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, 2019

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

Commission File Number 333-170781

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)

(Former name and address, if changed since last report)

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

Title of Each Class	**Trading Symbol(s)**	
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 ninety (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, 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 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 29, 2019) was approximately $9.0 million.

Affiliates for the purpose of this item refers to the issuer's 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 clienteles' beneficial interest) owning 10% or more of the issuer's common stock, both of record and beneficially.

APPLICABLE ONLY TO CORPORATE REGISTRANTS

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

28,930,493 shares as of December 9, 2019, 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 Shareholders expected to be held on February 10, 2020 are incorporated by reference in Part III of this Report.

Citius Pharmaceuticals, Inc.
FORM 10-K
September 30, 2019

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NOTES

In this annual report on Form 10-K, and unless the context otherwise requires the "Company," "we," "us" and "our" refer to Citius Pharmaceuticals, Inc. and its wholly-owned subsidiaries, Citius Pharmaceuticals, LLC and Leonard-Meron Biosciences, Inc., 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 prospectus, appear with the trade name, trademark or service mark notice and then throughout the remainder of this prospectus 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 clinical trials;
- the cost, timing and results of our clinical trials;
- our ability to obtain and maintain required regulatory approvals for our product candidates;
- the commercial feasibility and success of our technology;
- 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.

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 and unique prescription products. Our goal 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.

Since its inception, the Company has devoted substantially all of its efforts to business planning, acquiring our proprietary technology, research and development, recruiting management and technical staff, and raising capital. We are developing three proprietary products: Mino-Lok, an antibiotic lock solution used to treat patients with catheter-related bloodstream infections by salvaging the infected catheter; Mino-Wrap, a liquifying gel-based wrap for reduction tissue expander infections following breast reconstructive surgeries; and Halo-Lido, a corticosteroid-lidocaine topical formulation that is intended to provide anti-inflammatory and anesthetic relief to persons suffering from hemorrhoids. 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, 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 the MDACC. The efficacy of Mino-Lok therapy was 100% in salvaging CVCs, demonstrating equal effectiveness to removing the infected CVC and replacing 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.

Parameter	**Mino-Lok® Arm**		**Control Arm**	
	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 Initiation

In November 2016, the Company initiated site recruitment for Phase 3 clinical trials. From initiation through first quarter 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 30, 2019, there are 30 active sites currently enrolling patients including such academic centers as MDACC, Henry Ford Health Center, Georgetown University Medical Center, University of Chicago, and others. There are five additional well renowned 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, which the FDA is reviewing.

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.

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." The new 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. The new 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 ("SOC") 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 central line associated blood stream infections ("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, the Company 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, the Company 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 the 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.

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 the breast reconstruction occurs simultaneously with mastectomy, with most reconstructions occurring weeks later.

The current standard of care in post-mastectomy breast reconstructive 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 2 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 can be improved by re-formulating our topical preparation. Therefore, we have 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, will combine lidocaine with the higher potency corticosteroid halobetasol propionate for symptomatic relief of the pain and discomfort of hemorrhoids.

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

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.

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 for us. 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 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. NAT 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 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, the new 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." The new 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.

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 SOC of removing the culprit CVC and replacing a new CVC at a different vascular site. Citius is not aware of any Investigational New Drug Applications ("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 Neutrolin from CorMedix Inc. and B-Lock from Great Lakes Pharmaceuticals, Inc. ("GLP").

Neutrolin® (CorMedix Inc.)

Neutrolin 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 Qualified Infectious Disease Product ("QIDP") designations for Neutrolin. In December 2015, CorMedix initiated its Phase 3 clinical trial in hemodialysis patients in the United States. The clinical trial named Catheter Lock Solution Investigational Trial, or LOCK-IT-100 is a prospective, multicenter, randomized, double-blind, placebo-controlled, active control trial designed to show efficacy and safety of Neutrolin in preventing CRBSIs in subjects receiving hemodialysis therapy. On April 20, 2017, CorMedix provided an update on the LOCK-IT-100 trial. CorMedix had enrolled 368 patients to date and completed a safety review by an independent Data and Safety Monitoring Board ("DSMB") of the first 279 patients. The DSMB concluded that it was safe to continue the trial as designed; however, CorMedix initiated discussions with the FDA to make some protocol changes to include one or more interim efficacy analyses. According to CorMedix, the FDA accepted the CorMedix proposal.

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 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 is expected to submit the results of the interim analysis to the FDA for its review.

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 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 over the counter products. If approved by the FDA, Halo-Lido will be the only prescription product for the treatment of hemorrhoids.

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 and NDA to the FDA for each of Mino-Lok, Halo-Lido and Mino-Wrap.

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, clinical testing, and the approval process or after approval, 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 Investigational New Drug ("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 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 Good Manufacturing Practices (GMP); 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, 2019, we had 9 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, 72, 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, 74, 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, 52, 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.

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 and in any documents incorporated in this report by reference.

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 common stock 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 shareholders' equity. The process of developing our product candidates requires significant clinical, development and 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 $15,562,144, $12,536,638 and $10,384,953 for the years ended September 30, 2019, 2018 and 2017, respectively. At September 30, 2019, we had stockholders' equity of $24,378,672 and an accumulated deficit of $55,819,982. Our net cash used in operating activities was $12,437,751, $11,318,138 and $7,971,205 for the years ended September 30, 2019, 2018 and 2017, 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.

Currently, we do not have sufficient capital to continue our operations after the first six months of fiscal 2020. 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 shareholders, 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, 2019.

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 $47.9 million from our public and private placement offerings through September 30, 2019. 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' ability to continue to expand or fund existing research and development efforts. If these 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 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 products and we 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 businesses planning, acquiring our proprietary technology, research and development, recruiting management and technical staff, and raising capital. These operations provide a limited basis for you to assess our ability to successfully commercialize our product candidates and the advisability of investing in our securities.

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

At any time, we may decide to discontinue the development of any of our product candidates for a variety of reasons, including inadequate financial resources, the appearance of new technologies that render our product candidate 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 of an NDA 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 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.

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 and 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 corticosteriod, 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 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 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.

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 our product candidates;
- 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 candidates that receive 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 with third parties, we will experience delays in product 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 currently marketing or 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;
- 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 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 Current Good Manufacturing Practices, or cGMP, and applicable non-U.S. regulatory requirements. The cGMP requirements govern quality control and documentation policies and procedures. Complying with cGMP and non-U.S. regulatory requirements will require that we expend time, money, and effort in production, recordkeeping, and quality control to assure that the product meets applicable specifications and other requirements. Our contracted manufacturing facilities must also pass a pre-approval inspection prior to FDA approval. Failure to pass a pre-approval inspection might significantly delay FDA approval of our product candidates. If any of our collaborators fails to comply with these requirements, we would be subject to possible regulatory action which could limit the jurisdictions in which we are permitted to sell our product candidates. As a result, our business, financial condition, and results of operations might be materially harmed.

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

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

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

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

- Currently, our contract manufacturer for our clinical supplies is foreign, which increases the risk of shipping delays and adds the risk of import restrictions;

- 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; 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. 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 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 collaboration 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 difficult completing the development of any of our product candidates and potentially lose significant sources of revenue, which could result in volatility in our 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. 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 purchased technologies, products or business operations;
- maintaining uniform standards, procedures, controls and policies;
- unanticipated costs associated with the acquisition or investment;
- diversion of our management's attention from our preexisting business;
- maintaining or obtaining the necessary regulatory approvals or complying with regulatory standards; and
- adverse effects on existing business operations.

We have no current commitments with respect to any acquisition or investment in other technologies or businesses. We do not know if we will identify 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 would 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, and our Executive Chairman, Leonard Mazur, in particular have significant experience in the running of pharmaceutical companies as well as drug development itself. This depth of experience is of significant benefit to us, especially given the small size of our management team and company. The loss of the services of either Mr. Holubiak or Mr. Mazur, as well as any other member of our executive management or any key employees could harm our ability to attract capital and develop and commercialize our product candidates. We have no 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 part-time basis to assist us in managing our ongoing Phase 2 and Phase 3 trials and intend to do so for future 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. 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.

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. 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 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. 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 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 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 our product candidates. Failure to obtain FDA approval of our product candidates will 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. 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 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 our product candidates. 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, 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.

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. 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 via the Internet 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 products. We have obtained limited product liability insurance coverage for our pre-clinical and clinical trials of $2.0 million per occurrence and in the aggregate, subject to a deductible of $50,000 per occurrence. 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, recent 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

Our current failure to meet the continued listing requirements of Nasdaq 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 and maintaining a minimum level of stockholders' equity. In October 2019, we received a notice from Nasdaq that because the closing bid price for our common stock had 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 Listing Rules, we have until April 27, 2020 to regain compliance with the minimum bid price requirement. To regain compliance, the closing bid price of the Company's common stock must meet or exceed $1.00 per share for a minimum of 10 consecutive business days prior to April 27, 2020.

If we do not regain compliance by April 27, 2020, we may be eligible for an additional grace period. To qualify, we would be required to meet the continued listing requirements for market value of publicly held shares and all other initial listing standards for The Nasdaq Capital Market, with the exception of the minimum bid price requirement, and provide written notice of our intention to cure the minimum bid price deficiency during the second compliance period. If we meet these requirements, the Nasdaq staff will grant an additional 180 calendar days for us to regain compliance with the minimum bid price requirement. If the Nasdaq staff determines that we will not be able to cure the deficiency, or if we are otherwise not eligible for such additional compliance period, Nasdaq will provide notice that our common stock will be subject to delisting. We would have the right to appeal a determination to delist our common stock, and the common stock would remain listed on The Nasdaq Capital Market until the completion of the appeal process.

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 intend to consider all available alternatives to regain compliance with Rule 5550(a)(2) to allow for continued listing of the common stock on The Nasdaq Capital Market. However, we can provide no assurance that any 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. If we regain compliance and maintain the listing of the common stock on The Nasdaq Capital Market, we cannot assure you that we would be able to 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, shareholders 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 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 that 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). While we remediated these material weaknesses as of September 30, 2018, such that management determined that our internal controls over financial reporting were effective as of that date, and as of September 30, 2019, we cannot assure 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 shareholders 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 shareholders 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 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 private placements;
- regulatory actions regarding our product candidates or any approved products;
- announcements of developments by us or our competitors;
- additions or departures of key personnel;
- 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;
- introduction of new approved products by us or our competitors; 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, 2019, there were 28,930,493 shares of common stock outstanding, 25,492,513 shares underlying warrants with a weighted average exercise price of $1.62 per share (including 1,060,615 shares underlying pre-funded warrants with an exercise price of $0.0001), and 1,771,039 shares underlying options with a weighted average exercise price of $4.03 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.

The common stock is controlled by insiders.

As of November 30, 2019, our executive officers and directors beneficially owned approximately 56.84% 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 the business, it is currently anticipated 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 any 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.

Our publicly traded warrants may not have any value.

Our publicly traded warrants to purchase shares of our common stock may not have any value. These warrants have an exercise price of $4.125 per share. In the event that our common stock price does not exceed the exercise price of our publicly traded warrants during the period when the warrants are exercisable, the warrants may not have any value.

There is no established market for our publicly traded warrants.

There is no established trading market for our publicly traded warrants, and we do not expect a market to develop. In addition, we do not intend to apply for the listing of these warrants on any national securities exchange or other trading market. Without an active trading market, the liquidity of these warrants is limited.

Holders of our publicly traded warrants will have no rights as a common stockholder until they acquire our common stock.

Until holders of our publicly traded warrants acquire shares of our common stock upon exercise of their warrants, the warrant holders will have no rights with respect to shares of our common stock issuable upon exercise of their warrants. Upon exercise of the warrants, the warrant holders will be entitled to exercise the rights of a common stockholder only as to matters for which the record date occurs after the exercise date.

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. Annual base rent for the years ending September 30, 2020, 2021, 2022, 2023, 2024, 2025 and 2026 is $191,526, $234,447, $239,306, $244,165, $249,024, $253,883 and $21,460, respectively. We will also pay our proportionate share of real estate taxes and operating expenses in excess of the base year expenses.

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

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.

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, 2019, 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 certain of 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. The Company does not undertake any obligation to update forward-looking statements to reflect events or circumstances occurring after the filing date of this report.

Historical Background

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 September 12, 2014, we acquired Citius Pharmaceuticals, LLC as a wholly-owned subsidiary.

On March 30, 2016, the Company acquired all of the outstanding stock of Leonard-Meron Biosciences, Inc. ("LMB") by issuing shares of its common stock. The Company acquired identifiable intangible assets of $19,400,000 related to in-process research and development and recorded goodwill of $1,586,796 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.

Through September 30, 2019, the Company has devoted substantially all of its efforts to product development, raising capital, building infrastructure through strategic alliances and coordinating activities relating to its proprietary products. The Company has 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 commence. 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 ("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 FDA.

Under the license agreement, the Company 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.

Results of Operations for Year Ended September 30, 2019 compared to Year Ended September 30, 2018

	Year Ended September 30, 2019	Year Ended September 30, 2018
Revenues	$ -	$ -
Operating expenses:		
Research and development	8,596,898	6,562,925
General and administrative	6,285,480	6,446,517
Stock-based compensation – general and administrative	715,983	779,701
Total operating expenses	15,598,361	13,789,143
Operating loss	(15,598,361)	(13,789,143)
Interest income	52,660	-
Gain on extinguishment of liability	-	450,000
Other income	-	818,343
Interest expense	(16,443)	(15,838)
Net loss	$ (15,562,144)	$ (12,536,638)

Revenues

We did not generate any revenues for the years ended September 30, 2019 and 2018.

Research and Development Expenses

For the year ended September 30, 2019, research and development expenses were $8,596,898 as compared to $6,562,925 for the year ended September 30, 2018. The $2,033,973 increase in 2019 was primarily due to the ongoing Phase 3 trial of Mino-Lok which commenced during the quarter ended March 31, 2018. Research and development costs for Mino-Lok were $7,148,284 for the year ended September 30, 2019 as compared to $6,121,150 for the year ended September 30, 2018, an increase of $1,027,134. Research and development costs for Halo-Lido were $1,323,614 for the year ended September 30, 2019 as compared to $441,775 for the year ended September 30, 2018, an increase of $881,839. We also incurred $125,000 in research and development expense related to the Mino-Wrap license agreement during the year ended September 30, 2019. We expect that research and development expenses will continue to increase as we continue to focus on and expand our Phase 3 trial of Mino-Lok and pursue the development of Halo-Lido and Mino-Wrap. We are actively seeking additional capital in order to fund our research and development efforts.

General and Administrative Expenses

For the year ended September 30, 2019, general and administrative expenses were $6,285,480 as compared to $6,446,517 for the year ended September 30, 2018. The decrease of $161,037 in 2019 was primarily due to the $357,400 in settlement costs incurred during the year ended September 30, 2018 for the termination of the right of first refusal agreement with the underwriter of our 2017 public offering.

Stock-based Compensation Expense

For the year ended September 30, 2019, stock-based compensation expense was $715,983 as compared to $779,701 for the year ended September 30, 2018. Stock-based compensation expense decreased by $63,718 in comparison to the prior period as certain options have been fully expensed. At September 30, 2019, unrecognized total compensation cost related to unvested options of $741,843 is expected to be recognized over a weighted average period of 1.66 years.

Other Income (Expense)

During the year ended September 30, 2019, the Company earned $52,660 of interest income on investment of proceeds from its equity offerings. During the year ended September 30, 2018, the Company recorded a $450,000 gain on the extinguishment of a liability as the Company reversed an accrual for certain research and development expenses that was recorded in a prior year that will not be paid. In addition, during the year ended September 30, 2018, the Company recorded as other income a refund receivable in the amount of $818,343 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, 2019 was $16,443 as compared to $15,838 for the year ended September 30, 2018. Interest expense for both years is for the notes payable to related parties that were acquired in the acquisition of LMB.

Net Loss

For the year ended September 30, 2019, we incurred a net loss of $15,562,144 compared to a net loss of $12,536,638 for the year ended September 30, 2018. The $3,025,506 increase in the net loss was primarily due to the $2,033,973 increase in research and development expenses and the $1,216,288 decrease in net other income (expense).

Results of Operations for Year Ended September 30, 2018 compared to Year Ended September 30, 2017

	September 30, 2018	September 30, 2017
Revenues	$ -	$ -
Operating expenses:		
Research and development	6,562,925	2,936,252
General and administrative	6,446,517	6,063,439
Stock-based compensation – general and administrative	779,701	986,620
Total operating expenses	13,789,143	9,986,311
Operating loss	(13,789,143)	(9,986,311)
Gain on extinguishment of liability	450,000	-
Other income	818,343	-
Gain on revaluation of derivative warrant liability	-	452,147
Interest expense	(15,838)	(850,789)
Net loss	$ (12,536,638)	$ (10,384,953)

Revenues

We did not generate any revenues for the years ended September 30, 2018 and 2017.

Research and Development Expenses

For the year ended September 30, 2018, research and development expenses were $6,562,925 as compared to $2,936,252 for the year ended September 30, 2017. The $3,626,673 increase in 2018 was primarily due to the ongoing Phase 3 trial of Mino-Lok which commenced during the quarter ended March 31, 2018. Research and development costs for Mino-Lok were $6,121,150 for the year ended September 30, 2018 as compared to $2,688,937 for the year ended September 30, 2017, an increase of $3,432,213. Research and development costs for Halo-Lido were $441,775 for the year ended September 30, 2018 as compared to $247,315 for the year ended September 30, 2017, an increase of $194,460. We expect that research and development expenses will continue to increase as we continue to focus on and expand our Phase 3 trial of Mino-Lok and pursue the development of Halo-Lido and Mino-Wrap. We are actively seeking additional capital in order to fund our research and development efforts.

General and Administrative Expenses

For the year ended September 30, 2018, general and administrative expenses were $6,446,517 as compared to $6,063,439 for the year ended September 30, 2017. The increase of $383,078 in 2018 was primarily due to increased compensation costs, increased consulting fees incurred for financing activities and corporate development services, and increased investor relations fees. In addition, we incurred $357,400 in settlement costs for the termination of the right of first refusal agreement with the underwriter of our 2017 public offering during the year ended September 30, 2018 compared to $475,885 in settlement costs and $104,138 in financial consulting expenses incurred related to the issuance of a unit purchase option during the year ended September 30, 2017.

Stock-based Compensation Expense

For the year ended September 30, 2018, stock-based compensation expense was $779,701 as compared to $986,620 for the year ended September 30, 2017. Stock-based compensation expense includes the expense for options assumed in the March 30, 2016 acquisition of LMB, as well as grants to employees, directors and consultants. Stock-based compensation expense decreased by $206,919 in comparison to the prior period as certain options have been fully expensed.

Other Income (Expense)

During the year ended September 30, 2018, the Company recorded a $450,000 gain on the extinguishment of a liability. The Company reversed an accrual for certain research and development expenses that was recorded in a prior year that will not be paid. In addition, during the year ended September 30, 2018, the Company recorded as other income a refund receivable in the amount of $818,343 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 Suprenza applications.

There was no gain on revaluation of derivative warrant liability for the year ended September 30, 2018 as there were no warrants classified as derivative warrants during the year. Gain on revaluation of derivative warrant liability for the year ended September 30, 2017 was $452,147. The fair value of the derivative warrant liability fluctuated with changes in our stock price, volatility, remaining lives of the warrants, and interest rates.

Interest expense for the year ended September 30, 2018 was $15,838 as borrowings from our Chairman were converted to common stock on August 8, 2017. Interest expense on the notes payable acquired in the acquisition of LMB and borrowings from our Chairman was $850,789 for the year ended September 30, 2017, and includes net non-cash interest expense of $762,078 due to the beneficial conversion feature on the conversion price of $1,595,411 and the amortization of the previously recorded modification premium of $833,333.

Net Loss

For the year ended September 30, 2018, we incurred a net loss of $12,536,638 compared to a net loss of $10,384,953 for the year ended September 30, 2017. The $2,151,685 increase in the net loss was primarily due to the $3,626,673 increase in research and development expenses offset by the $1,651,147 increase in net other income (expense).

LIQUIDITY AND CAPITAL RESOURCES

Going Concern Uncertainty and Working Capital

Citius has incurred losses of $15,562,144, $12,536,638 and $10,384,953 for the years ended September 30, 2019, 2018 and 2017, respectively. At September 30, 2019, Citius had an accumulated deficit of $55,819,982. Citius' net cash used in operations during the years ended September 30, 2019, 2018 and 2017, was $12,437,751, $11,318,138 and $7,971,205, respectively.

The independent registered public accounting firm report on our September 30, 2019 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, 2019, Citius had working capital of $3,334,193. 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, 2019, Citius had cash and cash equivalents of $7,893,804 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, 2019, 2018 and 2017, the Company received net proceeds of $11,147,552, $17,298,033 and $6,673,088, respectively, from the issuance of equity. We also received $4,210,000 from the issuance of notes payable to our Chairman of the Board, Mr. Leonard Mazur, during the year ended September 30, 2017. Mr. Mazur converted the notes payable to common stock on August 8, 2017. 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 and travel expenses.

Financing Activities

The Board of Directors authorized revolving demand promissory notes with Leonard Mazur in an aggregate principal amount of up to $2,500,000 that accrue interest at the prime rate plus 1%. On September 7, 2016, the Company issued a $500,000 note. The Company issued $2,000,000 of additional notes through the period ended May 10, 2017. On May 10, 2017, the notes were converted into a single $2,500,000 convertible promissory note that was convertible into shares of common stock, at the sole discretion of Mr. Mazur, at a conversion price equal to 75% of the price per share paid by investors in the Company's 2017 registered public offering. In connection with the modification of the note, the Company recorded a charge of $833,333 to additional paid-in capital and increased the carrying value of the notes to $3,333,333 which is the fair value of the common stock issuable on conversion. On August 8, 2017, Leonard Mazur converted the $2,500,000 principal balance and accrued interest of $63,174 into 828,500 shares of common stock.

On May 10, 2017 and June 23, 2017, the Company executed a $1,500,000 future advance convertible promissory note and a $1,000,000 future advance convertible promissory note, respectively, with Leonard Mazur that accrued interest at the prime rate plus 1%. The notes were convertible into shares of common stock, at the sole discretion of Mr. Mazur, at a conversion price equal to 75% of the price per share paid by investors in the Company's 2017 registered public offering. On August 8, 2017, Mr. Mazur converted the outstanding $2,210,000 principal balances and accrued interest of $13,066 into 718,567 shares of common stock.

In February 2017, the Company sold 128,017 units at $6.00 per unit for gross proceeds of $768,100. Each unit consisted of one share of common stock and a five-year warrant to purchase one share of common stock at an exercise price of $8.25 per share. On June 8, 2017, the Company entered into agreements where it was released from the restrictions included in the purchase agreements. In exchange, the Company agreed to reprice the sale of the units to $4.125 per unit and reprice the warrants to an exercise price of $4.125 per share. During the year ended September 30, 2017, the Company issued an additional 58,191 shares of common stock to the investors.

On August 8, 2017, the Company closed an underwritten public offering of 1,648,484 shares of common stock and warrants to purchase 1,648,484 shares of common stock at an offering price of $4.125 per share and $0.01 per warrant. The warrants have a per share exercise price of $4.125, are exercisable immediately and will expire five years from the date of issuance. The gross proceeds to Citius from this offering were $6,802,469, before deducting underwriting discounts and commissions and other offering expenses of $685,573. The Company granted the underwriters a 45-day option to purchase up to an additional 247,272 shares of common stock and warrants to purchase 247,272 shares of common stock to cover over-allotments, if any. On August 8, 2017, the underwriters partially exercised the over-allotment to purchase an additional 247,272 warrants.

On December 19, 2017, the Company closed a registered direct offering for the sale of 1,280,360 shares of common stock at $4.6925 per share for gross proceeds of $6,008,089. Simultaneously, the Company privately sold and issued to the investors 640,180 immediately exercisable five and a half year warrants with an exercise price of $4.63 per share. Net proceeds from the offering were $5,482,523.

On March 29, 2018, the Company closed a registered direct offering for the sale of 669,504 shares of common stock at $2.985 per share for gross proceeds of $1,998,469. Simultaneously, the Company privately sold and issued to investors 669,504 immediately exercisable five and a half year warrants with an exercise price of $2.86 per share. Net proceeds from the offering were $1,763,576.

On August 13, 2018, the Company closed an offering for the sale of (i) 5,521,569 units, each unit consisted of one share of common stock and one immediately exercisable five-year warrant to purchase one share at $1.15 per share, and (ii) 2,321,569 pre-funded units, each pre-funded unit consisting of one pre-funded warrant to purchase one share of common stock and one immediately exercisable five-year warrant to purchase one share at $1.15 per share. The exercise price of the pre-funded warrant is $0.01 and the pre-funded warrants do not expire. The offering price was $1.275 per unit and $1.265 per pre-funded unit. Net proceeds from the offering were $8,926,786.

During the year ended September 30, 2018, an aggregate of 272,767 of the August 2017 public offering warrants were exercised at $4.125 per share for net proceeds of $1,125,148.

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. Net proceeds from the offering were $4,834,001.

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.

We expect that we will have sufficient capital to continue our operations through March 2020. 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 received in a timely manner to fully support our operations.

Inflation

Our management believes that inflation has not had a material effect on our results of operations.

Off Balance Sheet Arrangements

We do not have any off-balance sheet arrangements.

CRITICAL ACCOUNTING POLICIES

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

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 8 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 triggering events occurred since the acquisition of LMB that suggested a potential impairment had occurred through September 30, 2019.

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 initially performed a qualitative assessment for our 2019 analysis of goodwill. A decline in the Company's stock price and market capitalization were considered in determining whether it is more likely than not that the fair value of the reporting unit is less than its carrying amount. Management then performed the quantitative testing of comparing the fair value of the reporting unit to its carrying value resulting in the fair value of the reporting unit exceeding its carrying amount as of September 30, 2019.

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, 2019 and 2018, and the related consolidated statements of operations, changes in stockholders' equity and cash flows for each of the years in the three-year period ended September 30, 2019, 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, 2019 and 2018, and the results of its operations and its cash flows for each of the years in the three-year period ended September 30, 2019, 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, 2019

CITIUS PHARMACEUTICALS, INC.
CONSOLIDATED BALANCE SHEETS
SEPTEMBER 30, 2019 AND 2018

	2019	2018
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 7,893,804	$ 9,184,003
Other receivables	—	818,343
Prepaid expenses	48,111	57,732
Total Current Assets	7,941,915	10,060,078
Property and equipment, net	590	1,483
Other Assets:		
Deposits	57,093	2,167
In-process research and development	19,400,000	19,400,000
Goodwill	1,586,796	1,586,796
Total Other Assets	21,043,889	20,988,963
Total Assets	$ 28,986,394	$ 31,050,524
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	$ 2,713,542	$ 1,573,444
Accrued expenses	246,225	181,657
Accrued compensation	1,400,688	1,198,915
Accrued interest	74,297	57,854
Notes payable – related parties	172,970	172,970
Due to related party	—	—
Total Current Liabilities	4,607,722	3,184,840
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; 28,930,493 and 16,198,791 shares issued and outstanding at September 30, 2019 and 2018, respectively	28,930	16,199
Additional paid-in capital	80,169,724	68,107,323
Accumulated deficit	(55,819,982)	(40,257,838)
Total Stockholders' Equity	24,378,672	27,865,684
Total Liabilities and Stockholders' Equity	$ 28,986,394	$ 31,050,524

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, 2019, 2018 AND 2017

	2019	2018	2017
Revenues	$ —	$ —	$ —
Operating Expenses:			
Research and development	8,596,898	6,562,925	2,936,252
General and administrative	6,285,480	6,446,517	6,063,439
Stock-based compensation – general and administrative	715,983	779,701	986,620
Total Operating Expenses	15,598,361	13,789,143	9,986,311
Operating Loss	(15,598,361)	(13,789,143)	(9,986,311)
Other Income (Expense), Net:			
Interest income	52,660	—	—
Gain on extinguishment of liability	—	450,000	—
Other income	—	818,343	—
Gain on revaluation of derivative warrant liability	—	—	452,147
Interest expense	(16,443)	(15,838)	(850,789)
Total Other Income (Expense), Net	36,217	1,252,505	(398,642)
Loss before Income Taxes	(15,562,144)	(12,536,638)	(10,384,953)
Income tax benefit	—	—	—
Net Loss	$ (15,562,144)	$ (12,536,638)	$ (10,384,953)
Net Loss Per Share - Basic and Diluted	$ (0.77)	$ (1.17)	$ (1.89)
Weighted Average Common Shares Outstanding			
Basic and diluted	20,161,854	10,731,875	5,482,494

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, 2019, 2018 AND 2017

	Preferred Stock	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Equity
		Shares	Amount			
Balance, September 30, 2016	$ —	4,875,871	$ 4,876	$ 34,097,754	$ (17,336,247)	$ 16,766,383
Issuance of common stock in private placement, net of costs	—	128,016	128	491,223	—	491,351
Issuance of common stock in public offering, net of costs	—	1,648,484	1,648	6,115,248		6,116,896
Issuance of common stock for services and release agreements	—	140,843	141	703,878	—	704,019
Issuance of fractional shares for 1-for-15 reverse stock split	—	734	1	(1)	—	—
Stock options exercised	—	4,829	5	35	—	40
Conversion of convertible promissory notes – related party to common stock		1,547,067	1,547	4,784,693	—	4,786,240
Beneficial conversion feature on convertible promissory notes – related party	—	—	—	1,595,411	—	1,595,411
Premium on convertible promissory notes – related party	—	—	—	(833,333)	—	(833,333)
Issuance of unit purchase options	—	—	—	297,998	—	297,998
Issuance of warrants in settlement of liabilities	—	—	—	190,890	—	190,890
Reclassification of derivative warrant liability to additional paid-in capital, net	—	—	—	1,229,826	—	1,229,826
Stock-based compensation	—	—	—	986,620	—	986,620
Net loss	—	—	—	—	(10,384,953)	(10,384,953)
Balance, September 30, 2017	—	8,345,844	8,346	49,660,242	(27,721,200)	21,947,388
Issuance of common stock in registered direct offering, net of costs of $760,459	—	1,949,864	1,949	7,244,150		7,246,099
Issuance of common stock, net of issuance costs and underwriting discount of $1,049,999	—	5,521,569	5,522	8,921,264	—	8,926,786
Issuance of common stock upon exercise of warrants	—	289,314	290	1,124,858	—	1,125,148
Issuance of common stock for services and release agreement	—	92,200	92	377,108	—	377,200
Stock-based compensation expense				779,701	—	779,701
Net loss	—	—	—	—	(12,536,638)	(12,536,638)
Balance, September 30, 2018	—	16,198,791	16,199	68,107,323	(40,257,838)	27,865,684
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	$ (55,819,982)	$ 24,378,672

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, 2019, 2018 AND 2017

	2019	2018	2017
Cash Flows From Operating Activities:			
Net loss	$ (15,562,144)	$ (12,536,638)	$ (10,384,953)
Adjustments to reconcile net loss to net cash used in operating activities:			
Stock-based compensation	715,983	779,701	986,620
Gain on revaluation of derivative warrant liability	—	—	(452,147)
Gain on extinguishment of liability	—	(450,000)	—
Issuance of common stock for services and release agreements	211,597	377,200	704,019
Fair value of options issued to purchase units of common stock	—	—	104,138
Warrants issued and repriced in settlement agreements	—	—	190,890
Non-cash interest expense	—	—	762,078
Depreciation	893	1,753	2,632
Changes in operating assets and liabilities:			
Other receivables	818,343	(818,343)	—
Prepaid expenses	9,621	162,514	572,098
Deposits	(54,926)	—	—
Accounts payable	1,140,098	971,013	(306,725)
Accrued expenses	64,568	70,739	(397,183)
Accrued compensation	201,773	135,915	159,750
Accrued interest – related parties	16,443	15,645	87,578
Due to related party	—	(27,637)	—
Net Cash Used In Operating Activities	(12,437,751)	(11,318,138)	(7,971,205)
Cash Flows From Investing Activities:			
Purchase of property and equipment	—	—	(2,126)
Net Cash Provided By (Used In) Investing Activities	—	—	(2,126)
Cash Flows From Financing Activities:			
Proceeds from notes payable – related parties	—	—	4,210,000
Proceeds from common stock warrant exercises	23,216	1,125,148	—
Proceeds from stock option exercise	—	—	40
Net proceeds from underwritten offerings	6,290,335	8,926,786	—
Net proceeds from registered direct offering	4,834,001	7,246,099	—
Net proceeds from private placement	—	—	556,152
Net proceeds from public offering	—	—	6,116,896
Net Cash Provided By Financing Activities	11,147,552	17,298,033	10,883,088
Increase (Decrease) in Cash and Cash Equivalents	(1,290,199)	5,979,895	2,909,757
Cash and Cash Equivalents – Beginning of Year	9,184,003	3,204,108	294,351
Cash and Cash Equivalents – End of Year	$ 7,893,804	$ 9,184,003	$ 3,204,108
Supplemental Disclosures of Cash Flow Information and Non-cash Transactions:			
Interest paid	$ —	$ 193	$ 1,133
Premium on convertible promissory notes – related party	$ —	$ —	$ 833,333
Fair value of unit purchase option issued for future services	$ —	$ —	$ 193,860
Fair value of warrants recorded as derivative warrant liability	$ —	$ —	$ 641,385
Reclassification of derivative warrant liability to additional paid-in capital	$ —	$ —	$ 1,229,826
Beneficial conversion feature on convertible promissory notes – related party	$ —	$ —	$ 1,595,411
Conversion of convertible promissory notes – related party and related accrued interest into common stock	$ —	$ —	$ 4,786,240
Par value of common stock issued upon cashless exercise of warrants	$ —	$ 17	$ —

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 $1,586,796 for the excess of the purchase price over the net assets acquired.

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

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 $12,437,751, $11,318,138 and $7,971,205, for the years ended September 30, 2019, 2018 and 2017, respectively. The Company has no revenue and has relied on proceeds from equity transactions and debt to finance its operations. At September 30, 2019, 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. 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 maintenance fee expense of $90,000, $75,000 and $50,000 in 2019, 2018 and 2017, respectively under the terms of this agreement.

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, the Company 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. The Company intends 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"). The Company is 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, the Company paid a nonrefundable upfront payment of $125,000 which was recorded as research and development expense during the year ended September 30, 2019. 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. The agreement expires on the later of the expiration of the patents or January 2, 2034.

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.

Property and Equipment

Property and equipment are valued at cost and are being depreciated over their useful lives using the straight-line method for financial reporting purposes. Routine maintenance and repairs are charged to expense as incurred. Expenditures which materially increase the value or extend useful lives are capitalized. Property and equipment are depreciated over estimated useful lives of three to five years.

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 triggering events occurred since the acquisition of LMB that suggested that a potential impairment occurred through September 30, 2019.

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 initially performed a qualitative assessment for its 2019 analysis of goodwill. A decline in the Company's stock price and market capitalization were considered in determining that it is more likely than not that the fair value of the reporting unit is less than its carrying amount. Management then performed the quantitative testing by comparing the fair value of the reporting unit to its carrying value resulting in the fair value of the reporting unit exceeding its carrying amount as of September 30, 2019.

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, 2019.

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.

Derivative Instruments

The Company generally does not use derivative instruments to hedge exposures to cash-flow or market risks; however, certain warrants to purchase common stock that did not meet the requirements for classification as equity were classified as liabilities. In such instances, net-cash settlement was assumed for financial reporting purposes, even when the terms of the underlying contracts do not provide for a net-cash settlement. Such financial instruments were initially recorded at fair value with subsequent changes in fair value charged (credited) to operations in each reporting period. When these instruments subsequently met the requirements for classification as equity, in 2017, the Company reclassified the fair value to equity.

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, 2019.

Any interest or penalties are charged to expense. During the years ended September 30, 2019, 2018 and 2017, the Company did not recognize any interest and penalties. Tax years subsequent to September 30, 2015 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 January 2017, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2017-04,*Simplifying the Test for Goodwill Impairment.* This guidance eliminates Step 2 of the current goodwill impairment test, which requires a hypothetical purchase price allocation to measure goodwill impairment. Under this simplified one-step model, if the carrying amount exceeds the fair value, an impairment charge for the excess is recorded. ASU 2017-04 includes a new requirement to disclose the amount of goodwill allocated to reporting units with zero or negative carrying amounts and the segment in which the reporting unit is included. The amendments of this ASU are effective for annual or any interim goodwill impairment tests in fiscal years beginning after December 15, 2019. Early adoption is permitted for interim or annual goodwill impairment tests performed on testing dates after January 1, 2017. The Company early adopted this ASU on October 1, 2018.

Recently Issued 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. Early application is permitted. The Company will adopt the provisions of ASU 2016-02 in the quarter beginning October 1, 2019.This adoption approach will result in a balance sheet presentation that will not be comparable to the prior period in the first year of adoption. The adoption of this ASU will result in the recognition of a right of use asset and lease liability of approximately $1,138,000.

5. NOTES PAYABLE – RELATED PARTIES

A summary of notes payable outstanding as of September 30, 2019 and 2018 is as follows:

	2019	2018
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

Notes Payable - Related Parties

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.

The Board of Directors authorized revolving demand promissory notes with Leonard Mazur in an aggregate principal amount of up to $2,500,000 that accrued interest at the prime rate plus 1%. In September 2016, the Company issued a $500,000 note and issued $2,000,000 of additional notes through May 10, 2017. On May 10, 2017, the notes were converted into a single $2,500,000 convertible promissory note. The note was convertible into shares of common stock at a conversion price equal to 75% of the price per share paid by investors in the Company's 2017 registered public offering. In connection with the modification of the note, the Company recorded a charge of $833,333 to additional paid-in capital and increased the carrying value of the notes to $3,333,333 which was the fair value of the common stock issuable on conversion. On August 8, 2017, Leonard Mazur converted the $2,500,000 principal balance and accrued interest of $63,174 into 828,500 shares of common stock.

On May 10, 2017 and June 23, 2017, the Company executed future advance convertible promissory notes with Leonard Mazur that accrued interest at the prime rate plus 1%. The notes were convertible into shares of common stock at a conversion price equal to 75% of the price per share paid by investors in the Company's 2017 registered public offering. On August 8, 2017, Leonard Mazur converted the outstanding $2,210,000 principal balances and accrued interest of $13,066 into 718,567 shares of common stock.

In connection with the conversions, the Company recorded net non-cash interest expense of $762,078 due to the beneficial conversion feature on the conversion price of $1,595,411 and the amortization of the previously recorded modification premium of $833,333.

The Company evaluated all terms of the future advance convertible promissory notes, including the Change in Control provision, to identify any embedded features that required bifurcation and recording as derivative instruments. The Company determined that there were no such features requiring separate accounting.

Interest Expense

Interest expense on notes payable for the years ended September 30, 2019, 2018 and 2017 was $16,443, $15,645 and $850,789, respectively.

6. COMMON STOCK, STOCK OPTIONS AND WARRANTS

Private Offerings and Common Stock Issued for Services and Release Agreements

In February 2017, the Company completed its 2016 private placement (the "2016 Offering"). The Company sold 128,017 units at $6.00 per unit for gross proceeds of $768,100. Each unit consisted of (i) one share of common stock and (ii) a five-year warrant to purchase one share of common stock at an exercise price of $8.25 per share. The placement agent received a 10% cash commission on the gross proceeds, an expense allowance equal to 3% of the proceeds, and warrants to purchase 12,802 shares of common stock at an exercise price of $8.25 per share. The estimated fair value of the 128,017 warrants issued to the investors was $587,592 and the estimated fair value of the 12,802 warrants issued to the placement agent was $58,759. The placement agent commissions and expense allowance was $99,853. Other costs of the placement were $176,896.

During January 2017, the Company issued 29,729 shares of its common stock for investor relations services. The $298,774 fair value of the common stock was expensed during the year ended September 30, 2017.

On May 5, 2017, the Company issued 11,400 shares of common stock valued at $77,748 in connection with a settlement agreement and release with a consultant that had an agreement with Leonard-Meron Biosciences. The Company expensed the $77,748 as a settlement expense during the year ended September 30, 2017.

On June 7, 2017, the Company entered into a release agreement with the placement agent for the 2016 Offering. As consideration for the release, the Company issued 6,668 shares of common stock valued at $45,476 to the placement agent. The Company expensed the $45,476 as a settlement expense during the year ended September 30, 2017.

On June 8, 2017, the Company entered into release agreements with the investors in the 2016 Offering where each investor released the Company from the restrictions included in the unit purchase agreements. In exchange, the Company agreed that (i) in the event that a financing is conducted at a price per share or price per unit lower than $6.00, then the Company will issue additional shares to each investor sufficient to effectively reprice the sale of the 2016 Offering units to the lower price; (ii) in the event that the financing is conducted at a price per share or price per unit less than the $8.25 exercise price of the warrants issued in the 2016 Offering then the exercise price of the warrants shall be reduced to the lower price; and (iii) the Company will give each investor no less than 6 hours of notice before the closing of any subsequent financing, through and including the Company's 2017 registered public offering, and each investor shall have a 6-hour option to purchase up to 20% of the securities sold in such offering. In connection with these agreements the Company reclassified the $641,385 fair value of the 140,819 warrants issued in the 2016 Offering to derivative warrant liability on June 8, 2017. On August 8, 2017, the Company completed its 2017 public offering and issued 58,191 shares of common stock to the investors in the 2016 Offering to reprice the sale of the 2016 Offering units to $4.125 per unit and repriced the 2016 Offering Warrants to an exercise price of $4.125 per share. During the year ended September 30, 2017, the Company recorded a settlement expense of $161,771 in connection with the issuance of the additional 58,191 shares of common stock and reclassified the current fair value of the warrants to additional paid-in capital.

On February 7, 2018, the Company issued 22,200 shares of common stock for services provided by two consultants and expensed the $88,800 fair value of the common stock issued.

On April 1, 2018, the Company issued 10,000 shares of common stock for services provided by a consultant and expensed the $31,000 fair value of the common stock issued.

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.

2017 Public Offering and Release Agreement

On August 8, 2017, the Company closed an underwritten public offering of 1,648,484 shares of common stock and warrants to purchase 1,648,484 shares of common stock at an offering price of $4.125 per share and $0.01 per warrant. The warrants have a per share exercise price of $4.125, are exercisable immediately and will expire five years from the date of issuance. Gross proceeds were $6,802,469, before deducting underwriting discounts and commissions and other estimated offering expenses of $685,573. The Company granted the underwriters a 45-day option to purchase up to an additional 247,272 shares of common stock and warrants to purchase 247,272 shares of common stock to cover over-allotments, if any. On August 8, 2017, the underwriters partially exercised the over-allotment to purchase an additional 247,272 warrants. The estimated fair value of the 1,895,756 warrants issued to the investors was $4,160,195 and the estimated fair value of the 65,940 warrants issued to the underwriters was $142,419.

On November 7, 2017, the Company entered into a release agreement with the underwriter. The Company had previously granted a right of first refusal to underwrite all equity and debt offerings for a period of twelve months following completion of the 2017 public offering. Under the release, the Company paid the underwriter $100,000 in cash and issued 60,000 shares of restricted common stock with a fair value of $257,400 in exchange for a full release from all obligations related to the right of first refusal. The Company expensed the $357,400 cost of the release agreement in November 2017.

Registered Direct/Private Placement Offerings

On December 19, 2017, the Company closed a registered direct offering with several institutional and accredited investors for the sale of 1,280,360 shares of common stock at $4.6925 per share for gross proceeds of $6,008,089. Simultaneously, the Company sold the investors 640,180 immediately exercisable five and a half year warrants at $4.63 per share. The Company paid the placement agent a fee of 7% of the gross proceeds totaling $420,566 and issued the placement agent 89,625 immediately exercisable five-year warrants at $5.8656 per share. The Company also reimbursed the placement agent for $85,000 in expenses and incurred $20,000 in other expenses. Net proceeds from the offering were $5,482,523. The estimated fair value of the 640,180 warrants issued to the investors was $2,407,276 and the estimated fair value of the 89,625 warrants issued to the placement agent was $316,071.

On March 29, 2018, the Company closed a registered direct offering with an institutional and an accredited investor for the sale of 669,504 shares of common stock at $2.985 per share for gross proceeds of $1,998,469. Simultaneously, the Company sold the investors 669,504 immediately exercisable five and a half year warrants at $2.86 per share. The Company paid the placement agent a fee of 7% of the gross proceeds totaling $139,893 and issued the placement agent 46,866 immediately exercisable five-year warrants at $3.73125 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 $1,763,576. The estimated fair value of the 669,504 warrants issued to the investors was $1,679,482 and the estimated fair value of the 46,866 warrants issued to the placement agent was $110,511.

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.

August 2018 Offering

On August 13, 2018, Citius closed an underwritten offering of (i) 5,521,569 units, each unit consisting of one share of common stock and one immediately exercisable five-year warrant to purchase one share at $1.15 per share, and (ii) 2,321,569 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 $1.15 per share. The pre-funded warrants included in the pre-funded units are immediately exercisable at a price of $0.01 per share and do not expire. The offering price was $1.275 per unit and $1.265 per pre-funded unit. The net proceeds of the offering were $8,926,786. The Company issued underwriter warrants to purchase up to 549,020 shares at $1.59375 per share with an estimated fair value of $491,737. The underwriter warrants are exercisable following February 8, 2019 and expire on August 8, 2023. The estimated fair value of the 2,321,569 pre-funded warrants was $2,630,072, and the estimated fair value of the 7,843,138 warrants included in the units and the pre-funded units issued to the investors was $7,311,727.

September 2019 Offering

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.

Unit Purchase Options

On April 7, 2017, the Company issued a three-year Unit Purchase Option Agreement to a consultant for 38,000 units at a purchase price of $9.00 per unit. Each unit consists of one share of common stock and a warrant to purchase one share of common stock at an exercise price of $9.00 per share which expires on the earlier of three years after exercise of the Unit Purchase Option Agreement or April 7, 2023. The consultant provided the Company with business development and financing assistance for the three months ended June 30, 2017. The Company estimated the fair value of the unit purchase option agreement at $104,138 and expensed it during the year ended September 30, 2017.

On June 29, 2017, the Company issued a three-year Unit Purchase Option Agreement to a consultant for 62,667 units at a purchase price of $9.00 per unit. Each unit consists of one share of common stock and a warrant to purchase one share of common stock at an exercise price of $9.00 per share which expires on the earlier of three years after exercise of the Unit Purchase Option Agreement or June 29, 2022. The consultant provided the Company with business development and financing assistance through December 31, 2017. The Company estimated the fair value of the unit purchase option agreement at $193,860 and recorded it as a prepaid expense. The Company recorded an expense of $96,930 for this agreement during the year ended September 30, 2017 and expensed the remaining balance of $96,930 during the year ended September 30, 2018.

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, 2019, there were options to purchase 856,039 shares outstanding under the 2014 Plan, options to purchase 4,829 shares were exercised, and 5,799 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, 2019, there were options to purchase 915,000 shares outstanding under the 2018 Plan and 1,085,000 shares were 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, 2019, 2018 and 2017:

	2019	2018	2017
Risk-free interest rate	2.18 – 2.53%	2.78 – 2.99%	1.79 – 1.90%
Expected dividend yield	0%	0%	0%
Expected term	6.50 – 10 years	6.50 – 10 years	6.50 – 10 years
Expected volatility	119 – 121%	116%	85 – 108%

A summary of option activity under the 2014 Plan and 2018 Plan is presented below:

	Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term	Aggregate Intrinsic Value
Outstanding at September 30, 2018	1,601,039	$ 4.35		
Granted	190,000	1.04		
Exercised	—	—		
Forfeited or expired	(20,000)	0.94		
Outstanding at September 30, 2019	1,771,039	$ 4.03	7.75 years	$ 49,465
Exercisable at September 30, 2019	1,174,019	$ 5.24	7.11 years	$ 49,465

On January 1, 2017, the Board of Directors granted stock options to purchase a total of 8,669 shares to four consultants at $10.05 per share. The weighted average grant date fair value of the options was estimated at $8.41 per share. These options vest over terms of 12 to 36 months and have a term of 10 years.

In September 2017, the Board of Directors granted stock options to purchase a total of 225,000 shares to 12 employees and 50,000 options to two consultants at $3.45 per share. The weighted average grant date fair value of the options was estimated at $2.95 per share. These options vest over terms of 12 to 36 months and have a term of 10 years.

In September 2018, the Board of Directors granted stock options to purchase a total of 520,000 shares to six employees, 75,000 options to five directors, and 80,000 options to three consultants at $1.62 per share. In addition, the Board granted stock options to purchase 70,000 shares to a financial consultant at $1.75 per share. The weighted average grant date fair value of the options was estimated at $1.45 per share. These options vest over terms of 12 to 36 months and have a term of 10 years.

During the year ended September 30, 2019, the Board of Directors granted stock options to purchase a total of 25,000 shares to two employees at $0.94 per share and 165,000 options to four consultants at prices ranging from $0.94 to $1.27 per share. The weighted average grant date fair value of the options was estimated at $1.04 per share. These options vest over terms of 12 to 36 months and have a term of 10 years.

Stock-based compensation expense for the years ended September 30, 2019, 2018 and 2017 was $715,983, $779,701 and $986,620, respectively.

At September 30, 2019, unrecognized total compensation cost related to unvested awards of $741,843 is expected to be recognized over a weighted average period of 1.66 years.

Warrants

The Company has reserved 25,492,513 shares of common stock for the exercise of outstanding warrants. The following table summarizes the warrants outstanding at September 30, 2019:

	Exercise price	Number	Expiration Dates
Investor Warrants	$ 9.00	202,469	March 19, 2020 – September 14, 2020
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	9.90	4,985	January 8, 2020
LMB Warrants	20.70	17,721	November 3, 2019 – March 6, 2020
LMB Warrants	7.50	73,883	August 18, 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	669,504	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	3,430,421	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	7,821,230	September 27, 2024
September 2019 Offering Pre-Funded Unit Warrants	0.0001	1,060,615	No expiration date
September 2019 Offering Underwriter Warrants	1.12	547,486	September 27, 2024
		25,492,513	

During the year ended September 30, 2018, 272,767 of the 2017 Public Offering warrants were exercised at $4.25 per share for net proceeds of $1,125,148.

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.

At September 30, 2019, the weighted average remaining life of all of the outstanding warrants is 3.63 years, all warrants are exercisable, and the aggregate intrinsic value for the warrants outstanding was $805,961.

Common Stock Reserved

A summary of common stock reserved for future issuances as of September 30, 2019 is as follows:

Stock plan options outstanding	1,771,039
Stock plan shares available for future grants	1,090,799
Warrants	25,492,513
Unit purchase options	201,334
Total	28,555,685

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 2017 public offering, Mr. Mazur purchased 421,400 units consisting of 421,400 shares of common stock at $4.125 per share and 421,400 warrants at $0.01 per warrant and converted certain notes payable to common stock (See Note 5).

In connection with the December 2017 registered direct/private placement offering, Mr. Mazur purchased 213,106 shares of common stock at $4.6925 per share and received 106,553 warrants exercisable at $4.63 per share. In connection with the March 2018 registered direct/private placement Offering, Mr. Mazur purchased 167,504 shares of common stock at $2.985 per share and received 167,504 warrants exercisable at $2.86 per share. The purchases were made on the same terms as for all other investors.

In connection with the August 2018 offering, Mr. Mazur purchased 3,137,255 shares of common stock at $1.275 per share and received 3,137,255 warrants exercisable at $1.15 per share, and Mr. Holubiak purchased 784,314 shares of common stock at $1.275 per share and received 784,314 warrants exercisable at $1.15 per share. The purchases were made on the same terms as for all other investors.

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.

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. 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, pursuant to which the agreement was automatically renewed for a one-year term ending on February 29, 2020. 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.

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, 2019, 2018 and 2017 was $344,000, $422,000 and $372,000, respectively. Consulting expense for the years ended September 30, 2019, 2018 and 2017 includes $20,000, $48,000 and $48,000, respectively, paid to a financial consultant who is a stockholder of the Company. The consulting agreement with the stockholder ended in February 2019. In addition, one financial consulting services agreement provides for the grant of options to purchase 33,333 shares of common stock contingent upon approval by the Board of Directors. The options were granted on June 1, 2015.

9. FDA REFUND

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.

10. COMMITMENTS AND CONTINGENCIES

Operating Lease

The Company leased office space from Akrimax, a related party (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 years ended September 30, 2019, 2018 and 2017 under this agreement, including a two-month extension, was $56,063, $26,000 and $26,000, respectively.

Effective July 1, 2019, Citius entered into a 76-month lease for office space in Cranford, NJ. Annual base rent for the years ending September 30, 2020, 2021, 2022, 2023, 2024, 2025 and 2026 is $191,526, $234,447, $239,306, $244,165, $249,024, $253,883 and $21,460, respectively. Citius will also pay its proportionate share of real estate taxes and operating expenses in excess of the base year expenses. Rent expense under this agreement for the year ended September 30, 2019 was $57,349.

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, 2019, 2018 and 2017 due to the Company's operating losses and a full valuation reserve on deferred tax assets.

On December 22, 2017, the Tax Cuts and Jobs Act (the "Act"), was signed into law by the President of the United States. The Act includes a number of changes, including the lowering of the U.S. corporate tax rate from 35% to 21%, effective January 1, 2018, and the establishment of a territorial-style system for taxing foreign-source income of domestic multinational corporations. The Company has recognized provisional tax impacts related to the revaluation of the Company's deferred tax assets and the impact of revaluation of those deferred tax assets on the Company's valuation allowance and included those amounts in the consolidated financial statements for year ended September 30, 2018. There were no material differences from the Company's estimates due to, among other things, changes in interpretations and assumptions made and guidance that may be issued as a result of the Tax Act.

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, 2019, 2018 and 2017 due to the following:

	2019	2018	2017
Computed "expected" tax benefit	(21.0)%	(24.5)%	(35.0)%
Increase (decrease) in income taxes resulting from:			
State taxes, net of federal benefit	(6.3)%	(6.0)%	(5.2)%
Permanent differences	0.1%	0.0%	1.3%
Increase in the valuation reserve	27.2%	30.5%	38.9%
	0.0%	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, 2019	September 30, 2018
Deferred tax assets:		
Net operating loss carryforward	$ 10,994,000	$ 8.962,000
Stock-based compensation	1,133,000	1,350,000
Other	1,202,000	—
Valuation allowance	(13,329,000)	(10,312,000)
Deferred tax assets	$ —	$ —

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, 2019 and 2018, the valuation allowance increased by $3,017,000 and $1,764,000, respectively. The increase in the valuation allowance during the years ended September 30, 2019 and 2018 was primarily due to the Company's net operating loss offset by the decrease in the effective U.S. federal income tax rate from 35% to 21%. At September 30, 2019, the Company has a net operating loss carryforward of approximately $49,291,000 which begins expiring in 2034.

As of September 30, 2019, the Company also has federal research and development credits of $852,000 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

Nasdaq Listing

On October 30, 2019, Citius received notice from The Nasdaq Stock Market, indicating that, because the closing bid price for the common stock had fallen below $1.00 per share for 30 consecutive business days, the Company no longer complies with the $1.00 minimum bid price requirement for continued listing.

The notification of noncompliance has no immediate effect on the listing or trading of the Company's common stock or its warrants to purchase common stock under the symbols "CTXR" and "CTXRW," respectively. The Company has until April 27, 2020, to regain compliance with the minimum bid price requirement. To regain compliance, the closing bid price of the common stock must meet or exceed $1.00 per share for a minimum of 10 consecutive business days prior to April 27, 2020.

If the Company does not regain compliance by April 27, 2020, the Company may be eligible for an additional grace period. To qualify, the Company would be required to meet the continued listing requirements for market value of publicly held shares and all other initial listing standards for The Nasdaq Capital Market, with the exception of the minimum bid price requirement, and provide written notice of its intention to cure the minimum bid price deficiency during the second compliance period. If the Company meets these requirements, the Nasdaq staff will grant an additional 180 calendar days to regain compliance with the minimum bid price requirement. If the Nasdaq staff determines that the Company will not be able to cure the deficiency, or is not eligible for such additional compliance period, Nasdaq will provide notice that the Company's common stock will be subject to delisting. The Company would have the right to appeal a determination to delist its common stock, and the common stock would remain listed on The Nasdaq Capital Market until the completion of the appeal process.

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, 2019, 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, 2019, 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, 2019 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, 2019.

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 2019 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 2020 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, 2019 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	856,039	$ 6.71	5,799
2018 Omnibus Stock Incentive Plan	915,000	$ 1.52	1,085,000
Total	1,771,039	$ 4.03	1,090,799

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

The other information required by this Item is incorporated by reference to the information under the section captioned "Security Ownership of Certain Beneficial Owners and Management" 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 Accounting 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, 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	
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	

Exhibit Number	Description of Document	Registrant's Form	Dated	Exhibit Number	Filed Herewith
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	
21	Subsidiaries.	10-K	12/13/2017	21	
23.1	Consent of Independent Registered Public Accounting Firm.	--	--	--	X
31.1	Certification of the Chief Executive Officer pursuant to Exchange Act Rule 13a-14(a).	--	--	--	X
31.2	Certification of the Chief Financial Officer pursuant to Exchange Act Rule 13a-14(a).	--	--	--	X
32.1	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

+ Confidential treatment has been granted for certain portions of this exhibit. The omitted portions have been filed separately with the SEC.

Item 16. Form 10-K Summary.

Not applicable.

Signatures

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

CITIUS PHARMACEUTICALS, INC.

Date: December 16, 2019

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

In accordance with the Exchange Act, 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, 2019
/s/ Myron Holubiak Myron Holubiak	President and Chief Executive Officer and Director (Principal Executive Officer)	December 16, 2019
/s/ Jaime Bartushak Jaime Bartushak	Chief Financial Officer and Chief Accounting Officer (Principal Financial Officer and Principal Accounting Officer)	December 16, 2019
/s/ Suren Dutia Suren Dutia	Director	December 16, 2019
/s/ Carol Webb Carol Webb	Director	December 16, 2019
/s/ William Kane William Kane	Director	December 16, 2019
/s/ Howard Safir Howard Safir	Director	December 16, 2019
/s/ Eugene Holuka Eugene Holuka	Director	December 16, 2019

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 and 333-233759) and on Form S-3 (No. 333-221492) of Citius Pharmaceuticals, Inc. of our report dated December 16, 2019, 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, 2019.

/s/ Wolf & Company, P.C.

Wolf & Company, P.C.
Boston, Massachusetts
December 16, 2019

Exhibit 31.1

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

I, Myron Holubiak, certify that:

1. I have reviewed this 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, 2019

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

Exhibit 31.2

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

I, Jaime Bartushak, certify that:

1. I have reviewed this 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, 2019

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

Exhibit 32.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER
PURSUANT TO 18 U.S.C. SECTION 1350
AS ADOPTED 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, 2019 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Myron Holubiak, President and Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

(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, 2019

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

Exhibit 32.2

CERTIFICATION OF CHIEF FINANCIAL OFFICER
PURSUANT TO 18 U.S.C. SECTION 1350
AS ADOPTED 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, 2019 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Jaime Bartushak, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

(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, 2019

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