Filed pursuant to Rule 424(b)(3)
Registration No. 333-230919

PROSPECTUS

3,670,551 Shares of Common Stock

This prospectus relates to the sale or other disposition from time to time of up to 3,670,551 shares of our common stock, $0.001 par value per share, issuable upon the exercise of warrants held by the selling stockholders named in this prospectus, including their transferees, pledgees, donees or successors. We are not selling any shares of common stock under this prospectus and will not receive any of the proceeds from the sale of shares of common stock by the selling stockholders.

The selling stockholders may sell or otherwise dispose of the shares of common stock covered by this prospectus in a number of different ways and at varying prices. We provide more information about how the selling stockholders may sell or otherwise dispose of their shares of common stock in the section entitled "Plan of Distribution" beginning on page 33. The selling stockholders will pay all brokerage fees and commissions and similar expenses. We will pay all expenses (except brokerage fees and commissions and similar expenses) relating to the registration of the shares with the Securities and Exchange Commission. No underwriter or other person has been engaged to facilitate the sale of shares of our common stock in this offering.

Our common stock is listed on the Nasdaq Capital Market under the ticker symbol "CTXR." On April 25, 2019, the last reported closing price of our common stock on the Nasdaq Capital Market was $1.06.

Investing in our common stock involves a high degree of risk. You should review carefully the risks and uncertainties described under the heading "Risk Factors" beginning on page 8 of this prospectus, and under similar headings in any amendments or supplements to this prospectus.

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. Any representation to the contrary is a criminal offense.

The date of this prospectus is April 26, 2019.

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ABOUT THIS PROSPECTUS

You should rely only on the information that we have provided or incorporated by reference in this prospectus and any prospectus supplement that we may authorize to be provided to you. We have not, and the selling stockholders have not, authorized anyone to provide you with different information. No dealer, salesperson or other person is authorized to give any information or to represent anything not contained in this prospectus or any prospectus supplement that we may authorize to be provided to you. If anyone provides you with different or inconsistent information, you should not rely on it. You should assume that the information in this prospectus and any prospectus supplement is accurate only as of the date on the cover of the document and that any information we have incorporated by reference is accurate only as of the date of the document incorporated by reference, regardless of the time of delivery of this prospectus or any prospectus supplement or any sale of a security. Our business, financial condition, results of operations and prospects may have changed since those dates.

We urge you to carefully read this prospectus and any prospectus supplement, together with the information incorporated herein by reference as described under the heading "Where You Can Find More Information" and "Incorporation of Documents by Reference."

Unless the context indicates otherwise, as used in this prospectus, the terms "Citius," "we," "us," "our," "the Company," "our company" and "our business" refer to Citius Pharmaceuticals, Inc. and its subsidiaries.

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, 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.

PROSPECTUS SUMMARY

This summary highlights certain information about us and this offering contained elsewhere in this prospectus. Because it is only a summary, it does not contain all of the information that you should consider before investing in shares of 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. Before you decide to invest in our securities, you should read the entire prospectus carefully, including "Risk Factors" beginning on page 8, and the consolidated financial statements and related notes incorporated by reference into this prospectus.

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 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.

Since its inception, we have devoted substantially all of our 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.

Mino-Lok

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 the University of Texas 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 complication in the control arm group.

Parameter	**Mino-Lok Arm**		**Control Arm**	
	N	**(%)**	**N**	**(%)**
Patients	**30**	**(100%)**	**60**	**(100%)**
Cancer type				
- Hematologic	20	(67)	48	(80)
- Solid tumor	10	(33)	12	(20)
ICU Admission	**4**	**(13)**	**4**	**(7)**
Mech. Ventilator	**3**	**(10)**	**0**	**(0)**
Bacteremia				
- Gram+	17	(57)*	32	(53)
- Gram-	14	(47)*	28	(47)
Neutropenia (<500)	**19**	**(63)**	**36**	**(60)**
Microbiologic Eradication	**30**	**(100)**	**60**	**(100)**
- Relapse	0	(0)	3	(5)
Complications	**0**	**(0)**	**8**	**(13)**
SAEs related 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 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 is 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 March 25, 2019, there are 22 active sites currently enrolling patients including such academic centers as MD Anderson Cancer Center, Henry Ford Health Center, Georgetown University Medical Center, University of Chicago and others. There are 16 additional well renowned medical centers in startup mode. When these study centers are activated, site recruitment will have reached 76% of the target institutions planned; and there are another 23 centers in feasibility stage as of March 28, 2019.

Fast Track Designation

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

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

Mino-Lok International Study

In October 2017, data from an international study on Mino-Lok was presented at the Infectious Disease Conference, ("ID Week"), in San Diego, California. The 44-patient study was conducted in Brazil, Lebanon and Japan and showed Mino Lok therapy was an effective intervention to salvage long term, infected central venous catheters (CVCs) in catheter related bloodstream infections 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.

Stability Patent Application for Mino-Lok

In July 2018, we received notice from the MDACC that the U.S. Patent and Trademark Office has reviewed and examined the patent application US 2017/051373 A1 and that it is allowed for issuance as a patent. 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.

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

Mino-Wrap

On January 2, 2019, we entered into a patent and technology license agreement with the Board of Regents of the University of Texas System on behalf of the MDACC, whereby we in-licensed exclusive worldwide rights to the patented technology for any and all uses relating to breast implants. We intend to develop, a liquefying gel-based wrap containing minocycline and rifampin for the reduction of infections associated with breast implants following breast reconstructive surgeries ("Mino-Wrap"). We are required to use commercially reasonable efforts to commercialize Mino-Wrap under several regulatory scenarios and achieve milestones associated with these regulatory options leading to an approval from the FDA. Mino-Wrap will require pre-clinical development prior to any regulatory pathway, which pathway we have not yet determined.

Hydro-Lido

Overview

Hydro-Lido is a topical formulation of hydrocortisone 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 strengths of topical combination prescription products containing hydrocortisone 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 2 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.

In March 2018, we announced that we are selecting a higher potency corticosteroid in our steroid/anesthetic topical formulation program for the treatment of hemorrhoids. The original topical preparation, 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 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.

Corporate History and Information

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. ("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 its telephone number is (908) 976-6677.

THE OFFERING

Up to 3,670,551 Shares of Common Stock

This prospectus relates to the resale by the selling stockholders identified in this prospectus of up to 3,670,551 shares of our common stock issuable upon exercise of the following warrants:

- warrants for 3,430,421 shares of common stock issued in a private placement in April 2019 to investors with an exercise price of $1.42 that expire on April 5, 2021;
- warrants for 240,130 shares of common stock issued in April 2019 to the placement agent for the private placement, with an exercise price of $1.93125 per share that expire on April 5, 2021.

Common stock offered by the selling stockholders	3,670,551 shares
Common stock outstanding before the offering[(1)]	22,075,781 shares
Common stock to be outstanding after the offering	25,746,332 shares
Common stock Nasdaq Capital Market Symbol	CTXR

(1) Based on the number of shares outstanding as of April 9, 2019.

Use of Proceeds

The 3,670,551 shares of common stock issuable upon the exercise of currently outstanding warrants and that are being offered for resale by the selling stockholders will be sold for the accounts of the selling stockholders named in this prospectus. As a result, all proceeds from the sales of the 3,670,551 shares of common stock issuable upon the exercise of currently outstanding warrants and offered for resale hereby will go to the selling stockholders and we will not receive any proceeds from the resale of those shares of common stock by the selling stockholders.

We may receive up to a total of $5,334,949 in gross proceeds if all of the warrants are exercised hereunder for cash. However, as we are unable to predict the timing or amount of potential exercises of the warrants, we have not allocated any proceeds of such exercises to any particular purpose. Accordingly, all such proceeds are allocated to working capital. Pursuant to conditions set forth in the warrants, the warrants are exercisable under certain circumstances on a cashless basis, and should a selling stockholder elect to exercise on a cashless basis we will not receive any proceeds from the sale of common stock issued upon the cashless exercise of the warrant. It is possible that the warrants may expire and may never be exercised.

We will incur all costs associated with this registration statement and prospectus.

Dividend Policy

We have never paid dividends on our capital stock and do not anticipate paying any dividends for the foreseeable future.

Risk Factors

Investing in our common stock involves a high degree of risk. Please read the information contained under the heading “Risk Factors” beginning on page 8 of this prospectus.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus, including the sections entitled "Risk Factors," "Management's Discussion and Analysis of Financial Condition and Results of Operations" and "Business," 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, results and timing 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 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 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, or "SEC," 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.

Investors are cautioned not to place undue reliance on the forward-looking statements, which speak only as of the respective dates of this prospectus or any prospectus supplement or the date of the document incorporated by reference in this prospectus or any 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.

RISK FACTORS

Investing in our common stock includes a high degree of risk. Prior to making a decision about investing in our common stock, you should consider carefully the specific factors discussed below, together with all of the other information contained in and incorporated by reference into this prospectus. If any of the following risks actually occurs, our business, financial condition, results of operations and future prospects would likely be materially and adversely affected. This could cause the market price of our common stock to decline and could cause you to lose all or part of your investment.

Risks related to our Business and our Industry

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

We were formed as a limited liability company 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 and have not generated any revenues to date. We have incurred losses in each period of our operations, and we expect to continue to incur losses for the foreseeable future. These losses are likely to continue to adversely affect our working capital, total assets and shareholders' equity (deficit). The process of developing our products requires significant clinical, development and laboratory testing and clinical trials. In addition, commercialization of our product candidates will require that we obtain necessary regulatory approvals and establish sales, marketing and manufacturing capabilities, either through internal hiring or through contractual relationships with others. We expect to incur substantial losses for the foreseeable future as a result of anticipated increases in our research and development costs, including costs associated with conducting preclinical testing and clinical trials, and regulatory compliance activities. We incurred net losses of $12,536,638, $10,384,953, and $8,295,698 for the years ended September 30, 2018, 2017 and 2016, respectively, and $3,874,730 for the three months ended December 31, 2018. At December 31, 2018, we had stockholders' equity of $24,178,203 and an accumulated deficit of $44,132,568. Our net cash used for operating activities was $11,318,138, $7,971,205, and $5,900,421 for the years ended September 30, 2018, 2017 and 2016, respectively, and $2,158,530 for the three months ended December 31, 2018.

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; 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 products will be approved by the FDA, that we will successfully bring any product to market or, if so, that we will ever become profitable.

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

Currently, we do not have sufficient capital to continue our operations after the third fiscal quarter of 2019. You should not rely on our consolidated balance sheet as an indication of the amount of proceeds that would be available to satisfy claims of creditors, and potentially be available for distribution to shareholders, in the event of liquidation.

Our audited consolidated financial statements included within 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, 2018.

We need to secure additional financing.

We anticipate that we will incur operating losses for the foreseeable future. We have received gross proceeds of approximately $40.9 million from our public and private placement offerings through April 2019. Additionally, in connection with the acquisition of LMB our Executive Chairman, Leonard Mazur, made an equity investment of $3.0 million in March 2016. Mr. Mazur has also loaned us $4,710,000 pursuant to convertible promissory notes. On August 8, 2017, these notes and accrued interest of $76,240 were converted into 1,547,067 shares of common stock at a price of $3.09 per share as part of an underwritten public offering which closed on the same date.

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

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

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

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

Our strategy of using collaborative partners to assist us in the development of our therapeutic products is unproven. Our success will depend upon our ability to enter into additional collaboration agreements on favorable terms and to select an appropriate commercialization strategy for each product candidate that we and our collaborators choose to pursue. 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 products or product candidates will depend, among other things, on our ability to:

- successfully complete pre-clinical and clinical trials 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;
- 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;

- 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 face significant risks in our product candidate development efforts.

Our business depends on the successful development and commercialization of our product candidates. We are not permitted to market any of our product candidates in the United States until we receive approval of an NDA from the FDA, or in any foreign jurisdiction until we receive the requisite approvals from such jurisdiction. The process of developing new drugs and/or therapeutic products is inherently complex, unpredictable, time-consuming, expensive and uncertain. We must make long-term investments and commit significant resources before knowing whether our development programs will result in drugs 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 Hydro-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 our 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 manufacturing 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.

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.

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 test drug compared to placebo. This effect is likely to be observed in the treatment of hemorrhoids.

If any of our product candidates fail to demonstrate sufficient safety and efficacy in any clinical trial, we will experience potentially significant delays in, or may decide to abandon development of that product candidate. If we abandon or are delayed in our development efforts related to any of our 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 Hydro-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 under Section 505(b)(2), we may be unable to meet our anticipated development and commercialization timelines.

Our current plans for filing additional NDAs for our product candidates include efforts to minimize the data we will be required to generate in order to obtain marketing approval for our additional 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 Hydro-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 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 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.

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 drugs, 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. Drugs 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.

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 obtain regulatory approval, the 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 optimal commercial success. We believe that the degree of market acceptance and our ability to generate revenues from any approved produce candidate or acquired product will depend on a number of factors, including:

- prevalence and severity of any side effects;
- results of any post-approval studies of the drug;
- potential or perceived advantages or disadvantages over alternative treatments including generics;

- the relative convenience and ease of administration and dosing schedule;
- 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;
- product labeling or product insert requirements of the FDA or other regulatory authorities;
- strength of sales, marketing and distribution support;
- price of any future drugs, 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 products if we fail to establish marketing, sales and distribution capabilities, or fail to enter into 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, as well as marketing, sales and distribution activities. Currently, we do not have any sales, marketing or distribution capabilities. In order to generate sales of any product candidates that receive regulatory approval, we must either acquire or develop an internal marketing and sales force with technical expertise and with supporting distribution capabilities or make arrangements with third parties to perform these services for us. The acquisition or development of a sales and distribution infrastructure would require substantial resources, which may divert the attention of our management and key personnel and defer our product development efforts. To the extent that we enter into marketing and sales arrangements with other companies, our revenues will depend on the efforts of others. These efforts may not be successful. If we fail to develop sales, marketing and distribution channels, or enter into arrangements with third parties, we will experience delays in product sales and incur increased costs.

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

Competition in the pharmaceutical and medical products industries is intense and is characterized by costly and extensive research efforts and rapid technological progress. We are aware of several pharmaceutical companies also actively engaged in the development of therapies 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, human clinical trials and other regulatory approval procedures. Our competitors may develop technologies and products that are more effective than those we are currently marketing or researching and developing. Such developments could render our product candidates, if approved, less competitive or possibly obsolete. We are also competing with respect to marketing capabilities and manufacturing efficiency, areas in which we have no current capabilities and in which we have limited experience. 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 products and 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 drugs or surgical approaches 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 products 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 products will depend upon a number of factors, including:

- perceptions by members of the health care community, including physicians, about the safety and effectiveness of our products;
- cost-effectiveness of our product relative to competing products or therapies;
- availability of reimbursement for our product from government or other healthcare payers; and
- effective marketing and distribution efforts by us and/or our licensees and distributors, if any.

If 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 these products to find market acceptance would harm our business and would require us to seek additional financing.

Our two product candidates, Mino-Lok and Hydro-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 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 Hydro-Lido product candidate for the treatment of hemorrhoids is a combination product consisting of two drugs, hydrocortisone and lidocaine, that have each been separately approved by the FDA for other indications and which are commercially available and marketed by other companies. Hydrocortisone creams are available from strengths ranging from 0.5% to 2.5% 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. Our 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.

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.

We have not yet determined a regulatory pathway for Mino-Wrap, which we in-licensed in January 2019.

Our ability to generate product revenues will be diminished if any of our approved products 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 recently 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 products. If we are not able to charge a sufficient amount for our products, then our margins and our profitability will be adversely affected.

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 own product candidates, which are currently being manufactured entirely by a commercial third party. If any additional 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 to manufacture our product candidates, either for 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 products 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 products. 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 products. 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 products after receipt of FDA approval, if any;

- Our third-party manufacturers might be unable to formulate and manufacture our products 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 products;

- 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 products, 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; 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.

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

We are and will be dependent on third-party research organizations to conduct all of our human trials with respect to our product candidates, including those that we may develop in the future. If we are unable to obtain any necessary testing services on acceptable terms, we may not complete our product development efforts in a timely manner. 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 our 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 our future product candidates.

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

If we or any of our collaborators or licensees fail to renew or terminate any of our collaboration or license agreements or if either party fails to satisfy its obligations under any of our collaboration or license agreements or complete them in a timely manner, we could lose significant sources of revenue, which could result in volatility in our future revenue. In addition, our agreements with our collaborators and licensees may have provisions that give rise to disputes regarding the rights and obligations of the parties. These and other possible disagreements could lead to termination of the agreement or delays in collaborative research, development, supply or commercialization of certain products, 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 might seek 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.

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. For example, we recently in-licensed exclusive worldwide rights to Mino-Wrap that we intend to develop as a treatment to reduce infections associated with breast implants following breast reconstructive surgeries.

Potential and completed acquisitions and strategic investments involve numerous risks, including potential problems or issues associated with the following:

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

We have no current commitments with respect to any acquisition or investment in other technologies or businesses. We do not know if we will identify suitable acquisitions, whether we will be able to successfully complete any acquisitions, or whether we will be able to successfully integrate any acquired product, technology or business into our business 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, our business and financial condition might be adversely affected.

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

We utilize the services of a clinical management team on part-time basis to assist us in managing our ongoing Phase 2 and Phase 3 trials and intend to do so for future trials. While we believe this will provide us with sufficient staffing for our current and future development efforts, we will need to hire or contract with additional qualified personnel with expertise in preclinical testing, clinical research and testing, government regulation, formulation and manufacturing and sales and marketing in connection with the continued development, regulatory approval and commercialization of our product candidates. We compete for qualified individuals with numerous pharmaceutical and biopharmaceutical companies, universities and other research institutions. Competition for these individuals is intense, and we cannot be certain that our search for such personnel will be successful. Attracting and retaining qualified personnel will be critical to our success. In addition, we may be unable to attract and retain those qualified officers, directors and members of board committees required to provide for effective management. If we are unable to attract and retain qualified employees, officers and directors, the management and operation of our business could be adversely affected.

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

We will need to manage our anticipated growth and increased operational activity. Our personnel, systems and facilities currently in place may not be adequate to support this future growth. Our need to effectively execute our growth strategy will require that we:

- manage our regulatory trials effectively;
- attract and motivate sufficient numbers of talented employees;
- 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 reduced productivity among remaining employees. 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.

Product candidates and approved products such as ours are 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. The FDA regulates small molecule chemical entities, whether administered orally, topically or by injection, as drugs, subject to an NDA, under the Federal Food, Drug, and Cosmetic Act. 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 products. The regulatory review and approval process, which includes preclinical testing and clinical trials of each product candidate, is lengthy, expensive, and uncertain. Our collaborators or we must obtain and maintain regulatory authorization to conduct clinical trials and approval for each product we intend to market, and the manufacturing facilities used for the products must be inspected and meet legal requirements. Securing regulatory approval requires submitting extensive preclinical and clinical data and other supporting information for each proposed therapeutic indication 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. Even if we are able to obtain regulatory approval for a particular product, 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, delays in the approval of applications or supplements to approved applications; refusal of a regulatory authority, including the FDA, to review pending market approval applications or supplements to approved applications; warning letters; fines; import and export restrictions; product recalls or seizures; injunctions; total or partial suspension of production; civil penalties; withdrawals of previously approved marketing applications or licenses; recommendations by the FDA or other regulatory authorities against governmental contracts; and/or criminal prosecutions.

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

We cannot assure you that we will receive the approvals necessary to commercialize for sale any product candidates we are currently developing or that we may acquire or develop in the future. We will need FDA approval to commercialize our product candidates in the U.S. In order to obtain FDA approval of any product candidate, we must submit to the FDA an NDA demonstrating that the product candidate is safe for humans and effective for its intended use. This demonstration requires significant research, pre-clinical studies, and clinical trials. Satisfaction of the FDA's regulatory requirements typically takes many years, depends upon the type, complexity and novelty of the product candidate and requires substantial resources for research, development and testing. We cannot predict whether our research and clinical approaches will result in additional drugs 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. There is no guarantee that we will ever be able to develop or acquire any product candidate.

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

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 our products. Even if U.S. regulatory approval is obtained, the FDA may still impose significant restrictions on a drug's indicated uses or marketing or impose ongoing requirements for potentially costly post-approval studies. For example, the label ultimately approved for our products, if any, may include restrictions on use, including restrictions based on level of obesity and duration of treatment. 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 products. The FDA could also require a registry to track the patients utilizing the drug or implement a Risk Evaluation and Mitigation Strategy, or "REMS," that could restrict access to the drug, reduce our revenues and/or increase our costs. Potentially costly post-marketing clinical studies may be required as a condition of approval to further substantiate safety or efficacy, or to investigate specific issues of interest to the regulatory authority.

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

- issuance of Form 483 notices, warning letters and adverse publicity by the FDA or other regulatory agencies;
- imposition of fines and other civil penalties due to product liability or other issues;
- injunctions, suspensions or revocations of regulatory approvals;
- suspension of any ongoing 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.

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 clinical trials, and the sale of any approved products, may expose us to liability claims and financial losses resulting from the use or sale of our products. We have obtained limited product liability insurance coverage for our clinical trials of $2.0 million per occurrence and in the aggregate, subject to a deductible of $50,000 per occurrence. There can be no assurance that our existing insurance coverage will extend to any other products 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.

If we do not obtain protection for our intellectual property rights, our competitors might be able 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 products, 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 products 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 potential products 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 disease treatments 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. 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, customers 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 products 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.

Risks Related to Our Securities

Our failure to meet the continued listing requirements of Nasdaq could result in a delisting of our common stock and warrants.

Our common stock and warrants are currently listed on the Nasdaq Capital Market, or "Nasdaq." If we fail to satisfy the continued listing requirements of Nasdaq, such as the corporate governance requirements or the minimum closing bid price requirement, Nasdaq may take steps to delist our common stock and warrants. Such a delisting would likely have a negative effect on the price of our common stock and warrants and would impair your ability to sell or purchase our common stock and warrants when you wish to do so. In addition, we could face significant material adverse consequences, including:

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

In the event of a 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 Nasdaq, 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. For any transaction involving a "penny stock," unless exempt, the rules impose additional sales practice requirements on broker-dealers, subject to certain exceptions. If our common stock were delisted and determined to be a "penny stock," a broker-dealer may find it more difficult to trade our common stock and an investor may find it more difficult to acquire or dispose of our common stock on the secondary market.

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

We are subject to the reporting requirements of the Securities Exchange Act of 1934, as amended, or the "Exchange Act," 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 control over financial reporting to allow management to report on the effectiveness of our internal controls over financial reporting in our Annual Report on Form 10-K filing for that year, as required by Section 404 of SOX. We previously had identified material weaknesses in our internal control over financial reporting related to ineffective separation of duties due to our limited finance staff, our reliance on consultants to assist with the financial reporting function and a lack of documented policies and procedures, which weaknesses were reported in fiscal 2016 and 2017. While we remediated these material weaknesses as of September 30, 2018, such that management has determined that our internal controls over financial reporting were effective as of that date, we cannot assure that, in the future, a material weakness or significant deficiency will not exist or otherwise be discovered. If that were to happen, it could harm our operating results and cause shareholders to lose confidence in our reported financial information. Any such loss of confidence would have a negative effect on the trading price of our securities.

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

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

- actual or anticipated variations in our operating results;
- announcements of developments by us or our competitors;
- the completion and/or results of our clinical trials;
- regulatory actions regarding our product candidates or any approved products;
- announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures or capital commitments;
- adoption of new accounting standards affecting our industry;
- additions or departures of key personnel;
- introduction of new products by us or our competitors;
- sales of our common stock or other securities in the open market or in private placements; 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.

In the future, to finance our operations, including possible acquisitions or strategic transactions, we may 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 April 9, 2019, there were 22,075,781 shares of common stock outstanding, 12,871,623 shares underlying warrants with a weighted average exercise price of $2.604 per share, 1,646,039 shares underlying options with a weighted average exercise price of $4.252 per share, and 100,667 underlying unit purchase options to purchase shares of common stock and warrants at an exercise price of $9.00 per unit. 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 April 9, 2019, our executive officers and directors beneficially owned approximately 56.2% 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 the business, it is currently anticipated that any 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 a 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.

There is not an active liquid trading market for our common stock.

While our common stock is listed on the Nasdaq Capital Market, there has not been a regular active trading market in our common stock, and we cannot give any assurance that an active trading market will develop. If an active market for our common stock were to develop, there is a significant risk that the stock price could fluctuate dramatically in the future in response to any of the following factors, some of which are beyond our control:

- the results of our preclinical and clinical trials;
- announcements by us or our competitors of significant contracts, acquisitions, strategic partnerships, joint ventures or capital commitments;
- general economic slowdowns;
- issuances by us or resales by others of large amounts of our common stock;
- variations in our quarterly operating results; and
- announcements that our revenue or income are below analysts' expectations.

Sales of a substantial number of shares of our common stock in the public market, or the perception such sales may occur, could cause the market price of shares of our common stock to fall.

Sales of a substantial number of shares of our common stock in the public market could occur at any time. These sales, or the perception in the market of such sales or that the holders of a large number of shares intend to sell shares, could reduce the market price of our shares of our common stock. As of April 9, 2019, we had 22,075,781 shares of common stock outstanding. This includes registered shares of common stock as well as 5,002,573 shares of our common stock which are available for resale under Rule 144 of the Securities Act of 1933, as amended, or the "Securities Act."

USE OF PROCEEDS

The 3,670,551 shares of common stock issuable upon the exercise of currently outstanding warrants and that are being offered for resale by the selling stockholders will be sold for the accounts of the selling stockholders named in this prospectus. As a result, all proceeds from the sales of the 3,670,551 shares of common stock issuable upon the exercise of currently outstanding warrants and offered for resale hereby will go to the selling stockholders and we will not receive any proceeds from the resale of those shares of common stock by the selling stockholders.

We may receive up to a total of $5,334,949 in gross proceeds if all of the warrants are exercised hereunder for cash. However, as we are unable to predict the timing or amount of potential exercises of the warrants, we have not allocated any proceeds of such exercises to any particular purpose. Accordingly, all such proceeds are allocated to working capital. Pursuant to conditions set forth in the warrants, the warrants are exercisable under certain circumstances on a cashless basis, and should a selling stockholder elect to exercise on a cashless basis we will not receive any proceeds from the sale of common stock issued upon the cashless exercise of the warrant. It is possible that the warrants may expire and may never be exercised.

We will incur all costs associated with this registration statement and prospectus.

MARKET FOR COMMON STOCK

Prior to August 3, 2017, our common stock traded under the ticker symbol “CTXR.QB” on the OTCQB Venture Market operated by OTC Markets Group, Inc., or “OTCQB.” On August 3, 2017, our common stock began trading on the Nasdaq Capital Market under the symbol “CTXR”.

On April 25, 2019, the closing price as reported on the Nasdaq Capital Market of our common stock was $1.06. As of April 1, 2019, there were 99 holders of record of our common stock.

FINANCIAL STATEMENTS

Please see Part II, Item 8 in our Annual Report on Form 10-K for the fiscal year ended September 30, 2018, filed with the SEC on December 11, 2018, which is incorporated herein by reference, for the following financial statements:

- Report of Independent Registered Public Accounting Firm;
- Consolidated Balance Sheets as of September 30, 2018 and 2017;
- Consolidated Statements of Operations for the years ended September 30, 2018, 2017 and 2016;
- Consolidated Statements of Stockholders' Equity (Deficit) for the years ended September 30, 2018, 2017 and 2016;
- Consolidated Statements of Cash Flows for the years ended September 30, 2018, 2017 and 2016; and
- Notes to Consolidated Financial Statements.

See also Part I, Item 1 in our Quarterly Report on Form 10-Q for the quarter ended December 31, 2018, filed with the SEC on February 14, 2019, which is incorporated herein by reference, for the following financial statements:

- Condensed Consolidated Balance Sheets as of December 31 and September 30, 2018 (Unaudited);
- Condensed Consolidated Statements of Operations for the three months ended December 31, 2018 and 2017 (Unaudited);
- Condensed Consolidated Statement of Changes in Stockholders' Equity (Deficit) for the three months ended December 31, 2018 (Unaudited);
- Condensed Consolidated Statements of Cash Flows for the three months ended December 31, 2018 and 2017 (Unaudited); and
- Notes to Condensed Consolidated Financial Statements (Unaudited).

MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

Please see Item 7 in our Annual Report on Form 10-K for the fiscal year ended September 30, 2018, filed with the SEC on December 11, 2018, and Item 2 in our Quarterly Report on Form 10-Q for the quarter ended December 31, 2018, filed with the SEC on February 14, 2019, both of which are incorporated herein by reference, for our management's discussion and analysis of financial condition and results of operations for the respective periods.

BUSINESS

Please see Item 1 in our Annual Report on Form 10-K for the fiscal year ended September 30, 2018 filed with the SEC on December 11, 2018, which is incorporated herein by reference, for a discussion of our business.

Employees

As of March 31, 2019, the Company had 10 employees and various consultants providing support. Through our consulting and collaboration arrangements, and including our Scientific Advisory Board, we have access to more than 30 additional professionals, who possess significant expertise in business development, legal, accounting, regulatory affairs, clinical operations and manufacturing. We also rely upon a network of consultants to support our clinical studies and manufacturing efforts.

Properties

We maintain our offices at 11 Commerce Drive, First Floor, Cranford, NJ 07016. We do not intend to expand our operations for the foreseeable future and do not intend to lease additional space.

Legal Proceedings

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

MANAGEMENT

Please see "Election of Directors" and "Information Regarding the Board and its Committees" in our proxy statement on Schedule 14A for our 2019 Annual Meeting of Stockholders, filed with the SEC on December 20, 2018, which is incorporated herein by reference, for information regarding our board and directors. Please see "Executive Officers of Citius" in Item 1 of our Annual Report on Form 10-K for the fiscal year ended September 30, 2018, filed with the SEC on December 11, 2018, which is incorporated herein by reference, for information regarding our executive officers.

EXECUTIVE AND DIRECTOR COMPENSATION

Please see the sections captioned "Director Compensation," "Executive Compensation," and "Corporate Governance — Compensation Committee Interlocks and Insider Participation" in our proxy statement on Schedule 14A for our 2019 Annual Meeting of Stockholders, filed with the SEC on December 20, 2018, which is incorporated herein by reference, for a discussion of executive and director compensation.

TRANSACTIONS WITH RELATED PERSONS

Please see "Certain Relationships and Related Transactions" in our proxy statement on Schedule 14A for our 2019 Annual Meeting of Stockholders, filed with the SEC on December 20, 2018, which is incorporated herein by reference.

SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT

The following table shows the amount of our common stock beneficially owned as of April 9, 2019 by (i) each person or group, as those terms are used in Section 13(d)(3) of the Exchange Act, believed by us to beneficially own more than 5% of our common stock, (ii) each of our directors, (iii) each of our executive officers, and (iv) all of our directors and executive officers as a group. Except as otherwise noted, each person named in the table has sole voting and investment power with respect to all shares shown as beneficially owned by them, subject to applicable community property laws.

Name of Beneficial Owner[1]	Number of Shares of Common Stock Beneficially Owned[2]	Percentage of Shares of Common Stock Beneficially Owned[3]
Executive Officers and Directors		
Myron Holubiak	2,415,914[4]	10.48%
Leonard Mazur	13,412,047[5]	48.83%
Jaime Bartushak	121,168[6]	*
Suren Dutia	36,667[7]	*
Dr. William Kane	35,405[8]	*
Howard Safir	35,405[8]	*
Carol Webb	35,405[8]	*
Eugene Holuka	25,749[9]	*
All executive officers and directors as a group (8 people)	16,117,760	56.20%
Other 5% holders		
Armistice Capital Master Fund Ltd.	2,213,078[10]	9.99%

* Less than 1%.

(1) The address for our officers and directors is c/o of the Company, 11 Commerce Drive, First Floor, Cranford, New Jersey 07016.
(2) Beneficial ownership is determined in accordance with the rules of the SEC and generally includes voting or investment power with respect to securities. Shares of common stock subject to options or warrants currently exercisable or convertible, or exercisable or convertible within 60 days of April 9, 2019 are deemed outstanding for computing the percentage of the person holding such option or warrant but are not deemed outstanding for computing the percentage of any other person.
(3) Percentage based on 22,075,781 shares of common stock issued and outstanding at April 9, 2019.
(4) Consists of (i) 1,433,646 shares of common stock, (ii) 48,889 shares of common stock issuable upon exercise of options and (iii) warrants to purchase an aggregate of 933,379 shares of common stock.
(5) Consists of (i) 8,020,643 shares of common stock, (ii) 242,222 shares of common stock issuable upon exercise of options and (iii) warrants to purchase an aggregate of 5,149,182 shares of common stock.
(6) Consists of (i) 60,353 shares of common stock and (ii) 60,815 shares of common stock issuable upon exercise of options.
(7) Consists of 36,667 shares of common stock issuable upon exercise of options.
(8) Consists of 35,405 shares of common stock issuable upon exercise of options.
(9) Consists of 25,749 shares of common stock issuable upon exercise of options.
(10) Includes warrants to purchase 6,057,492 shares of common stock. The warrants held by Armistice Capital Master Fund Ltd., or "Armistice," are subject to a beneficial ownership limitation of either 9.99% or 4.99% (as specified in the individual warrant agreements), which does not permit Armistice to exercise that portion of the warrants that would result in Armistice and its affiliates owning, after exercise, a number of shares of common stock in excess of the beneficial ownership limitation. The amounts and percentages in the table give effect to the beneficial ownership limitation. The business address of Armistice is 510 Madison Avenue, 22nd Floor, New York, New York 10022.

DILUTION

The common stock to be sold by the selling stockholders upon conversion of their warrants is common stock that is issuable upon such exercise. To the extent the common stock underlying the warrants is issued, there will be dilution to the ownership interests of our existing stockholders.

SELLING STOCKHOLDERS

The following table set forth certain information regarding the selling stockholders and the shares of common stock beneficially owned by them, which information is available to us as of April 9, 2019. The selling stockholders may offer the shares under this prospectus from time to time and may elect to sell some, all or none of the shares set forth under this prospectus. However, for the purposes of the table below, we have assumed that, after completion of the offering, none of the shares covered by this prospectus will be held by the selling stockholders. In addition, a selling stockholder may have sold, transferred or otherwise disposed of all or a portion of that holder's shares of common stock since the date on which the selling stockholder provided information for this table. We have not made independent inquiries about such transfers or dispositions. See the section entitled "Plan of Distribution" beginning on page 33.

Beneficial ownership is determined in accordance with Rule 13d-3(d) promulgated by the SEC under the Exchange Act. The percentage of shares beneficially owned prior to the offering is based on 22,075,781 shares of our common stock outstanding as of April 9, 2019.

Selling Stockholder	Number of Shares of Common Stock Beneficially Owned Before Any Sale	% of Class	Number of Share of Common Stock Offering	Shares of Common Stock Beneficially Owned After Sale of All Shares of Common Stock Pursuant to this Prospectus	
				Number of Shares	% of Class
Armistice Capital Master Fund, Ltd.	2,213,078(1)(2)	9.99%(1)(2)	2,135,923	2,213,078(2)	9.99%(2)
Myron Holubiak	2,415,914(3)	10.48%(3)	129,450	2,286,464	9.97%
Leonard L. Mazur	13,412,047(4)	48.83%(4)	1,165,048	12,246,999	46.56%
Noam Rubinstein (5)	374,077(6)	1.67%(6)	75,641	298,436	1.34%
Michael Vasinkevich (5)	598,444(7)	2.64%(7)	154,884	443,560	1.97%
Mark Viklund (5)	26,364(8)	*(8)	7,204	19,160	*
Charles Worthman (5)	9,256(9)	*(9)	2,401	6,855	*
TOTAL	**19,049,180**	**64.62%**	**3,670,551**	**17,514,552**	**62.67%**

* Represents beneficial ownership of less than one percent of the outstanding shares of our common stock.

(1) Includes warrants to purchase 6,057,492 shares of common stock. The business address of Armistice is 510 Madison Avenue, 22nd Floor, New York, New York 10022.
(2) The warrants held by Armistice are subject to a beneficial ownership limitation of either 9.99% or 4.99% (as specified in the individual warrant agreements), which does not permit Armistice to exercise that portion of the warrants that would result in Armistice and its affiliates owning, after exercise, a number of shares of common stock in excess of the beneficial ownership limitation. The amounts and percentages in the table give effect to the beneficial ownership limitation.
(3) Consists of (i) 1,433,646 shares of common stock, (ii) 48,889 shares of common stock issuable upon exercise of options and (iii) warrants to purchase an aggregate of 933,379 shares of common stock.
(4) Consists of (i) 8,020,643 shares of common stock, (ii) 242,222 shares of common stock issuable upon exercise of options and (iii) warrants to purchase an aggregate of 5,149,182 shares of common stock.
(5) The selling stockholder is an affiliate of a registered broker-dealer.
(6) Consists of warrants to purchase 319,077 shares of common stock.
(7) Consists of warrants to purchase 598,444 shares of common stock.
(8) Consists of warrants to purchase 26,364 shares of common stock.
(9) Consists of warrants to purchase 9,256 shares of common stock.

Information about any other selling stockholders will be included in prospectus supplements or post-effective amendments, if required. Information about the selling stockholders may change from time to time. Any changed information with respect to which we are given notice will be included in prospectus supplements.

Certain Relationships and Transactions with the Selling Stockholders

In the last three fiscal years, we had the following transactions with the following selling stockholders.

Armistice Capital Master Fund, Ltd.

In August 2018, we sold to institutional and accredited investors in an underwritten at-the-market offering, (i) units, with each unit being comprised of one share of the Company's common stock and one warrant to purchase one share and (ii) pre-funded units, with each pre-funded unit being comprised of one pre-funded warrant to purchase one share and one warrant. Armistice purchased 1,600,000 shares of common stock, pre-funded warrants to purchase up to 2,321,569 shares of common stock, and warrants to purchase up to 3,921,569 shares of our common stock on the same terms as the other investors in the offering.

In April 2019, we sold to institutional and accredited investors shares of our common stock in an at-the-market offering public offering and warrants to purchase shares of our common stock in a concurrent private placement. Armistice purchased 2,135,923 shares of common stock and warrants to purchase up to 2,135,923 shares of our common stock on the same terms as the other investors in the offering.

Myron Holubiak

Myron Holubiak is the President, Chief Executive Officer and a director of the Company. Please see "Election of Directors" in our proxy statement on Schedule 14A for our 2019 Annual Meeting of Stockholders, filed with the SEC on December 11, 2018, which is incorporated herein by reference, for his biographical information.

In August 2018, we sold to institutional and accredited investors in an underwritten at-the-market offering, (i) units, with each unit being comprised of one share of the Company's common stock and one warrant to purchase one share and (ii) pre-funded units, with each pre-funded unit being comprised of one pre-funded warrant to purchase one share and one warrant. Mr. Holubiak purchased 784,314 shares of common stock and warrants to purchase up to 784,314 shares of our common stock on the same terms as the other investors in the offering.

In April 2019, we sold to institutional and accredited investors shares of our common stock in an at-the-market offering public offering and warrants to purchase shares of our common stock in a concurrent private placement. Mr. Holubiak purchased 129,450 shares of common stock and warrants to purchase up to 129,450 shares of our common stock on the same terms as the other investors in the offering.

Leonard Mazur

Leonard Mazur is the Executive Chairman of our Board of Directors. Please see "Election of Directors" in our proxy statement on Schedule 14A for our 2019 Annual Meeting of Stockholders, filed with the SEC on December 11, 2018, which is incorporated herein by reference, for his biographical information.

On March 30, 2016, we entered into that certain Agreement and Plan of Merger by and among the Company, Citius LMB Acquisition Corp., a Delaware corporation and wholly-owned subsidiary of our company ("SubCo"), and Leonard-Meron Biosciences, Inc., a Delaware corporation ("LMB"), pursuant to which SubCo was merged with and into LMB, with LMB continuing as the surviving corporation. Mr. Mazur was a co-founder of and significant shareholder in LMB. In connection with the acquisition of LMB, Mr. Mazur purchased an additional 333,333 shares of our common stock for a purchase price of $3,000,000.

On October 19, 2017, we entered into an amended and restated three-year employment agreement with Mr. Mazur which is described under "Executive Compensation" in our proxy statement on Schedule 14A for our 2018 Annual Meeting of Stockholders, filed with the SEC on December 13, 2017, which is incorporated herein by reference.

Our Board of Directors authorized revolving demand promissory notes with Mr. Mazur in an aggregate principal amount of up to $2,500,000 that accrue interest at the prime rate plus 1%. On September 7, 2016, the Company issued a $500,000 note. We issued $2,000,000 of additional notes through the period ended May 10, 2017. On May 10, 2017, the notes were converted into a $2,500,000 convertible promissory note that matures on June 30, 2018 and is convertible into shares of our common stock, at the sole discretion of Mr. Mazur, at a conversion price equal to 75% of the price per share paid by investors in the Company's securities offering pursuant to a Registration Statement on Form S-1 filed with the SEC (the "Securities Offering"). In connection with the modification of the note, we recorded a charge of $833,333 to additional paid-in capital and increased the carrying value of the notes to $3,333,333 which is the fair value of the common stock issuable on conversion. On August 8, 2017, we closed the Securities Offering at an offering price of $4.125 per share and Mr. Mazur converted the $2,500,000 principal balance and accrued interest of $63,174 into 828,500 shares of our common stock.

On May 10, 2017 and June 23, 2017, we executed a $1,500,000 future advance convertible promissory note and a $1,000,000 future advance convertible promissory note, respectively, with Mr. Mazur that both mature on December 31, 2017 and accrue interest at the prime rate plus 1%. The notes are convertible into shares of common stock, at the sole discretion of Mr. Mazur, at a conversion price equal to 75% of the price per share paid by investors in the Securities Offering. On August 8, 2017, we closed the Securities Offering at an offering price of $4.125 per share and Mr. Mazur converted the outstanding $2,210,000 principal balances and accrued interest of $13,066 into 718,567 shares of our common stock.

In the Securities Offering, Mr. Mazur purchased 421,400 units consisting of 421,400 shares of our common stock at $4.125 per share and warrants to purchase up to 421,400 shares of our common stock at $0.01 per warrant.

In December 2017, we sold to institutional and accredited investors shares of our common stock in a public offering and warrants to purchase shares of our common stock in a concurrent private placement. Mr. Mazur purchased 213,106 shares of common stock and warrants to purchase up to 106,553 shares of our common stock on the same terms as the other investors in the offering.

In March 2018, we sold to institutional and accredited investors shares of our common stock in a public offering and warrants to purchase shares of our common stock in a concurrent private placement. Mr. Mazur purchased 167,504 shares of common stock and warrants to purchase up to 167,504 shares of our common stock on the same terms as the other investor in the offering.

In August 2018, we sold to institutional and accredited investors in an underwritten at-the-market offering, (i) units, with each unit being comprised of one share of the Company’s common stock and one warrant to purchase one share and (ii) pre-funded units, with each pre-funded unit being comprised of one pre-funded warrant to purchase one share and one warrant. Mr. Mazur purchased 3,137,255 shares of common stock and warrants to purchase up to 3,137,255 shares of our common stock on the same terms as the other investors in the offering.

In April 2019, we sold to institutional and accredited investors shares of our common stock in an at-the-market offering public offering and warrants to purchase shares of our common stock in a concurrent private placement. Mr. Mazur purchased 1,165,048 shares of common stock and warrants to purchase up to 1,165,048 shares of our common stock on the same terms as the other investors in the offering.

PLAN OF DISTRIBUTION

The selling stockholders, which, as used herein, includes donees, pledgees, transferees or other successors-in-interest selling shares of common stock or interests in shares of common stock received after the date of this prospectus from a selling stockholder as a gift, pledge, partnership distribution or other transfer, may, from time to time, sell, transfer or otherwise dispose of any or all of their shares of common stock or interests in shares of common stock on any stock exchange, market or trading facility on which the shares are traded or in private transactions. These dispositions may be at fixed prices, at prevailing market prices at the time of sale, at prices related to the prevailing market price, at varying prices determined at the time of sale, or at negotiated prices.

The selling stockholders may use any one or more of the following methods when disposing of shares or interests therein:

- ordinary brokerage transactions and transactions in which the broker-dealer solicits purchasers;
- block trades in which the broker-dealer will attempt to sell the shares as agent, but may position and resell a portion of the block as principal to facilitate the transaction;
- purchases by a broker-dealer as principal and resale by the broker-dealer for its account;
- an exchange distribution in accordance with the rules of the applicable exchange;
- privately negotiated transactions;
- short sales effected after the date the registration statement of which this prospectus is a part is declared effective by the SEC;
- through the writing or settlement of options or other hedging transactions, whether through an options exchange or otherwise;
- broker-dealers may agree with the selling stockholders to sell a specified number of such shares at a stipulated price per share;
- a combination of any such methods of sale; and
- any other method permitted by applicable law.

The selling stockholders may, from time to time, pledge or grant a security interest in some or all of the shares of common stock owned by them and, if they default in the performance of their secured obligations, the pledgees or secured parties may offer and sell the shares of common stock, from time to time, under this prospectus, or under an amendment to this prospectus under Rule 424(b)(3) or other applicable provision of the Securities Act amending the list of selling stockholders to include the pledgee, transferee or other successors-in-interest as selling stockholders under this prospectus. The selling stockholders also may transfer the shares of common stock in other circumstances, in which case the transferees, pledgees or other successors-in-interest will be the selling beneficial owners for purposes of this prospectus.

In connection with the sale of our common stock or interests therein, the selling stockholders may enter into hedging transactions with broker-dealers or other financial institutions, which may in turn engage in short sales of the common stock in the course of hedging the positions they assume. The selling stockholders may also sell shares of our common stock short and deliver these securities to close out their short positions, or loan or pledge the common stock to broker-dealers that in turn may sell these securities. The selling stockholders may also enter into option or other transactions with broker-dealers or other financial institutions or the creation of one or more derivative securities which require the delivery to such broker-dealer or other financial institution of shares offered by this prospectus, which shares such broker-dealer or other financial institution may resell pursuant to this prospectus (as supplemented or amended to reflect such transaction).

The aggregate proceeds to the selling stockholders from the sale of the common stock offered by them will be the purchase price of the common stock less discounts or commissions, if any. Each of the selling stockholders reserves the right to accept and, together with their agents from time to time, to reject, in whole or in part, any proposed purchase of common stock to be made directly or through agents. We will not receive any of the proceeds from this offering. Upon any exercise of the warrants by payment of cash, however, we will receive the exercise price of the warrants.

The selling stockholders also may resell all or a portion of the shares in open market transactions in reliance upon Rule 144 under the Securities Act, provided that they meet the criteria and conform to the requirements of that rule.

The selling stockholders and any underwriters, broker-dealers or agents that participate in the sale of the common stock or interests therein may be "underwriters" within the meaning of Section 2(11) of the Securities Act. Any discounts, commissions, concessions or profit they earn on any resale of the shares may be underwriting discounts and commissions under the Securities Act. Selling stockholders who are "underwriters" within the meaning of Section 2(11) of the Securities Act will be subject to the prospectus delivery requirements of the Securities Act.

To the extent required, the shares of our common stock to be sold, the names of the selling stockholders, the respective purchase prices and public offering prices, the names of any agents, dealer or underwriter, any applicable commissions or discounts with respect to a particular offer will be set forth in an accompanying prospectus supplement or, if appropriate, a post-effective amendment to the registration statement of which this prospectus is a part.

In order to comply with the securities laws of some states, if applicable, the common stock may be sold in these jurisdictions only through registered or licensed brokers or dealers. In addition, in some states the common stock may not be sold unless it has been registered or qualified for sale or an exemption from registration or qualification requirements is available and is complied with.

We have advised the selling stockholders that the anti-manipulation rules of Regulation M under the Exchange Act may apply to sales of shares in the market and to the activities of the selling stockholders and their affiliates. In addition, to the extent applicable we will make copies of this prospectus (as it may be supplemented or amended from time to time) available to the selling stockholders for the purpose of satisfying the prospectus delivery requirements of the Securities Act. The selling stockholders may indemnify any broker-dealer that participates in transactions involving the sale of the shares against certain liabilities, including liabilities arising under the Securities Act.

We will pay all expenses of the registration of the shares of common stock, including, without limitation, SEC filing fees and expenses of compliance with state securities or "blue sky" laws; provided, however, that each selling stockholder will pay all underwriting discounts and selling commissions, if any and any related legal expenses incurred by it. We will indemnify the selling stockholders against certain liabilities, including some liabilities under the Securities Act, arising in connection with the registration statement of which this prospectus is a part.

We have agreed with the selling stockholders to keep the registration statement of which this prospectus is a part effective until the time that no purchaser of warrants in the April 2019 private placement owns any warrants or shares of common stock issuable upon exercise of the warrants.

DESCRIPTION OF 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, of which 22,075,781 shares were issued and outstanding as of April 9, 2019, 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 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.

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.

Options

As of March 31, 2019, under the Company's 2014 Stock Incentive Plan and 2018 Omnibus Stock Incentive Plan, we had outstanding options to purchase an aggregate of 1,646,039 shares of our common stock at a weighted average exercise price of $4.252 per share. Of these, an aggregate of 752,809 are exercisable. The remainder has vesting requirements.

Unit Purchase Options

On April 7, 2017, the Company issued a three-year Unit Purchase Option Agreement for the purchase of 38,000 units at a purchase price of $9.00 per unit. Each unit consists of one share of common stock and a warrant to purchase one share of common stock at an exercise price of $9.00 per share which expires on the earlier of three years after exercise of the Unit Purchase Option Agreement or April 7, 2023.

On June 29, 2017, the Company issued a three-year Unit Purchase Option Agreement for the purchase of 62,667 units at a purchase price of $9.00 per unit. Each unit consists of one share of common stock and a warrant to purchase one share of common stock at an exercise price of $9.00 per share which expires on the earlier of three years after exercise of the Unit Purchase Option Agreement or June 29, 2022.

Warrants

As of April 9, 2019, we had outstanding warrants to purchase an aggregate of 12,871,623 shares of our common stock at a weighted average price of $2.604 per share, with a weighted average remaining life of 3.92 years.

Trading Market

The shares of our common stock are currently quoted on the Nasdaq Capital Market under the symbol "CTXR".

Transfer Agent

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

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 April1, 2019, we have 99 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.

LEGAL MATTERS

The validity of the shares of common stock being offered by this prospectus will be passed upon for us by Wyrick Robbins Yates & Ponton, LLP, Raleigh, North Carolina.

EXPERTS

The consolidated financial statements incorporated by reference from our Annual Report on Form 10-K for the year ended September 30, 2018 have been audited by Wolf & Company, P.C., an independent registered public accounting firm, as stated in their report, which is incorporated by reference and has been so incorporated in reliance upon the report of such firm given upon their authority as experts in accounting and auditing.

WHERE YOU CAN FIND MORE INFORMATION

This prospectus, which constitutes a part of the Registration Statement on Form S-1 that we have filed with the SEC under the Securities Act, does not contain all of the information in the registration statement and its exhibits. For further information with respect to us and the common stock offered by this prospectus, you should refer to the registration statement and the exhibits filed as part of that document. Statements contained in this prospectus as to the contents of any contract or any other document referred to are not necessarily complete, and in each instance, we refer you to the copy of the contract or other document filed as an exhibit to the registration statement. Each of these statements is qualified in all respects by this reference.

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 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 CERTAIN 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 information that we file later with the SEC will automatically update and supersede this information. We filed a registration statement on Form S-1 under the Securities Act of 1933, as amended, with the SEC with respect to the securities being offered pursuant to this 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. Statements in this 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." We are incorporating by reference the documents listed below, which we have already filed with the SEC, and all documents subsequently filed by us pursuant to Sections 13(a), 13(c), 14 or 15(d) of the Exchange Act, except as to any portion of any future report or document that is not deemed filed under such provisions, prior to the termination of the offering:

- our Annual Report on Form 10-K for the fiscal year ended September 30, 2018, filed with the SEC on December 11, 2018;
- our Quarterly Report on Form 10-Q for the quarter ended December 31, 2018, filed with the SEC on February 14, 2019;

- our Current Reports on Form 8-K, filed with the SEC on January 8, 2019, February 14, 2019 and April 3, 2019;
- our proxy statement on Schedule 14A for our 2018 Annual Meeting of Stockholders, filed with the SEC on December 20, 2018; and
- the description of our common stock contained in our registration statement on Form 8-A, filed with the SEC on July 28, 2017.

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 filing or report incorporated by reference, including exhibits to the document. You should direct any requests for documents to Citius Pharmaceuticals, Inc., 11 Commerce Drive, First Floor, Cranford, New Jersey 07016, (908) 967-6677, Attention: Jaime Bartushak.