Filed Pursuant to Rule 424(b)(5)
Registration No. 333-221492

Prospectus Supplement
(To prospectus dated December 15, 2017)

7,964,804 shares of common stock

We are offering shares of our common stock, $0.001 par value per share, pursuant to this prospectus supplement and accompanying prospectus. Each share of common stock is being sold at a price per share of $1.05.

Our common stock is traded on the Nasdaq Capital Market, or Nasdaq, under the symbol "CTXR". The last reported sale price of our common stock on Nasdaq on August 5, 2020 was $1.27 per share.

As of the date of this prospectus supplement, the aggregate market value of our outstanding shares of common stock held by non-affiliates was $51,352,622, based on 46,316,298 outstanding shares of common stock, of which 34,008,359 shares were held by non-affiliates, and a price of $1.51 per share, which was the last reported sale price of our common stock on Nasdaq on July 22, 2020. During the 12-calendar month period that ends on, and includes, the date of this prospectus supplement, we sold securities with an aggregate market value of $7,500,001 pursuant to General Instruction I.B.6. of Form S-3 (excluding the value of the shares of common stock sold in this offering).

Investing in our common stock involves risks. You should carefully consider all of the information set forth in this prospectus supplement, the accompanying prospectus and the documents incorporated by reference in this prospectus supplement before deciding to invest in our common stock. Please see "Risk Factors" on page S-8 of this prospectus supplement and in the documents incorporated by reference in this prospectus supplement and the accompanying prospectus to read about factors you should consider before buying shares of our common stock.

	Per Share	Total
Public Offering price	$ 1.05	$ 8,363,044.20
Underwriting discounts and commissions[(1)]	$ 0.0735	$ 585,413.09
Proceeds to us, before expenses	$ 0.9765	$ 7,777,631.11

(1) We have agreed to reimburse the underwriter for certain of its expenses and to issue the underwriter (or its designees) warrants to purchase our common stock. See the section of this prospectus supplement entitled "Underwriting" for a description of the compensation payable to the underwriter.

We have granted the underwriter an option for a period of 30 days from the date of this prospectus supplement to purchase up to 1,194,720 additional shares of common stock at the public offering price per share, less underwriting discounts and commissions. If the underwriter exercises its option in full, the total underwriting discounts and commissions payable by us will be $673,225.01, and the total proceeds to us, before expenses, will be $8,944,275.19.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or passed upon the adequacy or accuracy of this prospectus supplement or the accompanying prospectus. Any representation to the contrary is a criminal offense.

The underwriter expects to deliver the shares of common stock on or about August 10, 2020.

Sole Book-Running Manager

H.C. Wainwright & Co.

The date of this prospectus supplement is August 5, 2020

TABLE OF CONTENTS

Prospectus Supplement

Prospectus

You should rely only on the information incorporated by reference or provided in this prospectus supplement and the accompanying prospectus. We have not authorized anyone to provide you with different information. If anyone provides you with different or inconsistent information, you should not rely on it. This prospectus supplement and the accompanying prospectus do not constitute an offer to sell, or a solicitation of an offer to purchase, the shares of common stock offered by this prospectus supplement and the accompanying prospectus in any jurisdiction where it is unlawful to make such offer or solicitation. You should not assume that the information contained in this prospectus supplement or the accompanying prospectus, or any document incorporated by reference in this prospectus supplement or the accompanying prospectus, is accurate as of any date other than the date on the front cover of the applicable document. Neither the delivery of this prospectus supplement nor any distribution of shares of common stock pursuant to this prospectus supplement shall, under any circumstances, create any implication that there has been no change in the information set forth or incorporated by reference into this prospectus supplement or in our affairs since the date of this prospectus supplement. Our business, financial condition, results of operations and prospects may have changed since that date.

ABOUT THIS PROSPECTUS SUPPLEMENT

This document is in two parts, both of which are part of a registration statement that we filed with the Securities and Exchange Commission, or SEC, using a "shelf" registration process. Under this shelf process, we may from time to time offer up to approximately $50.0 million of shares of our common stock, $0.001 par value per share, at prices and on terms to be determined at the time of sale.

We are providing information to you about this offering of shares of our common stock in two separate documents: (1) this prospectus supplement, which describes the specific details regarding this offering; and (2) the accompanying prospectus, which provides a general description of the securities we may offer, some of which may not apply to this offering. Generally, when we refer to this "prospectus," we are referring to both documents combined. If information in this prospectus supplement is inconsistent with the accompanying prospectus, you should rely on this prospectus supplement. You should read this prospectus supplement together with the additional information described below under the heading "Where You Can Find Additional Information" and "Incorporation of Documents by Reference."

The registration statement that contains this prospectus supplement and accompanying prospectus, including the exhibits to the registration statement and the information incorporated by reference, contains additional information about the shares of common stock offered under this prospectus supplement and accompanying prospectus. That registration statement can be read at the SEC website or at the SEC offices mentioned below under the heading "Where You Can Find Additional Information."

We are responsible for the information contained and incorporated by reference in this prospectus supplement, the accompanying prospectus and any related free writing prospectus we prepare or authorize. We have not authorized anyone to provide you with different information, and we take no responsibility for any other information that others may give you.

This prospectus supplement and the accompanying prospectus do not constitute an offer to sell or the solicitation of an offer to buy any securities other than the registered shares of common stock to which this prospectus supplement relates, nor do this prospectus supplement and the accompanying prospectus constitute an offer to sell or the solicitation of an offer to buy securities in any jurisdiction to any person to whom it is unlawful to make such offer or solicitation in such jurisdiction.

You should not assume that the information in this prospectus supplement and the accompanying prospectus is accurate at any date other than the date indicated on the cover page of this prospectus supplement or that any information we have incorporated by reference is correct on any date subsequent to the date of the document incorporated by reference.

Unless the context otherwise requires, "Citius," "the Company," "we," "us," "our" and similar terms refer to Citius Pharmaceuticals, Inc.

We own or have rights to various U.S. federal trademark registrations and applications, and unregistered trademarks and servicemarks, including Mino-Lok®. 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 supplement and accompanying 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.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus supplement and accompanying prospectus, including the sections entitled "Risk Factors," "Management's Discussion and Analysis of Financial Condition and Results of Operations" and "Business," and the related documents incorporated herein by reference, contains forward-looking statements that are based on our management's belief and assumptions and on information currently available to our management. Although we believe that the expectations reflected in these forward-looking statements are reasonable, these statements relate to future events or our future financial performance, and involve known and unknown risks, uncertainties and other factors that may cause our actual results, levels of activity, performance or achievements to be materially different from any future results, levels of activity, performance or achievements expressed or implied by these forward-looking statements. Forward-looking statements in this prospectus include, but are not limited to, statements about:

- our need for, and ability to raise, additional capital;
- the number, designs, timing and results of our pre-clinical and clinical trials;
- the regulatory review process and any regulatory approvals that may be issued or denied by the FDA or other regulatory agencies;
- the commercial success and market acceptance of any of our product candidates that are approved for marketing in the United States or other countries;
- the accuracy of our estimates and of third-party estimates of the size and characteristics of the markets that may be addressed by our product candidates;
- our ability to manufacture sufficient amounts of our product candidates for clinical trials and, if approved, our products for commercialization activities;
- our need to secure collaborators to license, manufacture, market and sell any products for which we receive regulatory approval;
- our ability to protect our intellectual property and operate our business without infringing upon the intellectual property rights of others;
- the medical benefits, effectiveness and safety of our product candidates;
- the safety and efficacy of medicines or treatments introduced by competitors that are targeted to indications for which our product candidates are being developed;
- our current or prospective collaborators' compliance or non-compliance with their obligations under our agreements with them;
- the impact of the COVID-19 pandemic on our clinical trials, business and operations;
- our expectations related to the use of proceeds from this offering; and
- other factors discussed elsewhere in this prospectus supplement.

In some cases, you can identify forward-looking statements by terminology such as "may," "will," "should," "expects," "intends," "plans," "anticipates," "believes," "estimates," "predicts," "potential," "continue" or the negative of these terms or other comparable terminology. These statements are only predictions.

You should not place undue reliance on forward-looking statements because they involve known and unknown risks, uncertainties and other factors, which are, in some cases, beyond our control and which could materially affect results. Factors that may cause actual results to differ materially from current expectations include, among other things, those listed under "Risk Factors" and elsewhere in this prospectus supplement or incorporated herein by reference. Actual events or results may vary significantly from those implied or projected by the forward-looking statements. No forward-looking statement is a guarantee of future performance. You should read this prospectus supplement and accompanying prospectus and the documents that we incorporated by reference in this prospectus supplement and have filed with the SEC as exhibits to this prospectus supplement completely and with the understanding that our actual future results may be materially different from any future results expressed or implied by these forward-looking statements.

Investors are cautioned not to place undue reliance on the forward-looking statements, which speak only as of the respective dates of this prospectus supplement or the date of the document incorporated by reference in this prospectus supplement. We expressly disclaim any obligation to update or alter any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by federal securities laws.

PROSPECTUS SUPPLEMENT SUMMARY

This summary highlights certain information about us and this offering contained elsewhere in, or incorporated by reference into, this prospectus supplement. Because it is only a summary, it does not contain all of the information that you should consider before investing in our securities and it is qualified in its entirety by, and should be read in conjunction with, the more detailed information appearing elsewhere in this prospectus supplement. Before you decide to invest in our securities, you should read the entire prospectus supplement carefully, including "Risk Factors" beginning on page S-8, and the consolidated financial statements and related notes and the other information incorporated by reference into this prospectus supplement.

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 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.

Since our inception, we have devoted substantially all of our efforts to business planning, acquiring our proprietary technology, research and development, recruiting management and technical staff, and raising capital. We are developing three proprietary product candidates: 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 the reduction of 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 product candidates are large, growing and underserved by the current prescription products or procedures.

We recently entered into a six-month option agreement with a subsidiary of Novellus, Inc. ("Novellus") whereby for the duration of the option we have the exclusive opportunity to in-license from Novellus on a worldwide basis, a novel cellular therapy for acute respiratory distress syndrome.

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 ("R&R") 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 (1) complication in the control arm group.

	Mino-Lok Arm		Control Arm	
Parameter	**N**	**(%)**	**N**	**(%)**
Patients	**30**	**(100)%**	**60**	**(100)%**
Cancer type				
- Hematologic	20	(67)	48	(80)
- Solid tumor	10	(33)	12	(20)
ICU Admission	**4**	**(13)**	**4**	**(7)**
Mech. Ventilator	**3**	**(10)**	**0**	**(0)**
Bacteremia				
- Gram+	17	(57)*	32	(53)
- Gram-	14	(47)*	28	(47)
Neutropenia (<500)	**19**	**(63)**	**36**	**(60)**
Microbiologic Eradication	**30**	**(100)**	**60**	**(100)**
- Relapse	0	(0)	3	(5)
Complications	**0**	**(0)**	**8**	**(13)**
SAEs related to 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, we initiated site recruitment for Phase 3 clinical trials. From initiation through first quarter 2017, we received input from several sites related to the control arm as being less than standard-of-care for some of the respective institutions. We worked closely with the 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 our concerns and would be acceptable to meet the requirements of a new drug application. We 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 July 31, 2020, there are 31 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 is one additional medical center in startup mode. There are no other remaining sites in feasibility.

In September 2019, we 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, we 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.

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

In October 2019, we announced that the Phase 3 trial had reached the 40% completion triggering an interim futility analysis. That analysis showed a positive outcome, as it met the prespecified interim futility analysis criteria. The next major milestone in the Mino-Lok trial, expected to be achieved in the second half of 2020, will be the 75% interim analysis for superior efficacy. The endpoints for this analysis require that the time to catheter failure be at least 38 days for Mino-Lok vs. 21 days for SOC antibiotic locks.

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

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

Fast Track Designation

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

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

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. On August 4, 2020, we announced that we had submitted a briefing package to the FDA for a pre-IND consultation on Mino-Wrap.

Halo-Lido

Overview

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

Development of Hemorrhoids Drugs

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

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

Grade I	Hemorrhoids not prolapsed but bleeding.
Grade II	Hemorrhoids prolapse and reduce spontaneously with or without bleeding.
Grade III	Prolapsed hemorrhoids that require reduction manually.
Grade IV	Prolapsed and cannot be reduced including both internal and external hemorrhoids that are confluent from skin tag to inner anal canal.

Development Activities to Date

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

Symptom improvement was observed based on a global score of disease severity ("GSDS"), and based on some of the individual signs and symptoms of hemorrhoids, specifically itching and overall pain and discomfort. Within the first few days of treatment, the combination products (containing both hydrocortisone and lidocaine) were directionally favorable versus the placebo and their respective individual active treatment groups (e.g., hydrocortisone or lidocaine alone) in achieving 'almost symptom free' or 'symptom free' status according to the GSDS scale. These differences suggested the possibility of a benefit for the combination product formulation.

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 believed that the performance of the active arms of the study relative to the vehicle could be improved by re-formulating our topical preparation. Therefore, we initiated work on vehicle formulation and evaluation of higher potency steroids.

In June and July 2016, we engaged the Dominion Group, a leading provider of healthcare and pharmaceutical marketing research services. The primary market research was conducted to understand the symptoms that are most bothersome to patients better in order to develop meaningful endpoints for the clinical trials. We also learned about the factors that drive patients to seek medical attention for hemorrhoids in an effort to understand the disease impact on quality of life. The results of this survey are able to help us develop patient reported outcome evaluation tools. These tools can be used in clinical trials to evaluate the patients' conditions and to assess the performance of the test articles.

In March 2018, we announced that we had selected a higher potency corticosteroid in our steroid/anesthetic topical formulation program for the treatment of hemorrhoids. The original topical preparation, which we referred to as Hydro-Lido or CITI-001, which was used in the Phase 2a study, was a combination of hydrocortisone acetate and lidocaine hydrochloride. The new formulation, CITI-002, which we refer to as Halo-Lido, 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. We anticipate beginning a Phase 2b clinical study in the second half of 2020.

Citius/Novellus Program

On March 31, 2020, we entered into an option agreement with a subsidiary of Novellus, Inc. ("Novellus") whereby for the duration of the option agreement we will have the exclusive opportunity to in-license from Novellus on a worldwide basis, a novel cellular therapy for acute respiratory distress syndrome (ARDS). The option exercise period runs for six months, during which period, if and when we exercise the option, we and Novellus must negotiate a mutually acceptable definitive license agreement. The option agreement contains the agreed upon financial terms for the license. Novellus also agreed to allow us access to such records as we deem necessary for our due diligence to determine whether to exercise the option. In April 2020, we paid Novellus $100,000 for the option. On June 26, 2020, we announced that we received a written response from the FDA in regard to our pre-investigational new drug ("PIND") application for induced mesenchymal stem cells (iMSCs) to treat and reduce the severity of ARDS in patients with COVID-19.

Corporate History and Information

We were 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. 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.

Our principal executive offices are located at 11 Commerce Drive, First Floor, Cranford, New Jersey 07016 and our telephone number is (908) 976-6677.

THE OFFERING

Common stock offered	7,964,804 shares
Public offering price	$1.05
Underwriter's option to purchase additional shares of common stock	We have granted the underwriter an option exercisable for a period of 30 days from the date of this prospectus supplement to purchase up to an additional 1,194,720 shares of our common stock.
Common stock to be outstanding after this offering (1)	54,281,102 shares (or 55,475,822 shares if the underwriter exercises its option to purchase additional shares in full).
Use of proceeds	We estimate that the net proceeds from this offering, after deducting the underwriting discounts and commissions and estimated offering expenses, will be approximately $7.4 million (or approximately $8.6 million if the underwriter exercises its option to purchase additional shares in full). We intend to use the net proceeds from the offering for general corporate purposes, including our Phase 3 clinical Mino-Lok® trial for the treatment of catheter related bloodstream infections, development of Mino-Wrap, our Phase 2b trial of Halo-Lido cream for the treatment of hemorrhoids, our other product development initiatives and working capital and capital expenditures. See "Use of Proceeds" on page S-31 of this prospectus supplement.
Risk factors	Your investment in shares of our common stock involves substantial risks. You should read "Risk Factors" on page S-8 of this prospectus supplement and in the documents incorporated by reference in this prospectus supplement for a discussion of factors to consider before deciding to purchase shares of our common stock.
Nasdaq Capital Market symbol	"CTXR"

(1) The number of shares of our common stock that will be issued and outstanding immediately after this offering as shown above is based on 46,316,298 shares of common stock issued and outstanding as of June 30, 2020 and excludes as of that date:

- warrants for 26,285,479 shares of our common stock, with a weighted average exercise price of $1.577 per share;
- options to purchase an aggregate of 2,765,171 shares of our common stock issued to our officers, directors and non-employee consultants under our 2014 and 2018 Stock Incentive Plans, with a weighted average exercise price of $2.803 per share;
- 100,667 shares of common stock and warrants to purchase 100,667 shares of common stock, at an exercise price of $9.00 per share, each issued or issuable pursuant to certain units, in the form of a unit purchase option agreement, with a price of $9.00 per unit;
- 3,090,000 shares of common stock available for future grants under our 2020 Stock Incentive Plan; and
- 557,536 shares of our common stock issuable upon the exercise of warrants issued to the underwriter (or its designees) which represent 7.0% of the aggregate number of shares sold this offering (and up to an additional 83,630 shares if the underwriter exercises its option to purchase additional shares in full), with an exercise price of $1.3125 per share.

Except as otherwise indicated, all information included or incorporated by reference in this prospectus supplement assumes no exercise of the outstanding options and warrants described above, no exercise of the underwriter's option to purchase additional share of common stock, and no exercise of the warrants to be issued to the underwriter in connection with this offering.

RISK FACTORS

Investing in our shares of common stock involves a high degree of risk. You should carefully consider and evaluate all of the information contained in this prospectus supplement, the accompany prospectus and in the documents we incorporate by reference into this prospectus supplement and accompanying prospectus before you decide to purchase shares of our common stock pursuant to this prospectus supplement. In particular, you should carefully consider and evaluate the risks and uncertainties described under the heading "Risk Factors" in our Annual Report on Form 10-K for the fiscal year ended September 30, 2019 and in our Quarterly Report on Form 10-Q for the quarter ended March 31, 2020. Any of the risks and uncertainties set forth in those reports, as updated by annual, quarterly and other reports and documents that we file with the SEC and incorporate by reference into this prospectus supplement or the accompanying prospectus, could materially and adversely affect our business, results of operations and financial condition, which in turn could materially and adversely affect the value of any securities offered by this prospectus supplement. As a result, you could lose all or part of your investment.

Risks Related to this Offering

We may be required to raise additional financing by issuing new securities with terms or rights superior to those of our existing securityholders, which could adversely affect your investment in our company, the market price of shares of our common stock and our business.

We will require additional financing to fund future operations, including our research and development activities and any possible sales and marketing activities. We may not be able to obtain financing on favorable terms, if at all. If we raise additional funds by issuing equity securities, the percentage ownership of our then current stockholders will be reduced, and the holders of the new equity securities may have rights superior to those of our then existing securityholders, which could adversely affect the market price of our common stock and the voting power of shares of our common stock. If we raise additional funds by issuing debt securities, the holders of these debt securities would similarly have some rights senior to those of our then existing securityholders, and the terms of these debt securities could impose restrictions on operations and create a significant interest expense for us which could have a materially adverse effect on our business.

Issuances of shares of our common stock or securities convertible into or exercisable for shares of our common stock following this offering, as well as the exercise of outstanding options and warrants, will dilute your ownership interests and may adversely affect the future market price of our common stock.

The issuance of additional shares of our common stock or securities convertible into or exchangeable for our common stock could be dilutive to stockholders if they do not invest in future offerings. We intend to use the net proceeds from this offering for the continued clinical development of our product candidates, Mino-Lok®, Mino-Wrap and Halo-Lido, and for other general corporate purposes, which may include working capital, research and development expenditures, the funding of in-licensing agreements for product candidates, additional technologies or other forms of intellectual property, expenditures relating to manufacturing infrastructure and other capital expenditures and general and administrative expenses. We may seek additional capital through a combination of private and public equity offerings, debt financings, strategic partnerships and alliances and licensing arrangements, which may cause your ownership interest to be diluted.

In addition, we have a substantial number of options and warrants to purchase shares of our common stock outstanding. If these securities are converted or exercised, you may incur further dilution. Moreover, to the extent that we issue in the future more options or warrants to purchase shares of our common stock, or other securities convertible into or exchangeable for shares of our common stock such as convertible notes or convertible preferred stock, and those options, warrants or other securities are exercised, converted or exchanged, stockholders may experience further dilution.

You will experience immediate and substantial dilution in the net tangible book value per share of the common stock you purchase.

The offering price per share of our common stock being offered is substantially higher than the net tangible book value per share of our outstanding common stock. As a result, the investors purchasing shares of our common stock in this offering will incur immediate dilution of $0.8588 per share, after giving effect to the sale of an aggregate of 7,964,804 shares of our common stock at an offering price of $1.05 per share, and after deducting the underwriting discounts and commissions and estimated offering expenses payable by us. Furthermore, if any of our outstanding options or warrants are exercised at prices below the offering price, or if we grant additional options or other awards under our equity incentive plans or issue additional warrants, you may experience further dilution of your investment. See "Dilution" on page S-32 of this prospectus supplement for a more detailed discussion of the dilution you will incur if you purchase shares in this offering.

A substantial number of shares of our common stock may be sold in this offering, which could cause the price of our common stock to decline.

In this offering we are selling shares of common stock, which represents approximately 14.7% of our outstanding common stock as of June 30, 2020, after giving effect to the sale of the shares of common stock in this offering (or approximately 16.5% if the underwriter exercises its option to purchase additional shares of common stock in full). In addition, the underwriter will receive unregistered warrants to purchase up to 7.0% of the aggregate number of shares of common stock sold in this offering. This sale and any future sales of a substantial number of shares of our common stock in the public market, or the perception that such sales may occur, could adversely affect the price of our common stock on Nasdaq. We cannot predict the effect, if any, that market sales of those shares of common stock or the availability of those shares of common stock for sale will have on the market price of our common stock.

Our management will have broad discretion in the use of the net proceeds from this offering and may not use them effectively.

Our management will have broad discretion in the application of the net proceeds from this offering, and our stockholders will not have the opportunity as part of their investment decision to assess whether the net proceeds are being used appropriately. Because of the number and variability of factors that will determine our use of the net proceeds from this offering, their ultimate use may vary substantially from their currently intended use. The failure by our management to apply these funds effectively could harm our business. See "Use of Proceeds" on page S-31 of this prospectus supplement for a description of our proposed use of proceeds from this offering.

Risks related to our Business and our Industry

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

We were formed in 2007 and since our inception have incurred a net loss in each of our previous operating years. Our ability to become profitable depends upon our ability to obtain marketing approval for and generate revenues from sales of our product candidates. We have been focused on product development, have not received approval for any of our product candidates, and have not generated any revenues to date. We have incurred losses in each period of our operations, and we expect to continue to incur losses for the foreseeable future. These losses are likely to continue to adversely affect our working capital, total assets and stockholders' equity. The process of developing our product candidates requires significant clinical development, laboratory testing and clinical trials. In addition, commercialization of our product candidates will require that we obtain necessary regulatory approvals and establish sales, marketing and manufacturing capabilities, either through internal hiring or through contractual relationships with others. We expect to incur substantial losses for the foreseeable future as a result of anticipated increases in our research and development costs, including costs associated with conducting preclinical testing and clinical trials, and regulatory compliance activities. We incurred net losses of $15,562,144, $12,536,638 and $10,384,953 for the years ended September 30, 2019, 2018 and 2017, respectively, and $8,747,339 for the six months ended March 31, 2020. At March 31, 2020, we had stockholders' equity of $22,443,707 and an accumulated deficit of $64,567,321. 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, and $9,581,869 for the six months ended March 31, 2020.

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

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

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

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

At March 31, 2020, after taking into account the proceeds from our common stock and warrant financing in May 2020, we expect that we have sufficient capital to continue our operations through November 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 stockholders, in the event of liquidation.

Our audited consolidated financial statements included in this report have been prepared assuming that we will continue as a going concern and do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets, or the amounts and classification of liabilities that may result if we do not continue as a going concern. We have concluded that substantial doubt about our ability to continue as a going concern exists and our auditors have made reference to this in their audit report on our audited consolidated financial statements for the year ended September 30, 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 $53.3 million from our public and private placement offerings through March 31, 2020. Additionally, in connection with the acquisition of LMB our Executive Chairman, Leonard Mazur, made an equity investment of $3.0 million in March 2016. Mr. Mazur has also loaned us $4,710,000 pursuant to convertible promissory notes. On August 8, 2017, these notes and accrued interest of $76,240 were converted into 1,547,067 shares of common stock at a price of $3.09 per share as part of an underwritten public offering which closed on the same date.

The amount and timing of our future funding requirements will depend on many factors, including, but not limited to:

- the rate of progress and cost of our trials and other product development programs for our current product candidates;
- the costs and timing of obtaining licenses for additional product candidates, especially a license from Novellus for a possible ARDS treatment candidate, 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. The recent turmoil in the financial markets due to the COVID-19 pandemic could also adversely impact future fundraising activities. If the COVID-19 pandemic and related and/or other economic conditions continue or become worse, our future cost of equity or debt capital and access to the capital markets could be adversely affected. If we are not successful in securing additional financing, we may be required to significantly delay, reduce the scope of or eliminate one or more of our research or development programs, downsize our general and administrative infrastructure, or seek alternative measures to avoid insolvency, including arrangements with collaborative partners or others that may require us to relinquish rights to certain of our technologies or product candidates.

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

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

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

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

We might not successfully negotiate a license with Novellus and even if we do, the in-licensed intellectual property would be early stage.

Assuming we want to in-license from Novellus a novel cellular therapy for ARDS, we have until September 30, 2020 to negotiate the license agreement. While the commercial terms of the license have been agreed to in the option agreement, we might be unsuccessful in reaching an agreement on the license. In addition, the therapy is in the early stage, which adds to the risk of development. There can be no assurance that we would be successful in in-licensing the therapy or in successfully developing it.

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

We are a clinical stage company and our success is dependent upon our ability to obtain regulatory approval for and commercialize our product candidates and we have not demonstrated an ability to perform the functions necessary for the approval or successful commercialization of any product candidates. While various members of our executive management and key employees have significant prior experience in pharmaceutical development, as a company we have to date not successfully completed any late stage clinical trials nor undertaken any commercialization activities. Our operations have been limited primarily to business planning, acquiring our proprietary technology, research and development, recruiting management and technical staff, and raising capital. These operations provide a limited basis for you to assess our ability to successfully commercialize our product candidates and the advisability of investing in our securities.

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

The COVID-19 pandemic has adversely impacted hospitals and medical facilities where we are currently conducting our Mino-Lok phase 3 trial. The full extent to which COVID-19 may impact this trial is not known at this time, but it has slowed the estimated completion date for the trial, which we now expect to be in the first half of 2021. The exact duration of the delay and any other impact will depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the duration of the outbreak, the severity of COVID-19, or the effectiveness of actions to contain and treat for COVID-19. The continued spread of COVID-19 also could adversely impact our ability to recruit and retain patients and principal investigators and site staff who, as healthcare providers, may have heightened exposure to COVID-19, which could further negatively impact the Mino-Lok trial. In addition, if the FDA elects to delay face-to-face meetings for an extended period of time due to COVID-19, it could have a material adverse effect on our Mino-Lok trial and our other product candidates. Any or all of these events could increase our operating expenses and the length of time to complete the trial and have a material adverse effect on our financial results.

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

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

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

We face significant risks in our product candidate development efforts.

Our business depends on the successful development and commercialization of our product candidates. We are not permitted to market any of our product candidates in the United States until we receive approval from the FDA, or in any foreign jurisdiction until we receive the requisite approvals from such jurisdiction. The process of developing new drugs and/or therapeutic products is inherently complex, unpredictable, time-consuming, expensive and uncertain. We must make long-term investments and commit significant resources before knowing whether our development programs will result in products that will receive regulatory approval and achieve market acceptance. Product candidates that appear to be promising at 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 corticosteroid, and lidocaine, that have each been separately approved by the FDA for other indications and which are commercially available and marketed by other companies. Halobetasol propionate cream is available in a 0.05% strength, and lidocaine creams are also available in strengths up to 5%. From our market analysis and discussions with a limited number of physicians, we know that patients sometimes obtain two separate cream products and co-administer them as prescribed, giving them a combination treatment which could be very similar to what we intend to study and seek approval for. As a branded, FDA-approved product with safety and efficacy data, we intend to price our product substantially higher than the generically available individual creams. We will then have to convince third-party payers and pharmacy benefit managers of the advantages of our product and justify our premium pricing. We may encounter resistance from these entities and will then be dependent on patients' willingness to pay the premium and not seek alternatives. In addition, pharmacists often suggest lower cost prescription treatment alternatives to both physicians and patients. If approved, our Section 505(b)(2) approval and the market exclusivity we may receive will not guarantee that such alternatives will not exist, that substitution will not occur, or that there will be immediate 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.

Any FDA programs related to the development and approval of treatments for COVID-19 and its symptoms may not be available to us or actually lead to a faster development or regulatory review or approval process for a treatment for ARDS that we might seek if we in-license the therapy from Novellus, nor will it assure FDA approval of such a treatment.

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

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 for such with third parties, we will experience delays in product launch and sales and incur increased costs.

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

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

- research and development resources, including personnel and technology;
- regulatory resources, experience and expertise;
- product candidate development and clinical trial resources and experience;
- product sourcing, sales and marketing resources and experience;
- experience and expertise in exploitation of intellectual property rights; and
- access to strategic partners and capital resources.

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

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

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

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

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

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

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

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

Significant uncertainty exists as to the reimbursement status of newly approved healthcare products. Healthcare payers, including Medicare, are challenging the prices charged for medical products and services. Government and other healthcare payers increasingly attempt to contain healthcare costs by limiting both coverage and the level of reimbursement for drugs. Even if our product candidates are approved by the FDA, insurance coverage might not be available, and reimbursement levels might be inadequate, to cover our products. If government and other healthcare payers do not provide adequate coverage and reimbursement levels for our products, once approved, market acceptance of such products could be reduced. Proposals to modify the current health care system in the U.S. to improve access to health care and control its costs are continually being considered by the federal and state governments. In March 2010, the U.S. Congress passed landmark healthcare legislation. Portions of this legislation have been repealed in recent years and members of the U.S. Congress and some state legislatures continue to seek to overturn at least some remaining portions of the legislation and we expect they will continue to review and assess this legislation and possibly alternative health care reform proposals. We cannot predict what impact on federal reimbursement policies this legislation will have in general or on our business specifically. We cannot predict whether new proposals will be made or adopted, when they may be adopted or what impact they may have on us if they are adopted.

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

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

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

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

We do not have and do not intend to establish our own manufacturing facilities. Consequently, we lack the physical plant to formulate and manufacture our product candidates, which are currently being manufactured entirely by commercial third party manufacturers. If any product candidate we might develop or acquire in the future receives FDA approval, we will rely on one or more third-party contractors to manufacture our products. If, for any reason, we become unable to rely on our current source or any future source or sources to manufacture our product candidates, either for pre-clinical or clinical trials or for commercial quantities, then we would need to identify and contract with additional or replacement third-party manufacturers to manufacture compounds for preclinical, clinical and commercial purposes. We might not be successful in identifying additional or replacement third-party manufacturers, or in negotiating acceptable terms with any that we do identify. If we are unable to secure and maintain third-party manufacturing capacity, the development and sales of our product candidates and our financial performance might be materially affected.

In addition, before any of our collaborators can begin to commercially manufacture our product candidates, each must obtain regulatory approval of the manufacturing facility and process. Manufacturing of drugs for clinical and commercial purposes must comply with the FDA's 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 or a pandemic such as COVID-19; and

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

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

If we materially breach or default under any of our license agreements, the licensor party to such agreement will have the right to terminate the license agreement, which termination may materially harm our business.

Our commercial success will depend in part on the maintenance of our license agreements. Currently, we are a party to two in-license agreements with MDACC, one for Mino-Lok (sub-licensed from the entity holding the license from MDACC) and one for Mino-Wrap. Additionally, we expect to enter into additional license agreements in the future. For example, we currently have an option to and may seek to negotiate a license agreement with Novellus for a novel cellular therapy to treat ARDS. Our license agreements impose, and we expect that future license agreements will impose, various diligence, milestone payment, royalty and other obligations on us. For example, under our current license agreements, we are required to use commercially reasonable diligence to develop and commercialize a product and to satisfy specified payment obligations. If we fail to comply with our obligations under our current license agreements or any future license agreements with any party, or we are subject to a bankruptcy, the licensor may have the right to terminate the license, in which event we would not be able to market products covered by the license. Each of our license agreements provides the licensor with a right to terminate the license agreement for our material breach or default under the agreement, including the failure to make any required milestone or other payments. Should the licensor under any of our license agreements exercise such a termination right, we would lose our right to the intellectual property under the respective license agreement, which loss may materially harm our business.

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

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

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

Our business strategy is based on the acquisition of additional product candidates. 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 other than the option agreement that we have with Novellus to in-license a novel cellular therapy as a treatment for ARDS. We do not know if we will identify other suitable acquisitions, whether we will be able to successfully complete any acquisitions, or whether we will be able to successfully integrate any acquired product, technology or business into our business operations or retain key personnel, suppliers or collaborators.

Our ability to successfully develop our business through acquisitions 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, our Executive Chairman, Leonard Mazur, and our Chief Medical Officer and Executive Vice President, Myron Czuczman, in particular have significant experience in the running of pharmaceutical companies and/or drug development itself. 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, Mr. Mazur or Dr. Czuczman, 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 a part-time basis to assist us in managing our ongoing Phase 2 and Phase 3 trials and intend to do so for future preclinical and clinical trials. While we believe this will provide us with sufficient staffing for our current and future development efforts, we will need to hire or contract with additional qualified personnel with expertise in preclinical testing, clinical research and testing, government regulation, formulation and manufacturing and sales and marketing in connection with the continued development, regulatory approval and commercialization of our product candidates. We compete for qualified individuals with numerous pharmaceutical and biopharmaceutical companies, universities and other research institutions. Competition for these individuals is intense, and we cannot be certain that our search for such personnel will be successful. Attracting and retaining qualified personnel will be critical to our success. In addition, we may be unable to attract and retain those qualified officers, directors and members of board committees required to provide for effective management. If we are unable to attract and retain qualified employees, officers and directors, the management and operation of our business could be adversely affected.

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

We will need to manage our anticipated growth and increased operational activity, including that which might result if we exercise our option with Novellus and in-license its novel cellular therapy for the treatment of ARDS. 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. or foreign regulatory approvals to commercialize any product candidates.

We cannot assure you that we will receive the approvals necessary to commercialize for sale any product candidates we are currently developing or that we may acquire or seek to develop in the future. We will need FDA approval to commercialize our product candidates in the U.S. In order to obtain FDA approval of any product candidate, we must submit to the FDA an NDA demonstrating that the product candidate is safe for humans and effective for its intended use. This demonstration requires significant research, pre-clinical studies, and clinical trials. Satisfaction of the FDA's regulatory requirements typically takes many years, depends upon the type, complexity and novelty of the product candidate and requires substantial resources for research, development and testing. We cannot predict whether our research and clinical approaches will result in products that the FDA considers safe for humans and effective for their indicated uses. The FDA has substantial discretion in the product approval process and might require us to conduct additional pre-clinical and clinical testing, perform post-marketing studies or otherwise limit or impose conditions on any additional approvals we obtain. The approval process might also be delayed by changes in government regulation, future legislation or administrative action or changes in FDA policy that occur prior to or during our 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. Foreign jurisdictions impose similar regulatory approval processes and we will face the same risks if we seek foreign approval for any of our product candidates. There is no guarantee that we will ever be able to successfully develop or acquire any product candidate.

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

If one of our product candidates is approved by the FDA or by a foreign regulatory authority, we will be required to comply with extensive regulations for product manufacturing, labeling, packaging, adverse event reporting, storage, distribution, advertising, promotion and record keeping. Regulatory approvals may also be subject to significant limitations on the indicated uses or marketing of the products or to whom and how we may distribute an approved product. Even if U.S. regulatory approval is obtained, the FDA may still impose significant restrictions on a product's indicated uses or marketing or impose ongoing requirements for potentially costly post-approval studies. For example, the label ultimately approved for 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. Similar risks apply in foreign jurisdictions.

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

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

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

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

Post-approval marketing and promotion of products, standards and regulations for direct-to-consumer advertising, dissemination of off-label product information, industry-sponsored scientific and educational activities and promotional activities 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 product candidates. We have obtained limited product liability insurance coverage for our pre-clinical and clinical trials of $5.0 million per occurrence and in the aggregate, subject to a deductible of $25,000 per bodily injury and property damage occurrence and a medical expense each person limit of $25,000. There can be no assurance that our existing insurance coverage will extend to any other product candidates in the future. Any product liability insurance coverage may not be sufficient to satisfy all liabilities resulting from product liability claims. A successful claim may prevent us from obtaining adequate product liability insurance in the future on commercially desirable terms, if at all. Even if a claim is not successful, defending such a claim would be time consuming and expensive, may damage that product's and our reputations in the marketplace, and would likely divert management's attention, any of which could have a material adverse effect on our company.

Risks Related to our Intellectual Property

Our business depends on protecting our intellectual property.

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

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

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

Because the time period from filing a patent application to the issuance, if ever, of the patent is often more than three years and because any regulatory approval and marketing for a pharmaceutical product often occurs several years after the related patent application is filed, the resulting market exclusivity afforded by any patent on our drug candidates and technologies will likely be substantially less than 20 years. For example, the U.S. patent on the original Mino-Lok composition expires in June 2024, and the U.S. patent on the stabilized Mino-Lok composition expires in November 2036. Since we anticipate significant additional time before FDA approval could be obtained, the maximum market exclusivity afforded by the statutory term of the currently issued patents would be less than 17 years. In the United States, the European Union and some other jurisdictions, patent term extensions are available for certain delays in either patent office proceedings or marketing and regulatory approval processes. However, due to the specific requirements for obtaining these extensions, there is no assurance that our patents will be granted extensions even if we encounter significant delays in patent office proceedings or marketing and regulatory approval.

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

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

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

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

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

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

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

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

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

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

The United States has enacted and is expected to continue to implement wide-ranging patent reform legislation. Further, 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

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

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

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

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

We have twice failed to meet the listing standards, most recently between October 2019 and January 2020. In October 2019, we received a notice from Nasdaq that we failed to comply with the $1.00 minimum bid price requirement. We regained compliance on January 31, 2020. On April 1, 2020, we received written notice from The Nasdaq Stock Market indicating that, because the closing bid price for the Company's common stock has fallen below $1.00 per share for 30 consecutive business days, we no longer comply with the $1.00 minimum bid price requirement for continued listing on The Nasdaq Capital Market under Rule 5550(a)(2) of the Nasdaq Listing Rules. Pursuant to Nasdaq Marketplace Rule 5810(c)(3)(A), we had been provided a compliance period of 180 calendar days, which ran until September 28, 2020, to regain compliance with the minimum bid price requirement. The date to regain compliance was extended by Nasdaq in response to the COVID-19 pandemic and its impact on the capital markets and listed companies' stock prices. As a result of the extension, to regain compliance, the closing bid price of our common stock had to meet or exceed $1.00 per share for a minimum of 10 consecutive business days prior to December 14, 2020. On July 10, 2020, we regained compliance.

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

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

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

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

We are subject to the reporting requirements of the Securities Exchange Act of 1934, as amended, or the Exchange Act, the Sarbanes-Oxley Act of 2002, or SOX, and Nasdaq rules and regulations. SOX requires, among other things, that we maintain effective disclosure controls and procedures and internal control over financial reporting. We perform system and process evaluation and testing of our internal controls over financial reporting to allow management to report on the effectiveness of our internal controls over financial reporting in our Annual Report on Form 10-K filing for each year, as required by Section 404 of SOX. We previously had identified material weaknesses in our internal control over financial reporting related to ineffective separation of duties due to our limited finance staff, our reliance on consultants to assist with the financial reporting function and a lack of documented policies and procedures, which weaknesses were reported in fiscal 2016 and 2017 (and prior to that by our predecessor company). 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 December 31, 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 stockholders to lose confidence in our reported financial information. Any such loss of confidence would have a negative effect on the trading price of our securities.

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

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

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

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

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

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

For the foreseeable future, to finance our operations, including possible acquisitions or strategic transactions, we expect to issue equity securities, resulting in the dilution of the ownership interests of our present stockholders. We are currently authorized to issue an aggregate of 200,000,000 shares of common stock and 10,000,000 shares of preferred stock. As of July 31, 2020, there were 46,316,298 shares of common stock outstanding, 26,285,479 shares underlying warrants with a weighted average exercise price of $1.577 per share and 2,765,171 shares underlying options with a weighted average exercise price of $2.803 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 July 31, 2020, our executive officers and directors beneficially owned approximately 39.2% of our outstanding shares of common stock. Such concentrated control of our company may adversely affect the price of our common stock. If you acquire common stock, you may have no effective voice in the management of our company. Sales by our directors and executive officers or their affiliates, along with any other market transactions, could adversely affect the market price of our common stock.

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

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

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

Our Board of Directors has the authority to issue up to 10,000,000 shares of preferred stock and to fix and determine the relative rights and preferences of any such preferred stock without further stockholder approval. As a result, our Board of Directors could authorize the issuance of one or more series of preferred stock that would grant preferential rights to our assets upon liquidation, the right to receive dividend payments before dividends are distributed to the holders of common stock and the right to the redemption of the preferred shares, together with a premium, prior to the redemption of the common stock. In addition, our Board of Directors could authorize the issuance of a series of preferred stock that has greater voting power than the common stock or that is convertible into our common stock, which could decrease the relative voting power of the common stock or result in dilution to our existing stockholders.

USE OF PROCEEDS

We estimate that the proceeds from this offering will be approximately $7,463,101, after deducting the underwriting discounts and commissions and estimated offering expenses payable by us, or approximately $8,617,200 if the underwriter exercises in full its option to purchase 1,194,720 additional shares.

We intend to use the net proceeds from the sale of our securities by us under this prospectus supplement for general corporate purposes, including our Phase 3 clinical Mino-Lok® trial for the treatment of catheter related bloodstream infections, development of Mino-Wrap, our Phase 2b trial of Halo-Lido cream for the treatment of hemorrhoids, our other product development initiatives and working capital and capital expenditures.

DIVIDEND POLICY

We have never declared dividends on our equity securities, and currently do not plan to declare dividends on shares of our common stock in the foreseeable future. We expect to retain our future earnings, if any, for use in the operation and expansion of our business. The payment of cash dividends in the future, if any, will be at the discretion of our Board of Directors and will depend upon such factors as earnings levels, capital requirements, our overall financial condition and any other factors deemed relevant by our Board of Directors.

DILUTION

If you invest in our common stock, you will experience dilution to the extent of the difference between the offering price per share and the net tangible book value per share of our common stock immediately after this offering.

Our net tangible book value on March 31, 2020 was $1,338,189 or $0.0351 per share of our common stock. "Net tangible book value" is total assets minus the sum of liabilities and intangible assets. "Net tangible book value per share" is net tangible book value divided by the total number of shares outstanding. Dilution in net tangible book value per share represents the difference between the amount per share paid by purchasers of shares of common stock in this offering and the net tangible book value per share of our common stock immediately after this offering.

After giving effect to the sale of 7,964,804 shares of our common stock in this offering at the offering price of $1.05 per share, and after deducting the underwriting discounts and commissions and estimated offering expenses payable by us, our as adjusted net tangible book value as of March 31, 2020, would have been approximately $8,801,290, or $0.1912 per share. This represents an immediate increase in net tangible book value of $0.1560 per share to existing stockholders and immediate dilution in net tangible book value of $0.8588 per share to new investors purchasing our common stock in this offering at the offering price. The following table illustrates this dilution on a per share basis:

Offering price per share of common stock		$ 1.05
Net tangible book value per share as of March 31, 2020	$ 0.0351	
Increase in net tangible book value per share attributable to new investors	$ 0.1560	
As adjusted net tangible book value per share as of March 31, 2020 after giving effect to this offering		$ 0.1912
Dilution in net tangible book value per share to investors in this offering		$ 0.8588

If the underwriter exercises its option to purchase 1,194,720 additional shares in full, the as-adjusted net tangible book value per share after giving effect to this offering would be $0.2108 per share, and the dilution in net tangible book value per share to new investors purchasing common shares in this offering would be $0.8392 per share, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

The above discussion and table are based on 38,078,062 shares of our common stock outstanding as of March 31, 2020 and excludes as of that date:

- warrants for 23,501,050 shares of our common stock with a weighted average exercise price of $1.675 per share;
- options to purchase an aggregate of 2,751,838 shares of our common stock issued to our officers, directors and non-employee consultants under our 2014 and 2018 Incentive Stock Plans, with a weighted average exercise price of $2.831 per share;
- 100,667 shares of common stock and warrants to purchase 100,667 shares of common stock, at an exercise price of $9.00 per share, each issued or issuable pursuant to certain units, in the form of a unit purchase option agreement, with a price of $9.00 per unit; and
- 3,110,000 shares of common stock available for future grants under our 2020 Stock Incentive Plan.

The above table also does not reflect shares, warrants and options issued subsequent to March 31, 2020. For those amounts see "The Offering" on page S-7.

The above illustration of dilution per share to the investors participating in this offering assumes no exercise of outstanding options to purchase our common stock or warrants to purchase shares of our common stock that will be outstanding after this offering. The exercise of outstanding options and warrants that will be outstanding after this offering having an exercise price less than the offering price will increase dilution to the new investors.

UNDERWRITING

Pursuant to an underwriting agreement with H.C. Wainwright & Co., LLC (the "underwriter"), we have agreed to issue and sell, and the underwriter has agreed to purchase, the number of shares of common stock listed opposite its name below, less the underwriting discount, on the closing date, subject to the terms and conditions contained in the underwriting agreement. The underwriting agreement provides that the obligations of the underwriter are subject to certain customary conditions precedent, representations and warranties contained therein.

Underwriter	Number of Shares
H.C. Wainwright & Co., LLC	7,964,804
Total	

Pursuant to the underwriting agreement, the underwriter has agreed to purchase all of the shares sold under the underwriting agreement if any of these shares are purchased, other than those shares covered by the underwriter's option to purchase additional shares of common stock described below. The underwriter has advised us that it does not intend to confirm sales to any account over which it exercises discretionary authority.

Discounts, Commissions and Expenses

The underwriter may offer the shares of common stock from time to time to purchasers directly or through agents, or through brokers in brokerage transactions on Nasdaq, or to dealers in negotiated transactions or in a combination of such methods of sale, or otherwise, at a fixed price or prices, which may be changed, or at market prices prevailing at the time of sale, at prices related to such prevailing market prices or at negotiated prices, subject to receipt and acceptance by it and subject to its right to reject any order in whole or in part. The difference between the price at which the underwriter purchases shares from us and the price at which the underwriter resells such shares may be deemed underwriting compensation. If the underwriter effects such transactions by selling shares of common stock to or through dealers, such dealers may receive compensation in the form of discounts, concessions or commissions from the underwriter and/or purchasers of shares of common stock for whom they may act as agents or to whom they may sell as principal.

The underwriter is offering the shares, subject to prior sale, when, as and if issued to and accepted by it, subject to approval of legal matters and other conditions specified in the underwriting agreement. The underwriter reserves the right to withdraw, cancel or modify offers to the public and to reject orders in whole or in part.

We have granted to the underwriter an option to purchase up to 1,194,720 additional shares of common stock at the public offering price, less the underwriting discount. The option is exercisable for 30 days.

The following table shows the public offering price, underwriting discount and proceeds, before expenses, to us. These amounts are shown assuming both no exercise and full exercise of the underwriter's option to purchase additional shares.

	Total without Option	Total with Option
Public offering price	$ 8,363,044.20	$ 9,617,500.20
Underwriting discounts and commissions payable by us	$ 585,413.09	$ 673,225.01
Proceeds, before expenses, to us	$ 7,777,631.11	$ 8,944,275.19

We have also agreed to pay the underwriter a management fee equal to 1% of the aggregate gross proceeds in this offering. We have agreed to reimburse the expenses of the underwriter in the non-accountable sum of $35,000 in connection with this offering, up to $100,000 for expenses of legal counsel and up to $12,900 for the clearing expenses of the underwriter in connection with this offering. Additionally, we agreed to grant the underwriter (or its designees) warrants to purchase 557,536 shares of our common stock, which represents 7.0% of the aggregate number of shares sold this offering (and up to an additional 83,630 shares if the underwriter exercises its option to purchase additional shares in full), with an exercise price of $1.3125 per share.

Right of First Refusal

We have granted the underwriter a twelve-month right of first refusal to act as our exclusive underwriter or placement agent for any further capital raising transactions undertaken by us, and to act as the exclusive advisor, manager or underwriter or placement agent, as applicable, if we sell or acquire a business, finance any indebtedness, or decide to raise funds by means of a public offering or a private placement or any other capital-raising financing of equity, equity-linked or debt securities using an underwriter or placement agent.

Tail Financing Payments

In the event that any investors that participate in this offering or were introduced to this offering by the underwriter provide any capital to us in a public or private offering or capital-raising transaction within 12 months following the termination of our engagement of the underwriter, we shall pay the underwriter the cash compensation provided above on the gross proceeds from such investors.

Indemnification

We have agreed to indemnify the underwriter against certain liabilities, including civil liabilities under the Securities Act of 1933, as amended, or the Securities Act, or to contribute to payments that the underwriter may be required to make in respect of those liabilities.

Lock-Up Agreements

We have agreed to not sell any shares of our common stock or any securities convertible into or exercisable or exchangeable into share of common stock, subject to certain exceptions, for a period of 30 days after the date of this prospectus.

In addition, subject to certain limited circumstances, each of our directors and executive officers has entered into a lock-up agreement with the underwriter. Under the lock-up agreements, the directors and executive officers may not, directly or indirectly, sell, offer to sell, contract to sell, or grant any option for the sale (including any short sale), grant any security interest in, pledge, hypothecate, hedge, establish an open “put equivalent position” (within the meaning of Rule 16a-1(h) under the Securities Exchange Act of 1934, as amended, or the Exchange Act), or otherwise dispose of, or enter into any transaction which is designed to or could be expected to result in the disposition of, any shares of our common stock or securities convertible into or exchangeable for shares of our common stock, or publicly announce any intention to do any of the foregoing, unless such directors and executive officers obtain prior written consent of the underwriter for a period of 90 days from the date of this prospectus supplement.

Price Stabilization, Short Positions and Penalty Bids

In connection with this offering, the underwriter may engage in stabilizing transactions, overallotment transactions, syndicate covering transactions and penalty bids in connection with our common stock.

Stabilizing transactions permit bids to purchase shares of common stock so long as the stabilizing bids do not exceed a specified maximum.

Overallotment transactions involve sales by the underwriter of shares of common stock in excess of the number of shares the underwriter is obligated to purchase. This creates a syndicate short position which may be either a covered short position or a naked short position. In a covered short position, the number of shares over-allotted by the underwriter is not greater than the number of shares that it may purchase in the overallotment option. In a naked short position, the number of shares involved is greater than the number of shares in the overallotment option. The underwriter may close out any short position by exercising its overallotment option and/or purchasing shares in the open market.

Syndicate covering transactions involve purchases of common stock in the open market after the distribution has been completed in order to cover syndicate short positions. Such a naked short position would be closed out by buying securities in the open market. A naked short position is more likely to be created if the underwriter is concerned that there could be downward pressure on the price of the securities in the open market after pricing that could adversely affect investors who purchase in the offering.

Penalty bids permit the underwriter to reclaim a selling concession from a syndicate member when the securities originally sold by the syndicate member are purchased in a stabilizing or syndicate covering transaction to cover syndicate short positions.

These stabilizing transactions, syndicate covering transactions and penalty bids may have the effect of raising or maintaining the market price of our common stock or preventing or retarding a decline in the market price of our common stock. As a result, the price of our common stock in the open market may be higher than it would otherwise be in the absence of these transactions. Neither we nor the underwriter make any representation or prediction as to the effect that the transactions described above may have on the price of our common stock. These transactions may be effected on The Nasdaq Capital Market, in the over-the-counter market or otherwise and, if commenced, may be discontinued at any time.

In connection with this offering, the underwriter also may engage in passive market making transactions in our common stock in accordance with Regulation M during a period before the commencement of offers or sales of shares of our common stock in this offering and extending through the completion of the distribution. In general, a passive market maker must display its bid at a price not in excess of the highest independent bid for that security. However, if all independent bids are lowered below the passive market maker's bid that bid must then be lowered when specific purchase limits are exceeded. Passive market making may stabilize the market price of the securities at a level above that which might otherwise prevail in the open market and, if commenced, may be discontinued at any time.

Electronic Distribution

A prospectus in electronic format may be made available on the websites maintained by the underwriter, if any, participating in this offering and the underwriter may distribute prospectuses electronically. Other than the prospectus in electronic format, the information on these websites is not part of this prospectus or the registration statement of which this prospectus form a part, has not been approved or endorsed by us or the underwriter, and should not be relied upon by investors.

Other Relationships

From time to time, the underwriter may provide in the future various advisory, investment and commercial banking and other services to us in the ordinary course of business, for which they have received and may continue to receive customary fees and discounts and commissions. However, except as disclosed in this prospectus supplement, we have no present arrangements with the underwriter for any further services. H.C. Wainwright & Co., LLC acted as our exclusive placement agent in connection with our registered direct offering we consummated in May 2020, our exclusive placement agent in connection with a warrant exchange offering we consummated in February 2020, as sole book-running manager in connection our underwritten public offering we consummated in September 2019, as sole book-running manager in connection our underwritten public offering we consummated in August 2018 and as our exclusive placement agent in connection with our registered direct offering we consummated in March 2018, in each case for which it received compensation.

Transfer Agent

The transfer agent of our common stock is VStock Transfer. Their address is 18 Lafayette Place, Woodmere, NY 11598.

Nasdaq Capital Market Listing

Our common stock is listed on The Nasdaq Capital Market under the symbol “CTXR”.

LEGAL MATTERS

The validity of the shares of common stock being offered hereby have been passed upon by Wyrick Robbins Yates & Ponton LLP, Raleigh, North Carolina. Dentons US LLP is counsel to the underwriter in connection with this offering.

EXPERTS

The financial statements of Citius Pharmaceuticals, Inc. appearing in its Annual Report on Form 10-K for the fiscal year ended September 30, 2019, have been incorporated herein by reference in reliance on the report of Wolf & Company, P.C., independent registered public accounting firm, given upon the authority of such firm as experts in accounting and auditing.

WHERE YOU CAN FIND ADDITIONAL INFORMATION

We have filed a registration statement on Form S-3 with the SEC for the securities we are offering by this prospectus supplement. This prospectus supplement does not include all of the information contained in the registration statement. You should refer to the registration statement and its exhibits for additional information. We will provide to each person, including any beneficial owner, to whom a prospectus supplement is delivered, a copy of any or all of the information that has been incorporated by reference in this prospectus supplement but not delivered with this prospectus supplement. We will provide this information upon oral or written request, free of charge. Any requests for this information should be made by calling or sending a letter to the Secretary of the Company, c/o Citius Pharmaceuticals, Inc., at our office located at 11 Commerce Drive, 1st Floor, Cranford, NJ 07016.

We are required to file annual and quarterly reports, current reports, proxy statements and other information with the SEC. We make these documents publicly available, free of charge, on our website at www.citiuspharma.com as soon as reasonably practicable after filing such documents with the SEC. You can read our SEC filings, including the registration statement, on the SEC's website at http://www.sec.gov.

INCORPORATION OF DOCUMENTS BY REFERENCE

The SEC allows us to "incorporate by reference" information that we file with them. Incorporation by reference allows us to disclose important information to you by referring you to those other documents. The information incorporated by reference is an important part of this prospectus supplement and the accompanying prospectus, and information that we file later with the SEC will automatically update and supersede this information. We filed a registration statement on Form S-3 under the Securities Act with the SEC with respect to the securities being offered pursuant to this prospectus supplement and the accompanying prospectus. This prospectus supplement and the accompanying prospectus omit certain information contained in the registration statement, as permitted by the SEC. You should refer to the registration statement, including the exhibits, for further information about us and the securities being offered pursuant to this prospectus supplement and the accompanying prospectus. Statements in this prospectus supplement and the accompanying prospectus regarding the provisions of certain documents filed with, or incorporated by reference in, the registration statement are not necessarily complete, and reference is made to the actual documents for complete information. Copies of all or any part of the registration statement, including the documents incorporated by reference or the exhibits, may be obtained upon payment of the prescribed rates at the offices of the SEC listed above in "Where You Can Find Additional Information." The documents we are incorporating by reference into this prospectus supplement are:

- the description of our common stock contained in our Registration Statement on Form 8-A, filed on July 28, 2017;
- our Annual Report on Form 10-K for the fiscal year ended September 30, 2019, filed with the SEC pursuant to Section 13 of the Exchange Act on December 16, 2019;
- our Quarterly Report on Form 10-Q for the quarter ended December 31, 2019, filed with the SEC pursuant to Section 13 of the Exchange Act on February 13, 2020;
- our Quarterly Report on Form 10-Q for the quarter ended March 31, 2020, filed with the SEC pursuant to Section 13 of the Exchange Act on May 14, 2020;
- our Current Reports on Form 8-K, filed with the SEC pursuant to Section 13 of the Exchange Act on October 7, November 1, November 5 and December 19, 2019, and January 22, February 3, February 4, February 10, February 14, February 19, February 25, April 1, April 7, April 28, April 29, May 12, May 18, May 26, June 2, June 26, July 10, July 14, and August 4, 2020;and
- our definitive proxy statement on Schedule 14A for the annual meeting of stockholders held on February 12, 2020, filed with the SEC pursuant to Section 14 of the Exchange Act on December 20, 2019.

In addition, all documents subsequently filed by us pursuant to Section 13(a), 13(c), 14 or 15(d) of the Exchange Act before the date our offering is terminated or completed are deemed to be incorporated by reference into, and to be a part of, this prospectus supplement.

Any statement contained in this prospectus supplement and the accompanying prospectus or in a document incorporated or deemed to be incorporated by reference into this prospectus supplement and the accompanying prospectus will be deemed to be modified or superseded for purposes of this prospectus supplement and the accompanying prospectus to the extent that a statement contained in this prospectus supplement and the accompanying prospectus or any other subsequently filed document that is deemed to be incorporated by reference into this prospectus supplement and the accompanying prospectus modifies or supersedes the statement. Any statement so modified or superseded will not be deemed, except as so modified or superseded, to constitute a part of this prospectus supplement and the accompanying prospectus.

We will furnish without charge to you, on written or oral request, a copy of any or all of the documents incorporated by reference, including exhibits to these documents. You should direct any requests for documents to Citius Pharmaceuticals, Inc., Attention: Secretary, 11 Commerce Drive, 1st Floor, Cranford, New Jersey 07016, (908) 967-6677.

You should rely only on information contained in, or incorporated by reference into, this prospectus supplement and the accompanying prospectus. We have not authorized anyone to provide you with information different from that contained in this prospectus supplement and the accompanying prospectus or incorporated by reference in this prospectus supplement and the accompanying prospectus. We are not making offers to sell the securities in any jurisdiction in which such an offer or solicitation is not authorized or in which the person making such offer or solicitation is not qualified to do so or to anyone to whom it is unlawful to make such offer or solicitation.

Prospectus

$50,000,000
Common Stock
Preferred Stock
Warrants
Units

We may offer and sell from time to time common stock, preferred stock and warrants to purchase common stock or preferred stock, in one or more transactions. We may also offer and sell from time to time, in one or more transactions, such securities as may be issuable upon the conversion, exercise or exchange of preferred stock or warrants. Any securities registered hereunder may be sold separately or as units with the other securities registered hereunder.

This prospectus provides you with a description of our common stock and a general description of the other securities we may offer. A prospectus supplement containing specific information about the terms of the securities being offered and the offering, including the compensation of any underwriter, agent or dealer, will accompany this prospectus to the extent required. Any prospectus supplement may also add, update or change information contained in this prospectus. If information in any prospectus supplement is inconsistent with the information in this prospectus, then the information in that prospectus supplement will apply and will supersede the information in this prospectus. You should carefully read both this prospectus and any prospectus supplement, together with additional information described in "Where You Can Find More Information" and "Incorporation of Certain Information by Reference," before you invest in our securities.

Investing in our securities involves a high degree of risk. See "*Risk Factors*" beginning on page 5 of this prospectus, in any accompanying prospectus supplement and in the documents incorporated by reference into this prospectus, to read about factors you should consider before investing in our securities.

Our common stock is listed on the Nasdaq Capital Market under the symbol "CTXR".

Neither the Securities and Exchange Commission nor any other regulatory body has approved or disapproved of these securities or passed upon the accuracy or adequacy of this prospectus. Any representation to the contrary is a criminal offense.

The date of this prospectus is December 15, 2017

TABLE OF CONTENTS

ABOUT THIS PROSPECTUS

This prospectus is part of a Registration Statement on Form S-3 that we filed with the Securities and Exchange Commission, or the SEC, using a "shelf" registration process or continuous offering process. By using a shelf registration statement, we may from time to time, sell common stock, preferred stock and warrants to purchase common stock or preferred stock in one or more offerings. Each time that we sell securities under this Registration Statement, we will provide a prospectus supplement that will contain specific information about the terms of that offering. A prospectus supplement may also add, update or change information contained in this prospectus with respect to that offering. If there is any inconsistency between the information in this prospectus and an applicable prospectus supplement, you should rely on the prospectus supplement. Before purchasing any securities, you should carefully read both this prospectus and any applicable prospectus supplement or free writing prospectus we file with the SEC, together with the additional information described under the headings "Where You Can Find More Information" and "Incorporation of Documents by Reference".

The rules of the SEC allow us to incorporate by reference information into this prospectus. This means that important information is contained in other documents that are considered to be a part of this prospectus. Additionally, information that we file later with the SEC will automatically update and supersede this information. You should carefully read both this prospectus and the applicable prospectus supplement together with the additional information that is incorporated or deemed incorporated by reference in this prospectus. See "Incorporation of Documents by Reference" before making an investment in our common stock. This prospectus contains summaries of certain provisions contained in some of the documents described herein, but reference is made to the actual documents for complete information. All of the summaries are qualified in their entirety by the actual documents. Copies of the documents referred to herein have been filed or will be filed or incorporated by reference as exhibits to the Registration Statement of which this prospectus is a part. The Registration Statement, including the exhibits and documents incorporated or deemed incorporated by reference in this prospectus, can be read on the SEC website or at the SEC offices mentioned under the heading "Where You Can Find More Information".

THIS PROSPECTUS MAY NOT BE USED TO SELL ANY SHARES OF OUR COMMON STOCK UNLESS ACCOMPANIED BY A PROSPECTUS SUPPLEMENT.

Neither the delivery of this prospectus or any applicable prospectus supplement nor any sale made using this prospectus or any applicable prospectus supplement implies that there has been no change in our affairs or that the information in this prospectus or in any applicable prospectus supplement is correct as of any date after their respective dates. You should not assume that the information included in or incorporated by reference in this prospectus or any applicable prospectus supplement or any free writing prospectus prepared by us, is accurate as of any date other than the date(s) on the front covers of those documents. Our business, financial condition, results of operations and prospects may have changed since those dates.

You should rely only on the information contained in or incorporated by reference in this prospectus or a prospectus supplement. We have not authorized anyone to give you different information, and if you are given any information that is not contained or incorporated by reference in this prospectus or a prospectus supplement, you must not rely on that information. We are not making an offer to sell securities in any jurisdiction where the offer or sale of such securities is not permitted.

We have filed or incorporated by reference exhibits to the Registration Statement of which this prospectus is a part. You should read the exhibits carefully for provisions that may be important to you.

Unless the context otherwise requires, we use the terms "Citius", "the Company", "our company", "we", "us", and "our" in this prospectus to refer to the consolidated operations of Citius Pharmaceuticals, Inc. and its consolidated subsidiaries as a whole.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS AND INDUSTRY DATA

This prospectus contains forward-looking statements that are based on our management's belief and assumptions and on information currently available to our management. Although we believe that the expectations reflected in these forward-looking statements are reasonable, these statements relate to future events or our future financial performance, and involve known and unknown risks, uncertainties and other factors that may cause our actual results, levels of activity, performance or achievements to be materially different from any future results, levels of activity, performance or achievements expressed or implied by these forward-looking statements. Forward-looking statements in this prospectus include, but are not limited to, statements about:

- the commercial success and market acceptance of any of our products and product candidates that are approved for marketing in the United States or other countries;
- the accuracy of our estimates of the size and characteristics of the markets that may be addressed by our products and product candidates;
- our ability to manufacture sufficient amounts of our product candidates for clinical trials and our products for commercialization activities;
- our need for, and ability to raise, additional capital;
- the number, designs, results and timing of our clinical trials;
- the regulatory review process and any regulatory approvals that may be issued or denied by the FDA or other regulatory agencies;
- our need to secure collaborators to license, manufacture, market and sell any products for which we receive regulatory approval in the future;
- our ability to protect our intellectual property and operate our business without infringing upon the intellectual property rights of others;
- the medical benefits, effectiveness and safety of our products and product candidates;
- the safety and efficacy of medicines or treatments introduced by competitors that are targeted to indications which our products and product candidates have been developed to treat;
- our current or prospective collaborators' compliance or non-compliance with their obligations under our agreements with them; and
- other factors discussed elsewhere in this prospectus.

In some cases, you can identify forward-looking statements by terminology such as "may," "will," "should," "expects," "intends," "plans," "anticipates," "believes," "estimates," "predicts," "potential," "continue" or the negative of these terms or other comparable terminology. These statements are only predictions. You should not place undue reliance on forward-looking statements because they involve known and unknown risks, uncertainties and other factors, which are, in some cases, beyond our control and which could materially affect results. Factors that may cause actual results to differ materially from current expectations include, among other things, those listed under "Risk Factors" and elsewhere in this prospectus. Actual events or results may vary significantly from those implied or projected by the forward-looking statements. No forward-looking statement is a guarantee of future performance. You should read this prospectus and the documents that we reference in this prospectus and have filed with the Securities and Exchange Commission as exhibits to this prospectus completely and with the understanding that our actual future results may be materially different from any future results expressed or implied by these forward-looking statements.

The forward-looking statements in this prospectus represent our views as of the date of this prospectus. We anticipate that subsequent events and developments will cause our views to change. However, while we may elect to update these forward-looking statements at some point in the future, we have no current intention of doing so except to the extent required by applicable law. You should therefore not rely on these forward-looking statements as representing our views as of any date subsequent to the date of this prospectus.

This prospectus and the documents incorporated by reference into this prospectus contain "forward-looking statements" that involve risks and uncertainties, as well as assumptions that, if they never materialize or prove incorrect, could cause our results to differ materially from those expressed or implied by such forward-looking statements. The statements contained in this prospectus and the documents incorporated by reference into this prospectus that are not purely historical are forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, or Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, or Exchange Act.

This prospectus, the documents incorporated by reference into this prospectus and the documents that we have filed as exhibits to the Registration Statement, of which this prospectus is a part, includes statistical and other industry and market data that we obtained from industry publications and research, surveys and studies conducted by third parties. Industry publications and third-party research, surveys and studies generally indicate that their information has been obtained from sources believed to be reliable, although they do not guarantee the accuracy or completeness of such information. We believe that the data obtained from these industry publications and third-party research, surveys and studies are reliable. We are ultimately responsible for all disclosure included in this prospectus.

You should rely only on the information contained in this prospectus, as supplemented and amended. We have not authorized anyone to provide you with information that is different. This prospectus may only be used where it is legal to sell these securities. The information in this prospectus may only be accurate on the date of this prospectus.

In addition, projections, assumptions, and estimates of our future performance and the future performance of the industry in which we operate are necessarily subject to a high degree of uncertainty and risk due to a variety of factors, including those described in "Risk Factors". These and other factors could cause results to differ materially from those expressed in the estimates made by the independent parties and by us.

THE COMPANY

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 new chemical entities have. New formulations of previously approved drugs with substantial safety and efficacy data are a core focus as we seek to reduce development and clinical risks associated with drug development. 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. On March 30, 2016, Citius acquired Leonard-Meron Biosciences, Inc. 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, research and development, recruiting management and technical staff, and raising capital. We are developing two proprietary products: Mino-Lok™, an antibiotic lock solution used to treat patients with catheter-related bloodstream infections by salvaging the infected catheter, and a hydrocortisone-lidocaine topical formulation that is intended to provide anti-inflammatory and anesthetic relief to persons suffering from hemorrhoids. We believe the markets for our products are large, growing, and underserved by the current prescription products or procedures.

In July 2016, the Company decided to discontinue Suprenza, its FDA-approved phentermine-based product for weight loss, due to a strategic change in direction following the acquisition of LMB and the Mino-Lok product. In September 2016, Citius notified the FDA of its decision to voluntarily withdraw both the Investigative New Drug Application and New Drug Application for commercial reasons and not due to safety concerns, effective immediately. The Company had received no royalties from Suprenza and believed costs associated with the ongoing regulatory expenses were depleting resources from our more promising Mino-Lok and Hydro-Lido product candidates.

RISK FACTORS

Investing in our securities involves a high degree of risk. You should consider carefully the risks and uncertainties described in "Risk Factors" and elsewhere in our most recently filed Annual Report on Form 10-K filed with the SEC, in each case as these risk factors are amended or supplemented by subsequent Annual Reports on Form 10-K or Quarterly Reports on Form 10-Q that have been or will be incorporated by reference in this prospectus. The prospectus supplement relating to a particular offering of common stock may also discuss certain risks of investing in that offering. The occurrence of any of such risks may materially and adversely affect our business, financial condition, results of operations and future prospects. In such an event, the market price of our common stock could decline, and you could lose part or all of your investment.

USE OF PROCEEDS

We cannot assure you that we will receive any proceeds in connection with securities offered by us pursuant to this prospectus. Unless otherwise provided in the applicable prospectus supplement, we intend to use the net proceeds from the sale of our securities by us under this prospectus for general corporate purposes, including clinical trials, research and development expenses, and general and administrative expenses. We will set forth in the applicable prospectus supplement our intended use for the net proceeds received from the sale of any securities by us. Pending the application of the net proceeds, we intend to invest the net proceeds generally in short-term, investment grade, interest-bearing securities.

PLAN OF DISTRIBUTION

We may sell the securities from time to time pursuant to underwritten public offerings, negotiated transactions, block trades or a combination of these methods. We may sell the securities to or through underwriters or dealers, through agents, or directly to one or more purchasers. We may distribute securities from time to time in one or more transactions:

- at a fixed price or prices, which may be changed;
- at market prices prevailing at the time of sale;
- at prices related to such prevailing market prices; or
- at negotiated prices.

A prospectus supplement or supplements (and any related free writing prospectus that we may authorize to be provided to you) will describe the terms of the offering of the securities, including, to the extent applicable:

- the name or names of the underwriters, if any;
- the purchase price of the securities or other consideration therefor, and the proceeds, if any, we will receive from the sale;
- any over-allotment options under which underwriters may purchase additional securities from us;
- any agency fees or underwriting discounts and other items constituting agents' or underwriters' compensation;
- any public offering price;
- any discounts or concessions allowed or reallowed or paid to dealers; and
- any securities exchange or market on which the securities may be listed.

Only underwriters named in the prospectus supplement will be underwriters of the securities offered by the prospectus supplement.

If underwriters are used in the sale, they will acquire the securities for their own account and may resell the securities from time to time in one or more transactions at a fixed public offering price or at varying prices determined at the time of sale. The obligations of the underwriters to purchase the securities will be subject to the conditions set forth in the applicable underwriting agreement. We may offer the securities to the public through underwriting syndicates represented by managing underwriters or by underwriters without a syndicate. Subject to certain conditions, the underwriters will be obligated to purchase all of the securities offered by the prospectus supplement, other than securities covered by any over-allotment option. Any public offering price and any discounts or concessions allowed or reallowed or paid to dealers may change from time to time. We may use underwriters with whom we have a material relationship. We will describe in the prospectus supplement, naming the underwriter, the nature of any such relationship.

We may sell securities directly or through agents we designate from time to time. We will name any agent involved in the offering and sale of securities and we will describe any commissions we will pay the agent in the prospectus supplement. Unless the prospectus supplement states otherwise, our agent will act on a best-efforts basis for the period of its appointment.

We may authorize agents or underwriters to solicit offers by certain types of institutional investors to purchase securities from us at the public offering price set forth in the prospectus supplement pursuant to delayed delivery contracts providing for payment and delivery on a specified date in the future. We will describe the conditions to these contracts and the commissions we must pay for solicitation of these contracts in the prospectus supplement.

We may provide agents and underwriters with indemnification against civil liabilities, including liabilities under the Securities Act, or contribution with respect to payments that the agents or underwriters may make with respect to these liabilities. Agents and underwriters may engage in transactions with, or perform services for, us in the ordinary course of business.

All securities we may offer, other than common stock, will be new issues of securities with no established trading market. Any underwriters may make a market in these securities, but will not be obligated to do so and may discontinue any market making at any time without notice. We cannot guarantee the liquidity of the trading markets for any securities.

Any underwriter may engage in over-allotment, stabilizing transactions, short-covering transactions and penalty bids in accordance with Regulation M under the Exchange Act. Over-allotment involves sales in excess of the offering size, which create a short position. Stabilizing transactions permit bids to purchase the underlying security so long as the stabilizing bids do not exceed a specified maximum price. Syndicate-covering or other short-covering transactions involve purchases of the securities, either through exercise of the over-allotment option or in the open market after the distribution is completed, to cover short positions. Penalty bids permit the underwriters to reclaim a selling concession from a dealer when the securities originally sold by the dealer are purchased in a stabilizing or covering transaction to cover short positions. Those activities may cause the price of the securities to be higher than it would otherwise be. If commenced, the underwriters may discontinue any of the activities at any time.

Our common stock and certain warrants are listed on the NASDAQ Capital Market. To facilitate the offering of securities, certain persons participating in the offering may engage in transactions that stabilize, maintain or otherwise affect the price of the securities. This may include over-allotments or short sales of the securities, which involve the sale by persons participating in the offering of more securities than were sold to them. In these circumstances, these persons would cover such over-allotments or short positions by making purchases in the open market or by exercising their over-allotment option, if any. In addition, these persons may stabilize or maintain the price of the securities by bidding for or purchasing securities in the open market or by imposing penalty bids, whereby selling concessions allowed to dealers participating in the offering may be reclaimed if securities sold by them are repurchased in connection with stabilization transactions. The effect of these transactions may be to stabilize or maintain the market price of the securities at a level above that which might otherwise prevail in the open market. These transactions may be discontinued at any time.

DESCRIPTION OF OUR CAPITAL STOCK

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

General

Our authorized capital stock consists of 200,000,000 shares of Common Stock, par value $0.001, 8,423,391 shares of which are issued and outstanding as of December 1, 2017, and 10,000,000 shares of preferred stock, none of which are issued and outstanding. Our preferred stock and/or Common Stock may be issued from time to time without prior approval by our stockholders. Our preferred stock and/or Common Stock may be issued for such consideration as may be fixed from time to time by our Board of Directors. Our Board of Directors may issue such shares of our preferred stock and/or Common Stock in one or more series, with such voting powers, designations, preferences and rights or qualifications, limitations or restrictions thereof as shall be stated in the resolution or resolutions.

Common Stock

The Company, a Nevada corporation, is authorized to issue 200,000,000 shares of Common Stock, $0.001 par value. Each share of Common Stock shall have one (1) vote per share for all purposes. The holders of a majority of the shares entitled to vote, present in person or represented by proxy shall constitute a quorum at all meetings of our stockholders. Our Common Stock does not provide preemptive, subscription or conversion rights and there are no redemption or sinking fund provisions or rights. Our Common Stock holders are not entitled to cumulative voting for election of the Board of Directors.

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

In the event of a liquidation, dissolution or winding up of our company, holders of Common Stock are entitled to share ratably in all of our assets remaining after payment of liabilities. Holders of Common Stock have no preemptive or other subscription or conversion rights. There are no redemption or sinking fund provisions applicable to the Common Stock.

Preferred Stock

Our Board of Directors is authorized to cause us to issue, from our authorized but unissued shares of preferred stock, one or more series of preferred stock, to establish from time to time the number of shares to be included in each such series, as well as to fix the designation and any preferences, conversion and other rights and limitations of such series. These rights and limitations may include voting powers, limitations as to dividends, and qualifications and terms and conditions of redemption of the shares of each such series.

Units

In a private offering commenced in October 2016 (the "2016 Offering"), we sold 128,017 Units, each Unit consisting of (i) one share of Common Stock and (ii) a Warrant to purchase one share of Common Stock (a "Warrant Share"). Each Warrant has an exercise price of $8.25 and is exercisable for a period of five years from the date of issuance.

Warrants Issued as Part of the Units

Each Warrant issued to investors in the 2016 Offering entitles the registered holder to purchase one share of our Common Stock at a price of $8.25 per share, with such exercise price to be subject to adjustment as set forth in the warrant agreement. The Warrants have a five-year term and a cashless exercise if there is no effective registration statement covering the resale of the shares underlying the warrants. The Warrants are redeemable at the Company's option provided the shares underlying the warrants can be sold pursuant to an effective registration statement filed with the SEC, upon the date the Company's Common Stock has traded for $30.00 per share for any 17 out of 20 consecutive days and the aggregate trading volume per day during that period is a minimum of 6,667 shares. The Warrants shall not provide for price or share based adjustments due to dilutive issuances of equity securities, other than stock splits, cash dividends, or the like.

Options

On September 12, 2014, our stockholders approved the Company's 2014 Stock Incentive Plan, which provides for the award of stock options, stock appreciation rights, restricted stock and other equity awards for up to an aggregate of 866,667 shares of common stock. The shares of common stock underlying any awards that are forfeited, canceled, reacquired by us prior to vesting, satisfied without any issuance of stock, expire or are otherwise terminated (other than by exercise) under the 2014 Plan will be added back to the shares of common stock available for issuance under the 2014 Plan.

As of September 30, 2017, we had outstanding options to purchase an aggregate of 861,039 shares of our common stock at a weighted average exercise price of $6.69 per share. Of these, an aggregate of 513,997 are exercisable. The remainder have vesting requirements.

The 2014 Plan is administered by our Board or a committee designated by the Board (as applicable, the Administrator). The Administrator has full power to select, from among the individuals eligible for awards, the individuals to whom awards will be granted, to make any combination of awards to participants, and to determine the specific terms and conditions of each award, subject to the provisions of the 2014 Plan. The Administrator may delegate to our Chief Executive Officer the authority to grant stock options and other awards to employees who are not subject to the reporting and other provisions of Section 16 of the Exchange Act and not subject to Section 162(m) of the Code, subject to certain limitations and guidelines.

Persons eligible to participate in the 2014 Plan are full or part-time officers, employees, non-employee directors, directors and other key persons (including consultants and prospective officers) of our company and its subsidiaries as selected from time to time by the Administrator in its discretion.

Warrants

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. In addition, the Company's underwriter in that offering, Aegis Capital Corp., exercised its over-allotment to purchase an additional 247,272 warrants for a total of 1,895,753 warrants issued (the "Offering Warrants"). The Company also issued a representative's warrant to purchase an aggregate of 65,940 shares of common stock with an exercise price of $4.5375 (the "Bankers Warrants").

Exercisability. The Offering Warrants are exercisable at any time after August 8, 2017, and up to August 8, 2022, with all Bankers Warrants exercisable at any time after February 2, 2018 until August 2, 2022. The warrants will be exercisable, at the option of each holder, in whole or in part by delivering to us a duly executed exercise notice and, at any time a registration statement registering the issuance of the shares of common stock underlying the warrants under the Securities Act is effective and available for the issuance of such shares, or an exemption from registration under the Securities Act is available for the issuance of such shares, by payment in full in immediately available funds for the number of shares of common stock purchased upon such exercise. If a registration statement registering the issuance of the shares of common stock underlying the warrants under the Securities Act is not effective or available and an exemption from registration under the Securities Act is not available for the issuance of such shares, the holder may, in its sole discretion, elect to exercise the warrant through a cashless exercise, in which case the holder would receive upon such exercise the net number of shares of common stock determined according to the formula set forth in the warrant. No fractional shares of common stock will be issued in connection with the exercise of a warrant. In lieu of fractional shares, we will pay the holder an amount in cash equal to the fractional amount multiplied by the exercise price or round up to the next whole share.

Exercise Limitation. A holder will not have the right to exercise any portion of the warrant if the holder (together with its affiliates) would beneficially own in excess of 4.99% of the number of shares of our common stock outstanding immediately after giving effect to the exercise, as such percentage ownership is determined in accordance with the terms of the warrants. However, any holder may increase or decrease such percentage to any other percentage not in excess of 9.99% upon at least 61 days' prior notice from the holder to us.

Exercise Price. The exercise price per whole share of common stock purchasable upon exercise of the warrants is expected to be $4.125 per share, which is equal to 100% of public offering price of common stock at a public offering price of $4.125 share). The exercise price is subject to appropriate adjustment in the event of certain stock dividends and distributions, stock splits, stock combinations, reclassifications or similar events affecting our common stock and also upon any distributions of assets, including cash, stock or other property to our shareholders.

Transferability. Subject to applicable laws, the warrants may be offered for sale, sold, transferred or assigned without our consent.

Fundamental Transactions. In the event of a fundamental transaction, as described in the warrants and generally including any reorganization, recapitalization or reclassification of our common stock, the sale, transfer or other disposition of all or substantially all of our properties or assets, our consolidation or merger with or into another person, the acquisition of more than 50% of our outstanding common stock, or any person or group becoming the beneficial owner of 50% of the voting power represented by our outstanding common stock, the holders of the warrants will be entitled to receive upon exercise of the warrants the kind and amount of securities, cash or other property that the holders would have received had they exercised the warrants immediately prior to such fundamental transaction.

Listing

The shares of our Common Stock were previously quoted on the OTCQB under the symbol "CTXR." Our common stock and warrants are listed on Nasdaq Capital Market under the symbols "CTXR" and "CTXRW", respectively.

Transfer Agent and Registrar

The transfer agent and registrar for our common stock and warrants is VStock Transfer, LLC. The transfer agent's address is 18 Lafayette Place, Woodmere, New York 11598 and its telephone number is (212) 828-8436.

Nevada's Anti-Takeover Law and Provisions of Our Articles of Incorporation and Bylaws

Acquisition of Controlling Interest Statutes. Nevada's "acquisition of controlling interest" statutes contain provisions governing the acquisition of a controlling interest in certain Nevada corporations. These "control share" laws provide generally that any person that acquires a "controlling interest" in certain Nevada corporations may be denied certain voting rights, unless a majority of the disinterested stockholders of the corporation elects to restore such voting rights. These statutes provide that a person acquires a "controlling interest" whenever a person acquires shares of a subject corporation that, but for the application of these provisions of the Nevada Revised Statutes, would enable that person to exercise (1) one-fifth or more, but less than one-third, (2) one-third or more, but less than a majority or (3) a majority or more, of all of the voting power of the corporation in the election of directors. Once an acquirer crosses one of these thresholds, shares which it acquired in the transaction taking it over the threshold and within the 90 days immediately preceding the date when the acquiring person acquired or offered to acquire a controlling interest become "control shares" to which the voting restrictions described above apply. Our articles of incorporation and bylaws currently contain no provisions relating to these statutes, and unless our articles of incorporation or bylaws in effect on the tenth day after the acquisition of a controlling interest were to provide otherwise, these laws would apply to us if we were to (i) have 200 or more stockholders of record (at least 100 of which have addresses in the State of Nevada appearing on our stock ledger) and (ii) do business in the State of Nevada directly or through an affiliated corporation. As of December 1, 2017, we have 115 record stockholders and do not have 100 stockholders of record with Nevada addresses appearing on our stock ledger. If these laws were to apply to us, they might discourage companies or persons interested in acquiring a significant interest in or control of the Company, regardless of whether such acquisition may be in the interest of our stockholders.

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

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

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

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

DESCRIPTION OF WARRANTS

We may issue warrants for the purchase of common stock or preferred stock. Warrants may be issued independently or together with other securities and may be attached to or separate from any offered securities. We may issue the warrants directly or under warrant agreements to be entered into between a warrant agent and us. Any warrant agent will act solely as our agent in connection with the warrants and will not have any obligation or relationship of agency or trust for or with any holders or beneficial owners of warrants.

The following outlines some of the general terms and provisions of the warrants that we may issue. A prospectus supplement will describe the particular terms of any warrants offered from time to time, and may supplement or change the terms outlined below. We will file as an exhibit to the registration statement of which this prospectus is a part, or will incorporate by reference from reports that we file with the SEC, a form of the warrant or form of the warrant agreement and warrant certificate that sets forth the terms of the particular warrants we are offering. The summary of such terms contained in this prospectus and in the applicable prospectus supplement is qualified in its entirety by reference to such warrant or warrant agreement and warrant certificate. We urge you to read the warrant or warrant agreement and warrant certificate and the additional description of the terms of the warrants included in the prospectus supplement.

General

The prospectus supplement relating to a particular issue of warrants will describe the terms of the warrants, including the following:

- the title of the warrants;
- the offering price for the warrants, if any;
- the aggregate number of the warrants;
- the designation and terms of the common stock, preferred stock or other class of security that may be purchased upon exercise of the warrants;
- if applicable, the date from and after which the warrants and any securities issued with the warrants will be separately transferable;
- the number of shares and price of common stock or preferred stock that may be purchased upon exercise of a warrant;
- the dates on which the right to exercise the warrants commence and expire;
- if applicable, the minimum or maximum amount of the warrants that may be exercised at any one time;
- if applicable, a discussion of material U.S. federal income tax considerations;
- anti-dilution provisions of the warrants, if any;
- redemption or call provisions, if any, applicable to the warrants; and
- any additional terms of the warrants, including terms, procedures and limitations relating to the exchange and exercise of the warrants.

Exercise of Warrants

Each warrant will entitle the holder of the warrant to purchase at the exercise price set forth in the applicable prospectus supplement the principal amount of debt securities or shares of common stock or preferred stock being offered. Holders may exercise warrants at any time up to the close of business on the expiration date set forth in the applicable prospectus supplement. After the close of business on the expiration date, unexercised warrants will be void. Holders may exercise warrants as set forth in the prospectus supplement relating to the warrants being offered.

Until a holder exercises the warrants to purchase any securities underlying the warrants, the holder will not have any rights as a holder of the underlying securities by virtue of ownership of warrants.

DESCRIPTION OF THE UNITS

We may issue units comprised of one or more of the other classes of securities offered hereby in any combination. Each unit will be issued so that the holder of the unit is also the holder of each security included in the unit. Thus, the holder of a unit will have the rights and obligations of a holder of each included security.

The units may be, but are not required to be, issued under unit agreements to be entered into between us and a unit agent, as detailed in the prospectus supplement relating to the units being offered. We will file as an exhibit to the registration statement of which this prospectus is a part, or will incorporate by reference from reports that we file with the SEC, a form of the unit agreement and unit certificate, if any, that sets forth the terms of the particular units we are offering. The summary of such terms contained in this prospectus and in the applicable prospectus supplement is qualified in its entirety by reference to such unit agreement and unit certificate. We urge you to read the unit agreement and unit certificate, if any, and the additional description of the terms of the units included in the prospectus supplement.

The prospectus supplement will describe the units and the price or prices at which we will offer the units. The description will include:

- the designation and terms of the units and of the securities comprising the units, including whether and under what circumstances the securities comprising the units may be held or transferred separately;
- a description of the terms of any unit agreement governing the units;
- a description of the provisions for the payment, settlement, transfer or exchange of the units;
- a discussion of material federal income tax considerations, if applicable; and
- whether the units if issued as a separate security will be issued in fully registered or global form.

The descriptions of the units in this prospectus and in any prospectus supplement are summaries of the material provisions of the applicable agreements.

LEGAL MATTERS

The validity of the securities being offered hereby will be passed upon by Wyrick Robbins Yates & Ponton LLP, Raleigh, North Carolina.

EXPERTS

The financial statements of Citius Pharmaceuticals, Inc. appearing in the Company's Annual Report on Form 10-K for the fiscal year ended September 30, 2017 have been audited by Wolf & Company, P.C., independent registered public accounting firm, as set forth in their report thereon appearing elsewhere herein, and are included in reliance upon such report given on the authority of such firm as experts in accounting and auditing.

WHERE YOU CAN FIND ADDITIONAL INFORMATION

We are subject to the reporting requirements of the Securities Exchange Act of 1934, as amended, and file annual, quarterly and current reports, proxy statements and other information with the SEC. You can read our SEC filings, including the registration statement, over the Internet at the SEC's website at *http://www.sec.gov*. We also maintain a website at *http://www.citiuspharma.com*, at which you may access these materials free of charge as soon as reasonably practicable after they are electronically filed with, or furnished to, the SEC. The information contained in, or that can be accessed through, our website is not part of this prospectus.

You may also read and copy any document we file with the SEC at its public reference facilities at 100 F Street, N.E., Room 1580, Washington, D.C. 20549. You may also obtain copies of these documents at prescribed rates by writing to the Public Reference Section of the SEC at 100 F Street, N.E., Washington, D.C. 20549. Please call the SEC at 1-800-SEC-0330 for further information on the operation of the public reference facilities. You may also request a copy of these filings, at no cost, by writing or telephoning us at: 11 Commerce Drive, First Floor, Cranford, New Jersey 07016, (908) 967-6677.

INCORPORATION OF DOCUMENTS BY REFERENCE

The SEC allows us to "incorporate by reference" information that we file with them. Incorporation by reference allows us to disclose important information to you by referring you to those other documents. The information incorporated by reference is an important part of this prospectus and any applicable accompanying prospectus, and information that we file later with the SEC will automatically update and supersede this information. We filed a registration statement on Form S-3 under the Securities Act of 1933, as amended, with the SEC with respect to the securities being offered pursuant to this prospectus and any applicable accompanying prospectus. This prospectus omits certain information contained in the registration statement, as permitted by the SEC. You should refer to the registration statement, including the exhibits, for further information about us and the securities being offered pursuant to this prospectus and any applicable accompanying prospectus. Statements in this prospectus and any applicable accompanying prospectus regarding the provisions of certain documents filed with, or incorporated by reference in, the registration statement are not necessarily complete and each statement is qualified in all respects by that reference. Copies of all or any part of the registration statement, including the documents incorporated by reference or the exhibits, may be obtained upon payment of the prescribed rates at the offices of the SEC listed above in "Where You Can Find More Information." The documents we are incorporating by reference into this prospectus are:

- our Annual Report on Form 10-K for the fiscal year ended September 30, 2017 filed on December 13, 2017;
- our Quarterly Reports on Form 10-Q for the fiscal quarter ended December 31, 2016 filed February 14, 2017, for the fiscal quarter ended March 31, 2017 filed on May 15, 2017, and for the fiscal quarter ended June 30, 2017 filed on August 14, 2017;

- our Current Reports on Form 8-K filed on October 10, 2017, October 24, 2017, October 31, 2017, November 7, 2017, November 7, 2017, November 9, 2017, and December 1, 2017;
- our definitive proxy statement on Schedule 14A, filed on December 13, 2017, for our annual meeting of stockholders scheduled to be held on February 7, 2018;
- the description of our common stock contained in our registration statement on Form 8-A filed on July 28, 2017; and
- all of the filings pursuant to the Exchange Act after the date of the filing of the registration statement and prior to the effectiveness of the registration statement.

In addition, all documents subsequently filed by us pursuant to Section 13(a), 13(c), 14 or 15(d) of the Exchange Act before the date our offering is terminated or completed are deemed to be incorporated by reference into, and to be a part of, this prospectus, provided that we are not incorporating by reference any information furnished to, but not filed with, the SEC.

Any statement contained in this prospectus and any applicable prospectus supplement or in a document incorporated or deemed to be incorporated by reference into this prospectus and any applicable prospectus supplement will be deemed to be modified or superseded for purposes of this prospectus and any prospectus supplement to the extent that a statement contained in this prospectus and any applicable prospectus supplement or any other subsequently filed document that is deemed to be incorporated by reference into this prospectus and any applicable prospectus supplement modifies or supersedes the statement. Any statement so modified or superseded will not be deemed, except as so modified or superseded, to constitute a part of this prospectus and any applicable prospectus supplement.

We will furnish without charge to you, on written or oral request, a copy of any or all of the documents incorporated by reference, including exhibits to these documents. You should direct any requests for documents to Citius Pharmaceuticals, Inc. 11 Commerce Drive, First Floor, Cranford, New Jersey 07016, (908) 967-6677.

You should rely only on information contained in, or incorporated by reference into, this prospectus and any applicable prospectus supplement. We have not authorized anyone to provide you with information different from that contained in this prospectus and any applicable prospectus supplement or incorporated by reference in this prospectus and any applicable prospectus supplement. We are not making offers to sell the securities in any jurisdiction in which such an offer or solicitation is not authorized or in which the person making such offer or solicitation is not qualified to do so or to anyone to whom it is unlawful to make such offer or solicitation.

7,964,804 shares of common stock

PROSPECTUS SUPPLEMENT

H.C. Wainwright & Co.

The date of this prospectus supplement is August 5, 2020