	(15,562,144)
Balance, September 30, 2019	—	28,930,493	28,930	80,169,724	(53,045,782)	27,152,872
Issuance of common stock upon exercise of warrants	—	9,804,415	9,804	7,146,745	—	7,156,549
Issuance of common stock for services	—	623,740	624	528,146	—	528,770
Issuance of common stock in registered direct offering, net of costs of $622,900	—	7,058,824	7,059	6,870,041	—	6,877,100
Issuance of common stock in underwritten offering, net of costs of $917,299	—	9,159,524	9,160	8,691,041	—	8,700,201
Stock-based compensation expense	—	—	—	803,261	—	803,261
Net loss	—	—	—	—	(17,548,085)	(17,548,085)
Balance, September 30, 2020	$ —	55,576,996	$ 55,577	$ 104,208,958	$ (70,593,867)	$ 33,670,668

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

CITIUS PHARMACEUTICALS, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS
FOR THE YEARS ENDED SEPTEMBER 30, 2020 AND 2019

	2020	2019
Cash Flows From Operating Activities:		
Net loss	$ (17,548,085)	$ (15,562,144)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	803,261	715,983
Issuance of common stock for services	528,770	211,597
Amortization of operating lease right-of-use asset	151,520	—
Depreciation	844	893
Changes in operating assets and liabilities:		
Other receivables	—	818,343
Prepaid expenses	(74,126)	9,621
Deposits	—	(54,926)
Accounts payable	(857,307)	1,140,098
Accrued expenses	(82,185)	64,568
Accrued compensation	254,231	201,773
Accrued interest	15,673	16,443
Operating lease liability	(123,254)	—
Net Cash Used In Operating Activities	(16,930,658)	(12,437,751)
Cash Flows From Investing Activities:		
Purchase of property and equipment	(1,831)	—
Net Cash Used In Investing Activities	(1,831)	—
Cash Flows From Financing Activities:		
Proceeds from notes payable – paycheck protection program	164,583	—
Proceeds from common stock warrant exercises	7,156,549	23,216
Net proceeds from underwritten offerings	8,700,201	6,290,335
Net proceeds from registered direct offerings	6,877,100	4,834,001
Net Cash Provided By Financing Activities	22,898,433	11,147,552
Increase (Decrease) in Cash and Cash Equivalents	5,965,944	(1,290,199)
Cash and Cash Equivalents – Beginning of Year	7,893,804	9,184,003
Cash and Cash Equivalents – End of Year	$ 13,859,748	$ 7,893,804
Supplemental Disclosures of Cash Flow Information and Non-cash Transactions:		
Operating lease right-of-use asset and liability recorded upon adoption of ASC 842	$ 1,137,724	$ —

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

1. NATURE OF OPERATIONS AND BASIS OF PRESENTATION

Business

Citius Pharmaceuticals, Inc. ("Citius" or the "Company") is a specialty pharmaceutical company dedicated to the development and commercialization of critical care products targeting unmet needs with a focus on anti-infectives, cancer care and unique prescription products.

On March 30, 2016, Citius acquired Leonard-Meron Biosciences, Inc. ("LMB") as a wholly-owned subsidiary. The Company acquired all of 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.

In-process research and development 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 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 of 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 and LMB, and its recently formed majority-owned subsidiary NoveCite. NoveCite, was inactive until October 2020. All significant inter-company balances and transactions have been eliminated in consolidation.

Restatement of Previously Issued Financial Statements

Our consolidated balance sheet as of September 30, 2019 and the beginning balances in the consolidated statements of changes in stockholders' equity for the year ended September 30, 2019, have been restated for an error made with regard to a deferred tax liability, goodwill and accumulated deficit.

We determined that a deferred tax liability should have been recorded in the amount of $7,760,000 related to the in-process research and development intangible asset recorded in connection with the acquisition of LMB in March 2016, which would have resulted in additional goodwill of $7,760,000. Had the deferred tax liability been recorded upon acquisition of LMB, we would have also recognized an income tax benefit of $2,774,200 in 2018 as a result of the Tax Cuts and Jobs Act enacted into law on December 21, 2017, which lowered the U.S. corporate tax rate from 35% to 21%.

The table below indicates the impact of the restatement at September 30, 2019:

	Previously Recorded	Adjustment	As Restated
ASSETS			
Goodwill	$ 1,586,796	$ 7,760,000	$ 9,346,796
Total Assets	$ 28,986,394	$ 7,760,000	$ 36,746,394
LIABILITIES AND STOCKHOLDERS' EQUITY			
Deferred Tax Liability	$ -	$ 4,985,800	$ 4,985,800
Total Liabilities	$ 4,607,722	$ 4,985,800	$ 9,593,522
Stockholders' Equity:			
Accumulated deficit	$ (55,819,982)	$ 2,774,200	$ (53,045,782)
Total Stockholders' Equity	$ 24,378,672	$ 2,774,200	$ 27,152,872
Total Liabilities and Stockholders' Equity	$ 28,986,394	$ 7,760,000	$ 36,746,394

2. GOING CONCERN UNCERTAINTY AND MANAGEMENT'S PLAN

The accompanying consolidated financial statements have been prepared on a going concern basis, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. The Company experienced negative cash flows from operations of $16,930,658 and $12,437,751, for the years ended September 30, 2020 and 2019, respectively. The Company has no revenue and has relied on proceeds from equity transactions and debt to finance its operations. At September 30, 2020, the Company had limited capital to fund its operations. This raises substantial doubt about the Company's ability to continue as a going concern within one year after the date that the accompanying consolidated financial statements are issued.

The Company plans to raise capital through equity financings from outside investors as well as raise additional funds from existing investors. There is no assurance, however, that the Company will be successful in raising the needed capital and, if funding is available, that it will be available on terms acceptable to the Company. While the COVID-19 pandemic has adversely impacted the progress of the Company's 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, the Company cannot be certain that any future impact of COVID-19 on its operations will not negatively impact its ability to raise capital. The accompanying consolidated financial statements do not include any adjustments that might result from the outcome of the above uncertainty.

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 2020 and 2019.

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 an annual maintenance fee of $30,000 in January 2020. The annual maintenance fee increases by $15,000 per year up to a maximum of $90,000. Annual maintenance fees cease on the first sale of product. We also must pay up to an aggregate of $2.1 million in milestone payments, contingent on the achievement of various regulatory and commercial milestones. Under the terms of the license agreement, we also must pay a royalty of mid- to upper-single digit percentages of net sales, depending on the amount of annual sales, and subject to downward adjustment to lower- to mid-single digit percentages in the event there is no valid patent for the product in the United States at the time of sale. After the first sale of product, we will owe an annual minimum royalty payment of $100,000 that will increase annually by $25,000 for the duration of the term. We will be responsible for all patent expenses incurred by Licensor for the term of the agreement although Licensor is responsible for 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, is a director and significant shareholder of Novellus. 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, we signed an exclusive agreement with Novellus and have created a subsidiary, NoveCite, that will be focused on developing cellular therapies. Upon execution of the agreement, we advanced $5,000,000 to NoveCite 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 stock subscription agreement between Novellus and NoveCite, if NoveCite issues additional equity, subject to certain exceptions, NoveCite must maintain Novellus's ownership at 25% by issuing additional shares to Novellus.

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

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. 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.

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

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 acquisition through September 30, 2020.

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 2020 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, 2020.

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, 2020.

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. Due to its limited operating history, limited number of sales of its common stock, and limited history of its shares being publicly traded, the Company estimated its volatility in consideration of a number of factors including the volatility of comparable public companies through December 31, 2018. Since January 1, 2019, the Company has estimated its 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, 2020. Any interest or penalties are charged to expense. During the years ended September 30, 2020 and 2019, the Company did not recognize any interest and penalties. Tax years subsequent to September 30, 2016 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 is computed by dividing net loss in each period by the weighted average number of shares of common stock outstanding during such period. For the periods presented, common stock equivalents, consisting of options, warrants and convertible securities 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 Adopted Accounting Standards

In February 2016, the FASB issued ASU 2016-02: *Leases (Topic 842)*. ASU 2016-02 requires a lessee to record a right-of-use asset and a corresponding lease liability, initially measured at the present value of the lease payments, on the balance sheet for all leases with terms longer than 12 months, as well as the disclosure of key information about leasing arrangements. ASU 2016-02 requires recognition in the statement of operations of a single lease cost, calculated so that the cost of the lease is allocated over the lease term, generally on a straight-line basis. ASU 2016-02 requires classification of all cash payments within operating activities in the statement of cash flows. Disclosures are required to provide the amount, timing and uncertainty of cash flows arising from leases. A modified retrospective transition approach is required for lessees for capital and operating leases existing at, or entered into after, the beginning of the earliest comparative period presented in the financial statements, with certain practical expedients available. The Company elected to adopt the package of practical expedients, which among other things, allows it to carry forward the historical lease classification and combine lease and non-lease components as a single lease component. ASU 2016-02 is effective for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years. The Company adopted the provisions of ASU 2016-02 in the quarter beginning October 1, 2019. This adoption approach resulted in a balance sheet presentation that is not comparable to the prior period in the year of adoption. The adoption of this ASU resulted in the recognition of a right of use asset and lease liability of $1,137,724.

In June 2018, the FASB issued ASU No. 2018-07, Compensation - Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting, which is intended to reduce cost and complexity and to improve financial reporting for nonemployee share-based payments. The amendment is effective for fiscal years beginning after December 15, 2018, including interim periods within that fiscal year. The Company adopted ASU 2018-07 on October 1, 2019 and it did not have a material effect on the Company's financial position, results of operations or disclosures.

Recently Issued Accounting Standards

In December 2019, the FASB issued ASU No. 2019-12 *Simplifications to Accounting for Income Taxes* ASU 2019-12 removes certain exceptions for recognizing deferred taxes for investments, performing intra-period allocation, and calculating income taxes in interim periods. The ASU also adds guidance to reduce complexity in certain areas, including deferred taxes for goodwill and allocating taxes for members of a consolidated group. ASU 2019-12 is effective for all entities for fiscal years beginning after December 15, 2020, and earlier adoption is permitted. The Company is currently evaluating the impact of adopting ASU 2019-12 on its consolidated financial statements.

5. NOTES PAYABLE

Notes Payable – Related Parties

A summary of notes payable – related parties outstanding as of September 30, 2020 and 2019 is as follows:

	2020	2019
Demand notes payable – Leonard Mazur	$ 160,470	$ 160,470
Demand notes payable – Myron Holubiak	12,500	12,500
Notes payable – related parties	$ 172,970	$ 172,970

On March 30, 2016, the Company assumed $772,970 of demand notes payable in the acquisition of LMB, including $760,470 to its Chairman, Leonard Mazur, and $12,500 to its Chief Executive Officer, Myron Holubiak. In April 2016, $600,000 of demand notes payable was repaid to Leonard Mazur. Notes with a principal balance of $104,000 accrue interest at the prime rate plus 1% and notes with a principal balance of $68,970 accrue interest at 12% per annum.

Interest expense on notes payable – related parties for the years ended September 30, 2020 and 2019 was $14,932 and $16,443, respectively.

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 accrues 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 funding in the amount of $164,583 from the Paycheck Protection Program through its bank.

Interest expense on the PPP loan was $741 for the year ended September 30, 2020.

6. COMMON STOCK, STOCK OPTIONS AND WARRANTS

Common Stock Issued for Services

On February 13, 2019, the Company issued 125,000 shares of common stock for investor relations services and expensed the $117,500 fair value of the common stock issued.

On September 16, 2019, the Company issued 94,097 shares of common stock for investor relations services and expensed the $94,097 fair value of the common stock issued.

On November 4, 2019, the Company issued 186,566 shares of common stock for strategic consulting and corporate development services and expensed the $100,000 fair value of the common stock issued.

On February 10, 2020, the Company issued 150,000 shares of common stock for investor relations services and 136,000 shares of common stock for general advisory and business development advisory services. The Company expensed the $306,020 fair value of the common stock issued.

On April 6, 2020, the Company issued 50,000 shares of common stock for strategic consulting and corporate development services and expensed the $22,750 fair value of the common stock issued.

On September 8, 2020, the Company issued 101,174 shares of common stock for investor relations services and expensed the $100,000 fair value of the common stock issued.

Common Stock Offerings

On April 3, 2019, the Company closed a registered direct offering with several institutional and accredited investors for the sale of 3,430,421 shares of common stock at $1.545 per share for gross proceeds of $5,300,001. Simultaneously, the Company also privately sold and issued 3,430,421 immediately exercisable two-year unregistered warrants to the investors with an exercise price of $1.42 per share. The Company paid the placement agent a fee of 7% of the gross proceeds totaling $371,000 and issued the placement agent 240,130 immediately exercisable two-year warrants with an exercise price of $1.93125 per share. The Company also reimbursed the placement agent for $85,000 in expenses and incurred $10,000 in other expenses. Net proceeds from the offering were $4,834,001. The estimated fair value of the 3,430,421 warrants issued to the investors was $2,709,467 and the estimated fair value of the 240,130 warrants issued to the placement agent was $169,854.

On September 27, 2019, Citius closed an underwritten at-the-market offering of (i) 6,760,615 units, each unit consisting of one share of common stock and one immediately exercisable five-year warrant to purchase one share at $0.77 per share, and (ii) 1,060,615 pre-funded units, each pre-funded unit consisting of one pre-funded warrant to purchase one share and one immediately exercisable five-year warrant to purchase one share at $0.77 per share. The pre-funded warrants included in the pre-funded units are immediately exercisable at a price of $0.0001 per share and do not expire. The offering price was $0.8951 per unit and $0.895 per pre-funded unit. The net proceeds of the offering were $6,290,335. The Company issued the underwriter immediately exercisable five-year warrants to purchase up to 547,486 shares at $1.118875 per share with an estimated fair value of $323,414. The estimated fair value of the 1,060,615 pre-funded warrants was $809,145, and the estimated fair value of the 7,821,230 warrants included in the units and the pre-funded units issued to the investors was $4,845,341.

On May 18, 2020, the Company closed a registered direct offering with several institutional and accredited investors for the sale of 7,058,824 shares of common stock at $1.0625 per share for gross proceeds of $7,500,001. The Company also agreed to issue 3,529,412 unregistered immediately exercisable warrants to the investors with an exercise price of $1.00 per share and a term of five and one-half years. The Company paid the placement agent for the offering a fee of 7% of the gross proceeds totaling $525,000 and issued the placement agent 494,118 immediately exercisable warrants with an exercise price of $1.3281 per share and a term of five years. The Company also reimbursed the placement agent for $85,000 in expenses and incurred $12,901 in other expenses. Net proceeds from the offering were $6,877,100. The estimated fair value of the 3,529,412 warrants issued to the investors was $2,138,998 and the estimated fair value of the 494,118 warrants issued to the placement agent was $275,724.

On August 10, 2020, the Company closed an underwritten public offering of 9,159,524 shares of common stock at a price of $1.05 per share for gross proceeds of $9,617,500. The Company paid the underwriter a fee of 7% of the gross proceeds totaling $673,225 and issued the underwriters 641,166 immediately exercisable warrants with an exercise price of $1.3125 per share and a term of five years. The Company also reimbursed the placement agent for $135,000 in expenses and incurred $109,074 in other expenses. Net proceeds from the offering were $8,700,201. The estimated fair value of the 641,166 warrants issued to the underwriter was $569,426.

Stock Option Plans

Pursuant to its 2014 Stock Incentive Plan (the "2014 Plan") the Company reserved 866,667 shares of common stock for issuance to employees, directors and consultants. The Board of Directors (or committees and/or executive officers delegated by the Board of Directors) may grant stock options, stock appreciation rights, restricted stock, restricted stock units, other stock-based awards and cash-based awards. As of September 30, 2020, 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 (the "2018 Plan") and the Company reserved 2,000,000 shares of common stock for issuance to employees, directors and consultants. Pursuant to the 2018 Plan, the Board of Directors (or committees and/or executive officers delegated by the Board of Directors) may grant stock options, stock appreciation rights, restricted stock, restricted stock units, other stock-based awards and cash-based awards. As of September 30, 2020, there were options to purchase 1,890,000 shares outstanding and no shares available for future grants.

On February 10, 2020, the Company's stockholders approved the 2020 Omnibus Stock Incentive Plan ("2020 Plan"). The 2020 Plan authorizes a maximum of 3,110,000 shares. The 2020 Plan provides incentives to employees, directors, and consultants of the Company in the form of granting an option, SAR, dividend equivalent right, restricted stock, restricted stock unit, or other right or benefit under the 2020 Plan. As of September 30, 2020, there were options to purchase 645,000 shares outstanding under the 2020 Plan and 2,465,000 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. Due to its limited operating history and limited number of sales of its common stock, the Company estimated its volatility in consideration of a number of factors including the volatility of comparable public companies through December 31, 2018. Since January 1, 2019, the Company has estimated its volatility using the trading activity of its 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, 2020 and 2019:

	2020	2019
Risk-free interest rate	0.26 – 1.66%	2.18 – 2.53%
Expected dividend yield	0%	0%
Expected term	6.50 – 10 years	6.50 – 10 years
Expected volatility	107 – 117%	119 – 121%

A summary of option activity under the plans is presented below:

	Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term	Aggregate Intrinsic Value
Outstanding at September 30, 2019	1,771,039	$ 4.03		
Granted	1,625,799	0.89		
Exercised	—	—		
Forfeited or expired	(6,667)	9.00		
Outstanding at September 30, 2020	3,390,171	$ 2.51	8.00 years	$ 440,336
Exercisable at September 30, 2020	1,507,141	$ 4.44	6.56 years	$ 72,566

The weighted average grant date fair value of the options granted during the year ended September 30, 2019 was estimated at $1.04 per share. 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, 2020 was estimated at $0.76 per share. All of 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, 2020 and 2019 was $803,261 and $715,983, respectively.

At September 30, 2020, unrecognized total compensation cost related to unvested awards of $1,166,073 is expected to be recognized over a weighted average period of 1.90 years.

Warrants

The Company has reserved 26,831,989 shares of common stock for the exercise of outstanding warrants. The following table summarizes the warrants outstanding at September 30, 2020:

	Exercise price	Number	Expiration Dates
Investor Warrants	$ 9.00	307,778	November 5, 2020 – April 25, 2021
LMB Warrants	6.15	38,771	November 20, 2020 – March 2, 2021
LMB Warrants	7.50	38,673	November 2, 2020 – March 14, 2021
LMB Warrants	7.50	53,110	March 24, 2022 – April 29, 2022
Financial Advisor Warrants	3.00	25,833	August 15, 2021
2016 Offering Warrants	4.13	140,819	November 23, 2021 – February 27, 2022
2017 Public Offering Warrants	4.13	1,622,989	August 2, 2022
2017 Public Offering Underwriter Warrants	4.54	65,940	February 2, 2023
December 2017 Registered Direct/Private Placement Offering Investor Warrants	4.63	640,180	June 19, 2023
December 2017 Registered Direct/Private Placement Offering Agent Warrants	5.87	89,625	December 19, 2022
March 2018 Registered Direct/Private Placement Offering Investor Warrants	2.86	218,972	October 2, 2023
March 2018 Registered Direct/Private Placement Offering Agent Warrants	3.73	46,866	March 28, 2023
August 2018 Offering Investor Warrants	1.15	7,843,138	August 14, 2023
August 2018 Offering Agent Warrants	1.59	549,020	August 8, 2023
April 2019 Registered Direct/Private Placement Offering Investor Warrants	1.42	1,294,498	April 5, 2021
April 2019 Registered Direct/Private Placement Offering Placement Agent Warrants	1.93	240,130	April 5, 2021
September 2019 Offering Investor Warrants	0.77	2,793,297	September 27, 2024
September 2019 Offering Underwriter Warrants	1.12	547,486	September 27, 2024
February 2020 Exercise Agreement Warrants	1.02	6,298,673	August 19, 2025
February 2020 Exercise Agreement Placement Agent Warrants	1.28	440,907	August 19,2025
May 2020 Registered Direct Offering Investor Warrants	1.00	2,400,000	November 18, 2025
May 2020 Registered Direct Offering Placement Agent Warrants	1.33	494,118	May 14, 2025
August 2020 Underwriter Warrants	1.31	641,166	August 10, 2025
		26,831,989	

During the year ended September 30, 2019, 2,321,569 August 2018 offering pre-funded unit warrants were exercised at $0.01 per share for net proceeds of $23,216.

In December 2019, 1,060,615 of the September 2019 Offering Pre-Funded Unit Warrants were exercised at $0.0001 per share for net proceeds of $106.

In January 2020, 1,315,715 of the September 2019 Offering Investor Warrants were exercised at $0.77 per share for net proceeds of $1,013,101.

On February 14, 2020, the Company entered into a warrant exercise agreement for an aggregate of 3,712,218 shares of common stock having an existing exercise price of $0.77 and 2,586,455 shares of common stock at a reduced exercise price of $1.02. In consideration for the exercise of the warrants for cash, the exercising holders received new unregistered warrants to purchase 6,298,673 shares of common stock at an exercise price of $1.02 per share, exercisable six months after issuance and which have a term of exercise equal to five years. The offering closed on February 19, 2020 and net proceeds were $5,013,930 after placement agent fees and offering expenses. The Company also issued warrants to purchase 440,907 shares to the placement agent. The placement agent warrants have identical terms to the investor warrants except that the exercise price is $1.275 per share. The estimated fair value of the 6,298,673 warrants issued to the investors was $5,360,465 and the estimated fair value of the 440,907 warrants issued to the placement agent was $367,022.

On June 26, 2020, 1,129,412 of the May 2020 Registered Direct Offering Investor Warrants were exercised at $1.00 per share for net proceeds of $1,129,412.

At September 30, 2020, the weighted average remaining life of all of the outstanding warrants is 3.55 years, all warrants are exercisable, and the aggregate intrinsic value for the warrants outstanding was $976,164.

Common Stock Reserved

A summary of common stock reserved for future issuances as of September 30, 2020 is as follows:

Stock plan options outstanding	3,390,171
Stock plan shares available for future grants	2,465,000
Warrants outstanding	26,831,989
Total	32,687,160

The three-year unit purchase options issued during the year ended September 30, 2017 expired during the year ended September 30, 2020.

7. RELATED PARTY TRANSACTIONS

Our Chairman of the Board, Leonard Mazur, was the cofounder and Vice Chairman of Akrimax Pharmaceuticals, LLC (“Akrimax”), a privately held pharmaceutical company specializing in producing cardiovascular and general pharmaceutical products. The Company leased office space from Akrimax through April 30, 2019 (see Note 10).

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

In connection with the April 2019 registered direct/private placement offering, Mr. Mazur purchased 1,165,048 shares of common stock at $1.545 per share and received 1,165,048 warrants with an exercise price of $1.42 per share, and Mr. Holubiak purchased 129,450 shares of common stock at $1.545 per share and received 129,450 warrants with an exercise price of $1.42 per share. The purchases were made on the same terms as for all other investors.

In connection with the September 2019 offering, Mr. Mazur purchased 2,234,700 shares of common stock at $0.8951 per share and received 2,234,700 warrants exercisable at $0.77 per share, and Mr. Holubiak purchased 558,597 shares of common stock at $0.8951 per share and received 558,597 warrants exercisable at $0.77 per share. The purchases were made on the same terms as for all other investors.

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

8. EMPLOYMENT AND CONSULTING AGREEMENTS

Employment Agreements

The Company entered into a three-year employment agreement with its then Chief Executive Officer, Leonard Mazur, effective September 12, 2014. Upon expiration, the agreement was to automatically renew for successive periods of one-year. The agreement required 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. Under the agreement, Leonard Mazur was granted options to purchase 220,000 shares of common stock. On March 30, 2016, in connection with the acquisition of LMB, Leonard Mazur resigned as Chief Executive Officer but continues to serve as Chairman of the Board under the agreement. On October 19, 2017, the Company and Mr. Mazur, entered into an amended employment agreement with a three-year term. Upon expiration, the agreement automatically renews for successive periods of one-year. Under the terms of the amended 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 March 30, 2016, in connection with the acquisition of LMB, the Company entered into a three-year employment agreement with Myron Holubiak to serve as Chief Executive Officer. Upon expiration, the agreement automatically renews for successive periods of one-year. 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 at will 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.

Consulting Agreements

Effective September 1, 2014, the Company entered into three consulting agreements. Two of the agreements are for financial consulting services including accounting, preparation of financial statements and filings with the SEC. The third agreement is for financing activities, product development strategies and corporate development. The agreements may be terminated by the Company or the consultant with 90 days written notice.

Consulting expense under the agreements for the years ended September 30, 2020 and 2019 was $324,000 and $344,000, respectively. Consulting expense for the year ended September 30, 2019 includes $20,000 paid to a financial consultant who is a stockholder of the Company. The consulting agreement with the stockholder ended in February 2019.

9. FDA REFUNDS

On August 29, 2018, the Company received notification from the Food and Drug Administration (“FDA”) that the Company was being refunded $818,343 of 2016 product and establishment fees because the fees paid by the Company exceeded the costs of the FDA’s review of the associated applications. The Company recorded the $818,343 receivable as other income during the year ended September 30, 2018 and received the refund on October 1, 2018.

In November 2019, the Company received an additional $110,207 refund from the FDA for 2016 product and establishment fees because the fees paid by the Company exceeded the costs of the FDA’s review of the associated applications. The Company recorded the $110,207 as other income during the year ended September 30, 2020.

10. COMMITMENTS AND CONTINGENCIES

Operating Lease

LMB leased office space from Akrimax (see Note 7) in Cranford, New Jersey at a monthly rental rate of $2,167 pursuant to an agreement which expired on April 30, 2019. Rent expense for the year ended September 30, 2019 was $56,063.

Effective July 1, 2019, Citius entered into a 76-month lease for office space in Cranford, NJ. Rent expense under this agreement for the year ended September 30, 2019 was $57,349.

Citius will also pay its proportionate share of real estate taxes and operating expenses in excess of the base year expenses. These costs are considered to be 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 current 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, 2020**
Operating lease cost	$ 228,828
Variable lease cost	—
Total lease cost	$ 228,828
Other information	
Weighted-average remaining lease term - operating leases	5.1 Years
Weighted-average discount rate - operating leases	8.0

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

Year Ending September 30,	
2021	$ 234,447
2022	239,306
2023	244,165
2024	249,024
2025	253,883
Thereafter	21,460
Total lease payments	1,242,285
Less: interest	(227,815)
Present value of lease liabilities	$ 1,014,470

Leases	**Classification**	**September 30, 2020**
Assets		
Lease asset	Operating	$ 986,204
Total lease assets		$ 986,204
Liabilities		
Current	Operating	$ 158,999
Non-current	Operating	855,471
Total lease liabilities		$ 1,014,470

Interest expense on the lease liability was $87,303 for the year ended September 30, 2020.

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.

11. INCOME TAXES

There was no provision for federal or state income taxes for the years ended September 30, 2020 and 2019 due to the Company's operating losses and the valuation reserve on deferred tax assets.

The income tax 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, 2020 and 2019 due to the following:

	2020	2019
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	0.7%	0.1%
Increase in the valuation reserve	26.6%	27.2%
	0.0%	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, 2020	September 30, 2019
Deferred tax assets:		
Net operating loss carryforward	$ 14,498,000	$ 10,994,000
Stock-based compensation	915,000	1,133,000
Other	1,507,000	1,202,000
Valuation allowance on deferred tax assets	(16,920,000)	(13,329,000)
Total deferred tax assets	—	—
Deferred tax liabilities:		
In-process research and development	(4,985,800)	(4,985,800)
Total deferred tax liability	(4,985,800)	(4,985,800)
Net deferred tax liability	$ (4,985,800)	$ (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, 2020 and 2019, the valuation allowance increased by $3,591,000 and $3,017,000, respectively. The increase in the valuation allowance during the years ended September 30, 2020 and 2019 was primarily due to the Company's net operating loss. At September 30, 2020, the Company has a federal net operating loss carryforward of approximately $65,000,000 which begins expiring in 2034.

As of September 30, 2020, the Company also has federal research and development credits of $1,055,000 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.

12. SUBSEQUENT EVENTS

Novellus License

On October 6, 2020 the Company, through its subsidiary NoveCite, entered into an exclusive agreement with Novellus to develop cellular therapies (see Note 3).

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, 2020, 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, 2020, 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, 2020 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, 2020.

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 2020 that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information.

None.

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 2021 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, 2020 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	1,890,000	$ 1.08	—
2020 Omnibus Stock Incentive Plan	645,000	1.22	2,465,000
Total	3,390,171	$ 2.51	2,465,000

Our equity compensation plans consist of the Citius Pharmaceuticals, Inc. 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 or the 2018 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" 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	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	Placement Agent's Unit Warrant in favor of Merriman Capital, Inc., dated September 12, 2014.	S-1/A	12/29/2015	10.12	
4.3	Form of Investor Warrant, dated September 12, 2014.	8-K	9/18/2014	10.3	
4.4	Form of Common Stock Purchase Warrant, dated May 10, 2017.	10-Q	5/15/2017	10.4	
4.5	Form of Representative's Warrant, dated August 3, 2017.	8-K	8/4/2017	4.2	
4.6	Form of Investor Warrant, dated December 15, 2017.	8-K	12/19/2017	4.1	
4.7	Form of Placement Agent Warrant, dated December 15, 2017.	8-K	12/19/2017	4.2	
4.8	Form of Investor Warrant, dated March 28, 2018.	8-K	3/29/2018	4.1	
4.9	Form of Placement Agent Warrant, dated March 28, 2018.	8-K	3/29/2018	4.2	
4.10	Form of Common Stock Purchase Warrant, dated August 13, 2018.	8-K	8/13/2018	4.1	
4.11	Form of Pre-Funded Common Stock Purchase Warrant, dated August 13, 2018.	8-K	8/13/2018	4.2	
4.12	Form of Underwriter's Common Stock Purchase Warrant, dated August 13, 2018.	8-K	8/13/2018	4.3	
4.13	Form of Investor Warrant issued April 3, 2019.	8-K	4/03/2019	4.1	
4.14	Form of Placement Agent Warrant issued April 3, 2019.	8-K	4/03/2019	4.2	
4.15	Form of Common Stock Purchase Warrant issued September 27, 2019.	8-K	9/27/2019	4.1	
4.16	Form of Pre-Funded Common Stock Purchase Warrant issued September 27, 2019.	8-K	9/27/2019	4.2	
4.17	Form of Underwriters Common Stock Purchase Warrant issued September 27, 2019.	8-K	9/27/2019	4.3	
4.18	Form of Investor Warrant issued on February 19, 2020.	8-K	2/19/2020	4.1	
4.19	Form of Placement Agent Warrant issued on February 19, 2020.	8-K	2/19/2020	4.2	
4.20	Form of Investor Warrant issued May 18, 2020.	8-K	5/18/2020	4.1	
4.21	Form of Placement Agent Warrant issued May 18, 2020.	8-K	5/18/2020	4.2	
4.22	Form of Underwriter Warrant issued August 10, 2020.	8-K	8/10/2020	4.1	

Exhibit Number	Description of Document	Registrant's Form	Dated	Exhibit Number	Filed Herewith
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	Employment Agreement between Myron Holubiak and Citius Pharmaceuticals, Inc., executed March 30, 2016, effective March 1, 2016.	8-K	4/5/2016	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	Warrant Agent Agreement between VStock Transfer, LLC and Citius Pharmaceuticals, Inc., dated August 3, 2017.	8-K	8/4/2017	4.1	
10.8	Amended and Restated Employment Agreement between Leonard Mazur and Citius Pharmaceuticals, Inc., dated October 19, 2017.	10-K	12/11/2018	10.23	
10.9	Employment Agreement between Jaime Bartushak and Citius Pharmaceuticals, Inc., dated November 27, 2017.	8-K	12/1/2017	10.1	
10.10	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	
10.11	Citius Pharmaceuticals, Inc. 2018 Omnibus Stock Incentive Plan	10-Q	2/14/2018	10.2	
10.12	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	
10.13	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	
10.14	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	
10.15	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	
10.16	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	
10.17	Citius Pharmaceuticals, Inc. 2020 Omnibus Stock Incentive Plan.	Schedule 14A	12/20/2019	Appendix A	
10.18	Form of Notice of Stock Option Grant and Stock Option Award Agreement.	10-Q	2/13/2020	10.2	

Exhibit Number	Description of Document	Registrant's Form	Dated	Exhibit Number	Filed Herewith
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	10.1	
10.20	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	
10.21	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	
10.22	Engagement letter, dated February 14, 2020, between Citius Pharmaceuticals, Inc. and the purchasers signatory thereto.	8-K	5/18/2020	10.2	
10.23	Employment Agreement, effective as of July 14, 2020, between Citius Pharmaceuticals, Inc. and Myron Czuczman.	10-Q	8/14/2020	10.3	
10.24	License Agreement, dated October 6, 2020, between NoveCite, Inc. and Novellus Therapeutics, Limited.+				X
21	Subsidiaries.	--	--	--	X
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	Certification of the Chief Executive Officer pursuant to 18 U.S.C. 1350, as adopted pursuant to Section 906 of the Sarbanes Oxley Act of 2002.	--	--	--	X
32.2	Certification of the 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.

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 16, 2020

By: /s/ Myron Holubiak
Myron Holubiak
President and 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	Executive Chairman of the Board of Directors	December 16, 2020
/s/ Myron Holubiak Myron Holubiak	President and Chief Executive Officer and Director (Principal Executive Officer)	December 16, 2020
/s/ Jaime Bartushak Jaime Bartushak	Chief Financial Officer and Chief Accounting Officer (Principal Financial Officer and Principal Accounting Officer)	December 16, 2020
/s/ Suren Dutia Suren Dutia	Director	December 16, 2020
/s/ Carol Webb Carol Webb	Director	December 16, 2020
/s/ William Kane William Kane	Director	December 16, 2020
/s/ Howard Safir Howard Safir	Director	December 16, 2020
/s/ Eugene Holuka Eugene Holuka	Director	December 16, 2020

Exhibit 10.24

Confidential

*Information in this exhibit marked [***] has been excluded pursuant to Regulation S-K, Item 601(b)(10). Such information is not material and would likely cause competitive harm to the registrant if publicly disclosed.

LICENSE AGREEMENT

THIS LICENSE AGREEMENT (this "*Agreement*") is entered into as of this 6th day of October 2020 (the "*Effective Date*"), by and between NOVELLUS THERAPEUTICS LIMITED, a company organized and existing under the laws of Ireland ("*Licensor*"), and NOVECITE, INC., a company organized and existing under the laws of the State of Delaware ("*Licensee*"). Licensor and Licensee may each be referred to in this Agreement individually as a "*Party*" and collectively as the "*Parties*."

WHEREAS, Licensor owns or has in-licensed certain Licensed Technology (as defined herein) pertaining to technology, processes and products, including, but not limited to, methods and compositions for generating the Original Cell Line (as such term is defined herein);

WHEREAS, Licensor and Citius Pharmaceuticals, Inc. ("*Citius*") entered into that certain Option Agreement, effective as of March 31, 2020 (the "*Option Agreement*"), pursuant to which Licensor granted to Citius, for the benefit of Licensee, an option to negotiate an exclusive license under the Licensed Technology in the Field (as defined herein);

WHEREAS, Licensee desires to receive from Licensor certain rights to the Licensed Technology in order that Licensee may develop and commercialize Licensed Products (as defined herein); and

WHEREAS, in furtherance of the foregoing, Citius exercised the option in accordance with the Option Agreement, Licensor agrees to grant such rights to Licensee, and Licensee agrees to use Commercially Reasonable Efforts (as defined herein) to develop and make commercially available one or more Licensed Products in accordance with this Agreement for commercial exploitation in the Field and in the Territory (as defined herein).

NOW, THEREFORE, in consideration of the mutual covenants contained in this Agreement, and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties agree as follows:

Section 1
Definitions

Unless otherwise specifically provided herein, the following terms, when used with a capital letter at the beginning, will have the following meanings:

1.1. "*ACB Specifications*" means the specifications for the ACB set forth inExhibit C.

1.2. "*Accession Cell Bank*" or "*ACB*" means the non-GMP-grade cell bank of the Original Cell Line produced by Licensor meeting the ACB Specifications and delivered to Licensee in accordance with Section 3.

1.3. "*Affiliate*" means, with respect to a Party, a person, corporation, partnership, or other entity that controls, is controlled by or is under common control with such Party. For the purposes of this definition, the word "control" (including, with correlative meaning, the terms "controlled by" or "under common control with") means the actual power, either directly or indirectly through one or more intermediaries, to direct or cause the direction of the management and policies of such entity, whether by the ownership of more than fifty percent (50%) of the voting stock of such entity, or by contract or otherwise. As of the Effective Date, Factor Bioscience Limited is an Affiliate of Licensor; provided, however, that for the purposes of Sections 1.27, 1.32, 5.5.2, 6, 8.2.1, 9.2, and 11.14, Factor Bioscience Limited shall be deemed to be an Affiliate of Licensor for the Term of this Agreement.

1.4. "*Agreement*" has the meaning set forth in the Preamble.

1.5. "*Applicable Law*" means all statutes, ordinances, regulations, rules or orders of any kind whatsoever of any agency, bureau, branch, office, court, commission, authority, department, ministry, official or other instrumentality of, or being vested with public authority under any law of, any country, state or local authority or any political subdivision thereof, or any association of countries that may be in effect from time to time and applicable to a Party's obligations or exercise of its rights under this Agreement.

1.6. "*Biosimilar Product*" means, with respect to a particular Licensed Product in a country, a product that (a) is highly similar to such Licensed Product with no clinically meaningful differences, as determined by the FDA, or a corresponding Regulatory Authority in a country other than the United States, as determined by reference to the Regulatory Approval for such product granted or approved by the applicable Regulatory Authority; (b) may be legally substituted by pharmacies in such country for such Licensed Product when filling a prescription written therefor without having to seek authorization to do so from the physician or other health care provider writing such prescription, and (c) is legally marketed and sold in such country by a third party under a Regulatory Approval filed with respect thereto by such third party.

1.7. "*Cell Line*" means (a) the Original Cell Line; (b) the Modified Cell Line; or (c) both the Original Cell Line and the Modified Cell Line.

1.8. "*Change of Control*" means, with respect to a Party, (a) a merger, share exchange, or other reorganization of such Party; (b) the sale, by one or more stockholders or holders of equity securities, of stock or equity securities representing a majority of the voting power of such Party; or (c) a sale or exclusive license of all or substantially all of the assets of such Party, or that portion of such Party's assets related to the subject matter of this Agreement, in which, for (a), (b), and (c) above, the stockholders or holders of other equity securities of such Party prior to such transaction do not own a majority of the voting power of the acquiring, surviving, or successor entity, as the case may be.

1.9. "*Combination Product*" means any product comprising a combination of (a) a Licensed Product and (b) any active ingredient(s) (other than a Licensed Product) for which rights are not included in the licenses granted under this Agreement but, with respect to the item(s) in (b) of this Section 1.9, which may each or collectively form the basis for a separately saleable product (an "*Other Product*").

1.10. "*Commercially Reasonable Efforts*" means the carrying out of obligations and tasks in a manner consistent with the efforts that a similarly situated party operating in the pharmaceutical or biologics industry would typically devote to research, development or marketing of a pharmaceutical or biologic product of similar market potential at a similar stage in development or product life, taking into account all scientific, regulatory, intellectual property, commercial and other factors that such a party would take into account, including issues of safety, toxicity and efficacy, regulatory requirements of the FDA or similar government agencies, target product profiles, costs, product labeling and competitive market conditions in the therapeutic or market niche, all based on conditions then prevailing.

1.11. "*Competitive Infringement*" means, on a Licensed Product-by-Licensed Product and country-by-country basis, where the making, using, selling, offering for sale, or importing, by any third party (other than any Sublicensee or authorized purchaser or other authorized transferee of a Party with respect to such Licensed Product), of any pharmaceutical product in the Field is Covered by any Valid Claim of any Patent within the Licensed Patents.

1.12. "*Confidential Information*" means all Information disclosed by or on behalf of one Party to the other during the negotiation of or under this Agreement in any manner, whether orally, visually, electronically, in writing or in other tangible or intangible form, that relates to Licensed Technology, the Cell Lines, Licensed Products, or this Agreement. Notwithstanding the foregoing, the following information shall not constitute "Confidential Information": (a) information lawfully in the receiving Party's possession or control prior to the time it received the information from the disclosing Party; (b) information developed by the receiving Party independently of, and without reference to, the Confidential Information of the disclosing Party; (c) information that was, at the time it was disclosed to or obtained by the receiving Party, or thereafter became, available to the public through no act or omission of the receiving Party; and (d) information lawfully obtained by the receiving Party from a third party with the right to disclose such information free of any obligations of confidentiality.

1.13. "*Control*" or "*Controlled by*" means, in the context of a license to or ownership of Intellectual Property, the ability on the part of a Party to grant access to or a license or sublicense of such Intellectual Property as provided for herein without violating the terms of any agreement or other arrangement between such Party and any third party existing at the time such Party grants such access or license or sublicense.

1.14. "*Cover*" or "*Covered*" means that the use, manufacture, sale, offer for sale, research, development, commercialization, importation or other commercial exploitation of the subject matter in question by an unlicensed entity: (a) would infringe a Valid Claim, or (b) incorporates, encompasses, references, uses or otherwise relies upon the Licensed Know-How.

1.15. "*Effective Date*" has the meaning set forth in the Preamble.

1.16. "*Exploit*" and "*Exploitation*" mean to develop, make, have made, use, sell, have sold, offer for sale, commercialize, and import.

1.17. "*Factor Agreement*" means the Second Amended and Restated Exclusive License Agreement, entered into as of March 16, 2020, by and between Factor Bioscience Limited and Licensor, as amended from time to time.

1.18. "*FDA*" means the United States Food and Drug Administration or any successor agency thereto.

1.19. "*Field*" means the treatment of acute pneumonitis of any etiology in which inflammation is a major agent in humans. For the avoidance of doubt, chronic respiratory conditions, including, but not limited to, Idiopathic Pulmonary Fibrosis (IPF), Interstitial Lung Disease, Cystic Fibrosis, Bronchiectasis, Chronic Pneumonia, Chronic Bronchitis, Asthma, Pulmonary Fibrosis, Chronic Obstructive Pulmonary Disease (COPD), Pulmonary Hypertension, Lung Cancer, Emphysema, and Pleural Effusion, and non- respiratory conditions are not included in the Field.

1.20. "*First Commercial Sale*" means, following Regulatory Approval in a particular jurisdiction, the first arm's-length sale or other transfer for value of a Licensed Product by or on behalf of Licensee, or an Affiliate or Sublicensee, to an unrelated third party in such jurisdiction.

1.21. "*Fiscal Quarter*" means each of the following three (3) month periods during each year: January 1 through March 31; April 1 through June 30; July 1 through September 30; and October 1 through December 31.

1.22. "*IND*" means an Investigational New Drug Application (or the foreign equivalent thereof) filed with the FDA required for the initiation of clinical trials in humans for the applicable Licensed Product in the United States.

1.23. "*Information*" means all information, know-how, data, results, technology, materials, business or financial information of any type whatsoever, in any tangible or intangible form, provided by or on behalf of one Party to the other Party, either in connection with the discussions and negotiations pertaining to this Agreement or in the course of performing this Agreement, or that otherwise relates to the Licensed Technology or the Cell Lines, whether disclosed orally, visually, electronically, in writing or in other tangible or intangible form, and which may include data, knowledge, practices, processes, ideas, research plans, antibodies, small molecules, compounds, targets, biological and chemical formulations, structures and designs, laboratory notebooks, proof of concept and pre-clinical studies, formulation or manufacturing processes and techniques, scientific, manufacturing, marketing and business plans, and financial and personnel matters relating to the disclosing Party or to its present or future products, sales, suppliers, customers, employees, investors or business.

1.24. "*Intellectual Property*" means all (A) patents, patent applications, patent disclosures and all related continuation, continuation-in-part, divisional, reissue, reexamination, post-grant proceeding, utility model, certificate of invention and design patents, applications, registrations and applications for registration, and any equivalent in any jurisdiction; (B) trademarks, service marks, trade dress, Internet domain names, logos, trade names and corporate names and registrations and applications for registration thereof; (C) copyrights and registrations and applications for registration thereof, including all moral rights; (D) Information, inventions, trade secrets and confidential information, whether patentable or non- patentable and whether or not reduced to practice, know-how, show how, manufacturing and product processes and techniques, research and development information, notebooks, formulae, diagrams, technical and engineering specifications, business and marketing plans and customer and supplier lists and other information; (E) other proprietary rights relating to any of the foregoing (including remedies against infringement thereof and rights of protection of interest therein under the laws of all jurisdictions); and (F) copies and tangible embodiments thereof.

1.25. "*Know-How*" means all unpatented inventions, technology, methods, materials (including biological and pharmaceutical materials), know-how, studies, pre-clinical and clinical data (including toxicology and safety data), tests and assays, reports, manufacturing processes, regulatory filings (including drafts) and regulatory approvals.

1.26. "*Licensed Know-How*" means all Know-How and other information Controlled by Licensor or its Affiliates as of the Effective Date or during the Term, that are reasonably necessary or useful to (a) Exploit Licensed Products in the Field in the Territory and (b) develop, make, have made, use and import the Cell Lines, the ACB, or the MCB for the purpose of Exploiting Licensed Products in the Field in the Territory.

1.27. "*Licensed Patents*" means (a) the Patents set forth on Exhibit B, (b) any Patents Controlled by Licensor and its Affiliates any time following the Effective Date that are necessary or reasonably useful for the Exploitation of the Licensed Products in the Field (which, for the avoidance of doubt, includes, without limitation, any and all such Patents that are useful for the developing, making, having made, using and importing of the Cell Lines, the ACB, or the MCB in connection with Exploiting the Licensed Products), and include at least one claim that is directed to subject matter disclosed in the Patents described in clause (a) above, (c) all foreign Patents corresponding to the foregoing specific patents and patent applications described in clause (a) through clause (c) above. The Parties shall work together in good faith from time to time to amend Exhibit B to include the Patents described in clause (b) of this Section 1.27, provided, however, that the failure to include such a patent in Exhibit B shall not affect its status as a Licensed Patent.

1.28. "*Licensed Product"* means a product that: (a) comprises one or more of the Cell Lines, and (b) is formulated for administration to a human subject.

1.29. "*Licensed Technology*" means the Licensed Patents and Licensed Know-How.

1.30. "*Licensee*" means Novecite, Inc.

1.31. "*Licensor*" means Novellus Therapeutics Limited.

1.32. "*Licensor Revenue*" means any consideration actually received by Licensor or its Affiliates from a third party as consideration for a sale, license, option or similar transaction involving the Original Cell Line (net of any tax or similar withholding obligations imposed by any tax or other governmental authority) including without limitation license fees, technology access fees, upfront payments, milestone payments, sales-based royalties, sales milestone payments, other payments calculated on the basis of sales, and minimum sales royalties. Licensor Revenue excludes (i) purchases of equity or debt of Licensor or any Affiliate; (ii) payments made for Licensor's or its Affiliates' performance of any research or development of any products (or reimbursement of any of Licensor's or its Affiliates' costs and expenses related to the research and development of any products); (iii) any payment or reimbursement of any costs resulting from Licensor's activities with respect to its patents; and (iv) other payments made by a third party as consideration for Licensor's or its Affiliates' performance of services or provision of goods.

1.33. "*Master Cell Bank*" or "*MCB*" means any one or more GMP-grade cell banks of a Cell Line that (a) is derived from the ACB, and (b) can be used as the starting material for the manufacturing of Licensed Products.

1.34. "*Modified Cell Line*" means all derivatives of the Original Cell Line, whether modified or unmodified, including without limitation, fully or partially differentiated cell lines derived from the Original Cell Line.

1.35. "*Net Sales*" means gross amounts invoiced or otherwise received for Licensee's, its Affiliates', or Sublicensees' sales of Licensed Product, less the sum of the following: (a) import, export, excise and sales taxes, custom duties, value added taxes, tariffs or other fees leveled by government authorities, and other consumption taxes similarly incurred or other governmental charges levied to the extent included on the bill or invoice or as a separate item; (b) costs of insurance, packing, shipping, handling, and transportation from the place of manufacture to the customer's premises or point of use; (c) credit for returns, allowances, or trades, including credits or allowances additionally granted upon rejections or recalls, claims returns pursuant to agreements (including, without limitation, managed care agreements), warranty claims, or claims allowed under government regulations, to the extent actually allowed and taken; (d) discounts, credits, charge-back payments, and rebates actually granted or administrative fees actually booked to trade customers, patients (including those in the form of a coupon or voucher), managed health care organizations, pharmaceutical benefit managers, group purchasing organizations and national, state or local governments, and to the agencies, purchasers and reimbursers of managed health organizations, pharmaceutical benefit managers, group purchasing organizations, or federal, state or local governments; and (e) amounts actually written off as uncollectible. The sale of a Licensed Product by a selling party to another selling party for resale by such selling party to a third party shall not be deemed a sale for the purposes of this definition of "Net Sales," *provided, however,* that the subsequent resale is included in the computation of "Net Sales" by the selling party that resells such Licensed Product. Transfers or dispositions of Licensed Products as free promotional samples in commercially reasonable amounts and Licensed Products used in pre-clinical or clinical development activities shall be disregarded in determining Net Sales. The gross amounts invoiced and all permitted deductions shall be determined in accordance with the selling party's usual and customary accounting methods, which are in accordance with U.S. generally accepted accounting principles (GAAP) or international financial reporting standards, in either case, consistently applied.

On a country-by-country basis, if a Licensed Product is sold in a country as part of a Combination Product, Net Sales of such Licensed Product for the purpose of determining royalties due hereunder shall be calculated as follows:

(i) In the event that both (x) the Licensed Product is sold separately in finished form in such country during a Fiscal Quarter and (y) the Other Product(s) in such Combination Product are sold separately in finished form in such country during such Fiscal Quarter, then Net Sales of such Licensed Product shall be determined by multiplying the actual Net Sales of the Combination Product calculated pursuant to the preceding provisions of this Section 1.35 ("*Actual Combination Product Net Sales*") in such country during such Fiscal Quarter by the fraction, A / (A+B) where A is the weighted average sale price of the Licensed Product when sold separately in finished form in such country during such Fiscal Quarter, and B is the weighted average sale price of the Other Product(s) in the Combination Product when sold separately in finished form in such country during such Fiscal Quarter.

(ii) In the event that the Licensed Product in such Combination Product is sold separately in finished form in such country during a Fiscal Quarter, but the Other Product(s) in such Combination Product are not sold separately in finished form in such country during such Fiscal Quarter, then Net Sales of such Licensed Product shall be calculated by multiplying the Actual Combination Product Net Sales of the Combination Product in such country during such Fiscal Quarter by the fraction A / C where A is the weighted average sale price of such Licensed Product when sold separately in finished form in such country during such Fiscal Quarter and C is the weighted average sale price of the Combination Product in such country during such Fiscal Quarter.

(iii) In the event that the Licensed Product in such Combination Product is not sold separately in finished form in such country during a Fiscal Quarter, but the Other Product(s) in such Combination Product are sold separately in finished form in such country during such Fiscal Quarter, Net Sales of such Licensed Product shall be calculated by multiplying the Actual Combination Product Net Sales of the Combination Product by the fraction one (1) minus (B / C), where B is the weighted average sale price of the Other Product(s) in the Combination Product when sold separately in finished form in such country during such Fiscal Quarter, and C is the weighted average sale price of the Combination Product in such country during such Fiscal Quarter.

(iv) In the event that neither the Licensed Product in such Combination Product is sold separately in finished form in such country during a Fiscal Quarter, nor the Other Product(s) in such Combination Product are sold separately in finished form in such country during such Fiscal Quarter, then the fair market value of the Licensed Product and such Other Product(s) shall be mutually agreed in good faith by the Parties to establish the Actual Combination Product Net Sales of such Combination Product.

1.36. "*Original Cell Line*" means the human cell line described in Exhibit D.

1.37. "*Other Product*" has the meaning set forth in Section 1.9.

1.38. "*Party*" or "*Parties*" has the meaning set forth in the Preamble.

1.39. "*Patent*" means all patents and patent applications and all substitutions, divisions, continuations, continuations-in-part, any patent issued with respect to any such patent applications, any reissue, reexamination, utility models or designs, renewal or extension (including any supplementary protection certificate) of any such patent, and any confirmation patent or registration patent or patent of addition based on any such patent, and all counterparts and equivalents of any of the foregoing in any country or jurisdiction.

1.40. "*Phase I Clinical Trial*" means a clinical trial generally consistent with 21 CFR §312.21(a) that is required for receipt of clearance or marketing authorization of a Licensed Product from the applicable Regulatory Authority and which is conducted to evaluate safety of a Licensed Product for a particular indication or indications in healthy subjects.

1.41. "*Phase IIb Clinical Trial*" means a clinical trial generally consistent with 21 CFR §312.21(b) that is required for receipt of clearance or marketing authorization of a Licensed Product from the applicable Regulatory Authority and which is conducted to assess the optimal manner of use of such a Licensed Product (dose and dose regimens) of a Licensed Product for a particular indication or indications in patients with the disease or condition under study. Any clinical trial that is not a Phase III Clinical Trial and which is conducted to evaluate a Licensed Product that has already been tested in a Phase I Clinical Trial shall be deemed a Phase IIb Clinical Trial.

1.42. "*Phase III Clinical Trial*" means a clinical trial generally consistent with 21 CFR §312.21(c) that is required for receipt of clearance or marketing authorization of a Licensed Product from the applicable Regulatory Authority and which is conducted after preliminary evidence suggesting effectiveness of the Licensed Product has been obtained, and is intended to gather additional information to evaluate the overall benefit-risk relationship of the Licensed Product for a particular indication and provide an adequate basis for physician labeling.

1.43. "*Regulatory Approval*" means the approval (including label expansions to include additional indications), license, registration, clearance or authorization of the applicable Regulatory Authority necessary for the lawful marketing, commercialization and sale of a Licensed Product (and, (a) as the term "Regulatory Approval" is used in Section 1.6 for the lawful marketing, commercialization and sale of a Biosimilar Product and (b) as the term "Regulatory Approval" is used in Section 11.14 for the lawful marketing, commercialization and sale of the applicable subject matter) in the Field in a country or jurisdiction of the Territory.

1.44. "*Regulatory Authority*" means the FDA or any similar foreign governmental regulatory authority involved in the granting of authorization to conduct clinical trials or Regulatory Approvals for the manufacture, sale, pricing and/or reimbursement of a Licensed Product in the Field.

1.45. "*Regulatory Exclusivity*" means, with respect to a Licensed Product, marketing exclusivity conferred by the applicable Regulatory Authority in a country or jurisdiction of the Territory on the holder of a Regulatory Approval for such Licensed Product in such country or jurisdiction, including, by way of example and not of limitation, regulatory data exclusivity, orphan drug exclusivity, new chemical entity exclusivity and pediatric exclusivity.

1.46. "*Royalty Term*" means, on a Licensed Product-by-Licensed Product and country-by- country basis, the period of time that begins on the date of First Commercial Sale of a particular Licensed Product in a particular country and ends on the earlier of (a) the date on which a Biosimilar Product is first marketed, sold, or distributed by Licensor or any third party in the applicable country of the Territory or (b) the ten (10) year anniversary of the date of expiration of the last-to-expire Valid Claim Covering such Licensed Product in such country. In the case of a country where no Licensed Patent ever exists, the Royalty Term shall mean the period of time that begins on the date of First Commercial Sale of a Licensed Product in such country and ends on the later of (x) the date of expiry of such Licensed Product's Regulatory Exclusivity, if any, in the particular country, and (y) the ten (10)-year anniversary of the date of such First Commercial Sale.

1.47. "*Sublicensee*" means a third party granted a sublicense to any of the rights granted to Licensee under this Agreement.

1.48. "*Sublicense Fees*" means any consideration actually received by Licensee or its Affiliates from a Sublicensee as consideration for a sublicense, option or immunity with respect to any of the rights granted to Licensee under this Agreement (net of any tax or similar withholding obligations imposed by any tax or other governmental authority), including without limitation license fees, technology access fees, upfront payments, milestone payments in excess of or in addition to the Milestone Payments payable to Licensor hereunder. Sublicense Fees excludes (i) Milestone Payments payable to Licensor hereunder; (ii) Sublicensing Royalty Revenue; (iii) purchases of equity or debt of Licensee or any Affiliate; (iv) payments made for Licensee's or its Affiliates' performance of any research or development of any Licensed Products (or reimbursement of any of Licensee's or its Affiliates' costs and expenses related to the research and development of any Licensed Products); (v) any payment or reimbursement of any costs resulting from Licensee's activities with respect to the Licensed Patents; and (vi) other payments made by a Sublicensee as consideration for Licensee's or its Affiliates' performance of services or provision of goods.

1.49. "*Sublicensing Royalty Revenue*" means sales-based royalties, sales milestone payments, other payments calculated on the basis of sales, and minimum sales royalties actually received by Licensee or its Affiliates from a Sublicensee as consideration for the grant of rights under Licensed Technology to such Sublicensee.

1.50. "*Term*" has the meaning set forth in Section 7.1.

1.51. "*Territory*" means Earth.

1.52. "*Valid Claim*" means: (a) any currently pending claim of a patent application within the Licensed Patents that has not been abandoned; or (b) a claim of a granted and unexpired patent within the Licensed Patents that (i) has not been revoked, held invalid, or declared unpatentable or unenforceable by a decision of a court or other governmental agency of competent jurisdiction that is unappealable or unappealed in the time allowed for appeal; (ii) has not been rendered or admitted to be invalid, dedicated to the public, abandoned or unenforceable through reissue or disclaimer or otherwise; or (iii) has not been lost through an interference proceeding. Notwithstanding the foregoing, if a particular claim has not issued within five (5) years of the date of first examination on the merits of such claim and the pending patent application containing such claim, it shall not be considered a Valid Claim for purposes of this Agreement unless and until such claim is included in an issued Patent.

Section 2
Licenses

2.1. *License Grant*.

Licensor hereby grants to Licensee an exclusive, even as to Licensor, royalty-bearing license, with the right to grant sublicenses pursuant to Section 2.2 and transferable with this Agreement pursuant to Section 11.2, under the Licensed Technology to (a) Exploit Licensed Products in the Territory in the Field and (b) develop, make, have made, use and import the ACB, MCB and Cell Lines for the purpose of Exploiting Licensed Products in the Territory in the Field.

2.2. Sublicensing.

Licensee may sublicense the rights granted to it under Section 2.1 through multiple tiers. Notwithstanding the foregoing, until a Change of Control of Licensee, Licensee shall not have the right to sublicense the rights granted to it under Section 2.1 to Licensee's Affiliates (inclusive of Citius or an Affiliate of Citius) without Licensor's prior written consent, and any Sublicensee shall not have the right to sublicense the rights granted to it by Licensee to Citius or Citius' Affiliates. Each such sublicense shall be in writing and contain terms not inconsistent with the terms and conditions of this Agreement applicable to the licenses granted to Licensee hereunder. In each case, Licensee will be responsible for the performance of its Sublicensees relevant to this Agreement, including, without limitation, making any payments provided for hereunder. Subject to Licensee's right to redact the confidential information of a Sublicensee, Licensee will provide Licensor with a complete, confidential copy of each such sublicense agreement executed by Licensee and any amendments thereto, and will promptly notify Licensor of the termination of any such sublicense, and any such copy shall be Licensee's Confidential Information subject to Section 8.5. For the avoidance of doubt, contract research organizations, contract manufacturing organizations and similar third parties to which Licensee or Sublicensees delegate development, manufacturing or commercialization activities relating to the Licensed Product may perform such development, manufacturing or commercialization activities on behalf of Licensee or such Sublicensees without a sublicense of the rights granted to Licensee hereunder.

2.3. *Publication Rights.*

Licensee shall have the right to publish, present or otherwise disclose, including in scientific journals or promotional literature, information pertaining to the Licensed Technology or any Licensed Product, subject to this Section 2.3. If Licensee desires to submit any publication that would disclose Confidential Information of Licensor, Licensee will provide Licensor with thirty (30) days' prior written notice of such proposed publication or fifteen (15) days' prior written notice of any presentation (such applicable period, the "*Review Period*") and a copy of such proposed publication or presentation. Licensor will use reasonable efforts to complete its review of such proposed publication or presentation promptly, and in any event will complete its review within the applicable Review Period. If during the Review Period, Licensee receives written notice from Licensor identifying specific Confidential Information of Licensor in such a proposed publication or presentation, then, at the reasonable request of Licensor in such notice, Licensee shall, and shall use Commercially Reasonable Efforts to ensure that its Affiliates and Sublicensees, delete such Confidential Information from the proposed publication or delay such publication or presentation for up to an additional thirty (30) days in order to permit Licensor to file a patent application covering such Confidential Information. For the avoidance of doubt, Licensee shall not be required to submit to Licensor for review publications pertaining to the Licensed Technology or any Licensed Product if such publications do not include Licensor's Confidential Information.

2.4. *No Additional Rights.*

2.4.1. *No Grant of Other Technology or Patent Rights.*

Each Party understands and acknowledges that the other Party owns its own Intellectual Property and all rights therein. Except as otherwise expressly provided in this Agreement, under no circumstances shall a Party hereto, as a result of this Agreement, obtain any ownership interest or license, or be deemed to obtain any ownership interest or license, in or to any technology, know-how, patents, patent applications, products, or materials of the other Party, including, but not limited to, items Controlled or developed by the other Party, at any time pursuant to this Agreement. This Agreement does not create, and shall under no circumstances be construed or interpreted as creating, an obligation on the part of either Party to grant any license to the other Party other than as expressly set forth herein. Any further contract or license agreement between the Parties shall be in writing. No licenses are implied by Licensor to Licensee, except as specifically stated in this Agreement. Except as explicitly set forth in this Agreement, Licensor shall not be deemed by estoppel or implication to have granted Licensee any license or other right to any Intellectual Property of Licensor or its Affiliates.

2.4.2. *Reserved Rights*.

Except as set forth in Section 11.14, all rights and interests not expressly granted to Licensee under this Agreement are reserved by Licensor (the "*Reserved Interests*") for itself, its licensors, and other licensees and sublicensees, including, but not limited to, the rights to use and grant licenses under the Licensed Technology and/or any other technology Controlled by Licensor or its Affiliates to make, have made, use, offer to sell, sell, have sold and import products (other than Licensed Products) in the Territory for use outside the Field. Subject to Licensor's payment obligations in Section 5.3, and except as set forth in Section 11.14, it shall not be a breach of this Agreement for Licensor, acting directly or indirectly, to exploit its Reserved Interests in any manner anywhere in the Territory, including, but not limited to, the research, development and commercialization or licensing of others to research, develop and commercialize products (other than Licensed Products), in the Territory.

Section 3
ACB and Licensed Know-How Supply

3.1. *General*.

As soon as is reasonably practicable following the Effective Date, at Licensee's cost and expense, Licensor shall develop and deliver the ACB meeting the ACB Specifications to Licensee (or third party selected by Licensee).

3.2. *Delivery and Nonconforming ACB*.

Licensor warrants that Licensor has made available to Licensee all material information regarding the ACB in Licensor's possession and control as of the Effective Date. Concurrently with its delivery of the ACB, Licensor shall deliver a report certifying that the ACB meets the ACB Specifications. Licensor warrants that the ACB will meet the ACB Specifications and be fit for the manufacture of the MCB by Licensee or its designee. If Licensee, acting reasonably, determines that the ACB does not conform to the ACB Specifications, then Licensee shall promptly notify Licensor of the details of such nonconformance and Licensor shall use its Commercially Reasonable Efforts to promptly deliver a conforming ACB to Licensee or third party designated by Licensee.

Section 4
Due Diligence

4.1. *Regulatory Approval*.

Licensee will be solely responsible, at Licensee's expense, for securing any federal, state, or local Regulatory Approval from Regulatory Authorities necessary for commercial sale of Licensed Products in the Field in the Territory, and Licensee shall deliver regular reports to Licensor concerning such Regulatory Approvals in accordance with Section 5.4.2.

4.2. *Licensee Responsibilities*.

4.2.1. Licensee shall be solely responsible, at its expense, for the commercialization of Licensed Products in the Field in the Territory. Licensee will use Commercially Reasonable Efforts to make commercially available at least one Licensed Product in the Field in the United States and at least one of the following countries: United Kingdom, France, Germany, China, or Japan (each a "*Major Market Country*") during the Term.

4.2.2. Licensee shall provide periodic updates on Licensee's Licensed Product development and commercialization activities in the Field in the Territory by submitting to Licensor written reports not later than June 30 and December 31 of each year during the Term.

4.2.3. Licensee shall achieve the following milestones ("*Milestones*"): (a) on or before the five (5) year anniversary of the Effective Date, file an IND for a Licensed Product in the Field; and (b) on or before the ten (10) year anniversary of the Effective Date, Licensee shall have received Regulatory Approval for a Licensed Product in the Field in the United States or in a Major Market Country.

Section 5
Consideration; Records & Reports

5.1. *Upfront Consideration*.

In partial consideration for the rights granted by Licensor to Licensee under this Agreement, Licensee shall: (a) pay to Licensor on or before the Effective Date the non-refundable, one- time upfront payment in the amount set forth in Section 5.1(a) of Exhibit A, and (b) issue to Novellus LLC Five Hundred (500) shares of Licensee's Common Stock pursuant to a subscription agreement in substantially the form as attached hereto as Exhibit E. The full amount of the payment obligations set forth in this Section 5.1 shall represent a mature obligation as of the Effective Date, which shall not be contingent on any action or performance by Licensor.

5.2. *Continuing Payments*.

5.2.1. *Milestone Payments*.

The first time a Milestone set forth in Section 5.2.1 of Exhibit A is achieved by Licensee, its Affiliate, or a Sublicensee, Licensee shall pay to Licensor the corresponding milestone payment set forth in Section 5.2.1 of Exhibit A (each, a "*Milestone Payment*"), such Milestone Payment to be made within thirty (30) days of the achievement of the applicable Milestone. For the avoidance of doubt, in the event that the achievement of one or more Milestones is skipped or avoided (*e.g.*, by obtaining Regulatory Approval for a Licensed Product before enrolling the first patient in a Phase IIb Clinical Trial or a Phase III Clinical Trial for such Licensed Product), then Licensee shall make the Milestone Payments associated with all such skipped or avoided Milestones upon the earlier of (a) achieving the next Milestone listed on Exhibit A, or (b) the First Commercial Sale of such Licensed Product. No Milestone Payment will be payable more than one time.

5.2.2. *Royalties on Net Sales*.

During the Royalty Term, on a Fiscal Quarter basis, Licensee shall pay to Licensor a royalty equal to the percentage of Net Sales set forth in Section 5.2.2 of Exhibit A ("*Royalty on Net Sales*"). On a country-by-country basis, upon expiration of the last to expire of a Valid Claim in the subject country or if no Valid Claim exists in the subject country, the Royalty on Net Sales due thereafter under this Section 5.2.2 shall be reduced by [***] ([***]%) in the applicable country. On a country-by-country basis, upon expiration of the Royalty Term in the subject country, Licensee shall have a fully-paid, royalty-free, non-exclusive license under the Licensed Know-How for development and commercialization of Licensed Products in the applicable country in the Field. Payments under this Section 5.2.2 shall be due within sixty (60) days of the end of each Fiscal Quarter.

5.2.3. *Royalties on Sublicense Fees*.

Licensee shall, within thirty (30) days of receipt of any Sublicensee Fees, pay to Licensor an amount equal to the percentage of such Sublicense Fees received as set forth in Section 5.2.3 of Exhibit A.

5.2.4. *No Multiple Royalties*.

For the avoidance of doubt, no multiple Royalties on Net Sales will be required to be paid because a Licensed Product or its manufacture, use, sale or importation is covered by more than one (1) Valid Claim.

5.3. *Licensor's Payment Obligations*.

Licensor shall, on a Fiscal Quarter basis, pay to Licensee an amount equal to fifty percent (50%) of the Licensor Revenue received in such Fiscal Quarter. Payments under this Section 5.3 shall be due within sixty (60) days of the end of any Fiscal Quarter during which Licensor Revenue is received.

5.4. *Records and Reports*.

5.4.1. *Reports on Development Activities*.

Licensee shall maintain customary records of the development and commercialization activities conducted by Licensee hereunder, and all data and other information resulting from such activities. Such records shall fully and properly reflect all work done and results achieved in the performance of the development and commercialization activities in good scientific manner appropriate for regulatory and patent purposes. Licensor shall have the right to review and copy such records maintained by Licensee at reasonable times and to obtain access to the originals to the extent necessary or useful for regulatory and patent purposes. Licensee shall provide Licensor with annual written reports detailing Licensee's development and commercialization activities under this Agreement for the immediately preceding year.

5.4.2. *Regulatory Reports*.

Licensee shall keep Licensor informed of regulatory developments relating to any Licensed Products in the Field in the Territory through its delivery of the reports described in Section 5.4.1.

5.4.3. Regulatory Responsibilities.

Subject to the terms and conditions of this Agreement, as between Licensee and Licensor, Licensee shall be solely responsible for all regulatory matters for Licensed Products in the Field in the Territory, including preparing and filing any and all regulatory materials for each Licensed Product, at its sole expense.

5.4.4. Royalty Reports and Payments.

5.4.4.1. *Licensee's Obligations*. Within sixty (60) days following the end of each Fiscal Quarter, commencing with the Fiscal Quarter in which the First Commercial Sale of any Licensed Product is made anywhere in the Territory, Licensee shall provide Licensor with a report containing the following information for the applicable Fiscal Quarter, on a Licensed Product basis: (i) the amount of Net Sales in the Territory; (ii) calculation of Net Sales in the Territory showing deductions provided for in the definition of "Net Sales"; (iii) a calculation of the royalty payment due on such Net Sales; and (iv) the exchange rate for such country. Concurrent with the delivery of the applicable quarterly report, Licensee shall pay in U.S. dollars all amounts due to Licensor pursuant to this Agreement with respect to Net Sales by Licensee and its Affiliates and Sublicensees for such Fiscal Quarter. All payments due to Licensor hereunder shall be made in U.S. dollars by wire transfer of immediately available funds into an account designated by Licensor. If Licensor does not receive payment of any sum due to by the due date, simple interest shall thereafter accrue on the sum due to Licensor until the date of payment at the per annum rate of [***] ([***]%) over the then-current prime rate reported in *The Wall Street Journal* or the maximum rate allowable by Applicable Laws, whichever is lower.

5.4.4.2. *Licensor's Obligations*. Within sixty (60) days following the end of each Fiscal Quarter during which Licensor receives Licensor Revenue, Licensor shall provide Licensee with a report containing sufficient information to demonstrate the accuracy of the payment made by Licensor pursuant to Section 5.3. Concurrent with the delivery of the applicable quarterly report, Licensor shall pay in U.S. dollars all amounts due to Licensee pursuant to this Agreement for such Fiscal Quarter. All payments due to Licensee hereunder shall be made in U.S. dollars by wire transfer of immediately available funds into an account designated by Licensee. If Licensee does not receive payment of any sum due to by the due date, simple interest shall thereafter accrue on the sum due to Licensee until the date of payment at the per annum rate of [***] ([***]%) over the then-current prime rate reported in *The Wall Street Journal* or the maximum rate allowable by Applicable Laws, whichever is lower.

5.5. Audit and Inspection Rights.

5.5.1. *Licensor's Rights*. Licensee and its Affiliates and Sublicensees will maintain records in sufficient detail to permit Licensor to confirm the accuracy of the calculation of payments made by Licensee under this Agreement, including royalty payments and the achievement of Milestones. Upon reasonable prior notice, the records of Licensee and its Affiliates shall be available during regular business hours (without undue disruption of Licensee's or its Affiliate's business) for a period of three (3) years from the end of the calendar year to which they pertain for examination by a nationally recognized independent accountant selected by Licensor and reasonably acceptable to Licensee or its Affiliate, for the sole purpose of verifying the accuracy of the reports and payments furnished by Licensee pursuant to this Agreement. Any such auditor shall not disclose Licensee's Confidential Information, except to the extent such disclosure is necessary to verify the accuracy of the reports furnished by Licensee or the amount of payments due by Licensee to Licensor under this Agreement. Licensor shall provide Licensee with a copy of the accountant's report. Licensor shall have the right, one time per calendar year, to request that Licensee exercise its audit rights with respect to any Sublicensee. If Licensee has already exercised its audit rights with respect to the subject Sublicensee for the relevant calendar year, then Licensor shall have the right to request that Licensee share the results of such audit with Licensor. Any amounts shown to be owed but unpaid shall be paid within thirty (30) days from Licensee's receipt of the accountant's report, plus interest (as set forth above) from the original due date. Licensor shall bear the full cost of such audit unless such audit discloses an underpayment by Licensee of more than five percent (5%) of the amount due during the Fiscal Quarter(s) audited, in which case Licensee shall reimburse Licensor for the reasonable, documented fees paid to the relevant accountant by Licensor.

5.5.2. *Licensee's Rights*. Licensor and its Affiliates will maintain records in sufficient detail to permit Licensee to confirm the accuracy of the calculation of payments made by Licensor under Section 5.4.4.2 of this Agreement. Upon reasonable prior notice, the records of Licensor and its Affiliates shall be available during regular business hours (without undue disruption of Licensor's or its Affiliate's business) for a period of three (3) years from the end of the calendar year to which they pertain for examination by a nationally recognized independent accountant selected by Licensee and reasonably acceptable to Licensor or its Affiliate, for the sole purpose of verifying the accuracy of the reports and payments furnished by Licensor pursuant to Section 5.4.4.2 of this Agreement. Any such auditor shall not disclose Licensor's Confidential Information, except to the extent such disclosure is necessary to verify the accuracy of the reports furnished by Licensor or the amount of payments due by Licensor to Licensee under Section 5.4.4.2 of this Agreement. Licensee shall provide Licensor with a copy of the accountant's report. Any amounts shown to be owed but unpaid shall be paid within thirty (30) days from Licensor's receipt of the accountant's report, plus interest (as set forth above) from the original due date. Licensee shall bear the full cost of such audit unless such audit discloses an underpayment by Licensor of more than five percent (5%) of the amount due during the Fiscal Quarter(s) audited, in which case Licensor shall reimburse Licensee for the reasonable, documented fees paid to the relevant accountant by Licensee.

5.6. *Taxes*.

Each Party shall be solely responsible for the payment of all taxes imposed on its share of income arising directly or indirectly from the efforts of the Parties under this Agreement. The Parties agree to cooperate with one another and use reasonable efforts to reduce or eliminate tax withholding or similar obligations in respect of payments made by a Party to the other Party under this Agreement. To the extent either Party is required to deduct and withhold taxes on any payment to the other Party, such Party shall pay the amounts of such taxes to the proper governmental authority in a timely manner and promptly transmit to the other Party an official tax certificate or other evidence of such withholding sufficient to enable the other Party to claim such payment of taxes. Each Party shall use reasonable efforts to provide the other Party with any tax forms that may be reasonably necessary in order for the other Party to not withhold tax or to withhold tax at a reduced rate under an applicable bilateral income tax treaty. Each Party shall provide the other with reasonable assistance to enable the recovery, as permitted by Applicable Laws, of withholding taxes, value added taxes, or similar obligations resulting from payments made under this Agreement, such recovery to be for the benefit of the Party bearing such withholding tax or value added tax.

Section 6
Representations, Warranties and Covenants

6.1. *Representations and Warranties of Licensor*. Licensor hereby represents and warrants to Licensee that, as of the Effective Date:

6.1.1. Licensor is duly organized, validly existing and in good standing under the laws of its jurisdiction of organization, with full power and authority to operate its properties and to carry on its business as presently conducted.

6.1.2. Except as set forth in Schedule 6.1.2, Licensor is the sole owner of the Licensed Technology. Factor is the sole owner of the Licensed Patents and the Licensed Know-How exclusively licensed to Licensor pursuant to the Factor Agreement.

6.1.3. The execution of this Agreement and performance of Licensor's obligations under this Agreement do not conflict with, cause a default under, or violate any existing contractual obligation that may be owed by Licensor or any Affiliate of Licensor to any third party.

6.1.4. There is no action, suit, proceeding or investigation pending or, to Licensor's and its Affiliates' knowledge, currently threatened orally or in writing against or affecting Licensor or any Affiliate thereof that questions the validity of this Agreement or the right of Licensor to enter into this Agreement or consummate the transactions contemplated hereby and, to Licensor's and its Affiliates' knowledge, there is no basis for the foregoing.

6.1.5. No consent, approval, order or authorization of, or registration, qualification, designation, declaration or filing with, any governmental authority, or any third party, on the part of Licensor or any Affiliate thereof is required in connection with its execution, delivery and performance of this Agreement.

6.1.6. Licensor has the right to grant the licenses and rights that it purports to grant under this Agreement and has not granted to any third party any license or other right that conflicts with the licenses and rights granted under this Agreement.

6.1.7. To Licensor's knowledge, the issued and unexpired claims included in the Licensed Patents existing as of the Effective Date are valid and enforceable.

6.1.8. To Licensor's knowledge, no reexamination, interference, invalidity, opposition, nullity or similar claim or proceeding is pending or threatened with respect to any Licensed Patent.

6.1.9. Other than the Licensed Patents set forth on Exhibit B, Licensor nor any of its Affiliates owns or controls any patents (i) necessary or useful for developing, making, having made, using and importing of the Cell Lines, the ACB, or the MCB or (ii) necessary or useful for or that would be infringed by, the manufacture, use, sale, offering for sale or import of Licensed Products in the Field.

6.1.10. None of Licensor or any of its Affiliates has received written notice from any third party claiming that the manufacture, use, sale, offer for sale or import of any Licensed Product infringes, misappropriates or violates, or would infringe, misappropriate or violate the patent or other intellectual property rights of any third party.

6.1.11. There are no claims, judgments, liens, encumbrances, or settlements against Licensor or any of its Affiliates with respect to the Licensed Technology, and none of Licensor or any of its Affiliates is a party to any legal action, suit or proceeding relating to the Licensed Technology.

6.1.12. None of Licensor or its Affiliates has received any communication from any third party, including any Regulatory Authority or other governmental authority, threatening any action, suit or proceeding which would be reasonably expected to adversely affect or restrict the ability of Licensor to consummate transactions perform its obligations contemplated under this Agreement.

6.1.13. To the actual knowledge of Licensor and its Affiliates, the developing, making, having made, using and importing of the Cell Lines, the ACB, or the MCB, or the manufacture, use, sale, offering for sale or import of Licensed Products in the Field do not infringe any patents owned or controlled by any third party.

6.1.14. None of Licensor or its Affiliates has employed, or otherwise used in any capacity, the services of any individual or entity debarred or disqualified under Applicable Laws.

6.1.15. None of Licensor's or its Affiliates' research or development of the Licensed Technology, manufacture of Licensed Products, or research leading to the inventions Covered by a Valid Claim of the Licensed Patents was supported in whole or part by funding or grants by any governmental agency or philanthropic or charitable organization.

6.1.16. Licensor has the right to deliver the ACB as set forth in Section 3.

6.1.17. The Factor Agreement is enforceable and in full force and effect. Licensor is in compliance with and has not materially breached, materially violated, or materially defaulted under, or received notice that it has breached, violated, or defaulted under any of the terms or conditions of the Factor Agreement. Licensor is not aware of any event that has occurred or circumstance or condition that exists that would, or would reasonably be expected to, constitute such a material breach, material violation, or material default with the lapse of time, giving of notice, or both. To the knowledge of Licensor, Factor is in material compliance in all material respects with the terms and conditions of the Factor Agreement. Other than the Factor Agreement, there are no contracts, agreements, commitments, or undertakings pursuant to which Licensor in-licenses or otherwise has rights under any Patent or intellectual property rights of any third party that are material to Licensee's exercise of its rights under this Agreement.

6.1.18. Licensor shall comply with all terms and conditions of, and fulfil all of its obligations under, the Factor Agreement, except for such noncompliance that could not reasonably be expected to result in a material adverse effect on the rights granted to Licensee hereunder. Licensor may not materially amend or waive any material term of, or terminate the Factor Agreement without Licensee's prior written consent, except where such amendment or waiver could not reasonably be expected to result in a material adverse effect on the rights granted to Licensee hereunder.

6.2. *Representations and Warranties of Licensee*. Licensee hereby represents and warrants to Licensor that, as of the Effective Date:

6.2.1. Licensee is duly organized, validly existing and in good standing under the laws of its jurisdiction of organization, with full power and authority to operate its properties and to carry on its business as presently conducted.

6.2.2. The execution and performance of Licensee's obligations under this Agreement do not conflict with, cause a default under, or violate any existing contractual obligation that may be owed by Licensee to any third party.

6.2.3. None of Licensee or its Affiliates have employed, or otherwise used in any capacity, the services of any individual or entity debarred or disqualified under Applicable Laws.

6.3. *Disclaimer*.

Except as expressly provided in Section 6.1, nothing in this Agreement will be construed as:

6.3.1. a warranty or representation by Licensor as to the validity or scope of any of the Licensed Technology;

6.3.2. a warranty or representation by Licensor that anything made, used, sold or otherwise disposed of under the licenses granted in this Agreement, or the practice of the Licensed Technology, will or will not infringe patents of third parties; or

6.3.3. an obligation of Licensor to bring or prosecute actions or suits against third parties for infringement of Licensed Patents or misappropriation of Licensed Know-How.

6.4. *Express Disclaimer*.

EXCEPT AS EXPRESSLY PROVIDED IN THIS AGREEMENT, LICENSOR IS PROVIDING THE LICENSED TECHNOLOGY "AS IS." EXCEPT AS EXPRESSLY PROVIDED IN THIS AGREEMENT, NEITHER PARTY MAKES ANY REPRESENTATIONS, EXTENDS ANY WARRANTIES OF ANY KIND, EITHER EXPRESS OR IMPLIED, INCLUDING, WITHOUT LIMITATION, ANY IMPLIED WARRANTIES OF MERCHANTABILITY OR ANY IMPLIED WARRANTIES OF FITNESS FOR A PARTICULAR PURPOSE OR NON-INFRINGEMENT AND ASSUMES ANY RESPONSIBILITIES WHATSOEVER WITH RESPECT TO USE, SALE, OR OTHER DISPOSITION OF PRODUCTS INCORPORATING OR MADE BY USE OF LICENSED PATENTS UNDER THIS AGREEMENT.

Section 7
Term and Termination

7.1. *Term*.

The term of this Agreement will begin on the Effective Date and will continue (a) until it is terminated in its entirety under the provisions of this Section 7 and (b) 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 (the period from the Effective Date until such termination, the "*Term*").

7.2. *Termination by Either Party*. Either Party may terminate this Agreement at any time upon written notice to the other Party if the other Party is in material default or breach of this Agreement and such material default or breach is not cured within (i) forty-five (45) days in the event a breach of a Party's payment obligations after written notice thereof is delivered to the defaulting or breaching Party, (ii) ninety (90) days after written notice thereof is delivered to the defaulting or breaching Party, or (iii) in the case of a breach (other than a breach of a Party's payment obligation) that cannot be cured within ninety (90) days, within a reasonable period not exceeding one hundred twenty (120) days after written notice thereof is delivered to the defaulting or breaching Party, so long as the breaching Party is making a good faith effort to cure such default or breach of this Agreement.

7.3. *Termination by Licensor*. Licensor may, at its option, terminate this Agreement effective upon thirty (30) days written notice to Licensee if Licensee (i) files for protection under bankruptcy laws; (ii) makes an assignment for the benefit of creditors; (iii) appoints or suffers appointment of a receiver or trustee over its property; (iv) files a petition under any bankruptcy or insolvency act or has any such petition filed against it, which is not discharged within sixty (60) days of the filing thereof; or (v) is unable to pay its debts as they become due in the ordinary course of business. Nothing in this Section 7 shall prohibit Licensor from pursuing any other remedies at law which it may have in connection with Licensee's uncured material breach.

7.4. *Termination by Licensee*.

Licensee may, at its option, terminate this Agreement, in its entirety, upon written notice to Licensor of any of the following events or otherwise as provided in this Agreement:

7.4.1. at any time without cause, by giving at least ninety (90) days prior written notice of such termination to Licensor; or

7.4.2. effective upon thirty (30) days written notice to Licensor if Licensor (i) files for protection under bankruptcy laws; (ii) makes an assignment for the benefit of creditors; (iii) appoints or suffers appointment of a receiver or trustee over its property; (iv) files a petition under any bankruptcy or insolvency act or has any such petition filed against it, which is not discharged within sixty (60) days of the filing thereof; or (v) is unable to pay its debts as they become due in the ordinary course of business.

Nothing in the foregoing subsections of this Section 7 shall prohibit Licensee from pursuing any other remedies at law which it may have in connection with Licensor's uncured material breach.

7.5. *Challenging Validity*.

Licensor has the right to terminate this Agreement upon written notice to Licensee in the event that Licensee or any of its Affiliates or Sublicensees directly or indirectly challenges in a legal or administrative proceeding the patentability, enforceability or validity of any Licensed Patent or the scope or construction of any Valid Claim (each, a "*Patent Challenge*"); provided that (i) this Section 7.5 will not apply to any such Patent Challenge that is first made by Licensee or any of its Affiliates or Sublicensees in defense of a claim of patent infringement brought by Licensor under the applicable Licensed Patent, and (ii) with respect to any Sublicensee, Licensor will not have the right to terminate this Agreement under this Section 7.5 if Licensee (A) causes such Patent Challenge to be terminated or dismissed (or in the case of ex-parte proceedings, multi-party proceedings, or other Patent Challenges in which the challenging party does not have the power to unilaterally cause the Patent Challenge to be withdrawn, causes such Sublicensee to withdraw as a party from such Patent Challenge and to cease actively assisting any other party to such Patent Challenge), or (B) terminates such Sublicensee's sublicense to the Licensed Patents being challenged by the Sublicensee, in each case, within sixty (60) days of the Licensor's notice to Licensee under this Section 7.5.

7.6. Effects of Termination.

7.6.1. *Termination of License*.

Upon a termination (but not upon an expiration) of this Agreement for any reason, Licensee's rights to the Licensed Technology, inclusive of the Cell Lines and Licensed Products, which have been granted hereunder and all use thereof will terminate, any and all rights in the Licensed Technology, inclusive of the Cell Lines and the Licensed Products, will revert back to Licensor and Licensee will cease using the Cell Lines, and will cease selling, offering for sale, importing, exporting, developing and commercializing all Licensed Products. Subject at all times to Licensee's continuing compliance with the terms of this Agreement, for a period of one (1) year following the termination of this Agreement (the "*Sell-Off Period*"), Licensee shall have the right to sell off its inventory of finished Licensed Product then in Licensee's, its Affiliates' or Sublicensees' possession. Following the Sell-Off Period, upon Licensor's request, Licensee will, (i) to the extent they are in the possession of Licensee, promptly destroy or return the ACB and all Licensed Products to Licensee or (ii) to the extent they are in the possession of a third party agent of Licensee, Licensee shall use Commercially Reasonable Efforts to direct such third party agent to promptly destroy or return the ACB and all unsold Licensed Products to Licensee.

7.6.2. *Effect on Sublicenses*.

In the event that this Agreement is terminated for any reason by Licensor in accordance with Sections 7.2 or 7.3, any sublicense agreement shall be considered a direct license from Licensor to such surviving Sublicensee, provided that the Licensor is provided a copy of such sublicense agreement and all amendments thereto in within a reasonable amount of time following such termination and the Sublicensee agrees in a writing delivered to Licensor within sixty (60) days of such termination that (i) Licensor is entitled to enforce all relevant provisions of this Agreement directly against such Sublicensee, and (ii) Licensor shall not assume any obligations to such Sublicensee in excess of those obligations corresponding to, and consistent with, those of Licensor set forth in this Agreement with respect to the applicable rights of such Sublicensee to Licensed Technology. An expiration of this Agreement shall have no effect on sublicenses.

7.6.3. Right to Reference Regulatory Filings.

In the event that this Agreement is terminated for any reason, Licensee will, if requested by Licensor within thirty (30) days following such termination, engage in good faith negotiations to agree upon terms pursuant to which Licensor and its licensors, licensees and sublicensees may reference Regulatory Approvals obtained from, and filings made by Licensee with Regulatory Authorities with respect to the Licensed Products.

7.6.4. *Accrued Obligations.*

Expiration or termination of this Agreement will not release either Party from any obligation that matured prior to the effective date of such expiration or termination. Upon expiration or termination of this Agreement for any reason, any unpaid amounts payable to Licensor shall become immediately due, and payment thereof shall remain an ongoing obligation of Licensee until such amount is paid in full.

7.6.5. *Survival*.

Upon expiration or termination of this Agreement, Sections 2.3, 5.5, 6.3, 6.4, 7.5, 7.6 and 8.5, the license under Section 5.2.2, and Section 9 through and including Section 11 will, with related definitions, survive and remain in full force and effect.

Section 8
Protection of Intellectual Property Rights

8.1. *Patent Prosecution*.

During the Term, Licensor will be responsible for preparing, filing, prosecuting and maintaining all patent applications and patents included in the Licensed Patents in the Territory. For the sake of clarity, as used herein the term "prosecution" shall include interference, opposition, and derivation proceedings in connection with the Licensed Patents. Licensor shall (a) select patent counsel to conduct such activities regarding the Licensed Patents and (b) provide Licensee with a reasonable opportunity to comment thereon and will reasonably consider in good faith such comments. Should Licensor decide that it is not interested in maintaining a particular Licensed Patent or in preparing, filing, or prosecuting a Patent that is, as of the Effective Date, a Licensed Patent, it will promptly advise Licensee in writing, and Licensee will have the right, but not the obligation, to assume such responsibilities in the Territory at its sole cost and expense. If Licensee desires to assume such responsibilities of any such Licensed Patent pursuant to the immediately preceding sentence, then Licensor will not, as the case may be, so abandon or fail to prepare, file, prosecute or maintain such Licensed Patents if Licensee advises Licensor, within fourteen (14) calendar days of Licensee's receipt of notice of Licensor's intention not to file or to abandon or not to prosecute or maintain the applicable Licensed Patents, that Licensee desires to assume filing, prosecution or maintenance of the applicable Licensed Patents at Licensee's expense. Licensee has no obligation to pay any costs of preparing, filing, prosecuting, and maintaining any Licensed Patent prior to the Effective Date.

8.2. *Enforcement of Licensed Patents.*

8.2.1. *Notice*. Each Party will promptly report in writing to the other Party of any Competitive Infringement of which such Party (or any of its Affiliates or Sublicensees) becomes aware.

8.2.2. *Competitive Infringement of Licensed Patents by Third Parties*.

8.2.2.1. In the case of any Competitive Infringement by any third party, Licensee will have the first right, but not the obligation, to cause such third party to cease infringement and to otherwise enforce such Licensed Patent, or to defend the Licensed Patent in any declaratory judgment action brought by third party(ies) which alleges the invalidity, unenforceability or non-infringement of the Licensed Patent in the Field.

8.2.2.2. If Licensee does not, within a reasonable period after becoming aware of Competitive Infringement of the Licensed Patents in the Field, but in any event no less than ninety (90) calendar days from the date of receipt of written notice from Licensor, (i) initiate legal proceedings against such threatened or actual Competitive Infringement, or defend legal proceedings brought by a third party, as provided in Section 8.2.2.1 above, or (ii) take other reasonable steps to cause such Competitive Infringement to terminate (for example, by initiating licensing discussions), Licensor may deliver written notice to Licensee that it intends to take action to cause such Competitive Infringement to terminate, and Licensor may take such action as it deems reasonably necessary to enforce its rights in the Licensed Patents in the Field, including, without limitation, to bring, at its own expense, an infringement action or file any other appropriate action or claim related to such Competitive Infringement against any third party.

8.2.2.3. For any action or proceeding brought by a Party under this Section 8.2.2 (the "*Initiating Party*"), regardless of which Party brings such action or proceeding, the other Party (the "*Non-Initiating Party*") shall cooperate reasonably in any such effort, all at the Initiating Party's expense, and the Parties shall reasonably cooperate to address new facts or circumstances that come to light during the course of any such action or proceeding that may affect the need for one Party or the other to participate in such action. The Non-Initiating Party agrees to be joined as a party plaintiff, at the Initiating Party's expense, in any such action if needed for the Initiating Party to bring or continue an infringement action hereunder. The Non-Initiating Party shall, at its own expense and with its own counsel, have the right to observe and provide comments with respect to any action brought by the Initiating Party under this Section 8.2.2 (which comments the Initiating Party shall consider in good faith but be under no obligation to incorporate). Neither Party may settle an action or proceeding brought under this Section 8.2.2 in a manner that, or knowingly take any other action in the course thereof that, (i) imposes any monetary restriction or obligation on or admit fault of the other Party or (ii) adversely affects the value, scope or validity of, or otherwise adversely affects the other Party's rights under this Agreement to as applicable, any Patents within the Licensed Patents, without the written consent of the other Party, which consent shall not be unreasonably withheld, conditioned or delayed.

8.2.2.4. Any recovery realized as a result of any litigation under this Section 8.2.2 (including, for greater certainty, the proceeds of any settlement relating to such litigation), after reimbursement of any litigation expenses of Licensee and Licensor (including reasonable attorneys' fees) on a *pro rata* basis for each of their such expenses relating to such litigation, as applicable, will be retained by the Party that controlled such litigation at the time of such recovery for purposes of this Agreement.

8.3. *Infringement of Third-Party Rights*.

Each Party will promptly notify the other Party in writing of any notice or claim of any allegation of infringement or commencement against it of any suit or action for infringement of a third-party patent based upon or arising from actions taken under the licenses granted in this Agreement ("*Third-Party Infringement Claim*"). If such Third-Party Infringement Claim is alleged or commenced against Licensee, Licensee will have the sole right to defend and settle such Third-Party Infringement Claim, and Licensee will not be obligated to enter into negotiations with such third party to obtain rights for either Licensee or Licensor under the third-party patent. If such Third-Party Infringement Claim is alleged or commenced against Licensor, Licensee will have the first right, but not the obligation, to defend and settle such Third- Party Infringement Claim, *provided, however*, that Licensee will not be obligated to enter into negotiations with such third party to obtain rights for Licensor under the third-party patent. With respect to any such defense by Licensee of a Third-Party Infringement Claim alleged or commenced against Licensor, Licensee will not make any settlements of such Third-Party Infringement Claim that would materially adversely affect Licensor's rights or interests in the Licensed Technology without first obtaining Licensor's prior written consent. If Licensee opts not to defend or settle such Third-Party Infringement Claim alleged or commenced against Licensor, Licensee will notify Licensor of such decision and, at Licensor's expense, Licensor will have the right to undertake the defense or settlement of such Third-Party Infringement Claim.

8.4. *Patent Marking*.

Licensee and its Sublicensee(s) shall comply with the patent marking provisions of 35 U.S.C. § 287(a) with respect to any Licensed Product offered for sale or sold in the United States. To the extent required by Applicable Law, Licensee will mark Licensed Products sold or distributed by Licensee (and will require that Licensee's Affiliates and Sublicensees mark Licensed Products sold or distributed by Licensee's Sublicensees) in a given country in the Territory with a notice that will recite that such Licensed Products are made under one or more of the Licensed Patents.

8.5. *Confidential Information*.

8.5.1. Each Party will maintain the Confidential Information of the other Party in strict confidence, and will not disclose, divulge or otherwise communicate such Confidential Information to others, or use it for any purpose, except pursuant to, and in order to carry out, the terms and objectives of this Agreement, or with the express written consent of the Party who provided such Confidential Information. Each Party will maintain the confidentiality of the other Party's confidential information using methods and practices that are substantially similar to those that the receiving Party uses to maintain the confidentiality of its own confidential information, but in no event less than a reasonable degree of care. Except as may be authorized in advance in writing by the disclosing Party, the receiving Party will disclose or grant access to the Confidential Information to only those of its employees and agents as reasonably necessary or useful to exercise its rights or perform its obligations under this Agreement and such employees and agents will have entered into non-disclosure agreements, or be bound by professional obligations of confidentiality, no less protective of the disclosing party's Confidential Information than those set forth in this Section 8.5.

8.5.2. Notwithstanding the foregoing, a receiving Party may disclose Confidential Information of the disclosing Party to:

8.5.2.1. its Affiliates, and to its and their directors, employees, consultants, contractors, attorneys, advisors and agents, in each case who have a specific need to know such Confidential Information in connection with an activity under or relating to this Agreement and who are bound in writing by obligations of confidentiality and restrictions on use at least as stringent as those herein;

8.5.2.2. any bona fide actual or prospective collaborators who are under written obligations of confidentiality and non-use at least as stringent as those herein, to the extent reasonably necessary to enable such actual or prospective collaborators to (i) determine their interest in collaborating with the receiving Party on the development and/or commercialization of Licensed Products and (ii) engage in such a collaboration;

8.5.2.3. governmental authorities in connection with filing, prosecuting, or maintaining patent rights as permitted by this Agreement;

8.5.2.4. Regulatory Authorities in connection with regulatory filings for Products that the receiving Party has a license or right to develop hereunder in a given country or jurisdiction;

8.5.2.5. the extent required to do so by Applicable Law or a proper legal, governmental or other competent authority, or by the rules of any securities exchange on which any security issued by either Party is traded, or included in any filing or action taken by the receiving Party to obtain or maintain government clearance or approval to market a subject Licensed Product; *provided, however,* that, (i) to the extent permissible and practicable, the receiving Party required to make such disclosure shall give the disclosing Party reasonable advance notice of such disclosure requirement and shall afford the disclosing Party a reasonable opportunity to oppose, limit or secure confidential treatment for such required disclosure, or, where it is impracticable or illegal to give an advance notice, the Party required to make such disclosure shall give the disclosing Party reasonable notice promptly after such required disclosure; (ii) the Party required to make such disclosure shall disclose only that portion of the Confidential Information legally required to be disclosed; (iii) the Party required to make such disclosure shall use reasonable efforts to secure confidential treatment of such Confidential Information; and

8.5.2.6. to any bona fide potential Sublicensee or successor to said Party's interest under this Agreement, to a bona fide potential lender from which said Party is considering borrowing money, to a bona fide potential collaborator in connection with development or commercialization of Licensed Products, or to any bona fide financial investor from which said Party may take money; *provided, however*, in any such case said Party shall first obtain a written obligation of confidentiality no less stringent than that imposed in this Section 8.5 from the bona fide potential Sublicensee or successor, bona fide potential lender, bona fide potential collaborator or bona fide financial investor.

8.5.3. Any information disclosed pursuant to Section 8.5.2 shall remain Confidential Information and subject to the restrictions set forth in this Agreement, including the foregoing provisions of this Section 8.5.2.3.

8.6. *Use of Names*.

Neither Party may identify the other Party in any promotional advertising or other promotional materials to be disseminated to the public or any portion thereof, or use the name of any staff member or employee of the other Party or any trademark, service mark, trade name, symbol or logo that is associated with the other Party, without the other Party's prior written consent. Notwithstanding the foregoing, and for the avoidance of doubt, without the consent of the other Party either Party may comply with disclosure requirements of all Applicable Laws relating to its business, including, without limitation, United States and state securities laws. During the Term, and with the prior, written consent of the other Party, each Party may include the other Party's name, logo, and a brief description of such other Party on said Party's website and such other Party hereby consents to such inclusion of its name, logo, and a brief description on said Party's website; provided, however, that (i) the Party whose name, logo, and description is being included on the other Party's website shall have first approved in writing the manner in which its name and logo are being used and (ii) either Party shall have the right to revoke such consent at any time and for any reason, and promptly following written notice of such revocation, and in any event within ten (10) days of the other Party's receipt of such notice, the posting Party shall remove the other Party's name, logo, and description from the posting Party's website.

8.7. *Press Releases*.

The Parties shall mutually agree upon the timing and content of any press releases or other public announcement relating to this Agreement and the transactions and/or activities contemplated herein

8.8. *Licensee's Affiliates and Sublicensees*.

For the avoidance of doubt, and notwithstanding anything to the contrary in this Agreement, Licensee' Affiliates and Sublicensees may exercise Licensee's rights under Sections 8.1, 8.2 and 8.3.

Section 9
Indemnification; Insurance

9.1. *Indemnification by Licensee*.

Licensee will indemnify, defend and hold harmless Licensor, its Affiliates and their respective directors, officers, employees, consultants, licensors and agents, and their respective successors, heirs, and assigns (each a "*Licensor Indemnitee*"), against all suits, actions, claims, proceedings, in each case brought by a third party (each, a "*Claim*") and the resulting liabilities, demands, damages, losses, or expenses (including legal expenses, investigative expenses, and attorneys' fees) ("*Losses*") to the extent arising out of Licensee's or, as applicable Licensee's Affiliate's or Sublicensee's: (a) gross negligence or intentional misconduct, (b) failure to comply with Applicable Laws, or (c) Licensee's, its Affiliates' or Sublicensee's Exploitation of Licensed Product or the exercise of the licenses granted under this Agreement, including the production, manufacture, sale, use, lease, consumption, administration, shipping, storage, transfer, advertisement, analysis, measurement, description, or characterization of the Licensed Technology, or Licensed Products, or any activity arising from or in connection with any right or obligation of Licensee hereunder, except in each case (a) through (c) to the extent resulting from a Licensor Indemnitee's (i) gross negligence or intentional misconduct; (ii) failure to comply with Applicable Law; (iii) Exploitation of the Licensed Technology; or (iv) breach of this Agreement.

9.2. *Indemnification by Licensor*.

Licensor will indemnify, defend and hold harmless Licensee, its Affiliates, Sublicensees, any contractors of the foregoing, and their respective directors, officers, employees, consultants, licensors and agents, and their respective successors, heirs, and assigns (each a "*Licensee Indemnitee*") against any Claims and Losses to the extent arising out of Licensor's or its Affiliate's: (a) gross negligence or intentional misconduct; (b) failure to comply with Applicable Laws; or (c) Exploitation of the Licensed Technology, including, for the avoidance of doubt, the Cell Lines, outside the Field; except in each case (a) through (c) to the extent resulting from a Licensee Indemnitee's (i) gross negligence or intentional misconduct; (ii) failure to comply with Applicable Law; (iii) Exploitation of the Licensed Technology; or (iv) breach of this Agreement.

9.3. *Indemnification Procedure*.

Each Party's agreement to indemnify, defend, and hold harmless under Section 9.1 or 9.2, as applicable, is conditioned upon the indemnified Party (a) providing written notice to the indemnifying Party of any Claim as soon as reasonably possible, and in any event no later than within thirty (30) days after the indemnified Party has actual knowledge of such Claim, (b) permitting the indemnifying Party to assume control over the investigation of, preparation and defense against, and settlement or voluntary disposition of any such Claim, (c) assisting the indemnifying Party, at the indemnifying Party's reasonable expense, in the investigation, preparation, defense, and settlement or voluntary disposition of any such Claim, and (d) not compromising, settling, or entering into any voluntary disposition of any such Claim without the indemnifying Party's prior written consent, which consent shall not be unreasonably withheld; *provided, however*, that, if the Party entitled to indemnification fails to promptly notify the indemnifying Party pursuant to the foregoing clause (a), the indemnifying Party will only be relieved of its indemnification obligation to the extent materially prejudiced by such failure. In no event may the indemnifying Party compromise, settle, or enter into any voluntary disposition of any Claim in any manner that admits material fault or wrongdoing on the part of the indemnified Party or incurs non-indemnified liability on the part of the indemnified Party without the prior written consent of the indemnified Party, and in no event may the indemnifying Party settle, compromise, or agree to any voluntary disposition of any matter subject to indemnification hereunder in any manner which (i) imposes any monetary restriction or obligation on or admits fault of the other Party or (ii) adversely affects the other Party's rights under this Agreement, without such other Party's prior written consent.

9.4. *Insurance*.

Licensee shall maintain in full force and effect during the Term and for a period of three (3) years after expiration or termination of this Agreement, worker's compensation, general liability and professional liability insurance coverage and, in addition Licensee shall maintain clinical trial liability and product liability insurance coverage, all in such amounts as are customary in the life sciences and pharmaceutical industries. Upon written request, Licensee shall provide evidence of such insurance to Licensor. Licensor shall be named as an additional insured with respect to such insurance policies, and Licensee shall ensure that Licensor will receive no less than thirty (30) days' prior notice of any cancelation, non-renewal or material change in such insurance coverage.

Section 10
Alternative Dispute Resolution

10.1. *Negotiation*.

In the event of any dispute or disagreement between the Parties as to the interpretation of any provision of this Agreement (or the performance of any obligations hereunder), the matter, upon written request of either Party, shall be referred to representatives of the Parties for decision, each Party being represented by an executive officer (the "*Representatives*"). The Representatives shall promptly meet in a good faith effort to resolve the dispute. If the Representatives do not mutually agree upon a decision within thirty (30) calendar days after reference of the matter to them, each of the Parties shall be free to exercise the remedies available to it under Section 10.2. Each Party may extend the period of time for negotiation among the Representatives for an additional period of fourteen (14) calendar days on one (1) occasion per dispute.

10.2. *Submission to Arbitration*.

If the Parties are unable to resolve such dispute pursuant to Section 10.1, either Party may submit the dispute to binding arbitration (without any recourse to the federal or state courts except to enforce any arbitral award or, within forty five (45) days of an Arbitrator's rendering of a final decision, to appeal such final decision based solely on a claim that the Arbitrator engaged in gross misconduct or made a material error or miscalculation in his or her decision) in accordance with the rules of JAMS/End Dispute ("*JAMS*") then in force (except as expressly modified below), and the arbitration hearings shall be held before a single arbitrator ("*Arbitrator*") in New York, New York. The Parties agree to appoint an Arbitrator who is knowledgeable in the patenting prosecution, patent licensing, biotechnology and/or life sciences industries. If the Parties cannot agree upon an Arbitrator within ten (10) days after a demand for arbitration has been filed with the JAMS by either of them, either or both Parties may request the JAMS to name a panel of five (5) candidates to serve as Arbitrator. The Parties shall each, in successive rounds (with the Party demanding the arbitration having the first chance to strike a name), strike one name off this list until only one name remains, and such last-named person shall be the Arbitrator.

10.3. *Conduct of Arbitration*.

The Arbitrator shall be required to (a) follow the substantive rules of New York State or Federal law, as applicable, (b) require all testimony to be transcribed, and (c) accompany his or her award with findings of fact and a statement of reasons for the decision. The Arbitrator shall have the authority to permit discovery for no more than ninety (90) days, to the extent deemed appropriate by the Arbitrator, upon reasonable request of a Party. The Arbitrator shall have no power or authority to (i) add to or detract from the written agreement of the Parties set forth herein, (ii) modify or disregard any provision of this Agreement or any of the other related documents, or (iii) address or resolve any issue not submitted by the Parties. The Arbitrator shall hold proceedings during a period of no longer than thirty (30) calendar days promptly following conclusion of discovery, and the Arbitrator shall render a final decision within thirty (30) days following conclusion of the hearings. The Arbitrator shall have the power to grant injunctive relief (without the necessity of a Party posting a bond) in the event a Party has violated the confidentiality provisions set forth in this Agreement, but shall have no power to award punitive and/or exemplary damages in the event of a breach, *provided, however*, that nothing in this Agreement will operate to prevent a Party from seeking injunctive relief in a court of competent jurisdiction. In the event of any conflict between the commercial arbitration rules then in effect and the provisions of this Agreement, the provisions of this Agreement shall prevail and be controlling.

10.4. *Interim Relief*.

Either Party may, without waiving any remedy under this Agreement, apply to the Arbitrator for interim injunctive relief until the arbitration award is rendered or the controversy is otherwise resolved. Either Party also may, without waiving any remedy under this Agreement, seek from any court having jurisdiction any injunctive or provisional relief necessary to protect the rights regarding the Intellectual Property of that Party pending the arbitration award. The Arbitrator shall have no authority to award punitive or any other type of damages not measured by a Party's compensatory damages.

10.5. *Cost of Arbitration*.

Each Party shall share in the actual and direct costs of the engagement of the Arbitrator, but the prevailing Party in the arbitration shall be reimbursed by the non-prevailing Party for the prevailing Party's fees and costs of arbitration (e.g., the costs, fees and expenses of outside experts and counsel retained by the prevailing Party). If one Party is not deemed by the Arbitrator to be the primary prevailing Party, then each Party will pay its own costs, fees and expenses (including attorneys' fees) and an equal share of the Arbitrator's fees and any administrative fees of arbitration.

10.6. *Excluded Claims*.

Notwithstanding anything to the contrary herein, nothing in this Section 10 shall preclude a Party from seeking injunctive relief or specific performance in a court of competent jurisdiction. Unless otherwise mutually agreed upon by the Parties in writing, any Excluded Claims shall be brought in the federal court for the Southern District of New York, if federal jurisdiction is available, or, alternatively, in the state courts in New York, New York. Each of the Parties hereby submits to the exclusive jurisdiction of such courts for the purpose of any such litigation; *provided, however*, that a final judgment in any such litigation shall be conclusive and may be enforced in other jurisdictions by suit on the judgment or in any other manner provided by law. Each Party irrevocably and unconditionally agrees not to assert (a) any objection which it may ever have to the laying of venue of any such litigation in such courts, (b) any claim that any such litigation brought in any such court has been brought in an inconvenient forum, and (c) any claim that such court does not have jurisdiction with respect to such litigation. As used in this Section 10.6, the term "*Excluded Claim*" means a dispute, controversy or claim that concerns: (w) the scope, construction, validity or infringement of a patent, trademark or copyright; (x) any antitrust, anti-monopoly or competition law or regulation, whether or not statutory; or (y) the Licensee's or, as applicable Licensee's Affiliates or Sublicensee(s), Exploitation of Licensed Products or use of the Licensed Technology outside of the Field.

10.7. *Injunctive Relief; Specific Performance*.

Notwithstanding anything to the contrary herein, nothing in this Section 10 shall preclude a Party from seeking injunctive relief or specific performance in a court of competent jurisdiction.

10.8. *Confidentiality*.

Except to the extent necessary to confirm an award or as may be required by law, neither a Party nor an Arbitrator may disclose the existence, content, or results of the arbitration without the prior written consent of both Parties, except to its directors, officers and investors. In no event shall arbitration be initiated after the date when commencement of a legal or equitable proceeding based on the dispute, controversy or claim would be barred by the applicable Massachusetts statute of limitations.

Section 11
Miscellaneous

11.1. *Compliance with Law*.

In connection with its Exploitation of Licensed Products, Licensee agrees to comply with all Applicable Laws. Without limiting the foregoing, by entering into this Agreement, the Parties specifically intend to comply with all Applicable Laws pertaining to Licensed Products, including (i) the federal anti- kickback statute (42 U.S.C. §1320a-7b) and the related safe harbor regulations; and (ii) the Limitation on Certain Physician Referrals, also referred to as the "*Stark Law*" (42 U.S.C. §1395nn). Accordingly, no part of any consideration paid hereunder is a prohibited payment for the recommending or arranging for the referral of business or the ordering of items or services; nor are the payments intended to induce illegal referrals of business.

11.2. *Assignment*.

This Agreement will be binding upon and will inure to the benefit of each Party and each Party's respective transferees, successors and assigns, pursuant to the provisions set forth below. Licensee may not transfer or assign this Agreement without the prior written consent of Licensor, except that Licensee may transfer or assign this Agreement without the prior written consent of Licensor in the event that a third party (the "*Acquiring Party*") acquires all or substantially all of Licensee's business, capital stock or assets, whether by sale, merger, change of control, operation of law or otherwise (an "*Acquisition*"). Upon an Acquisition, the rights granted to Licensee under this Agreement pertaining to any and all Licensed Products shall inure to the benefit of the Acquiring Party. For the avoidance of doubt, in the event of an Acquisition, the Acquiring Party will be responsible for all payments and other obligations set forth in this Agreement, including, but not limited to, all payments set forth herein, and any obligations that matured prior to the Acquisition date. Upon an Acquisition, any unpaid portion of any deferred payments payable to Licensor hereunder shall remain an ongoing obligation of the Acquiring Party until such amount is paid in full. For the avoidance of doubt, an Acquisition shall not include any transaction or series of transactions principally for bona fide equity financing purposes in which cash is received by Licensee or any successor, indebtedness of Licensor is cancelled or converted or any combination thereof. Any attempted assignment in contravention of this Section 11.2 will be null and void.

11.3. *Entire Agreement.*

This Agreement constitutes the entire agreement between the Parties hereto with respect to the subject matter thereof and supersedes all previous agreements, negotiations, commitments, and writings with respect to such subject matter, inclusive of the Option Agreement. Neither Party shall be obligated by any undertaking or representation regarding that subject matter other than those expressly stated herein or as may be subsequently agreed to by the Parties hereto in writing. In the event of any conflict or inconsistency between any provision of any Exhibit hereto and any provision of this Agreement, the provisions of this Agreement shall prevail.

11.4. *Amendment.*

No amendment, modification or supplement of any provision of this Agreement will be valid or effective unless made in writing and signed by a duly authorized officer of each Party.

11.5. *Notices*.

Any notice required to be given pursuant to the provisions of this Agreement will be in writing and will be deemed to have been given at the time when actually received as a consequence of any effective method of delivery, including but not limited to hand delivery, transmission by electronic transmission, including PDF (portable document format), delivery by a professional courier service or delivery by first class, certified or registered mail (postage prepaid) addressed to the Party for whom intended at the address below, or at such changed address as the Party will have specified by written notice in accordance with this Section 11.5; *provided, however*, that any notice of change of address will be effective only upon actual receipt.

If to Licensor:

Novellus Therapeutics Limited
c/o Novellus, Inc.
1035 Cambridge Street, Suite 17B
Cambridge, MA 02141
Attn: Matt Angel, Ph.D.,
Director [***].

with copy (which shall not constitute notice) to:

Morse, Barnes-Brown & Pendleton, P.C.
480 Totten Pond Road, 4th Floor
Waltham, MA 02451
Attn: Stanley F. Chalvire, Esq
[***].

If to Licensee:

Novecite, Inc.
11 Commerce Drive, 1st Floor
Cranford, NJ 07016
Attn: Myron Holubiak, Chief Executive Officer
[***].

with copy (which shall not constitute notice) to:

Citius Pharmaceuticals, Inc.
11 Commerce Drive, 1st Floor
Cranford, NJ 07016
Attn: Myron Holubiak, Chief Executive Officer
[***].

11.6. *Governing Law*.

11.6.1. The substantive law governing this Agreement (which shall be applied in the arbitration) shall be, with respect to disputes involving general contract or trade secret matters, the internal laws of the State of New York, and with respect to matters involving patents, the United States Patent Act, as to copyright matters, the United States Copyright Act, and as to trademark matters, the United States Trademark Act, each as amended from time to time. Any award rendered by the Arbitrator shall be final, conclusive and binding upon the Parties to this Agreement, and judgment thereon may be entered and enforced in any state or federal court of competent jurisdiction.

11.6.2. If any provisions of this Agreement are or will come into conflict with the laws or regulations of any jurisdiction or any governmental entity having jurisdiction over the Parties or this Agreement, those provisions will be deemed automatically deleted, if such deletion is allowed by relevant law, and the remaining terms and conditions of this Agreement will remain in full force and effect. If such a deletion is not so allowed or if such a deletion leaves terms thereby made clearly illogical or inappropriate in effect, the Parties agree to substitute new terms as similar in effect to the present terms of this Agreement as may be allowed under Applicable Law.

11.7. *Descriptive Headings*.

This Agreement has been prepared jointly by the Parties and shall not be strictly construed against either Party. Ambiguities, if any, in this Agreement shall not be construed against any Party, irrespective of which Party may be deemed to have authored the ambiguous provision. The headings of each Section in this Agreement have been inserted for convenience of reference only and are not intended to limit or expand on the meaning of the language contained in the particular Section. Except where the context otherwise requires, the use of any gender shall be applicable to all genders, and the word "or" is used in the inclusive sense (and/or). The term "including" as used herein means including, without limiting the generality of any description preceding such term.

11.8. *Independent Contractors*.

Both Parties are independent contractors under this Agreement. Nothing contained in this Agreement will be deemed to create an employment, agency, joint venture or partnership relationship between the Parties hereto or any of their agents or employees, or any other legal arrangement that would impose liability upon one Party for the act or failure to act of the other Party. Neither Party will have any express or implied power to enter into any contracts or commitments or to incur any liabilities in the name of, or on behalf of, the other Party, or to bind the other Party in any respect whatsoever. Notwithstanding anything contained herein to the contrary, and for the avoidance of doubt, Licensor shall not be deemed an Affiliate of Licensee, and Licensee shall not be deemed an Affiliate of Licensor.

11.9. *Severability*.

The illegality or partial illegality of any provision of this Agreement will not affect the validity of the remainder of the Agreement, or any provision thereof, and the illegality or partial illegality of any provision of this Agreement will not affect the validity of the Agreement in any jurisdiction in which such determination of illegality or partial illegality has not been made, except in either case to the extent such illegality or partial illegality causes the Agreement to no longer contain all of the material provisions reasonably expected by the Parties to be contained therein. Moreover, in the event that a court of competent jurisdiction determines that any provision of this Agreement is illegal or partially illegal, then it is the intention of the Parties that such provision be modified to the minimum extent deemed necessary by such court to make such provision enforceable and to give effect to the original intention of the Parties.

11.10. *Waiver of Compliance*.

The failure of either Party to comply with any obligation, covenant, agreement or condition under this Agreement may be waived by the Party entitled to the benefit thereof only by a written instrument signed by the Party on granting such waiver, but such waiver or failure to insist upon strict compliance with such obligation, covenant, agreement or condition will not operate as a waiver of, or estoppel with respect to, any subsequent or other failure. The failure of any Party to enforce at any time any of the provisions of this Agreement will in no way be construed to be a waiver of any such provision, nor in any way to affect the validity of the Agreement or any part thereof or the right of any Party thereafter to enforce each and every such provision. No waiver of any breach of such provisions will be held to be waiver of any other or subsequent breach.

11.11. *Counterparts*.

This Agreement may be executed by original or facsimile signature in any number of counterparts, each of which need not contain the signature of more than one Party but all such counterparts taken together will constitute one and the same agreement.

11.12. *Authority*.

The persons signing on behalf of Licensor and Licensee hereby warrant and represent that they have authority to execute this Agreement on behalf of the Party for whom they have signed.

11.13. *Non-Solicitation*.

During the Term, neither Party shall, without the prior written consent of the other Party, directly or indirectly solicit for employment any employee of the other Party or any of its Affiliates or subsidiaries, or any person who has terminated his or her employment with the other Party or any of its Affiliates or subsidiaries within the previous twelve (12)-month period prior to any purported solicitation; *provided, however,* the foregoing will not prevent a Party from employing any such person who contacts such Party on his or her own initiative without any direct or indirect solicitation by or encouragement from the soliciting or hiring person. General advertising which is not directed at any specific employee of a Party will not be deemed solicitation, and hiring of employees of such Party which are solicited in this manner will not be a breach of this provision.

11.14. *Non-Competition*.

During the Term, Licensor shall not (and shall ensure that its Affiliates do not): (a) Commercialize any Cell Products in the Field; (b) enter into any agreement (except a Sponsored Research Agreement) pursuant to which any third party may Exploit any Cell Product in the Field; (c) otherwise enable any third party, directly or indirectly, to Exploit any Cell Product in the Field, except with respect to research regarding a Cell Product pursuant to Sponsored Research Agreements; (d) Exploit the ACB or MCB for any purpose either in the Field or outside of the Field, (e) enter into any agreement pursuant to which any third party may Exploit the ACB or MCB for any purpose either in the Field or outside of the Field or (f) otherwise enable any third party, directly or indirectly, to Exploit the ACB or MCB in the Field or outside of the Field. For the purpose of this Section 11.14, "*Cell Product*" means any product that includes mesenchymal stem cells. "*Sponsored Research Agreement*" means an agreement between (x) Licensor or its Affiliates on the one hand and (y) a not-for-profit academic institution on the other hand, pursuant to which (i) the parties thereto engage in the conduct of research regarding Cell Products and (ii) subject to any research use licenses granted to the academic institution for the purpose of conducting such research, Licensor and its Affiliates own all right, title and interest in and to all of their Intellectual Property rights. "*Commercialize*" means, with respect to any subject matter, seeking Regulatory Approval for, marketing, selling or promoting such subject matter.

11.15. *Right of First Negotiation*. During the Term, if Licensor or any of its Affiliates develops or acquires ownership or Control of a product or potential product (including a molecule or composition) that may be used in the Field (a "*New Product*"), Licensor shall not (and shall ensure that its Affiliates do not) enter into any material negotiations or agreement involving a license of the New Product in the Field or pursuant to which any third party may Exploit such New Product in the Field without first complying with all of its obligations set forth in this Section 11.15. New Products exclude the Licensed Products. Licensor hereby recognizes that Licensee has a right of first negotiation to obtain a license to develop and Commercialize a New Product, as further described below. For this purpose, prior to Licensor or any of its Affiliates entering into any material negotiations or agreement with any third party with respect to any license of a New Product including rights in the Field or the Exploitation of a New Product in the Field, Licensor shall offer (including on behalf of its Affiliates) to Licensee a license to fully Exploit such New Product (a "*New Product Transaction*") before commencing such negotiations or entering into such agreement. Such offer shall be effected by providing to Licensee written notice of the offer and all material terms of such offer. For the avoidance of doubt, references in this Section 11.15 to "ownership or Control of a product or potential product" means ownership or Control of Intellectual Property rights pertaining to such product or potential product. For the avoidance of doubt, references in this Section 11.15 to licensing a New Product mean licensing such Intellectual Property rights and related tangible materials such as cells. Licensor and its Affiliates retain the right to enter into Sponsored Research Agreements with third party academic institutions with respect to New Products and, notwithstanding anything set forth in this Section 11.15 to the contrary, any such Sponsored Research Agreements with third party academic institutions shall not be subject to the right of first negotiation set forth herein.

If, within thirty (30) days of Licensor's provision of such notice and the material terms of such offer (such thirty (30) day period, the "*ROFN Notice Period*"), Licensee notifies Licensor in writing of Licensee's desire to negotiate an agreement for a New Product Transaction (such notice, a "*Negotiation Notice*"), the Parties shall use reasonable efforts to negotiate, on an exclusive basis, in good faith the terms and conditions applicable to a New Product Transaction during a period of one hundred fifty (150) days following the date of the Negotiation Notice (the "*New Product Agreement*"). During the ROFN Notice Period, and, in the event that Licensee provides Licensor with a Negotiation Notice, until the earlier of (a) the date on which the Parties conclude a New Product Agreement or (b) one hundred fifty (150) days following the date of the Negotiation Notice, Licensor shall reasonably and promptly cooperate with Licensee's due diligence inquiries with respect thereto.

During the ROFN Notice Period and one hundred fifty (150) day negotiation period (if applicable), neither Licensor nor any Affiliate thereof shall enter into any transaction pursuant to which any third party may Exploit the applicable New Product in the Field. Should (i) the Parties not enter into a New Product Agreement within the one hundred fifty (150) day negotiation period or (ii) Licensee not provide a Negotiation Notice during the thirty (30) day ROFN Notice Period, then Licensor and its Affiliates will be entitled to discuss, propose, negotiate, and/or execute a New Product Transaction for the applicable New Product(s) with a third party, provided that (1) if Licensee provided a Negotiation Notice with respect to such New Product(s), the terms of any such agreement executed with a third party shall not be on material terms more favorable on the whole to such third party than the last terms offered to Licensee by Licensor unless Licensor has provided first to Licensee a reasonable opportunity (not to exceed twenty (20) business days) to execute such an agreement with Licensor and (2) if a New Product Transaction with such a third party is not executed within twelve (12) months following the (a) end of the one hundred fifty (150) day negotiation period or (b) expiration of the ROFN Notice Period without Licensee's exercise of its negotiation rights, as applicable, Licensor shall be required to follow the process set forth in this paragraph again with respect to such New Product(s) before executing a New Product Transaction therefor with a third party.

11.16. *Force Majeure*.

Neither Party hereto shall be liable for failures and delays in performance due to strikes, lockouts, fires, acts of God or the public enemy, riots, incendiaries, interference by civil or military authorities, acts of terrorism, endemic, pandemic, and the results related to such acts, compliance with the laws of various states/countries, or with the orders of any governmental authorities, delays in transit or delivery on the part of transportation companies, failures of communication facilities, or any failure of sources of material.

Remainder of page intentionally left blank.

IN WITNESS WHEREOF, the Parties hereto have duly executed this License Agreement as of the Effective Date.

NOVELLUS THERAPEUTICS LIMITED (LICENSOR)

By: /s/ Christopher Rohde
Name: Christopher Rohde
Title: Director

NOVECITE, INC. (LICENSEE)

By: /s/ Myron Holubiak
Name: Myron Holubiak
Title: CEO

Exhibit A

Financial Terms

Sec. 5.1(a) Licensee shall pay Licensor an upfront fee equal to $5,000,000, payable on the Effective Date.

Sec. 5.1(b) Licensee shall issue to Novellus LLC the number of shares of Licensee's Common Stock representing no less than twenty-five percent (25%) of Licensee's outstanding common and preferred shares on a fully diluted basis.

Sec. 5.2.1 For each Licensed Product, each time a Milestone set forth below is achieved, Licensee shall pay to Licensor the corresponding Milestone Payment set forth below:

Milestone		Milestone Payment
Development Milestones		
IND Filing with a Regulatory Authority	$	[***]
First Patient Enrolled in a Phase I Clinical Trial	$	[***]
First Patient Enrolled in a Phase IIb Clinical Trial or Phase III Clinical Trial	$	[***]
Application for Regulatory Approval (either NDA or BLA) filed with a Regulatory Authority	$	[***]
Regulatory Approval of Licensed Product from Regulatory Authority by Licensee, its Affiliates or Sublicensees	$	[***]
Regulatory Approval of Licensed Product from EMEA by Licensee, its Affiliates or Sublicensees	$	[***]
Regulatory Approval of Licensed Product from PMDA by Licensee, its Affiliates or Sublicensees	$	[***]

Sec. 5.2.2 During the Royalty Term, and subject to adjustment as set forth in the Agreement, on a Fiscal Quarter basis, Licensee shall pay to Licensor a Royalty on Net Sales in such Fiscal Quarter equal to [***] ([***]%) of Net Sales of such Licensed Product.

Sec. 5.2.3 Licensee shall, within thirty (30) days of receipt of any Sublicense Fees, pay to Licensor [***] ([***]%) of Sublicense Fees received in such Fiscal Quarter.

Exhibit B

Licensed Patents

Docket Number	Assignee	Country	Application No. Application Date	Registration No. Registration Date	Case Status
FAB-001AU	Factor Bioscience	Australia	2012347919 Dec-05-2012	2012347919 May-18-2017	PATENTED
FAB-001AUD1	Factor Bioscience	Australia	2016277545 Dec-05-2012	2016277545 Sep-28-2017	PATENTED
FAB-001AUD3	Factor Bioscience	Australia	2019203662 Dec-05-2012	2019203662 May-14-2020	PATENTED
FAB-001AUD4	Factor Bioscience	Australia	2020202780 Dec-05-2012	N/A	Pending
FAB-001BR	Factor Bioscience	Brazil	1120140136645 Dec-05-2012	N/A	Pending
FAB-001CA	Factor Bioscience	Canada	2,858,148 Dec-05-2012	N/A	Pending
FAB-001CN	Factor Bioscience	China	201280068223.0 Dec-05-2012	ZL201280068223.0 Nov-25-2015	PATENTED
FAB-001CND1	Factor Bioscience	China	201510852019.3 Dec-05-2012	ZL201510852019.3 May-29-2017	PATENTED
FAB-001CND2	Factor Bioscience	China	201510853689.7 Dec-05-2012	ZL201510853689.7 Aug-13-2019	PATENTED
FAB-001CND3	Factor Bioscience	China	201510853690.X Dec-05-2012	ZL201510853690.X Jul-31-2020	PATENTED
FAB-001CND4	Factor Bioscience	China	202010626574.5 Dec-05-2012	N/A	Pending
FAB-001EP	Factor Bioscience	Europe	12813595.1 Dec-05-2012	2788033 May-31-2017	PATENTED Validated in CH DE FR GB IE

Docket Number	Assignee	Country	Application No. Application Date	Registration No. Registration Date	Case Status
FAB-001EPD1	Factor Bioscience	Europe	17170810.0 May-02-2017	N/A	Allowed
FAB-001HK	Factor Bioscience	Hong Kong	15103141.5 Dec-05-2012	1202443 Mar-23-2018	PATENTED
FAB-001HKD1	Factor Bioscience	Hong Kong	16108558.9 Dec-05-2012	1220490 Feb-23-2018	PATENTED
FAB-001HKD2	Factor Bioscience	Hong Kong	16110473.7 Dec-05-2012	N/A	Pending
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FAB-001JP	Factor Bioscience	Japan	2014-546024 Dec-05-2012	6073916 Jan-13-2017	PATENTED
FAB-001JPD1	Factor Bioscience	Japan	2016-213019 Oct-31-2016	6294944 Feb-23-2018	PATENTED
FAB-001KR	Factor Bioscience	Republic of Korea	10-2014-7018569 Dec-05-2012	N/A	Allowed
FAB-001MX	Factor Bioscience	Mexico	MX/a/2014/00666 3 Dec-05-2012	354995 Mar-27-2018	PATENTED
FAB-001RU	Factor Bioscience	Russian Federation	2014127505 Dec-05-2012	2624139 Jun-30-2017	PATENTED
FAB-001RUD2	Factor Bioscience	Russian Federation	RU 2018112719 Apr-10-2018	N/A	Pending
FAB-003	Factor Bioscience	USA	13/465,490 May-07-2012	8,497,124 Jul-30-2013	PATENTED
FAB-003C1	Factor Bioscience	USA	13/931,251 Jun-28-2013	9,127,248 Sep-08-2015	PATENTED
FAB-003C2	Factor Bioscience	USA	14/810,123 Jul-27-2015	9,399,761 Jul-26-2016	PATENTED
FAB-003C3	Factor Bioscience	USA	15/178,190 Jun-9-2016	9,562,218 Feb-07-2017	PATENTED

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FAB-003C5	Factor Bioscience	USA	15/605,513 May-25-2017	9,879,228 Jan-30-2018	PATENTED
FAB-003C6	Factor Bioscience	USA	15/844,063 Dec-15-2017	9,969,983 May-15-2018	PATENTED
FAB-003C7	Factor Bioscience	USA	15/947,741 April-06-2018	10,131,882 Nov-20-2018	PATENTED
FAB-003C8	Factor Bioscience	USA	US 16/037,597 July-17-2018	10,301,599 May-28-2019	PATENTED
FAB-003C9	Factor Bioscience	USA	US 16/374,482 April 3, 2019	10,443,045 Oct 15, 2019	PATENTED
FAB-003C10	Factor Bioscience	USA	US 16/562,497 Sept-05-2019	N/A	Pending
FAB-016PR	Factor Bioscience	USA	US 63/016,626 April 28,2020	N/A	Pending

Exhibit C

ACB Specifications

The ACB shall consist of: (a) at least five vials, each vial containing at least one million viable human induced mesenchymal stem cells and having the specifications set forth below, and (b) a characterization data package including cell count, viability, surface markers, protein secretion, and sterility test results.

Type	Assay	Specification
1. Cell Density	Cell Count	[***]
2. Cell Viability	Viable Staining	[***]
3. Microbial Safety	Sterility	[***]
4. Surface Markers	[***]	[***]
	[***]	[***]
5. Protein Secretion	[***]	[***]
6. Other	[***]	[***]
	[***]	[***]

Exhibit D

Original Cell Line

The mesenchymal stem cells (MSCs) that were derived from an induced pluripotent stem cell line that was made using the mRNA cell reprogramming methods disclosed in the Licensed Patents and having the unique identifier: [***].

Exhibit E

Form of Subscription Agreement

THE SECURITIES SUBJECT TO THIS SUBSCRIPTION AGREEMENT ARE SUBJECT TO RESTRICTIONS ON TRANSFERABILITY AND RESALE AND MAY NOT BE TRANSFERRED OR RESOLD EXCEPT AS PERMITTED UNDER THE SECURITIES ACT OF 1933 (the " ***1933 Act***"), AS AMENDED, AND APPLICABLE STATE SECURITIES LAWS, PURSUANT TO REGISTRATION OR EXEMPTION THEREFROM. PURCHASER SHOULD BE AWARE THAT THEY WILL BE REQUIRED TO BEAR THE FINANCIAL RISKS OF THIS INVESTMENT FOR AN INDEFINITE PERIOD OF TIME.

NAME OF PURCHASER: NOVELLUS LLC

NOVECITE, INC.

SUBSCRIPTION AGREEMENT

The undersigned, Novellus LLC, a Delaware limited liability company (the "***Purchaser***"), hereby subscribes to and agrees to purchase Five Hundred (500) shares (the "***Shares***") of common stock, $0.001 par value per share (the "***Common Stock***") of NoveCite, Inc., a Delaware corporation (the "***Corporation***"), at the purchase price of $1.00 per share for the aggregate total purchase price of Five Hundred Dollars ($500.00).

The Shares to be issued to the Purchaser hereunder shall equal twenty five percent (25%) of the capital stock of the Corporation, calculated on a Fully Diluted Basis (as defined herein), as of the date of issuance and after giving effect to the issuance, and to be calculated in the future after giving effect to the anti-dilutive provisions hereof triggered by the issuance of any Additional Securities (as defined herein), as further provided in Section 3(a).

Section 1. Representation and Warranties of the Purchaser. The Purchaser hereby represents, warrants and agrees as follows:

(a) Purchaser is a limited liability company organized and existing under the laws of Delaware.

(b) Purchaser understands that the sale and issuance of securities contemplated hereby is made in reliance upon the Purchaser's representation to the Corporation, which by the Purchaser's acceptance hereof the Purchaser hereby confirms, that the Shares to be received by the Purchaser will be acquired for investment for the Purchaser's own account, not as a nominee or agent, and not with a view to the sale or distribution of any part thereof, and that the Purchaser has no present intention of selling, granting participation in, or otherwise distributing the same. By executing this Subscription Agreement, the Purchaser further represents that the Purchaser does not have any contract, undertaking, agreement, or arrangement with any person to sell, transfer or grant participations to such person, or to any third person, with respect to any of the Shares.

(c) Purchaser understands that the Shares have not been registered under the 1933 Act on the grounds that the sale provided for in this Agreement and the issuance of securities hereunder is exempt from registration under the 1933 Act, and that the Corporation's reliance on such exemption is predicated in part on the Purchaser's representations set forth herein. The Purchaser realizes that the basis for the exemption may not be present if, notwithstanding such representations, the Purchaser has in mind merely acquiring the Shares for a fixed or determined period in the future, or for a market rise, or for sale if the market does not rise. The Purchaser does not have any such intention.

(d) Purchaser represents that the Purchaser is experienced in evaluating early-stage companies such as the Corporation, is able to fend for the Purchaser's own self in the transactions contemplated by this Agreement, has such knowledge and experience in financial and business matters as to be capable of evaluating the merits and risks of the Purchaser's investment, and has the ability to bear the economic risks of the Purchaser's investment. The Purchaser further represents that the Purchaser has had access, during the course of the transactions contemplated hereby and prior to the Purchaser's acquisition of Shares, to all such information as the Purchaser deemed necessary or appropriate (to the extent the Corporation possessed such information or could acquire it without unreasonable effort or expense), and that the Purchaser has had, during the course of the transactions and prior to the Purchaser's acquisition of Shares, the opportunity to ask questions of, and receive answers from, the Corporation concerning the terms and conditions of the offering and to obtain additional information (to the extent the Corporation possessed such information or could acquire it without unreasonable effort or expense) necessary to verify the accuracy of any information furnished to the Purchaser or to which the Purchaser had access.

(e) Purchaser understands that the Shares may not be sold, transferred or otherwise disposed of without registration under the 1933 Act, or any other applicable securities laws, or an exemption therefrom, and that in the absence of an effective registration statement covering the Shares or an available exemption from registration under the 1933 Act or any other applicable securities laws, the Shares must be held indefinitely. In particular, the Purchaser is aware that the Shares may not be sold pursuant to Rule 144 promulgated under the 1933 Act unless all of the conditions of that Rule are met. Among the conditions for use of Rule 144 is the availability of current information to the public about the Corporation. Such information is not now available and the Corporation has no present plans to make such information available. The Purchaser represents that, in the absence of an effective registration statement covering the Shares the Purchaser will sell, transfer, or otherwise dispose of the Shares only in a manner consistent with the Purchaser's representations set forth herein.

(f) Purchaser agrees that in no event will the Purchaser make a transfer or disposition of any of the Shares (other than pursuant to an effective registration statement under the 1933 Act or, to the Corporation's reasonable satisfaction, pursuant to Rule 144), unless and until (i) the Purchaser shall have notified the Corporation of the proposed disposition and shall have furnished the Corporation with a statement of the circumstances surrounding the disposition, and (ii) if requested by the Corporation, at the expense of the Purchaser or transferee, the Purchaser shall have furnished to the Corporation an opinion of counsel, reasonably satisfactory to the Corporation, to the effect that such transfer may be made without registration under the 1933 Act.

(g) Purchaser understands that each certificate representing the Shares will be endorsed with a legend substantially as follows.

"THE SECURITIES REPRESENTED BY THIS CERTIFICATE HAVE NOT BEEN REGISTERED UNDER THE SECURITIES ACT OF 1933, AS AMENDED (THE "1933 ACT"), OR APPLICABLE STATE SECURITIES LAWS. THESE SECURITIES HAVE BEEN ACQUIRED FOR INVESTMENT AND NOT WITH A VIEW TO DISTRIBUTION OR RESALE, AND MAY NOT BE SOLD, MORTGAGED, PLEDGED, HYPOTHECATED OR OTHERWISE TRANSFERRED WITHOUT AN EFFECTIVE REGISTRATION STATEMENT FOR SUCH SECURITIES UNDER THE 1933 ACT, AND ANY APPLICABLE STATE SECURITIES LAWS, OR THE AVAILABILITY OF AN EXEMPTION FROM THE REGISTRATION PROVISIONS OF THE 1933 ACT AND APPLICABLE STATE SECURITIES LAWS."

(h) Purchaser will indemnify the Corporation, its officers, directors, shareholders, employees and agents against any losses or damages suffered by any of them as a result of the failure of the above representations and warranties to be true or the failure of the Purchaser to comply with the agreements set forth herein.

(i) Purchaser understands that no public market now exists for any of the securities issued by the Corporation and that there is no assurance that a public market will ever exist for the Shares.

Section 2. Representations and Warranties of the Corporation. The Corporation hereby represents, warrants and agrees as follows:

(a) The Corporation is duly organized, validly existing and in good standing under the laws of Delaware. The Corporation has all requisite power and authority to carry on its business as proposed to be conducted.

(b) The Corporation has full legal power and authority to enter into this Agreement and to carry out and perform its obligations hereunder. The execution, delivery and performance by Corporation of this Agreement and the consummation of the transactions as contemplated hereby have been duly authorized and approved by all necessary action. This Agreement has been duly authorized, executed and delivered by the Corporation and, assuming due authorization, execution and delivery by the other party hereto, constitutes the legal, valid and binding obligation of the Corporation enforceable against the Corporation in accordance with its terms, except as enforceability may be limited by bankruptcy, insolvency, fraudulent transfer, reorganization, moratorium and other similar laws relating to or affecting creditor's rights generally and to general equitable principles.

(c) The execution and delivery of this Agreement, the consummation of the transactions contemplated hereby and the performance of the Corporation's obligations hereunder will not conflict with, or result in a violation of or default (or event which after passage of time or notice, or both, would constitute a default) under, any provision of any governing instrument applicable to the Corporation or any other agreement or other instrument to which the Corporation is a party or by which the Corporation or any of its properties are bound, or any foreign or domestic permit, franchise, judgment, decree, stature, rule or regulation applicable to the Corporation or the Corporation's business or properties.

(d) Assuming the Purchaser's representations and warranties set forth in Section 1 are true and correct in all material respects, the offer and sale, issuance and delivery of the Shares contemplated hereby are exempt from registration under the 1933 Act, and under applicable state securities and "blue sky" laws, as currently in effect.

(e) The Shares being purchased by the Purchaser hereunder, when issued, sold and delivered in accordance with the terms of this Agreement for the consideration expressed herein, will be duly authorized and validly issued, fully paid, and nonassessable, and will be free of restrictions on transfer other than restrictions on transfer under this Agreement and under applicable federal and state securities laws.

Section 3. Anti-Dilution Protection; Registration Rights; Director Designation.

(a) Anti-Dilution. If, at any time, until the earliest of (i) the initial public offering of the Corporation's equity securities under the 1933 Act ("***IPO***") or (ii) a Change of Control of the Corporation, the Corporation issues Additional Securities, but excluding any Excluded Securities, that would cause the Purchaser's collective shareholdings in the Corporation to drop below twenty five percent (25%) on a Fully Diluted Basis, then concurrently with the issuance of such Additional Securities, the Corporation shall issue directly to the Purchaser for no additional consideration such additional number of shares of common stock of the Corporation such that the Purchaser's shareholdings in Corporation shall equal twenty five percent (25%) of the capital stock of the Corporation on a Fully Diluted Basis, as calculated after giving effect to the issuance of such Additional Securities and the resulting anti-dilutive issuance to the Purchaser hereunder. Upon request, but no more frequently than once per calendar quarter, the Corporation will deliver to the Purchaser a statement of the outstanding capital stock of the Corporation on a Fully Diluted Basis in sufficient detail as to permit the Purchaser to calculate its percentage equity ownership in the Corporation.

The following terms shall have the following meanings:

(i) "***Additional Securities***" means shares of capital stock of any class or series (including preferred stock), warrants or other rights to subscribe for, purchase or acquire from the Corporation any capital stock of the Corporation, but excluding any Excluded Securities.

(ii) ***"Change of Control***" means (x) the acquisition of the Corporation or its equity securities by another person or entity by means of any transaction or series of related transactions (including, without limitation, any reorganization, merger or consolidation) that results in the transfer of all of the outstanding equity securities of the Corporation, or (y) a sale of all or substantially all of the assets of the Corporation.

(iii) "***Excluded Securities***" means equity awards issued by the Corporation pursuant to a stockholder-approved plan and the shares of Common Stock issued pursuant to the exercise of such awards; provided, however, that such Excluded Securities reserved under any plan (whether or not approved by the stockholders) shall not exceed twenty percent (20%) of the outstanding equity securities of the Corporation.

(iv) "***Fully Diluted Basis***" means, as of a specified date of any issuance of Additional Securities, the number of shares of common stock of the Corporation then-outstanding, plus the number of shares of common stock of the Corporation issuable upon exercise or conversion of then-outstanding preferred shares, options (excluding any Excluded Securities), rights or warrants of the Corporation (which shall be determined without regard to whether such securities are then exercisable or convertible), but excluding any Excluded Securities, and plus the number of shares of capital stock issuable under any convertible promissory notes containing a fixed or determinable valuation cap.

(b) Demand Registration Rights. Subject to any applicable lock-up agreement (including any lock-up provisions in any applicable underwriting agreement) the Purchaser or the Corporation may enter into and subject to the conditions set forth in this Section 3(b), at any time after the Corporation's IPO, if the Corporation shall receive from the Purchaser a written request that the Corporation effect any registration under the 1933 Act with respect to the Shares specifying the number of Shares and intended method(s) of disposition of the Shares (the "***Demand Notice***"), the Corporation will: (i) promptly give written notice of the proposed registration to the Purchaser; and (ii) as soon as practicable, file and use its commercially reasonable and diligent efforts to effect such registration (including, without limitation, filing post-effective amendments, appropriate qualifications under applicable "blue sky" or other state securities laws, and appropriate compliance with the 1933 Act) and to permit or facilitate the sale and distribution of all such Shares as specified in the Demand Notice. The aggregate offering price for such registration under this Section shall not be less than $5,000,000. Notwithstanding the foregoing, the Purchaser may not exercise its demand registration rights after three (3) years from the effective date of the Corporation's IPO, and may not exercise its demand rights on more than two occasions.

(c) Piggyback Registration Rights. For a period of three (3) years from the closing of the Corporation's IPO, if at any time the Corporation shall determine to register in a public offering for its own account (or the account of selling stockholders) under the 1933 Act any of its Common Stock, it shall send to the Purchaser written notice of such determination and, if within twenty (20) days after receipt of such notice, the Purchaser shall so request in writing, the Corporation shall use its commercially reasonable efforts to include in such registration statement all or any part of the Shares such Purchaser requests to be registered. This right shall not apply to a registration of shares of Common Stock on Form S-4 or Form S-8 (or their then equivalents) relating to shares of Common Stock to be issued by the Corporation in connection with any acquisition of any entity or other business combination involving the Corporation, or shares of Common Stock issuable in connection with any stock option, stock compensation or other employee benefit plan of the Corporation for the benefit of employees, officers, directors or consultants of the Corporation. If, in connection with any offering involving an underwriting or best efforts placement of Common Stock to be issued by the Corporation and/or selling stockholders, the managing underwriter or the sales agent, as applicable, of such offering or the Corporation shall impose a limitation on the number of shares of such Common Stock which may be included in any such registration statement because, in its judgment, such limitation is necessary to effect an orderly public distribution of the Common Stock and to maintain a stable market for the securities of the Corporation, then the Corporation shall be obligated to include in such registration statement only such limited portion (which may be none) of the Shares with respect to which the Purchaser has requested inclusion thereunder, *pro rata* based upon the number of shares originally requested for inclusion in such registration statement by all selling stockholders requesting inclusion thereunder. In the case of a registration under Section 3(b) or this paragraph (c), the Corporation shall bear the expenses of any filing of any registration, including, but not limited to, printing, legal and accounting expenses, Securities and Exchange Commission and FINRA filing fees and all related "Blue Sky" fees and expenses; *provided, however*, that the Corporation shall have no obligation to pay or otherwise bear any portion of the underwriters' commissions or discounts attributable to the Shares being offered and sold by the Purchaser, or the fees and expenses of any counsel, tax advisor or accountant selected by the Purchaser in connection with the registration of the Shares.

(d) Director Designation. For so long as the Purchaser holds at least fifty percent (50%) of the Shares initially issued to it hereunder, the Purchaser shall have the right to designate one director of the Corporation (the "***Director Designee***"). At any meeting of stockholders at which directors of the Corporation are proposed for election (or through the distribution of any written consent or proxy of stockholders solicited by the Corporation or any third party for the election of directors), the Corporation shall propose the Director Designee for election to the Board of Directors, subject to approval by the stockholders. In lieu of a request for designation and nomination as a director, the Purchaser may substitute the Director Designee with a non-voting observer to the Board of Directors. The non-voting observer, if any, shall be bound by the same duties, including confidentiality, as would a director of the Corporation, as well as any Corporation policies applicable to directors of the Corporation; provided, however, the non-voting observer shall have no fiduciary duty to the Corporation.

Section 4. Miscellaneous.

(a) Notices. The Purchaser agrees that the Corporation may deliver any notice of any meeting of the shareholders of the corporation to the Purchaser by electronic mail or other electronic means and that any notice sent to the Purchaser by the Corporation by such means will be deemed effective when sent as provided in the Delaware General Corporation Law. The Purchaser and the Corporation agree that the Purchaser may terminate this Section 4(a) at any time by written notice to the Corporation and such notice of termination of this Section 4(a) shall be effective upon receipt by the Corporation.

(b) Transferability. Notwithstanding the other provisions of this Agreement, upon ten (10) business days' prior written notice, the Purchaser shall be entitled to transfer or assign all or any portion of the Shares issued hereunder to an entity or person which is an affiliate or stockholder of the Purchaser or any affiliated entity of Purchaser, provided such transferee or assignee is bound by the provisions of this Agreement and any such transfer or assignment shall be made in accordance with applicable federal securities laws.

(c) Governing Law. The substantive law governing this Agreement (which shall be applied in the arbitration) shall be, with respect to disputes involving general contract or trade secret matters, the internal laws of the State of New York. Notwithstanding anything contained herein to the contrary the rights of the Purchaser solely with respect to the Shares shall be governed by the Delaware General Corporation Law and any relevant case law interpreting such law. Any award rendered by the arbitrator shall be final, conclusive and binding upon the parties to this Agreement, and judgment thereon may be entered and enforced in any state or federal court of competent jurisdiction. If any provisions of this Agreement are or will come into conflict with the laws or regulations of any jurisdiction or any governmental entity having jurisdiction over the Corporation or the Purchaser or this Agreement, those provisions will be deemed automatically deleted, if such deletion is allowed by relevant law, and the remaining terms and conditions of this Agreement will remain in full force and effect. If such a deletion is not so allowed or if such a deletion leaves terms thereby made clearly illogical or inappropriate in effect, the parties agree to substitute new terms as similar in effect to the present terms of this Agreement as may be allowed under applicable law.

(c) Counterparts; Delivery. This Subscription Agreement may be executed in any number of counterparts and may be delivered via electronic mail (including .pdf or any electronic signature complying with the U.S. federal ESIGN Act of 2000, e.g., DocuSign) or other transmission method, and any counterpart so delivered shall be deemed to have been duly and validly delivered and be valid and effective for all purposes, each of which shall be deemed an original, and all of which together shall constitute one instrument.

(d) Entire Agreement. This Agreement constitutes the entire agreement between the parties hereto with respect to the subject matter thereof and supersedes all previous agreements, negotiations, commitments, and writings with respect to such subject matter. Neither party shall be obligated by any undertaking or representation regarding that subject matter other than those expressly stated herein or as may be subsequently agreed to by the parties hereto in writing.

(e) Amendment. No amendment, modification or supplement of any provision of this Agreement will be valid or effective unless made in writing and signed by a duly authorized officer of each party hereto.

(f) Assignment. This Agreement will be binding upon and will inure to the benefit of each party hereto and each party's respective permitted transferees, successors and assigns, pursuant to the provisions set forth below. The Corporation may not transfer or assign this Agreement without the prior written consent of Purchaser, except that the Corporation may transfer or assign this Agreement without the prior written consent of Purchaser in the event of a Change of Control. Upon a Change of Control, the rights and obligations of the Corporation under this Agreement shall inure to the benefit of the acquiring party in the Change of Control. The Purchaser may not transfer or assign this Agreement without the prior written consent of the Corporation; provided, however, the Purchaser may transfer the Shares to an affiliated entity or to the stockholders or equity owners of any affiliated entity, and all rights and obligations of the transferees shall be binding upon, and inure to the benefit of, all parties. Notwithstanding anything contained herein to the contrary, the right of the Purchaser to designate a director or non-voting observer of the Corporation under Section 3(d) shall not be transferable.

[Signatures on next page]

IN WITNESS WHEREOF, the parties have duly executed this Subscription Agreement effective as of October 2, 2020.

CORPORATION:

NOVECITE, INC.

By: _____
Name:
Title:

11 Commerce Drive, 1st Floor
Cranford, New Jersey 07016

PURCHASER:

NOVELLUS LLC

By: _____
Name:
Title:

1035 Cambridge Street, Suite 17B
Cambridge, Massachusetts 02141

Schedule 6.1.2

Factor is the sole owner of the Licensed Patents below and the Licensed Know-How exclusively licensed to Licensor pursuant to the Factor Agreement.

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FAB-001AU	Factor Bioscience	Australia	2012347919 Dec-05-2012	2012347919 May-18-2017	PATENTED
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FAB-003C4	Factor Bioscience	USA	15/358,818 Nov-22-2016	9,695,401 Jul-04-2017	PATENTED
FAB-003C5	Factor Bioscience	USA	15/605,513 May-25-2017	9,879,228 Jan-30-2018	PATENTED
FAB-003C6	Factor Bioscience	USA	15/844,063 Dec-15-2017	9,969,983 May-15-2018	PATENTED
FAB-003C7	Factor Bioscience	USA	15/947,741 April-06-2018	10,131,882 Nov-20-2018	PATENTED
FAB-003C8	Factor Bioscience	USA	US 16/037,597 July-17-2018	10,301,599 May-28-2019	PATENTED
FAB-003C9	Factor Bioscience	USA	US 16/374,482 April 3, 2019	10,443,045 Oct 15, 2019	PATENTED

Docket Number	Assignee	Country	Application No. Application Date	Registration No. Registration Date	Case Status
FAB-003C10	Factor Bioscience	USA	US 16/562,497 Sept-05-2019	N/A	Pending
FAB-016PR	Factor Bioscience	USA	US 63/016,626 April 28,2020	N/A	Pending

Exhibit 21

Listing of Subsidiaries

Name of Subsidiary	Jurisdiction of Incorporation
Citius Pharmaceuticals, LLC	Massachusetts
Leonard-Meron Biosciences, Inc.	Delaware
NoveCite, Inc.	Delaware

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the Registration Statements on Forms S-1 (No.'s 333-224386, 333-226395, 333-230919, 333-233759, 333-237638 and 333-238975) and on Form S-3 (No. 333-248748) of Citius Pharmaceuticals, Inc. of our report dated December 16, 2020, 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, 2020.

/s/ Wolf & Company, P.C.

Wolf & Company, P.C.
Boston, Massachusetts

December 16, 2020

Exhibit 31.1

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

I, Myron Holubiak, 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 16, 2020

By: /s/ Myron Holubiak
Myron Holubiak
President and 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 16, 2020

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, 2020 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), Myron Holubiak, President and 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 16, 2020

By: /s/ Myron Holubiak
Myron Holubiak
President and Chief Executive Officer
(Principal Executive Officer,
Principal Financial Officer and
Principal Accounting Officer)

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