Filed Pursuant to Rule 424(b)(3)
Registration Statement 333-222538

729,805 Shares of Common Stock

This prospectus relates to the sale or other disposition from time to time of up to 729,805 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 58. 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 January 31, 2018, the last reported closing price of our common stock on the Nasdaq Capital Market was $4.27.

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 February 1, 2018.

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ABOUT THIS PROSPECTUS

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

We urge you to read carefully this prospectus, as supplemented and amended, before deciding whether to invest in any of the common stock being offered.

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.

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.

Company 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, the Company has devoted substantially all of its efforts to business planning, research and development, recruiting management and technical staff, and raising capital. We are developing two proprietary products: Mino-Lok™, an antibiotic lock solution used to treat patients with catheter-related bloodstream infections by salvaging the infected catheter, and a hydrocortisone-lidocaine topical formulation that is intended to provide anti-inflammatory and anesthetic relief to persons suffering from hemorrhoids. We believe the markets for our products are large, growing, and underserved by the current prescription products or procedures.

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 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 (4) 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 (6) patients had more than one (1) complication in the control arm group.

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

* 1 Polymicrobal patient had a Gram+ and a Gram- organism cultured
** 6 Patients had > 1 complication

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

Phase 3 Initiation

In November 2016, the Company initiated site recruitment for Phase 3 clinical trials. From initiation through first quarter 2017, the Company received input from several sites related to the control arm as being less than standard of care for some of the respective institutions. The Company worked closely with the FDA with respect to the design of the phase 3 trial, and received feedback on August 17, 2017. The FDA stated that they recognized that there is an unmet medical need in salvaging infected catheters and agreed that an open label, superiority design would address the Company's concerns and would be acceptable to meet the requirements of a new drug application. The Company amended the phase 3 study design to remove the saline and heparin placebo control arm and to use an active control arm that conforms with today's current standard of care. As of January 31, 2018, the first patient had not been enrolled in the trial, however, as sites are fully implemented and are actively screening patients, we continue to anticipate trial enrollment to begin in the first quarter of 2018.

Fast Track Designation

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

- More frequent meetings with FDA to discuss the drug's development plan and ensure collection of appropriate data needed to support drug approval;

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

Mino-Lok TM International Study

In October 2017, data from an international study on Mino-LokTM 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.

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.

Corporate 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.

The Company's principal executive offices are located at 11 Commerce Drive, Cranford, New Jersey 07016 and its telephone number is (908) 976-6677.

THE OFFERING

Up to 729,805 Shares of Common Stock

This prospectus relates to the resale by the selling stockholders identified in this prospectus of up to 729,805 shares of our common stock issuable upon exercise of the following warrants:

- warrants for 640,180 shares of common stock issued in a private placement in December 2017 to investors with an exercise price of $4.63 that expire on June 19, 2023; and
- warrants for 89,625 shares of common stock issued in December 2017 to the placement agent for the private placement, with an exercise price of $5.8656 per share that expire on December 15, 2022.

Common stock offered by the selling stockholders	729,805 shares
Common stock outstanding before the offering (1)	9,975,518 shares
Common stock to be outstanding after the offering	10,705,323 shares
Common stock Nasdaq Capital Market Symbol	CTXR

(1) Based on the number of shares outstanding as of January 24, 2018.

Use of Proceeds

The 729,805 shares of common stock issuable upon the exercise of 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 729,805 shares of common stock currently outstanding 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 $3,489,737.80 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. It is possible that the warrants may expire and may never be exercised.

After the exercise of any of the warrants, we would not receive any proceeds from the resale of those shares by the selling stockholders because those shares will be sold for the accounts of the selling stockholders named in this prospectus.

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. See “Dividend Policy” on page 29.

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 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 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.

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

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

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

Citius was formed as a limited liability company in 2007 and since its inception has incurred a net loss in each of its previous operating years. Our ability to become profitable depends upon our ability to generate revenues from sales of our product candidates. Citius has been focused on product development and has not generated any revenues to date. Citius has 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. Citius incurred net losses of $10,384,953, $8,295,698 and $2,902,268 for the years ended September 30, 2017, 2016 and 2015, respectively. At September 30, 2017, Citius had stockholders' equity of $21,947,388 and an accumulated deficit of $27,721,200. Citius' net cash used for operating activities was $7,971,205, $5,900,421 and $2,385,416 for the years ended September 30, 2017, 2016 and 2015, respectively.

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

- developing and testing product candidates;
- receiving regulatory approvals;
- commercializing our products;
- manufacturing commercial quantities of our product candidates at acceptable cost levels; and
- establishing a favorable competitive position.

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.

Our independent registered accountants report on our September 30, 2017 consolidated financial statements contains an emphasis of a matter regarding substantial doubt about our ability to continue as a going concern, that the consolidated financial statements have been prepared assuming we will continue as a going concern and do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets, or the amounts and classification of liabilities that may result if we do not continue as a going concern. Currently, we do not have sufficient capital to continue our operations after the next six months. 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.

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 $14.6 million from our public and private placement offerings through September 2017. 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 the Company $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 Company has engaged Paulson Investment Company, LLC to secure debt financing. We may need to seek additional financing, including from affiliates, to continue our clinical programs and manufacturing for clinical programs.

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 potential therapeutic product we and our collaborators choose to pursue. If we are not successful in implementing our strategy to commercialize our potential therapeutic products, 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 our clinical trials;
- produce, through a validated process, sufficiently large quantities of our drug compound(s) to permit successful commercialization;
- receive marketing approvals from the FDA and similar foreign regulatory authorities;

- establish commercial manufacturing arrangements with third-party manufacturers;
- build and maintain strong sales, distribution and marketing capabilities sufficient to launch commercial sales of the drug(s) or establish collaborations with third parties for such commercialization;
- secure acceptance of the drug(s) from physicians, health care payers, patients and the medical community; and
- manage our spending as costs and expenses increase due to clinical trials, regulatory approvals and commercialization.

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 may fail to realize any of the anticipated benefits of the recent merger.

The success of our recent merger with Leonard-Meron Biosciences, Inc. will depend on, among other things, our ability to realize anticipated benefits and to combine the businesses of the Company and LMB in a manner that achieves synergy and a shared strategy but that does not materially disrupt the existing activities of the companies. If we are not able to successfully achieve these objectives, the anticipated benefits of the merger may not be realized fully, if at all, or may take longer to realize than expected.

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 will be further developed using the proceeds of our private placements 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 any of our 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; 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 necessarily 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. It may 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 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 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 obtain a shortened review period for the applications. The timeline for filing and review of our NDAs is based upon our plan to submit those NDAs 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 our product candidates under Section 505(b)(2) may therefore be delayed until patent exclusivity expires or until we successfully challenge the applicability of those patents 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 our product candidates. Even if no exclusivity periods apply to our applications 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 any of our product candidates, to conduct substantial new research and development activities beyond those we currently plan to engage in order to obtain approval of our product candidates. 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, and the FDA may not agree that our products 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 our product candidates. 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 new 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, civil RICO, 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 and financial prospects.

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

Even if our product candidates obtain regulatory approval, those drugs 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 such drugs 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;
- 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;
- availability of coverage and reimbursement from government and other third-party payers;
- patient access programs that require patients to provide certain information prior to receiving new and refill prescriptions;
- requirements for prescribing physicians to complete certain educational programs for prescribing drugs;
- the willingness of patients to pay out of pocket in the absence of government or third-party coverage; and
- product labeling or product insert requirements of the FDA or other regulatory authorities.

If approved, our product candidates 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 our product candidates 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 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 products, if approved, less competitive or possibly obsolete. We are also competing with respect to marketing capabilities and manufacturing efficiency, areas in which we have limited experience. Mergers, acquisitions, joint ventures and similar events may also significantly increase the competition. 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 experience;
- product candidate development and clinical trial 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 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 product or therapies;
- availability of reimbursement for our product from government or other healthcare payers; and
- effective marketing and distribution efforts by us and 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) does 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.

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

Our ability to commercialize our products, 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. We cannot predict what impact on federal reimbursement policies this legislation will have in general or on our business specifically. Members of the U.S. Congress and some state legislatures are seeking to overturn at least 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 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 drugs 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 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 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 will be dependent on third-party contract research organizations to conduct all of our future human studies.

We will be dependent on third-party research organizations to conduct all of our human studies with respect to pharmaceutical products 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 studies, 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 studies. 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.

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 Phase 2 and Phase 3 trials. While we believe this will provide us with sufficient staffing for our current 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 because of the rules and regulations that govern publicly held companies, including, but not limited to, certifications by principal executive officers. The enactment of the Sarbanes-Oxley Act has resulted in the issuance of a series of related rules and regulations and the strengthening of existing rules and regulations by the SEC, as well as the adoption of new and more stringent rules by the stock exchanges. The perceived increased personal risk associated with these changes may deter qualified individuals from accepting roles as directors and executive officers. Further, some of these changes heighten the requirements for board or committee membership, particularly with respect to an individual's independence from the corporation and level of experience in finance and accounting matters. The Company may have difficulty attracting and retaining directors with the requisite qualifications. If we are unable to attract and retain qualified officers and directors, the management of our business could be adversely affected.

We will need to increase the size of our organization, 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 approval trials effectively;
- 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;
- improve our operational, financial and management controls, reporting systems and procedures; and
- attract and motivate sufficient numbers of talented employees.

This 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 product candidates and approved products such as ours are 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 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 another product candidate

Following 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 another regulatory authority for a territory outside of the U.S., 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 product candidates 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 drug products and their facilities are subject to continual review and periodic inspections by the FDA and other regulatory authorities for compliance with current good manufacturing practices, or 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 drugs, if any, and these facilities are subject to ongoing regulatory inspections. In addition, regulatory agencies subject a drug, its manufacturer and the manufacturer's facilities to continual review and inspections. The subsequent discovery of previously unknown problems with a drug, including adverse events of unanticipated severity or frequency, or problems with the facility where the drug is manufactured, may result in restrictions on the marketing of that drug, up to and including, withdrawal of the drug 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;
- criminal prosecutions;
- 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 drugs to be imported into or exported from the U.S.;
- restrictions on operations, including costly new manufacturing requirements; and
- product recalls or seizures.

In addition, the law or regulatory policies governing pharmaceuticals 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 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 our 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 our reputation in the marketplace, and would likely divert management's attention.

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 drugs. 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;
- 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; and
- 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.

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 drug 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.

In addition to patents, we also rely on trade secrets and proprietary know-how. Although we take measures to protect this information by entering into confidentiality and inventions agreements with our employees, scientific advisors, consultants, and collaborators, we cannot provide any assurances that these agreements will not be breached, that we will be able to protect ourselves from the harmful effects of disclosure if they are breached, or that our trade secrets will not otherwise become known or be independently discovered by competitors. If any of these events occurs, or we otherwise lose protection for our trade secrets or proprietary know-how, the value of this information may be greatly reduced.

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 forgo selling our future 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 and Liquidity Risks

Nasdaq may delist our common stock and warrants from quotation on its exchange. Failure to maintain NASDAQ listing could limit investors' ability to make transactions in our common stock and warrants and subject us to additional trading restrictions.

Our common stock and warrants are currently listed on Nasdaq. We may not be able to meet the continued listing requirements for our common stock and warrants in the future. Failure to meet the continued listing requirements could result in Nasdaq delisting our ordinary shares from trading on its exchange. If this should happen, 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.

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

If our common stock were removed from listing with the Nasdaq Capital Market, it may be subject to the so-called "penny stock" rules. The SEC has adopted regulations that define a "penny stock" to be any equity security that has a market price per share of less than $5.00, subject to certain exceptions, such as any securities listed on a national securities exchange. 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. Investors in penny stocks should be prepared for the possibility that they may lose their whole investment.

Compliance with the reporting requirements of federal securities laws can be expensive.

While the Company was not previously subject to the filing requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, it filed certain reports with the Securities and Exchange Commission, or the SEC, on a voluntary basis. On October 22, 2015, the Company registered its Common Stock under the Exchange Act and the filing of the reports with the SEC became mandatory. The quotation of the Company's Common stock on Nasdaq is contingent upon the Company staying current on such Exchange Act filings. The costs of preparing and filing annual and quarterly reports and other information with the SEC and furnishing audited reports to stockholders will cause our expenses to be higher than they would be if we remained privately-held.

If the Company fails to maintain an effective system of internal controls, it may not be able to accurately report its financial results or detect fraud. Consequently, shareholders could lose confidence in the Company's financial reporting and this may decrease the trading price of its stock.

The Company must maintain effective internal controls to provide reliable financial reports and to be able to detect fraud. The Company has been assessing its internal controls to identify areas that need improvement and as of September 30, 2017, management identified material weaknesses in its internal controls over financial reporting. While the Company is in the process of implementing changes to internal controls, it has not yet completed implementing these changes and there is no assurance that the changes will remediate the material weakness or that the controls will prevent or defect future material weakness. Failure to implement these changes to the Company's internal controls or any others that it identifies as necessary to maintain an effective system of internal controls could harm its operating results and cause shareholders to lose confidence in the Company's reported financial information. Any such loss of confidence would have a negative effect on the trading price of the Company's stock.

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 the Company's operating results;
- announcements of developments by the Company or its competitors;
- the completion and/or results of the Company's clinical trials;
- regulatory actions regarding the Company's products;
- announcements by the Company or its competitors of significant acquisitions, strategic partnerships, joint ventures or capital commitments;
- adoption of new accounting standards affecting the Company's industry;
- additions or departures of key personnel;
- introduction of new products by the Company or its competitors;
- sales of the Company's common stock or other securities in the open market; and
- other events or factors, many of which are beyond the Company's 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. Litigation initiated against the Company, whether or not successful, could result in substantial costs and diversion of its management's attention and resources, which could harm the Company's business and financial condition.

We completed a reverse stock split of our shares of common stock, which may reduce and may limit the market trading liquidity of the shares due to the reduced number of shares outstanding, and may potentially have an anti-takeover effect.

We completed a reverse stock split of our common stock by a ratio of 1-for-15 effective June 9, 2017, referred to in this prospectus as the Reverse Stock Split. The liquidity of our common stock may be adversely affected by the Reverse Stock Split as a result of the reduced number of shares outstanding following the Reverse Stock Split. In addition, the Reverse Stock Split may increase the number of stockholders who own odd lots of our common stock, creating the potential for such stockholders to experience an increase in the cost of selling their shares and greater difficulty affecting such sales. Reducing the number of outstanding shares of our common stock through the Reverse Stock Split is intended, absent other factors, to increase the per share market price of our common stock. However, other factors, such as our financial results, market conditions and the market perception of our business may adversely affect the market price of our common stock. As a result, there can be no assurance that the Reverse Stock Split will result in the intended benefits, that the market price of our common stock will remain higher following the Reverse Stock Split or that the market price of our common stock will not decrease in the future. Further, since the Reverse Stock Split was not accompanied by a corresponding decrease in the number of shares authorized for issuance under our Amended and Restated Articles of Incorporation, the relative increase in the number of shares authorized for issuance could, under certain circumstances, have an anti-takeover effect by enabling the Board of Directors to issue additional shares of common stock in a transaction making it more difficult for a party to obtain control of us by tender offer or other means.

You may experience dilution of your ownership interests because of the future issuance of additional shares of the Company's common stock.

In the future, the Company may issue additional authorized but previously unissued equity securities, resulting in the dilution of the ownership interests of its present stockholders. The Company is currently authorized to issue an aggregate of 200,000,000 shares of common stock and 10,000,000 shares of preferred stock. As of September 30, 2017, there are 8,345,844 shares of common stock outstanding, 3,346,920 shares underlying warrants with a weighted average exercise price of $5.77 per share, and 861,039 shares underlying options with a weighted average exercise price of $6.69 per share. The Company may also issue additional shares of its common stock or other securities that are convertible into or exercisable for common stock in connection with hiring or retaining employees, future acquisitions, future sales of its securities for capital raising purposes, or for other business purposes. The future issuance of any such additional shares of common stock may create downward pressure on the trading price of the common stock.

The common stock is controlled by insiders.

As of January 24, 2018, the former managing members of Citius Pharmaceuticals, LLC beneficially own approximately 12.1% of our outstanding shares of common stock and the Company's current officers and directors beneficially own approximately 47.1% of our outstanding shares of common stock. Such concentrated control of the Company may adversely affect the price of the common stock. If you acquire common stock, you may have no effective voice in the management of the Company. Sales by insiders or affiliates of the Company, along with any other market transactions, could affect the market price of the 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 it is not anticipated 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 the board of directors to create new series of preferred stock without further approval by stockholders, which could adversely affect the rights of the holders of the common stock.

The Company's Board of Directors has the authority to fix and determine the relative rights and preferences of preferred stock. The Company's Board of Directors has the authority to issue up to 10,000,000 shares of preferred stock without further stockholder approval. As a result, the Company's Board of Directors could authorize the issuance of a series of preferred stock that would grant to holders the preferred right 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 shares, together with a premium, prior to the redemption of the common stock. In addition, the Company's 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 are a significant number of shares of common stock eligible for sale, which could depress the market price of such shares.

A large number of shares of common stock will be available for sale in the public market, which could harm the market price of the stock. Further, shares may be offered from time to time in the open market pursuant to Rule 144, and these sales may have a depressive effect as well.

Risks Related to Ownership of our Securities

There is not an active liquid trading market for the Company's common stock.

The Company files reports under the Exchange Act and is listed on Nasdaq. However, there has not been a regular active trading market in the Company's common stock, and we cannot give any assurance that an active trading market will develop. If an active market for the Company's common stock develops, there is a significant risk that the Company's stock price may fluctuate dramatically in the future in response to any of the following factors, some of which are beyond our control:

- variations in our quarterly operating results;
- announcements that our revenue or income are below analysts' expectations;
- general economic slowdowns;
- sales of large blocks of the Company's common stock; and
- announcements by us or our competitors of significant contracts, acquisitions, strategic partnerships, joint ventures or capital commitments.

Because we became a public company by means of a reverse acquisition, we may not be able to attract the attention of brokerage firms.

Because we became public through a "reverse acquisition", securities analysts of brokerage firms may not provide coverage of us since there is little incentive to brokerage firms to recommend the purchase of our common stock. No assurance can be given that brokerage firms will want to conduct any secondary offerings on behalf of the Company in the future.

Applicable regulatory requirements, including those contained in and issued under the Sarbanes-Oxley Act of 2002, may make it difficult for the Company to retain or attract qualified officers and directors, which could adversely affect the management of its business and its ability to obtain or retain listing of its common stock and warrants.

The Company may be unable to attract and retain those qualified officers, directors and members of board committees required to provide for effective management because of the rules and regulations that govern publicly held companies, including, but not limited to, certifications by principal executive officers. The enactment of the Sarbanes-Oxley Act has resulted in the issuance of a series of related rules and regulations and the strengthening of existing rules and regulations by the SEC, as well as the adoption of new and more stringent rules by the stock exchanges. The perceived increased personal risk associated with these changes may deter qualified individuals from accepting roles as directors and executive officers.

Further, some of these changes heighten the requirements for board or committee membership, particularly with respect to an individual's independence from the corporation and level of experience in finance and accounting matters. The Company may have difficulty attracting and retaining directors with the requisite qualifications. If the Company is unable to attract and retain qualified officers and directors, the management of its business and its ability to obtain or retain listing of our shares of common stock on any stock exchange (assuming the Company is successful in obtaining such listing) could be adversely affected.

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 January 24, 2018, we have 9,975,518 shares of common stock outstanding. Of these shares, an aggregate of 4,821,819 shares of our common stock are subject to restriction on resale under Rule 144 of the Securities Act of 1933, as amended, or the "Securities Act". We also have registered for sale an aggregate of 2,418,734 shares upon the exercise of outstanding warrants to purchase common stock, including the shares offered by this prospectus. In addition, on December 15, 2017, our executive officers and directors entered into lock-up agreements pursuant to which they agreed not to sell any of our shares for a period of 90 days from the closing date of our recent public offering, which was December 19, 2017. As the placement agent for the offering, H. C. Wainwright & Co., LLC may, in its sole discretion, allow early releases under the referenced lock-up restrictions.

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

If we fail to satisfy the continued listing requirements of the Nasdaq Capital Market, 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 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.

Risks Related to Our Reverse Stock Split

We completed the Reverse Stock Split in order to meet the initial listing requirements of Nasdaq. However, the Reverse Stock Split may not result in our stock price remaining compliant with the minimum price requirements of Nasdaq.

We completed the Reverse Stock Split in order to achieve the requisite increase in the market price of our common stock to be in compliance with the minimum price requirements of Nasdaq. We cannot assure you that the market price of our common stock following the Reverse Stock Split will remain at the level required for the period of time required for listing or for continuing compliance with that requirement. It is not uncommon for the market price of a Company's common stock to decline in the period following a Reverse Stock Split. If the market price of our common stock declines following the Reverse Stock Split, the percentage decline may be greater than would occur in the absence of a Reverse Stock Split. In any event, other factors unrelated to the number of shares of our common stock outstanding, such as negative financial or operational results, could adversely affect the market price of our common stock and jeopardize our ability to maintain Nasdaq's minimum price requirements. In addition to specific listing and maintenance standards, Nasdaq has broad discretionary authority over the continued listing of securities, which it could exercise with respect to the listing of our common stock.

Even if the Reverse Stock Split increases the market price of our common stock, there can be no assurance that we will be able to comply with other continued listing standards of Nasdaq.

We cannot assure you that we will be able to comply with the other standards that we are required to meet in order to maintain a listing of our common stock and warrants on Nasdaq. Our failure to meet these requirements may result in our common stock and warrants being delisted from Nasdaq, irrespective of our compliance with the minimum bid price requirement.

The Reverse Stock Split may decrease the liquidity of the shares of our common stock.

The liquidity of the shares of our common stock may be affected adversely by the Reverse Stock Split given the reduced number of shares that will be outstanding following the Reverse Stock Split, especially if the market price of our common stock does not increase as a result of the Reverse Stock Split. In addition, the Reverse Stock Split may increase the number of stockholders who own odd lots (less than 100 shares) of our common stock, creating the potential for such stockholders to experience an increase in the cost of selling their shares and greater difficulty affecting such sales.

Following the Reverse Stock Split, the resulting market price of our common stock may not attract new investors, including institutional investors, and may not satisfy the investing requirements of those investors. Consequently, the trading liquidity of our common stock may not improve.

Although we believe that a higher market price of our common stock may help generate greater or broader investor interest, there can be no assurance that the Reverse Stock Split will result in a share price that will attract new investors, including institutional investors. In addition, there can be no assurance that the market price of our common stock will satisfy the investing requirements of those investors. As a result, the trading liquidity of our common stock may not necessarily improve.

USE OF PROCEEDS

The 729,805 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 729,805 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 $3,489,737.80 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.

After the exercise of any of the warrants, we would not receive any proceeds from the resale of those shares by the selling stockholders because those shares will be sold for the accounts of the selling stockholders named in this prospectus.

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, or Nasdaq, under the symbol "CTXR".

The following table sets forth the range of the high and low bid quotations of our common stock for the periods shown, as reported by the OTCQB through August 2, 2017, and the high and low closing prices as reported on the Nasdaq Capital Market beginning on August 3, 2017. The OTCQB quotations reflect inter-dealer prices, without retail mark-up, mark-down or commission and may not necessarily represent actual transactions.

	Year Ended September 30, 2016	
	High	Low
First Quarter	$ 27.75	$ 15.00
Second Quarter	$ 37.50	$ 23.25
Third Quarter	$ 37.50	$ 11.70
Fourth Quarter	$ 18.00	$ 8.70

	Year Ended September 30, 2017	
	High	Low
First Quarter	$ 14.85	$ 2.55
Second Quarter	$ 14.63	$ 5.40
Third Quarter	$ 11.40	$ 4.75
Fourth Quarter	$ 6.37	$ 2.60

	Year Ending September 30, 2018	
	High	Low
First Quarter	$ 5.10	$ 2.65
Second Quarter (through January 31, 2018)	$ 4.50	$ 3.92

On January 31, 2018, the closing price as reported on the Nasdaq Capital Market of our common stock was $4.27. As of January 24, 2018, there were 113 holders of record of our common stock.

DIVIDEND POLICY

We have not paid any cash dividends on our common stock and our Board of Directors presently intends to continue a policy of retaining earnings, if any, for use in our operations. The declaration and payment of dividends in the future, of which there can be no assurance, will be determined by the Board of Directors in light of conditions then existing, including earnings, financial condition, capital requirements and other factors. Nevada law prohibits us from declaring dividends where, if after giving effect to the distribution of the dividend:

- we would not be able to pay our debts as they become due in the usual course of business; or
- except as otherwise specifically allowed by our articles of incorporation, our total assets would be less than the sum of our total liabilities plus the amount that would be needed to satisfy the rights of stockholders who have preferential rights superior to those receiving the distribution.

Except as set forth above, there are no restrictions that currently materially limit our ability to pay dividends or which we reasonably believe are likely to limit materially the future payment of dividends on common stock.

Our Board of Directors has the right to authorize the issuance of preferred stock, without further stockholder approval, the holders of which may have preferences over the holders of our common stock as to payment of dividends.

FINANCIAL STATEMENTS

Please see Part II, Item 8 in our Annual Report on Form 10-K for the fiscal year ended September 30, 2017, filed with the SEC on December 13, 2017, 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, 2017 and 2016
- Consolidated Statements of Operations for the years ended September 30, 2017, 2016 and 2015
- Consolidated Statements of Stockholders' Equity (Deficit) for the years ended September 30, 2017, 2016 and 2015
- Consolidated Statements of Cash Flows for the years ended September 30, 2017, 2016 and 2015
- Notes to Consolidated Financial Statements

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

The following discussion and analysis of our financial condition and results of operations should be read together with our consolidated financial statements and related notes incorporated by reference into this prospectus. Management's discussion and analysis contains forward-looking statements, such as statements of our plans, objectives, expectations and intentions. Any statements that are not statements of historical fact are forward-looking statements. When used, the words "believe," "plan," "intend," "anticipate," "target," "estimate," "expect" and the like, and/or future tense or conditional constructions ("will," "may," "could," "should," etc.), or similar expressions, identify certain of these forward-looking statements. These forward-looking statements are subject to risks and uncertainties including those under "Risk Factors" in this prospectus that could cause actual results or events to differ materially from those expressed or implied by the forward-looking statements. Our actual results and the timing of events could differ materially from those anticipated in these forward-looking statements as a result of several factors. We do not undertake any obligation to update forward-looking statements to reflect events or circumstances occurring after the date of this prospectus, except as required by law.

Historical Background

Citius Pharmaceuticals, Inc. ("Citius" or the "Company") is a specialty pharmaceutical company dedicated to the development and commercialization of critical care products targeting unmet needs with a focus on anti-infectives, cancer care and unique prescription products. On September 12, 2014, we acquired Citius Pharmaceuticals, LLC as a wholly-owned subsidiary.

Citius Pharmaceuticals, LLC was founded in Massachusetts in January 2007. Activities since Citius Pharmaceuticals, LLC's inception through September 30, 2017, were devoted primarily to the development and commercialization of therapeutic products for large and growing markets using innovative patented or proprietary formulations and novel drug delivery technology.

On March 30, 2016, the Company acquired all of the outstanding stock of Leonard-Meron Biosciences, Inc. ("LMB") by issuing 1,942,456 shares of its common stock. As of March 30, 2016, the stockholders of LMB received approximately 41% of the issued and outstanding common stock of the Company. In addition, the Company converted the outstanding common stock warrants of LMB into 243,020 common stock warrants of the Company and converted the outstanding common stock options of LMB into 77,252 common stock options of the Company. Management estimated the fair value of the purchase consideration to be $19,015,073.

In connection with the acquisition, the Company acquired net assets of $17,428,277, including identifiable intangible assets of $19,400,000 related to in-process research and development and other assets and liabilities. The Company recorded goodwill of $1,586,796 for the excess of the purchase price over the net assets acquired.

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

Through September 30, 2017, the Company has devoted substantially all of its efforts to product development, raising capital, building infrastructure through strategic alliances and coordinating activities relating to its proprietary products. On July 1, 2016, the Company announced that it was discontinuing Suprenza and was focusing on the Phase 3 development of Mino-Lok™, an antibiotic lock solution used to treat patients with catheter-related bloodstream infections, and the Phase 2b development of Hydro-Lido for hemorrhoids. The Company has not yet realized any revenues from its operations.

Patent and Technology License Agreement

LMB has a patent and technology license agreement with Novel Anti-Infective Therapeutics, Inc., ("NAT") to develop and commercialize Mino-Lok™ on an exclusive worldwide sub licensable basis, as amended. Since May 2014, LMB has paid an annual maintenance fee of $30,000 that increases over five years to $90,000, until commercial sales of a product subject to the license. LMB will also pay annual royalties on net sales of licensed products, with royalties ranging from the mid-single digits to the low double digits. In limited circumstances in which the licensed product is not subject to a valid patent claim and a competitor is selling a competing product, the royalty rate is in the low-single digits. After a commercial sale is obtained, LMB must pay minimum aggregate annual royalties that increase in subsequent years. LMB must also pay NAT up to $1,390,000 upon achieving specified regulatory and sales milestones. Finally, LMB must pay NAT a specified percentage of payments received from any sub licensees.

Results of Operations for Year Ended September 30, 2017 compared to Year Ended September 30, 2016

	Year Ended September 30, 2017	Year Ended September 30, 2016
Revenues	$ -	$ -
Operating expenses:		
Research and development	2,936,252	2,933,199
General and administrative	6,063,439	3,783,941
Stock-based compensation – general and administrative	986,620	732,151
Total operating expenses	9,986,311	7,449,291
Operating loss	(9,986,311)	(7,449,291)
Interest income	-	806
Gain (loss) on revaluation of derivative warrant liability	452,147	(838,219)
Interest expense	(850,789)	(8,994)
Net loss	$ (10,384,953)	$ (8,295,698)

Revenues

We did not generate any revenues for the years ended September 30, 2017 and 2016.

Research and Development Expenses

For the year ended September 30, 2017, research and development expenses were $2,936,252 as compared to $2,933,199 during the year ended September 30, 2016. The $3,053 increase in 2017 was primarily due to an increase of $776,192 in costs incurred in the development of Mino-Lok™ offset by a decrease of $773,139 in costs incurred in the development of our product for the treatment of hemorrhoids and costs related to Suprenza, including $292,575 received in 2016 from Alpex as reimbursement for regulatory filing fees. We are actively seeking to raise additional capital in order to fund our research and development efforts.

General and Administrative Expenses

For the year ended September 30, 2017, general and administrative expenses were $6,063,439 as compared to $3,783,941 during the year ended September 30, 2016. The $2,279,498 increase in 2017 was primarily due to the acquisition of LMB on March 30, 2016, which resulted in increased compensation costs, increased consulting fees incurred for financing activities and corporate development services, and increased investor relations fees. In addition, the year ended September 30, 2016 only includes six months of expenses for LMB as the acquisition was completed on March 30, 2016.

Stock-based Compensation Expense

For the year ended September 30, 2017, stock-based compensation expense was $986,620 as compared to $732,151 for the year ended September 30, 2016. The $254,469 increase in expense includes the expense for unvested options assumed in the acquisition of LMB, as well as new grants to directors, employees and consultants.

Other Income (Expense)

There was no interest income earned on our cash balances for the year ended September 30, 2017 and only $806 in interest income earned for the year ended September 30, 2016.

Gain (loss) on revaluation of derivative warrant liability for the year ended September 30, 2017 was $452,147 compared to $(838,219) for the year ended September 30, 2016. The fair value of the derivative warrant liability fluctuates with changes in our stock price, volatility, remaining lives of the warrants, and interest rates. The gain for the year ended September 30, 2017 was primarily due to a decrease in the fair value of our stock from $9.45 per share at September 30, 2016 to $4.125 per share at August 8, 2017 when the final derivative warrants were reclassified to equity. The loss for the year ended September 30, 2016 was primarily due to an increase in the fair value of our common stock from $8.10 at September 30, 2015 to $9.45 at September 30, 2016. At September 30, 2017, the Company has no outstanding warrants that are considered to be derivative instruments.

Interest expense on the notes payable acquired in the acquisition of LMB and recent borrowings from our Chairman was $850,789 for the year ended September 30, 2017, and includes net non-cash interest expense of $762,078 due to the beneficial conversion feature on the conversion price of $1,595,411 and the amortization of the previously recorded modification premium of $833,333. After the August 8, 2017 conversions of debt to common stock, the Company has $172,970 in outstanding notes payable at September 30, 2017. Interest expense on the notes payable acquired in the acquisition of LMB was $8,994 for the year ended September 30, 2016.

Net Loss

For the year ended September 30, 2017, we incurred a net loss of $10,384,953 compared to a net loss for the year ended September 30, 2016 of $8,295,698. The $2,089,255 increase in the net loss was primarily due to the $2,279,498 increase in general and administrative expenses and the 841,795 increase in interest expense offset by the $1,290,366 change in the (gain) loss on revaluation of the derivative warrant liability.

Results of Operations for Year Ended September 30, 2016 compared to Year Ended September 30, 2015

	Year Ended September 30, 2016	Year Ended September 30, 2015
Revenues	$ -	$ -
Operating expenses:		
Research and development	2,933,199	1,797,045
General and administrative	3,783,941	946,613
Stock-based compensation – general and administrative	732,151	486,271
Total operating expenses	7,449,291	3,229,929
Operating loss	(7,449,291)	(3,229,929)
Interest income	806	3,066
Gain (loss) on revaluation of derivative warrant liability	(838,219)	332,095
Interest expense	(8,994)	(7,500)
Net loss	$ (8,295,698)	$ (2,902,268)

Revenues

We did not generate any revenues for the years ended September 30, 2016 and 2015.

Research and Development Expenses

For the year ended September 30, 2016, research and development expenses were $2,933,199 as compared to $1,797,045 for the year ended September 30, 2015. The $1,136,154 increase in 2016 was primarily due to the $1,912,745 in costs incurred in the development of Mino-Lok™ offset by a decrease in the costs on our product for the treatment of hemorrhoids and the reimbursement of $292,575 from Alpex for regulatory filing fees. We are actively seeking additional capital in order to fund our research and development efforts.

General and Administrative Expenses

For the year ended September 30, 2016, general and administrative expenses were $3,783,941 as compared to $946,613 for the year ended September 30, 2015. The increase of $2,837,328 in 2016 was primarily due to the acquisition of LMB which resulted in increased compensation costs, increased consulting fees incurred for financing activities and corporate development services, and increased investor relations fees.

Stock-based Compensation Expense

For the year ended September 30, 2016, stock-based compensation expense was $732,151 as compared to $486,271 for the year ended September 30, 2015, an increase of $245,880. The $732,151 expense for the year ended September 30, 2016 includes the expenses for our Chairman's options, an option granted to a consultant, options granted to six directors (including our current Chief Executive Officer), options granted to three employees, and options granted in connection with the acquisition of LMB. The $486,271 expense for the year ended September 30, 2015 was due to the stock options granted to our Chairman in connection with his employment agreement and options granted to two consultants.

Other Income (Expense)

Interest income earned was $806 for the year ended September 30, 2016 compared to $3,066 for the year September 30, 2015. The interest income was earned on the proceeds of our private offerings that were invested in money market accounts.

Loss on revaluation of derivative warrant liability for the year ended September 30, 2016 was $838,219 compared to a gain of $332,095 for the year ended September 30, 2015. The $838,219 loss for the year ended September 30, 2016 was primarily due to the increase in the fair value of our Common Stock from $8.10 per share at September 30, 2015 to $9.45 per share at September 30, 2016 and an increase in volatility from 57% at September 30, 2015 to 73% at September 30, 2016. The $332,095 gain for the year ended September 30, 2015 was primarily due to the decrease in our stock price used to calculate the fair value of the derivative liability from $9.00 at September 30, 2014 to $8.10 at September 30, 2015.

For the year ended September 30, 2016, interest expense increased by $1,494 in comparison to the year ended September 30, 2015. Interest expense for the year ended September 30, 2016 related to the demand notes payable assumed in the acquisition of LMB and the new $500,000 demand note payable issued in September 2016. For the year ended September 30, 2015, interest expense related to promissory notes issued to two existing investors. On December 31, 2014, the outstanding $600,000 promissory notes and accrued interest of $33,333 were converted into 1,055,554 shares of Common Stock at a conversion price of $0.60 per share. From December 31, 2014 to March 30, 2016, the Company had no outstanding interest bearing debt.

Net Loss

For the year ended September 30, 2016, we incurred a net loss of $8,295,698 compared to a net loss of $2,902,268 for the year ended September 30, 2015. The $5,393,430 increase in the net loss was primarily due to the $2,837,328 increase in general and administrative expenses, the $1,136,154 increase in research and development expenses and the $1,170,314 change in the gain (loss) on revaluation of derivative warrant liability.

Liquidity and Capital Resources

Going Concern Uncertainty and Working Capital

Citius has incurred losses of $10,384,953, $8,295,698 and $2,902,268 for the years ended September 30, 2017, 2016 and 2015, respectively. At September 30, 2017, Citius had an accumulated deficit of $27,721,200. Citius' net cash used in operations during the years ended September 30, 2017, 2016 and 2015, was $7,971,205, $5,900,421 and $2,385,416, respectively.

Our independent registered accountants report on our September 30, 2017 consolidated financial statements contains an emphasis of a matter regarding substantial doubt about our ability to continue as a going concern and that the consolidated financial statements have been prepared assuming we will continue as a going concern and do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets, or the amounts and classification of liabilities that may result if we do not continue as a going concern.

As of September 30, 2017, Citius had working capital of $955,189. Our limited working capital was attributable to the operating losses incurred by the Company since inception offset by our capital raising activities. At September 30, 2017, Citius had cash and cash equivalents of $3,204,108 available to fund its operations. The Company's only source of cash flow since inception has been from financing activities. During the years ended September 30, 2017, 2016 and 2015, the Company received net proceeds of $6,673,088, $5,427,688 and $1,509,493, respectively from the issuance of equity. We also received $4,210,000 from the issuance of notes payable to our Chairman of the Board, Mr. Leonard Mazur, during the year ended September 30, 2017. Mr. Mazur converted the notes payable to common stock on August 8, 2017. Our primary uses of operating cash were for product development and commercialization activities, regulatory expenses, employee compensation, consulting fees, legal and accounting fees, and insurance and travel expenses.

On September 12, 2014, the Company sold 226,671 units ("Units") for a purchase price of $9.00 per Unit for gross proceeds of $2,040,040. Each Unit consists of one share of Common Stock and one five-year warrant (the "Investor Warrants") to purchase one share of Common Stock at an exercise price of $9.00 (the "Private Offering").

On December 31, 2014, the note holders requested conversion of $600,000 in Promissory Notes and accrued interest of $33,333 into 70,371 shares of Common Stock at a conversion price of $9.00 per share.

Between March 19, 2015 and September 14, 2015, the Company sold an additional 189,136 Units for a purchase price of $8.10 per Unit and 13,333 Units for a purchase price of $9.00 per Unit for gross proceeds of $1,652,000.

During the year ended September 30, 2016, the Company sold an additional 290,000 Units for a purchase price of $8.10 per Unit and 17,778 Units for a purchase price of $9.00 per Unit for gross proceeds of $2,509,000.

On March 22, 2016, the Company sold 333,333 shares of Common Stock at $9.00 per share to its Chairman of the Board, Leonard Mazur, for gross proceeds of $3,000,000.

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

On May 10, 2017 and June 23, 2017, the Company executed a $1,500,000 future advance convertible promissory note and a $1,000,000 future advance convertible promissory note, respectively, with Leonard Mazur that 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 Company's 2017 registered public offering. On August 8, 2017, Leonard Mazur converted the outstanding $2,210,000 principal balances and accrued interest of $13,066 into 718,567 shares of common stock.

In February 2017, the Company completed an offering (the "2016 Offering") and sold 128,017 units at $6.00 per unit for gross proceeds of $768,100. Each unit consisted of (i) one share of common stock and (ii) a five year warrant to purchase one share of common stock at an exercise price of $8.25 per share (the "2016 Offering Warrants"). The placement agent received a 10% cash commission on the gross proceeds, an expense allowance equal to 3% of the proceeds, and warrants to purchase 12,802 shares of common stock at an exercise price of $8.25 per share. The placement agent commissions and expense allowance was $99,853. Other costs of the placement were $176,896. On June 8, 2017, the Company entered into release agreements with the investors in the 2016 Offering where each investor released the Company from the restrictions included in the unit purchase agreements. In exchange, the Company agreed to reprice the sale of the 2016 Offering units to $4.125 per unit and reprice the 2016 Offering Warrants to an exercise price of $4.125 per share. During the year ended September 30, 2017, the Company issued an additional 58,191 shares of common stock to the investors.

On August 8, 2017, the Company closed an underwritten public offering of 1,648,484 shares of common stock and warrants to purchase 1,646,484 shares of common stock at an offering price of $4.125 per share and $0.01 per warrant. The warrants have a per share exercise price of $4.125, are exercisable immediately and will expire five years from the date of issuance. The gross proceeds to Citius from this offering were $6,802,469, before deducting underwriting discounts and commissions and other offering expenses of $685,573. The Company granted the underwriters a 45-day option to purchase up to an additional 247,272 shares of common stock and warrants to purchase 247,272 shares of common stock to cover over-allotments, if any. On August 8, 2017, the underwriters partially exercised the over-allotment to purchase an additional 247,272 warrants.

We expect that we will have sufficient capital to continue our operations for the next six months from September 30, 2017. We plan to raise additional capital in the future to support our operations. There is no assurance, however, that we will be successful in raising the needed capital or that the proceeds will be received in a timely manner to fully support our operations.

Inflation

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

Off Balance Sheet Arrangements

We do not have any off balance sheet arrangements.

Critical Accounting Policies

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

Research and Development

Research and development costs, including upfront fees and milestones paid to collaborators who are performing research and development activities under contractual agreement with us, are expensed as incurred. We defer and capitalize our nonrefundable advance payments that are for research and development activities until the related goods are delivered or the related services are performed. When we are reimbursed by a collaboration partner for work we perform, we record the costs incurred as research and development expenses and the related reimbursement as a reduction to research and development expenses in our statement of operations. Research and development expenses primarily consist of clinical and non-clinical studies, materials and supplies, third-party costs for contracted services, and payments related to external collaborations and other research and development related costs.

In-process Research and Development and Goodwill

In process research and development represents the value of LMB's leading drug candidate, Mino-Lok ™, an antibiotic lock solution in phase 3 clinical development, which if approved, would be used to assist in the treatment of catheter related bloodstream infections and is expected to be amortized on a straight line basis over 8 years upon revenue generation. Goodwill represents the value of LMB's industry relationships and its assembled workforce. Goodwill will not be amortized and will be tested at least annually for impairment.

The Company reviews intangible assets annually to determine if any adverse conditions exist or a change in circumstances has occurred that would indicate impairment or a change in the remaining useful life of any intangible asset. If the carry value of an asset exceeds its undiscounted cash flows, the Company writes down the carrying value of the intangible asset to its fair value for the period identified. No triggering events occurred since the acquisition of LMB that would suggest a potential impairment may have occurred through September 30, 2017.

The Company evaluates the recoverability of goodwill annually or more frequently if events or changes in circumstances indicate that the carrying value of an asset may be impaired. Goodwill is first qualitatively assessed to determine whether further impairment testing is necessary. Factors that management considers in the assessment include macroeconomic conditions, industry and market conditions, overall financial performance, (both current and projected), changes in management and strategy as well as changes in the composition of the carrying amount of net assets. If this qualitative assessment indicates that it is more likely that not that the fair value of a reporting unit is less than its carrying amount, a two-step process is then performed.

The Company performed a qualitative assessment for its 2017 analysis of goodwill. Based on this assessment, management does not believe that it is more likely than not, that the carrying value of the reporting unit exceeds its fair value. Accordingly, no further testing was performed as management believes that there are no impairment issues with respect to goodwill as of September 30, 2017.

Derivative Warrant Liability

The FASB ASC 815-40: *Derivatives and Hedging-Contracts in Entity's Own Equity* requires freestanding contracts that are settled in a company's own stock, including common stock warrants, to be designated as an equity instrument, asset or a liability. Under the provisions of ASC 815-40, a contract designated as an asset or a liability must be carried at fair value on a company's balance sheet, with any changes in fair value recorded in the company's results of operations. A contract designated as an equity instrument must be included within equity, and no fair value adjustments are required from period to period. The issuance of certain warrants were classified as liabilities at issuance because the exercise price of the warrants was subject to adjustment in the event that the Company issued common stock for less than the original issuance price per share within one-year of the issuance of the warrants. Subsequent private placements did not result in an adjustment of the exercise price of these warrants.

The Company performed valuations of the warrants classified as derivative warrants using a probability weighted Black-Scholes Pricing Model which value was compared to a Binomial Option Pricing Model for reasonableness. The model uses market-sourced inputs such as underlying stock prices, risk-free interest rates, volatility, expected life and dividend rates and has also considered the likelihood of "down-round" financings. Selection of these inputs involves management's judgment and may impact net income (loss). Due to our limited operating history and limited number of sales of our common stock, we estimate our volatility based on a number of factors including the volatility of comparable publicly traded pharmaceutical companies. The volatility factor used in the Black-Scholes Pricing Model has a significant effect on the resulting valuation of the derivative liabilities on our balance sheet. The volatility calculated at September 30, 2016 was 73%. We used a risk-free interest rate of 1.14% and estimated lives of 4.10 to 4.57 years, which are the remaining contractual lives of the warrants.

As of September 30, 2017, there were no outstanding warrants classified as a derivative warrant liability.

Income Taxes

We follow accounting guidance regarding the recognition, measurement, presentation and disclosure of uncertain tax positions in the financial statements. Tax positions taken or expected to be taken in the course of preparing our tax returns are required to be evaluated to determine whether the tax positions are "more-likely-than-not" of being sustained by the applicable tax authorities. Tax positions not deemed to meet a more-likely-than-not threshold would be recorded in the financial statements. There are no uncertain tax positions that require accrual or disclosure as of September 30, 2017.

Any interest or penalties are charged to expense. None have been recognized in these financial statements. Generally, we are subject to federal and state tax examinations by tax authorities for all years subsequent to December 31, 2013.

We recognize deferred tax assets and liabilities based on differences between the financial reporting and tax basis of assets and liabilities using the enacted tax rates and laws that are expected to be in effect when the differences are expected to reverse. We provide a valuation allowance for deferred tax assets for which we do not consider realization of such assets to be more likely than not.

BUSINESS

Business Overview

Citius Pharmaceuticals, Inc., headquartered in Cranford, New Jersey, is a specialty pharmaceutical company dedicated to the development and commercialization of critical care products targeting important medical needs with a focus on anti-infective products in adjunct cancer care and unique prescription products. Our goal is to achieve leading market positions by providing therapeutic products that address unmet medical needs yet have a lower development risk than is associated with new chemical entities. New formulations or combinations of previously approved drugs with substantial existing safety and efficacy data are a core focus as we seek to reduce development and clinical risks associated with drug development. Our strategy centers on products that have intellectual property and regulatory exclusivity protection, while providing competitive advantages over other existing therapeutic approaches.

The Company was founded as Citius Pharmaceuticals, LLC, a Massachusetts limited liability company, on January 23, 2007. On September 12, 2014, Citius Pharmaceuticals, LLC entered into a Share Exchange and Reorganization Agreement, with Citius Pharmaceuticals, Inc. (formerly Trail One, Inc.), a publicly traded company incorporated under the laws of the State of Nevada. Citius Pharmaceuticals, LLC became a wholly-owned subsidiary of Citius. On March 30, 2016, Citius acquired Leonard-Meron Biosciences, Inc. as a wholly-owned subsidiary. LMB was a pharmaceutical company focused on the development and commercialization of critical care products with a concentration on anti-infectives.

Since its inception, the Company has devoted substantially all of its efforts to business planning, research and development, recruiting management and technical staff, and raising capital. We are developing two proprietary products: Mino-Lok™, an antibiotic lock solution used to treat patients with catheter-related bloodstream infections by salvaging the infected catheter, and a hydrocortisone-lidocaine topical formulation that is intended to provide anti-inflammatory and anesthetic relief to individuals suffering from hemorrhoids. We believe the markets for our products are large, growing, and underserved by the current prescription products or procedures.

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

Mino-Lok™

Overview

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

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

Phase 2b Results

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

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

The main purpose of the study was to show that Mino-Lok therapy was at least as effective as the removal and replacement of CVCs when CRBSIs are present, and that the safety was better, that is, the complications of removing an infected catheter and replacing with a new one could be avoided. In addition to having a 100% efficacy rate with all CVCs being salvaged, Mino-Lok therapy had no significant adverse events ("SAEs"), compared to an 18% SAE rate in the matched cohort where patients had the infected CVCs removed and replaced ("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 (4) 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 (6) patients had more than one (1) complication in the control arm group.

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

* 1 Polymicrobal patient had a Gram+ and a Gram- organism cultured
** 6 Patients had > 1 complication

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

Phase 3 Initiation

In November 2016, the Company initiated site recruitment for Phase 3 clinical trials. From initiation through first quarter 2017, the Company received input from several sites related to the control arm as being less than standard of care for some of the respective institutions. The Company worked closely with the FDA with respect to the design of the phase 3 trial, and received feedback on August 17, 2017. The FDA stated that they recognized that there is an unmet medical need in salvaging infected catheters and agreed that an open label, superiority design would address the Company's concerns and would be acceptable to meet the requirements of a new drug application. The Company amended the phase 3 study design to remove the saline and heparin placebo control arm and to use an active control arm that conforms with today's current standard of care. As of January 31, 2018, the first patient had not been enrolled in the trial, however, as sites are fully implemented and actively screening patients, we continue to anticipate trial enrollment to begin in the first quarter of 2018.

Fast Track Designation

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

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

Mino-Lok TM International Study

In October 2017, data from an international study on Mino-LokTM 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.

Market Opportunity

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

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

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

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

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

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

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

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

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.

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

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

In addition to the safety and dose-ranging information, information was obtained relating to the use of the GSDS as an assessment tool for measuring the effectiveness of the test articles. Individual signs and symptoms were also assessed but can vary from patient to patient. Therefore, the goal of the GSDS was to provide an assessment tool that could be used for all patients regardless of which signs and symptoms they are experiencing. The GSDS proved to be a more effective tool for assessing the severity of the disease and the effectiveness of the drug when compared to the assessment of the individual signs and symptoms. Citius believes that we can continue to develop this assessment tool as well as other patient reported outcome endpoints for use in the next trials and in the pivotal trial.

Information was also obtained about the formulation of the drug and the vehicle. As a result of this study, we believe that the performance of the active arms of the study relative to the vehicle can be improved by re-formulating our topical preparation. Therefore, we have initiated work on vehicle formulation and evaluation of higher potency steroids.

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

A Phase 2b study will begin once the new formulation is completed and the updated evaluation tools are developed. This study will be a 300 patient four arm study of individuals with Class II and III hemorrhoids. The cost is estimated at approximately $4.0 million and is expected to require approximately one year to complete.

Market Opportunity

The current market for OTC and topical DESI formulations of hydrocortisone and lidocaine is highly fragmented, and includes approximately 20 million units of OTC hemorrhoid products and over 4 million prescriptions for non-approved prescription treatments. Several topical combination prescription products for the treatment of hemorrhoids are available containing hydrocortisone in strengths ranging from 0.5% to 3.0%, combined with lidocaine in strengths ranging from 1.0% to 3.0%. The various topical formulations include creams, ointments, gels, lotions, enemas, pads, and suppositories. The most commonly prescribed topical combination gel is sold as a branded generic product and contains 2.5% hydrocortisone and 3.0% lidocaine.

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

Market Exclusivity

We believe that we will be the first company to conduct rigorous clinical trials and receive FDA approval of a topical hydrocortisone-lidocaine combination product for the treatment of hemorrhoids. If we receive FDA approval, we will qualify for 3 years of market exclusivity for our dosage strength and formulation. In addition, we will also be the only product on the market specifically proven to be safe and effective for the treatment of hemorrhoids. Generally, if a company conducts clinical trials and receives FDA approval of a product for which there are similar, but non FDA-approved, prescription products on the market, the manufacturers of the unapproved but marketed products are required to withdraw them from the market. However, the FDA has significant latitude in determining how to enforce its regulatory powers in these circumstances. We have not had any communication with the FDA regarding this matter and cannot predict what action, if any, the FDA will take with respect to the unapproved products.

We believe that should our product receive an FDA approval and demonstrate, proven safety and efficacy data, and if our products obtain 3 years of market exclusivity based on our dosage strength and formulation, Citius is likely to have a meaningful advantage in its pursuit of achieving a significant position in the market for topical combination prescription products for the treatment of hemorrhoids.

Sales and Marketing

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

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

Intellectual Property

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

Mino-Lok Intellectual Property

Mino-Lok is covered by an issued U.S. patent (no. 7,601,731), "Antimicrobials in Combination with Chelators and Ethanol for the Rapid Eradication of Microorganisms Embedded in Biofilm," which was issued on October 13, 2009. This patent is a composition of matter patent and provides intellectual property protection until June 7, 2024. There are corresponding applications pending in Europe and Canada (European Application No. EP 1644024; Canadian Patent Application No. 0252852). On April 15, 2014, a patent application was filed for an enhanced formulation that provides greater stability of the reconstituted Mino-Lok solution. In June 2017, the Company was notified that US Patent Application 15/344,113 has been published by the US Patent Office with a publication date of June 1, 2017. This patent is a step forward for Mino-Lok as it overcomes limitations in mixing antimicrobial solutions where components may precipitate because of physical and/or chemical factors, thus limiting the stability of the post-mix solutions.

On May 14, 2014, LMB entered into a patent and technology license agreement with Novel Anti-Infective Therapeutics, Inc., ("NAT") to develop and commercialize Mino-Lok on an exclusive, worldwide (except for South America), sub licensable basis. LMB incurred a one-time license fee in May 2014. On March 20, 2017, LMB entered into an amendment to the license agreement that expanded the licensed territory to include South America, providing LMB with worldwide rights. Under the license agreement, the Company will pay (i) an annual maintenance fee until commercial sales of a product subject to the license, (ii) upon commercialization, we will pay annual royalties on net sales of licensed products, (iii) and certain regulatory and milestone payments. Unless earlier terminated by NAT based on the failure to achieve certain development or commercial milestones, the license agreement remains in effect until the date that all patents licensed under the agreement have expired and all patent applications within the licensed patent rights have been cancelled, withdrawn or expressly abandoned.

Mino-Lok has received a Qualified Infectious Disease Product ("QIDP") designation. QIDP provides New Drug Applications an additional 5 years of market exclusivity with Hatch-Waxman for a combined total of 8 ½ years regardless of patent protection.

Hydro-Lido Intellectual Property

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

We seek to achieve approval for Hydro-Lido by utilizing the FDA's 505(b)(2) pathway. This pathway will provide 3 years of market exclusivity.

Competition

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

Mino-Lok Competition

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

At this time, there are no pharmacologic agents approved in the U.S. for the prevention or treatment of CLABSIs in central venous catheters. Citius is aware that there are several agents in development for prevention but none for salvage. The most prominent of these appear to be Neutrolin from CorMedix and B-Lock from Great Lakes Pharmaceuticals, Inc. ("GLP").

Neutrolin® (CorMedix Inc.)

Neutrolin is a formulation of Taurolidine 1.35%, Citrate 3.5%, and Heparin 1000 units/mL. Neutrolin is an anti-microbial catheter lock solution being developed by CorMedix to prevent CRBSIs and to prevent clotting. In January 2015, the U.S. Food and Drug Administration (the "FDA") granted Fast Track and Qualified Infectious Disease Product ("QIDP") designations for Neutrolin. In December 2015, CorMedix initiated its Phase 3 clinical trial in hemodialysis patients in the United States. The clinical trial named Catheter Lock Solution Investigational Trial, or LOCK-IT-100 is a prospective, multicenter, randomized, double-blind, placebo-controlled, active control trial designed to show efficacy and safety of Neutrolin in preventing CRBSIs in subjects receiving hemodialysis therapy. On April 20, 2017, CorMedix provided an update on the LOCK-IT-100 trial. CorMedix had enrolled 368 patients to date and completed a safety review by an independent Data and Safety Monitoring Board ("DSMB") of the first 279 patients. The DSMB concluded that it was safe to continue the trial as designed; however, CorMedix initiated discussions with the FDA to make some protocol changes to include one or more interim efficacy analyses. According to CorMedix, the FDA accepted the CorMedix proposal. Recently, CorMedix stated that the LOCK-IT-100 is an event-driven study and that study completion would be dependent upon capturing 56 total CRBSI events. CorMedix now believes that an interim efficacy analysis will occur in the fourth quarter 2017, followed by enrollment completion in the second quarter 2018. The study is expected to conclude around year end 2018.

CorMedix is assessing the structure of its second planned Phase 3 study to seek possible efficiencies and improvements in design and execution.

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

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

Neither of these lock solutions have been shown to be effective in salvaging catheters in bacteremic patients as Mino-Lok is intended to do, and Citius does not expect that either would be pursued for this indication.

Hydro-Lido Competition

The primary competition in the hemorrhoid market is non-prescription over the counter products. When approved, Hydro-Lido will be the only prescription product for the treatment of hemorrhoids.

Supply and Manufacturing

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

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

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

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

Regulatory Strategy

United States Government Regulation

The research, development, testing, manufacture, labeling, promotion, advertising, distribution and marketing, among other things, of our products are extensively regulated by governmental authorities in the United States and other countries. Citius' products may be classified by the FDA as a drug or a medical device depending upon the indications for use or claims. Because certain of our product candidates are considered as medical devices and others are considered as drugs for regulatory purposes, we intend to submit applications to regulatory agencies for approval or clearance of both medical devices and pharmaceutical product candidates.

In the United States, the FDA regulates drugs and medical devices under the Federal Food, Drug, and Cosmetic Act and the agency's implementing regulations. If Citius fails to comply with the applicable United States requirements at any time during the product development process, clinical testing, and the approval process or after approval, we may become subject to administrative or judicial sanctions. These sanctions could include the FDA's refusal to approve pending applications, license suspension or revocation, withdrawal of an approval, warning letters, adverse publicity, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, civil penalties or criminal prosecution. Any agency enforcement action could have a material adverse effect on Citius.

Foreign Regulatory Requirements

Citius and any collaborative partners may be subject to widely varying foreign regulations, which may be different from those of the FDA, governing clinical trials, manufacture, product registration and approval and pharmaceutical sales. Whether or not FDA approval has been obtained, Citius or its collaboration partners must obtain a separate approval for a product by the comparable regulatory authorities of foreign countries prior to the commencement of product marketing in such countries. In certain countries, regulatory authorities also establish pricing and reimbursement criteria. The approval process varies from country to country, and the time may be longer or shorter than that required for FDA approval. In addition, under current United States law, there are restrictions on the export of products not approved by the FDA, depending on the country involved and the status of the product in that country.

International sales of medical devices manufactured in the U.S. that are not approved by the FDA for use in the U.S., or are banned or deviate from lawful performance standards, are subject to FDA export requirements. Exported devices are subject to the regulatory requirements of each country to which the device is exported. Some countries do not have medical device regulations, but in most foreign countries, medical devices are regulated. Frequently, regulatory approval may first be obtained in a foreign country prior to application in the U.S. to take advantage of differing regulatory requirements. Most countries outside of the U.S. require that product approvals be recertified on a regular basis, generally every 5 years. The recertification process requires that Citius evaluate any device changes and any new regulations or standards relevant to the device and conduct appropriate testing to document continued compliance. Where recertification applications are required, they must be approved in order to continue selling Citius' products in those countries.

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

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

Employees

As of September 30, 2017, the Company had 7 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, 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

Below are the names and certain information regarding the Company's executive officers and directors. Each director will serve until the Company's next annual meeting of stockholders and until a successor is elected and qualified.

Name	Age	Position(s)
Myron Holubiak	70	President and Chief Executive Officer and Director
Leonard Mazur	72	Executive Chairman of the Board of Directors
Suren Dutia	73	Director
Carol Webb	70	Director
Dr. William Kane	73	Director
Howard Safir	73	Director
Dr. Eugene Holuka	58	Director
Jaime Bartushak	50	Chief Financial Officer and Chief Accounting Officer

Myron Holubiak is the President, Chief Executive Officer and has been a member of the Board since October 2015. Mr. Holubiak has extensive experience in managing and advising large and emerging pharmaceutical and life sciences companies. Mr. Holubiak was the President of Roche Laboratories, Inc. ("Roche"), a major research-based pharmaceutical company, from December 1998 to August 2001. Prior to that, he held sales and marketing positions at Roche during his 19-year tenure. From September, 2002 to July, 2016, Mr. Holubiak served on the board of directors and for the last 2 years was the Chairman of the board of directors of BioScrip, Inc. ("BioScrip") (Nasdaq: BIOS). BioScrip is a leading national provider of infusion and home care management solutions. Since July 2010, Mr. Holubiak has served as a member of the board of directors of Assembly Biosciences, Inc. ("Assembly") (Nasdaq: ASMB) and its predecessor Ventrus Biosciences, Inc. ("Ventrus"). Assembly is a biopharmaceutical company developing innovative treatments for hepatitis B virus infection (HBV) and C. difficile-associated diarrhea (CDAD). In March, 2013, Mr. Holubiak founded Leonard-Meron Biosciences, Inc. ("LMB"), the Company's wholly-owned subsidiary, and he served as the Chief Executive Officer and President of LMB until March, 2016. In addition, Mr. Holubiak was also a trustee of the Academy of Managed Care Pharmacy Foundation until the current year. Mr. Holubiak received a B.S. in Molecular Biology and Biophysics from the University of Pittsburgh.

Leonard Mazur is the Executive Chairman and Secretary of the Company and has been a member of the Board since September 2014. Mr. Mazur is the cofounder and Vice Chairman of Akrimax Pharmaceuticals, LLC ("Akrimax"), a privately held pharmaceutical company specializing in producing cardiovascular and general pharmaceutical products. Akrimax was founded in September 2008 and has successfully launched prescription drugs while acquiring drugs from major pharmaceutical companies. From January 2005 to May 2012, Mr. Mazur also co-founded and served as the Chief Operating Officer of Triax Pharmaceuticals LLC ("Triax"), a specialty pharmaceutical company producing prescription dermatological drugs. Prior to joining Triax, he was the founder and, from 1995 to 2005, Chief Executive Officer of Genesis Pharmaceutical, Inc. ("Genesis"), a dermatological products company that marketed its products through dermatologists' offices as well as co-promoting products for major pharmaceutical companies. In 2003, Mr. Mazur successfully sold Genesis to Pierre Fabre, a leading pharmaceutical company. Mr. Mazur has extensive sales, marketing and business development experience from his tenures at Medicis Pharmaceutical Corporation as executive vice president, ICN Pharmaceuticals, Inc. as vice president, sales & marketing, Knoll Pharma (a division of BASF), and Cooper Laboratories, Inc. Mr. Mazur is a member of the Board of Trustees of Manor College, is a recipient of the Ellis Island Medal of Honor and was previously the chairman of the board of directors of LMB, the Company's wholly-owned subsidiary. Mr. Mazur received both his BA and MBA from Temple University and has served in the U.S. Marine Corps Reserves.

Suren Dutia has been a member of the Board since October 2015. Mr. Dutia has served as Senior Fellow of the Ewing Mario Kauffman Foundation since March 2011 and as Senior Fellow of Skandalaris Center for Entrepreneurial Studies at Washington University, St. Louis since 2013. He has served as a member of the advisory board of Center for Digital Transformation, University of California, Irvine since May 2012 and as chairman of the board of directors of AccelPath, LLC since October 2009. From February 2006 to May 2010, Mr. Dutia served as the Chief Executive Officer of TiE Global, a non-profit organization involved in globally fostering entrepreneurship. From February 2011 to May 2013, Mr. Dutia served as a director of LifeProof Cases and from July 2000 to December 2011, he served as a director of Anvita Health. From 1989 to 1998, Mr. Dutia served as the Chief Executive Officer and chairman of the board of directors of Xscribe Corporation. Prior to his positions with Xscibe Corporation, Mr. Dutia held several positions with Dynatech Corporation, and in addition, he was the president of a medical instruments company. Previously, Mr. Dutia worked for the U.S. Department of Education. Mr. Dutia received his B.S. and M.S. degrees in chemical engineering and B.A. in political science from Washington University, St. Louis. In addition, he obtained an M.B.A. from University of Dallas.

Carol Webb has served as a director of LMB and, upon LMB's acquisition by the Company in March 2016, a director of the Company. From 2000 to 2005, she served as Company Group Chairman of Johnson & Johnson, and from 1987 to 2000 she served in capacities including President, Vice President, Executive Director, Product Management and Senior Product Director of Ortho Biotech. Ms. Webb has worked in various positions including Sales Representative, Sales Trainer, Product Manager and Manager of Public Policy at Roche Laboratories from 1972 to 1983. Ms. Webb received her B.S. in Biology from Bowling Green State University.

Dr. William (Terry) Kane has served as a director of LMB and, upon LMB's acquisition by the Company in March 2016, a director of the Company. He has served as a Clinical Professor at Duke University Medical Center since 2003. From 2006 to 2009, he served as the Chief Executive Officer of RadarFind Corporation, and from 2002 to 2003, he served as the Interim Chief Medical Officer of Mercy Fitzgerald Hospital. From 1996 until 2002, Dr. Kane served as the President and Chief Executive Officer of InteCardia, Inc., and from 1995 until 1996, he was with Health Care Consultant. From 1993 to 1995, Dr. Kane served in various capacities at Sharp Healthcare including Executive Vice President, Operations and Executive Vice President, Community Care. From 1992 to 1993, he was the Senior Vice President, Medical Affairs at Independence Blue Cross, and from 1990 to 1992, he served in various capacities at CentraState Medical Center including President, Chief Executive Officer, Executive Vice President and Chief Operating Officer. From 1989 to 1990, Dr. Kane was with Cain Brothers, Shattuck & Co., and from 1988 to 1989, he was the Senior Vice President, Health Services Division of American International Healthcare (formerly JBI). From 1986 to 1987, Dr. Kane was the Executive Vice President and Corporate Medical Director of CIGNA Healthplan, Inc., and from 1984 to 1986, he was at U.S. Healthcare, Inc. and served in various capacities including Senior Vice President Medical Delivery, President and Senior Medical Director. Dr. Kane is currently the chair of the board of directors of Research Triangle Park and was a past member of the board of directors of Pisacano Leadership Foundation and Make-A-Wish Foundation. In addition, he previously served on the Management Advisory Committee of Cornucopia House Cancer Support Center. Dr. Kane received his B.S. in Biology from the University of Scranton and his M.D. with Honors from the Temple University School of Medicine.

Howard Safir has served as a director of LMB since April 2014 and, upon LMB's acquisition by the Company in March 2016, a director of the Company. He has served as Chairman and Chief Executive Officer of VRI Technologies LLC, a security consulting and law enforcement integrator since July 2010. From 2001 until 2010, Mr. Safir served as the Chairman and Chief Executive Officer of Safir Rosetti, a provider of security and investigation services and a wholly-owned subsidiary of Global Options Group Inc. Mr. Safir served as the Vice Chairman of Global Options Group Inc. from its 2005 acquisition of Safir Rosetti until 2010. He served as Chief Executive Officer of Bode Technology, also a wholly-owned subsidiary of Global Options Group Inc., from 2007 to 2010. Mr. Safir currently serves as a director of Implant Sciences Corporation, an explosives device detection company, and LexisNexis Special Services, Inc., a leading provider of information and technology solutions to governments, as well as Verint Systems Inc. During his career, Mr. Safir served as the 39th Police Commissioner of the City of New York, as Associate Director for Operations, U.S. Marshals Service and as Assistant Director of the Drug Enforcement Administration.

Dr. Eugene Holuka has served as a director of the Company since June 2016. Dr. Holuka is an internist and has practiced in critical care medicine for almost thirty years. He is presently an attending physician at the Staten Island University Hospital where he has practiced since 1991. Dr. Holuka has also served as an Adjunct Clinical Assistant Professor at the Touro College of Osteopathic Medicine since 2011. Prior to the acquisition of LMB by the Company in March 2016, he was a member of the LMB Scientific Advisory Board from April 2014 until the present day. Dr. Holuka received the Ellis Island Medal of Honor in 2000 and has served on the NECO Committee Board since 2005. He was an Executive Committee Member on the Forum's Children Foundation from 2000 until 2008.

Jaime Bartushak

Mr. Bartushak previously served as Chief Financial Officer of LMB, a wholly-owned subsidiary of the Citius. Mr. Bartushak is an experienced finance professional for early stage pharmaceutical companies, and has over 20 years of corporate finance, business development, restructuring, and strategic planning experience. Mr. Bartushak was one of the founders of LMB in 2014 and was instrumental in its startup as well as in obtaining initial investment capital. Prior to his work at LMB, in 2014, Mr. Bartushak helped lead the sale of PreCision Dermatology, Inc. to Valeant Pharmaceuticals International, Inc.

Family Relationships

There are no family relationships among or between any of our current or former executive officers and directors.

Board Independence

After review of all relevant transactions or relationships between each director and nominee for director, or any of his or her family members, and the Company, its senior management and its Independent Registered Public Accounting Firm, the Board of Directors has determined that all of the Company's directors and the Company's nominees for director are independent within the meaning of the applicable NASDAQ listing standards, except Leonard Mazur, the Executive Chairman, Secretary and a director of the Company, and Myron Holubiak, the Chief Executive Officer, President and a director of the Company.

Director Compensation

On June 23, 2016, the board approved a director compensation plan for non-employee directors. Non-employee directors will each receive (1) an annual retainer of $10,000, (2) $2,000 for each meeting attended, and (3) $500 for each telephone meeting. In addition; (i) the Lead Independent Director and the Audit and Risk Committee chairman will each receive an additional annual retainer of $10,000, (ii) the Compensation Committee, and Nominating and Corporate Governance Committee chairmen will each receive an additional annual retainer of $5,000 and (iii) each committee member will receive an annual retainer of $2,500.

On November 27, 2017, the board increased the annual retainer for non-employee directors to $15,000.
Director compensation for the year ended September 30, 2017 was as follows.

Name	Fees Earned or Paid in Cash ($)(1)	Stock Awards ($)	Option Awards ($)(1)	All Other Compensation ($)	Total ($)
Suren Dutia(2)	25,000	—	18,321	—	43,321
Carol Webb(3)	19,000	—	83,331	—	102,331
Dr. William Kane(4)	22,500	—	86,344	—	108,844
Howard Safir(5)	33,000	—	86,344	—	119,344
Dr. Eugene Holuka(6)	19,000	—	71,881	—	90,881

(1) The dollar amount set forth in the table represents the dollar amount recognized for financial statement reporting purposes with respect to the fiscal year on an accrual basis for fees earned and in accordance with FASB ASC Topic 718 for option awards.

(2) On October 8, 2015, Mr. Dutia was granted options to purchase 26,667 shares of common stock at an exercise price of $8.10 per share that vested over 14 months. On September 15, 2017, Mr. Dutia was granted options to purchase 10,000 shares of common stock at an exercise price of $3.45 per share that vest on September 13, 2018.

(3) On March 17, 2014, Ms. Webb was granted options to purchase 12,071 shares of common stock at an exercise price of $0.015 per share by LMB that vested over 36 months and were assumed by the Company when it acquired LMB. On June 23, 2016, Ms. Webb was granted options to purchase 13,334 shares of common stock at an exercise price of $12.00 per share that vested over 12 months. On September 15, 2017, Ms. Webb was granted options to purchase 10,000 shares of common stock at an exercise price of $3.45 per share that vest on September 13, 2018.

(4) On March 28, 2014, Dr. Kane was granted options to purchase 12,071 shares of common stock at an exercise price of $0.015 per share by LMB that vested over 36 months and were assumed by the Company when it acquired LMB. On June 23, 2016, Dr. Kane was granted options to purchase 13,334 shares of common stock at an exercise price of $12.00 per share that vested over 12 months. On September 15, 2017, Dr. Kane was granted options to purchase 10,000 shares of common stock at an exercise price of $3.45 per share that vest on September 13, 2018.

(5) On April 11, 2014, Mr. Safir was granted options to purchase 12,071 shares of common stock at an exercise price of $0.015 per share by LMB that vested over 36 months and were assumed by the Company when it acquired LMB. On June 23, 2016, Mr. Safir was granted options to purchase 13,334 shares of common stock at an exercise price of $12.00 per share that vested over 12 months. On September 15, 2017, Mr. Safir was granted options to purchase 10,000 shares of common stock at an exercise price of $3.45 per share that vest on September 13, 2018.

(6) On April 4, 2014, Dr. Holuka was granted options to purchase 2,415 shares of common stock at an exercise price of $0.015 per share by LMB that vested over 36 months and were assumed by the Company when it acquired LMB. On June 23, 2016, Dr. Holuka was granted options to purchase 13,334 shares of common stock at an exercise price of $12.00 per share that vested over 12 months. On September 15, 2017, Dr. Holuka was granted options to purchase 10,000 shares of common stock at an exercise price of $3.45 per share that vest on September 13, 2018.

Executive Compensation

The following table sets forth information regarding compensation paid to our executive officers for the years ended September 30, 2017 and 2016.

Name & Position	Fiscal Year	Salary ($)	Nonequity Incentive Plan Compensation ($)	Option Awards ($)	All Other Compensation ($)	Total ($)
Leonard Mazur(1)	2017	250,000	—	57,353(5)	—	307,353
Executive Chairman	2016	250,000	120,000	187,653(6)	—	557,653
Myron Holubiak(2)	2017	450,000	225,000(4)	19,114(7)	—	694,114
Chief Executive Officer	2016	225,000	112,500	95,346(8)	—	432,846
Jaime Bartushak(3)	2017	250,000	100,000(4)	105,149(9)	—	455,149
Chief Financial Officer	2016	125,000	50,500	18,200(10)	—	193,700

(1) Appointed as Chief Executive Officer on September 12, 2014 and became the Executive Chairman on March 30, 2016 as part of Citius' acquisition of Leonard-Meron Biosciences, Inc.

(2) Appointed as Chief Executive Officer on March 30, 2016 as part of Citius' acquisition of Leonard-Meron Biosciences, Inc. Fiscal Year 2016 Compensation does not include compensation paid by Leonard-Meron Biosciences, Inc.

(3) Was appointed Chief Financial Officer of Citius on November 27, 2017 and previously served as Director, Executive Vice President, CFO, and Treasurer of Leonard-Meron Biosciences, Inc., a wholly owned subsidiary of Citius. Fiscal Year 2016 Compensation does not include compensation paid by Leonard-Meron Biosciences, Inc.

(4) This is the maximum amount of a discretionary bonus capable of being earned by the officer (50% of Mr. Holubiak's base salary and 40% of Mr. Bartushak's base salary), based on the attainment of certain goals established by the Company's Board of Directors. The Board has not yet determined the attainment of the goals nor the actual dollar amount to be granted, and expects to do so by March 2018. When determined, the amounts will be reported in a Current Report on Form 8-K.

(5) On September 15, 2017, Leonard Mazur was granted options to purchase 40,000 shares of common stock at an exercise price of $3.45 per share that vest 13,333 shares on September 13, 2018, and then vest approximately 1,111 shares per month for the next 24 months. The dollar amount set forth in the table represents the dollar amount recognized for financial statement reporting purposes for all options granted to the Executive Officer with respect to the fiscal year in accordance with FASB ASC Topic 718.

(6) On September 12, 2014, Leonard Mazur was granted options to purchase 220,000 shares of common stock at an exercise price of $6.75 per share that vested 86,667 shares on the grant date; 33,334 shares on September 12, 2015; 33,333 shares on March 12, 2016; 33,333 shares on September 12, 2016; and 33,333 shares on September 12, 2017. The dollar amount set forth in the table represents the dollar amount recognized for financial statement reporting purposes for all options granted to the Executive Officer with respect to the fiscal year in accordance with FASB ASC Topic 718.

(7) On September 15, 2017, Myron Holubiak was granted options to purchase 40,000 shares of common stock at an exercise price of $3.45 per share that vest 13,333 shares on September 13, 2018, and then vest approximately 1,111 shares per month for the next 24 months. The dollar amount set forth in the table represents the dollar amount recognized for financial statement reporting purposes for all options granted to the Executive Officer with respect to the fiscal year in accordance with FASB ASC Topic 718.

(8) On October 1, 2015, Myron Holubiak was granted options to purchase 26,667 shares of Common Stock at an exercise price of $8.10 per share that vested 2,667 shares on the grant date and then vest 2,000 shares per month commencing on December 31, 2015. The dollar amount set forth in the table represents the dollar amount recognized for financial statement reporting purposes for all options granted to the Executive Officer with respect to the fiscal year in accordance with FASB ASC Topic 718.

(9) On September 15, 2017, Jaime Bartushak was granted options to purchase 25,000 shares of common stock at an exercise price of $3.45 per share that vest 8,333 shares on September 13, 2018, and then vest approximately 694 share per month for the next 24 months. The dollar amount set forth in the table represents the dollar amount recognized for financial statement reporting purposes for all options granted to the Executive Officer with respect to the fiscal year in accordance with FASB ASC Topic 718.

(10) On July 6, 2016, Jaime Bartushak was granted options to purchase 48,267 shares of Common Stock at an exercise price of $10.50 per share that vest 16,089 shares on the July 7, 2017 and then vest approximately 1,341 shares per month for the next 24 months. The dollar amount set forth in the table represents the dollar amount recognized for financial statement reporting purposes for all options granted to the Executive Officer with respect to the fiscal year in accordance with FASB ASC Topic 718.

Outstanding Equity Awards at Fiscal Year-End

	Option Awards					Stock Awards			
Name (a)	Number of Securities Underlying Unexercised Options (#) Exercisable (b)	Number of Securities Underlying Unexercised Options (#) Unexercisable (c)	Equity Incentive Plan Awards: Number of Securities Underlying Unexercised Unearned Options (#) (d)	Option Exercise Price ($) (e)	Option Expiration Date (f)	Number Of Shares Or Units of Stock That Have Not Vested (#) (g)	Market Value of Shares or Units of Stock That Have Not Vested ($) (h)	Equity Incentive Plan Awards: Number of Unearned Shares, Units or Other Rights That Have Not Vested (#) (i)	Equity Incentive Plan Awards: Market or Payout Value of Unearned Shares, Units or Other Rights That Have Not Vested (#) (j)
Leonard Mazur	220,000	—	—	$ 6.75	9/12/24	—	—	—	—
Leonard Mazur	—	40,000	—	$ 3.45	9/13/27	—	—	—	—
Myron Holubiak	26,667	—	—	$ 8.10	10/01/25	—	—	—	—
Myron Holubiak	—	40,000	—	$ 3.45	9/13/27	—	—	—	—
Jaime Bartushak	18,771	29,496	—	$ 10.50	7/06/26	—	—	—	—
Jaime Bartushak	—	25,000	—	$ 3.45	9/13/27	—	—	—	—

Employment Agreements

Leonard Mazur

On October 19, 2017, the Company and Mr. Leonard L. Mazur, the Company's Secretary and the Executive Chairman of the Company's Board of Directors, entered into an Amended and Restated Employment Agreement with the following terms.

Compensation and Benefits. In exchange for his services with the Company, Mr. Mazur will receive an annual salary of $250,000 and will be eligible for an annual bonus of up to fifty percent (50%) of his annual salary. Mr. Mazur's bonus will be based on his attainment of certain financial, clinical development and business milestones as established annually by the Board. Mr. Mazur will also be entitled to participate in any benefit plans that the Company may from time to time establish and have in effect for all or most of its senior executives.

Term and Termination. The Employment Agreement has a three-year initial term ending on October 19, 2020 that will automatically renew for additional one-year terms unless terminated by the Company or by Mr. Mazur. If the Company terminates Mr. Mazur's employment for Cause, Mr. Mazur will be entitled to receive only the accrued compensation due to him as of the date of such termination. If Mr. Mazur resigns without Good Reason, he will be entitled only to payment of his accrued compensation as of such date. If the Company terminates Mr. Mazur's employment due to his Disability, he will continue to receive his full salary, subject to certain adjustments that may apply, for up to ninety (90) consecutive days or one hundred eighty (180) days in the aggregate during any consecutive twelve (12) month period.

If the Company terminates Mr. Mazur's employment without Cause or Mr. Mazur resigns for Good Reason, then conditioned upon Mr. Mazur executing a release following such termination, Mr. Mazur will continue to receive his annual salary and certain benefits for a period of twelve (12) months following the effective date of the termination of his employment. In addition, the portion of Mr. Mazur's unvested options to purchase shares of the Company's common stock that would have vested at the next immediate vesting event following his termination date will vest and become immediately exercisable upon his termination date. In the event Mr. Mazur is terminated under either of these circumstances within ninety (90) days prior to a Change of Control or within two (2) years following a Change of Control, Mr. Mazur will receive a lump sum payment for eighteen (18) months' salary, continue to receive benefits for a period of eighteen (18) months, and all of Mr. Mazur's unvested Company stock options will vest and become immediately exercisable.

Appointment to Board of Directors. In connection with Mr. Mazur's employment, the Company agrees to use its best efforts to cause Mr. Mazur to be elected as a member of the Board and to include him in management's slate of nominees for election to the Board at every stockholders meeting during the term of the Employment Agreement at which Mr. Mazur's term as a director would otherwise expire. In addition, Mr. Mazur agrees to accept election, and to serve during the term of the Employment Agreement, as a member of the Board without any compensation therefore other than as specified in the Employment Agreement.

Myron Holubiak

On March 30, 2016, the Company entered into an employment agreement ("Holubiak Employment Agreement") with Myron Holubiak pursuant to which Mr. Holubiak will serve as the Company's Chief Executive Officer for a term of 3 years, which term will automatically be extended for additional one year periods unless earlier terminated ("Term"). In consideration for Mr. Holubiak's services, the Company shall pay to Mr. Holubiak (i) an annual base salary equal to $450,000, (ii) a discretionary bonus on each anniversary of the effective date during the Term in an amount up to 50% of Mr. Holubiak's then current base salary based on the attainment of certain financial, clinical development and business milestones as established annually by the Company's Board of Directors and (iii) an incentive bonus based upon Market Capitalization (as defined in the Holubiak Employment Agreement) of the Company. Upon termination of Mr. Holubiak's employment with the Company, under certain circumstances, Mr. Holubiak shall be entitled to receive certain severance as described in the Holubiak Employment Agreement.

Jaime Bartushak

One November 27, 2017 the Company's Board of Directors appointed Jaime Bartushak to serve as the Chief Financial Officer and Principal Financial Officer of the Company and entered into an employment agreement with Mr. Bartushak, pursuant to which he serves on at at-will basis. In consideration for his services, the Company shall pay to Mr. Bartushak (i) an annual base salary equal to $250,000, and (ii) a discretionary annual bonus in an amount up to 40% of his then current base salary. Upon termination of Mr. Bartushak' s employment with the Company, under certain circumstances, he shall be entitled to receive certain severance as described in the agreement.

TRANSACTIONS WITH RELATED PERSONS

Related Party Transactions

Our headquarters were located in the office space of Ischemix, LLC ("Ischemix"), a company majority-owned by Dr. Geoffrey Clark and Dr. Reinier Beeuwkes until March 30, 2016. Although Dr. Clark and Dr. Beeuwkes resigned as officers and directors of the Company effective as of September 12, 2014, the Company had an oral agreement with Ischemix to continue to maintain its headquarters in the office spare of Ischemix. The Company was not required to pay for use of the space.

As of September 30, 2016, the Company owes $27,637 to Ischemix LLC for expenses paid on the Company's behalf and services performed by Ischemix. Ischemix is owned by Reinier Beeuwkes and Geoffrey Clark who were both officers and directors, as well as principal stockholders of the Company. Reinier Beeuwkes and Geoffrey Clark have resigned as both officers and directors effective September 12, 2014.

In November 2011, we entered into an exclusive license agreement with Prenzamax LLC ("Prenzamax"), pursuant to which we granted to Prenzamax a license for sales of Suprenza in the U.S. Prenzamax's performance of this agreement is guaranteed by Akrimax LLC ("Akrimax"), a specialty pharmaceuticals sales and marketing company. The exclusive license agreement provides that all of the sales and marketing expenses will be incurred and borne by Prenzamax. Both we and Prenzamax will equally share the expenses related to FDA establishment fees, product fees and post-marketing studies and the resulting earnings will be shared equally by us and Prenzamax. The co-founder and Vice Chairman of Akrimax is Leonard Mazur, our Executive Chairman of the Board of Directors. On July 1, 2016, the Company announced that it notified Prenzamax that it was discontinuing Suprenza.

In May 2014, Citius sold Membership Interests that converted to 200,000 shares of Common Stock to Leonard Mazur for an aggregate purchase price of $50,000.

Between July 12, 2010 and March 25, 2013, Citius issued convertible promissory notes in the aggregate principal amount of $1,685,000, including $850,000 to Geoffrey Clark and $835,000 to Reinier Beeuwkes. On July 31, 2014, the note holders demanded conversion of the outstanding $1,685,000 notes and accrued interest of $151,813 into 3,061,355 shares of Common Stock at a conversion price of $0.60 per share.

On November 19, 2013, Citius issued two promissory notes, each in the principal amount of $300,000, to Geoffrey Clark and Reinier Beeuwkes, respectively. On December 31, 2014, the note holders requested conversion of $600,000 in notes and accrued interest of $33,333 into 1,055,554 shares of Common Stock at a conversion price of $0.60 per share, which is the same price that the Company sold Units for in the September 2014 Private Placement.

Effective as of September 1, 2014, the Company entered into a consulting agreement (the "Consulting Agreement") with Neeta Wadekar, a stockholder of the Company. Pursuant to the terms of the Consulting Agreement, Mrs. Wadekar shall receive $4,000 per month and shall: (i) maintain and manage the Company's accounts including, but not limited to, accounts payable and accounts receivable, (ii) prepare bank reconciliations, (iii) assist with the preparation of quarterly and annual financial statements to be filed with the SEC and (iv) assist with the preparation of filings required by the SEC including, but not limited to, registration statements, current reports and proxy statement. Consulting expenses pursuant to the Consulting Agreement for the years ended September 30, 2016 and 2015 and the nine months ended September 30, 2014 were $48,000, $48,000 and $4,000, respectively.

On March 30, 2016, the Company 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 the 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. Our Chairman of the Board, Leonard Mazur, and our Chief Executive Officer, Myron Holubiak, were co-founders and significant shareholders in LMB. In connection with the acquisition of LMB, our Chairman purchased an additional 5,000,000 shares of the Company for a purchase price of $3,000,000.

The Company entered into three-year employment agreements with Leonard Mazur and Myron Holubiak and granted options to certain of our Directors as more fully described, in all cases, in our Proxy Statement.

The Company executed demand promissory notes in favor of Leonard Mazur, Chairman of the Board, on September 7, 2016 in the principal amount of $500,000, on October 20, 2016 in the principal amount of $500,000, on December 9, 2016 in the principal amount of $50,000 and on December 14, 2016 in the principal amount of $100,000 (collectively, the "Notes"). The Notes bear interest at the "Prime Rate" as published in the Wall Street Journal on the last day of the month plus 1%.

Review, Approval or Ratification of Transactions with Related Persons

We intend to adopt a written related person transactions policy that our executive officers, directors, nominees for election as a director, beneficial owners of more than 5% of our Common Stock, and any members of the immediate family of and any entity affiliated with any of the foregoing persons, are not permitted to enter into a material related person transaction with us without the review and approval of our audit committee, or a committee composed solely of independent directors in the event it is inappropriate for our audit committee to review such transaction due to a conflict of interest. We expect the policy to provide that any request for us to enter into a transaction with an executive officer, director, nominee for election as a director, beneficial owner of more than 5% of our Common Stock or with any of their immediate family members or affiliates, in which the amount involved exceeds $120,000 will be presented to our audit committee for review, consideration and approval. In approving or rejecting any such proposal, we expect that our audit committee will consider the relevant facts and circumstances available and deemed relevant to the audit committee, including, but not limited to, whether the transaction is on terms no less favorable than terms generally available to an unaffiliated third party under the same or similar circumstances and the extent of the related person's interest in the transaction.

Although we have not had a written policy for the review and approval of transactions with related persons, our board of directors has historically reviewed and approved any transaction where a director or officer had a financial interest, including all of the transactions described above. Prior to approving such a transaction, the material facts as to a director's or officer's relationship or interest as to the agreement or transaction were disclosed to our board of directors. Our board of directors would take this information into account when evaluating the transaction and in determining whether such transaction was fair to us and in the best interest of all of our stockholders.

SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT

The following table shows the amount of our common stock beneficially owned as of January 24, 2018 by (i) each person or group as those terms are used in Section 13(d)(3) of the Securities Exchange Act of 1934, as amended (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	563,249(4)	5.62%
Leonard Mazur	4,450,216(5)	40.92%
Jaime Bartushak	84,487(6)	*
Suren Dutia	26,667(7)	*
Dr. William Kane	25,405(8)	*
Howard Safir	25,405(8)	*
Carol Webb	25,405(8)	*
Eugene Holuka	15,749(9)	*
All executive officers and directors as a group (8 people)	**5,216,583**	47.15%
Other 5% holders		
Dr. Reinier Beeuwkes	606,991(10)	6.06%
Geoffrey C. Clark	603,413(11)	6.03%
Citius Special Purpose Fund, LLC	596,390(12)	5.80%
Craig Drill Capital, L.P.	521,716(13)	5.15%

* Less than 1%.

(1) The address for our officers and directors is c/o of the Company, 11 Commerce Drive, 1st 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 January 24, 2018 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 9,975,518 shares of common stock issued and outstanding at January 24, 2018.

(4) Myron Holubiak holds (i) 516,967 shares of common stock, (ii) an option to purchase 26,667 shares of common stock at an exercise price of $8.10 per share and (iii) a warrant to purchase 19,615 shares of common stock at an exercise price of $6.15 per share.

(5) Leonard Mazur holds (i) 3,550,836 shares of common stock, (ii) an option to purchase 220,000 shares of common stock at an exercise price of $6.75 per share and (iii) warrants to purchase an aggregate of 679,380 shares of common stock at a weighted average exercise price of $4.815 per share.

(6) Jaime Bartushak holds (i) 60,353 shares of common stock and (ii) an option to purchase 24,134 shares of common stock at an exercise price of $10.50 per share.

(7) Suren Dutia holds an option to purchase 26,667 shares of common stock at an exercise price of $8.10 per share.

(8) Dr. William Kane, Howard Safir and Carol Webb each hold an option to purchase 12,071 shares of common stock at an exercise price of $.015 per share and a separate option to purchase 13,334 shares of common stock at an exercise price of $12.00 per share.

(9) Eugene Holuka holds an option to purchase 2,415 shares of common stock at an exercise price of $.015 per share and a separate option to purchase 13,334 shares of common stock at an exercise price of $12.00 per share.

(10) Consists of 570,628 shares of common stock and warrants to purchase 36,363 shares of common stock at an exercise price of $4.125 per share. Reinier Beeuwkes resigned as an executive officer and director upon completion of the Reverse Acquisition on September 12, 2014. His address is 1360 Monument Street, Concord MA 01742.

(11) Beneficial ownership consists of 567,050 shares of common stock and warrants to purchase 36,363 shares of common stock at an exercise price of $4.125 per share. Geoffrey Clark is the trustee of Geoffrey C. Clark Revocable Trust, and in such capacity he is deemed to hold voting and dispositive power over the 495,471 shares of common stock held by such entity. Geoffrey Clark resigned as an executive officer and director upon completion of the Reverse Acquisition on September 12, 2014. His address is 152 Middle Street, Portsmouth NH 03801.

(12) Consists of 281,698 shares of common stock and warrants to purchase 314,692 shares of common stock at an exercise price of $9.00 per share. Joe McGowan is the control person, and in such capacity he is deemed to hold voting and dispositive power over the securities held by such entity. His address is 90 Park Avenue, 17th Floor, New York, NY 10046.

(13) Consists of 374,012 shares of common stock and warrants to purchase 147,704 shares of common stock at an exercise price of $4.63 per share. The address is 724 Fifth Avenue, 9th Floor, New York, New York 10019.

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 January 24, 2018. 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.

The selling stockholders named below, or their respective successors, including transferees, may from time to time sell or otherwise dispose of, pursuant to this prospectus, all, some or none of their shares of our common stock being registered hereby. See the section entitled "Plan of Distribution" beginning on page 58.

Beneficial ownership is determined in accordance with Rule 13d-3(d) promulgated by the SEC under the Securities Exchange Act of 1934, or the Exchange Act. The percentage of shares beneficially owned prior to the offering is based on 9,975,518 shares of our common stock outstanding as of January 24, 2018.

Selling Stockholder	Number of Shares of Common Stock Beneficially Owned Before Any Sale	% of Class	Number of Shares of Common Stock Offered	Shares of Common Stock Beneficially Owned After Sale of All Shares of Common Stock Offered Pursuant to this Prospectus	
				Number of Shares	% of Class
Craig Drill Capital, L.P.(1)	521,716	5.15%	147,704	374,012	3.75%
Craig Drill Capital, II L.P.(2)	229,302	2.28%	65,402	163,900	1.64%
Empery Asset Master, Ltd.(3)	147,858	1.47%	62,174	85,684	*
Empery Tax Efficient, LP(4)	31,953	*	13,436	18,517	*
Empery Tax Efficient II, LP(5)	73,586	*	30,943	42,643	*
Intracoastal Capital, LLC(6)	153,935	1.53%	79,915	74,020	*
Leonard L. Mazur(7)	4,450,216	40.92%	106,553	4,343,663	40.34%
Noam Rubinstein(8)(13)	110,732	1.10%	55,732	55,000	*
Sabby Volatility Warrant Master Fund, Ltd.(9)	308,471	3.06%	106,553	201,918	2.02%
Michael Vasinkevich(10)(13)	57,808	*	57,808	-	*
Mark Viklund(11)(13)	2,689	*	2,689	-	*
Charles Worthman(12)(13)	896	*	896	-	*
TOTAL	**6,089,162**	**52.96%**	**729,805**	**5,359,357**	**49.77%**

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

(1) Includes warrants to purchase 147,704 shares of common stock.
(2) Includes warrants to purchase 65,402 shares of common stock.
(3) Includes warrants to purchase 62,174 shares of common stock. Empery Asset Management LP, the authorized agent of Empery Asset Master, Ltd ("EAM"), has discretionary authority to vote and dispose of the shares held by EAM and may be deemed to be the beneficial owner of these shares. Martin Hoe and Ryan Lane, in their capacity as investment managers of Empery Asset Management LP, may also be deemed to have investment discretion and voting power over the shares held by EAM. EAM, Mr. Hoe and Mr. Lane each disclaim any beneficial ownership of these shares.
(4) Includes warrants to purchase 13,436 shares of common stock. Empery Asset Management LP, the authorized agent of Empery Tax Efficient, LP ("ETE"), has discretionary authority to vote and dispose of the shares held by ETE and may be deemed to be the beneficial owner of these shares. Martin Hoe and Ryan Lane, in their capacity as investment managers of Empery Asset Management LP, may also be deemed to have investment discretion and voting power over the shares held by ETE. ETE, Mr. Hoe and Mr. Lane each disclaim any beneficia1 ownership of these shares.
(5) Includes warrants to purchase 30,943 shares of common stock. Empery Asset Management LP, the authorized agent of Empery Tax Efficient II, LP ("ETE II"), has discretionary authority to vote and dispose of the shares held by ETE II and may be deemed to be the beneficial owner of these shares. Martin Hoe and Ryan Lane, in their capacity as investment managers of Empery Asset Management LP, may also be deemed to have investment discretion and voting power over the shares held by ETE II. ETE II, Mr. Hoe and Mr. Lane each disclaim any beneficia1 ownership of these shares.

(6) Includes warrants to purchase 79,915 shares of common stock. Mitchell P. Kopin and Daniel B. Asher, each mangers of Intracoastal Capital LLC ("Intracoastal"), have discretionary authority to vote and dispose of the shares held by Intracoastal and may be deemed to be the beneficial owner of these shares. Mr. Asher, the manager of Intracoastal, is also a control person of a broker-dealer and therefore may be deemed to be an affiliate of a broker-dealer. Intracoastal acquired the shares being registered hereunder in the ordinary course of business, and at the time of the acquisition of its shares and warrants, did not have any arrangements or understandings with any person to distribute such securities.
(7) Includes (i) 3,550,836 shares of common stock, (ii) an option to purchase 220,000 shares of common stock at an exercise price of $6.75 per share and (iii) warrants to purchase an aggregate of 679,380 shares of common stock at a weighted average exercise price of $4.815 per share.
(8) Includes warrants to purchase 55,732 shares of common stock.
(9) Includes warrants to purchase 106,553 shares of common stock. Sabby Management, LLC, the investment manager of Sabby Volatility Warrant Master Fund, Ltd. ("Sabby Volatility"), has discretionary authority to vote and dispose of the shares held by Sabby Volatility and may be deemed to be the beneficial owner of these shares. Hal Mintz, in his capacity as manager of Sabby Management, LLC, may also be deemed to have investment discretion and voting power over the shares held by Sabby Volatility. Mr. Mintz disclaims any beneficia1 ownership of these shares.
(10) Consists of warrants to purchase 57,808 shares of common stock.
(11) Consists of warrants to purchase 2,689 shares of common stock.
(12) Consists of warrants to purchase 896 shares of common stock.
(13) The selling stockholder is an affiliate of a registered broker-dealer.

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.

Leonard Mazur

Leonard Mazur is the Executive Chairman of our Board of Directors. See his biographical information on page 47 of this prospectus.

In May 2014, we sold membership interests that converted to 13,333 shares of our common stock to Mr. Mazur for an aggregate purchase price of $50,000.

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 Leonard Mazur which is described on page 52 of this prospectus.

Our Board of Directors authorized revolving demand promissory notes with Leonard Mazur in an aggregate principal amount of up to $2,500,000 that accrue interest at the prime rate plus 1%. On September 7, 2016, the Company issued a $500,000 note. 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 an S-1 registration statement 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 Leonard 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. Leonard Mazur purchase 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.

PLAN OF DISTRIBUTION

The selling stockholders, which as used herein includes donees, pledgees, assignees, 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 or assignment, 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 December 2017 private placement owns any warrants or shares of common stock issuable upon exercise of the warrants.

Once sold under the registration statement of which this prospectus is a part, the shares of our common stock will be freely tradable in the hands of persons other than our affiliates.

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 9,975,518 shares were issued and outstanding as of January 24, 2018, and 10,000,000 shares of preferred stock, none of which are issued and outstanding. Our preferred stock and/or Common Stock may be issued from time to time without prior approval by our stockholders. Our preferred stock and/or Common Stock may be issued for such consideration as may be fixed from time to time by our Board of Directors. Our Board of Directors may issue such shares of our preferred stock and/or Common Stock in one or more series, with such voting powers, designations, preferences and rights or qualifications, limitations or restrictions thereof as shall be stated in the resolution or resolutions.

Common Stock

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

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

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

Preferred Stock

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

Options

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

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

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

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

The 2014 Plan provides that upon the effectiveness of a "sale event" as defined in the 2014 Plan, except as otherwise provided by the Administrator in the award agreement, all stock options, stock appreciation rights and other awards will be assumed or continued by the successor entity and adjusted accordingly to take into account the impact of the transaction. To the extent, however, that the parties to such sale event do not agree that all stock options, stock appreciation rights or any other awards shall be assumed or continued, then such stock options and stock appreciation rights shall become fully exercisable and the restrictions and conditions on all such other awards with time-based conditions will automatically be deemed waived. Awards with conditions and restrictions relating to the attainment of performance goals may become vested and non-forfeitable in connection with a sale event in the Administrator's discretion. In addition, in the case of a sale event in which our stockholders will receive cash consideration, we may make or provide for a cash payment to participants holding options and stock appreciation rights equal to the difference between the per share cash consideration and the exercise price of the options or stock appreciation rights in exchange for the cancellation thereto.

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 January 24, 2018, we have 113 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 financial statements of Citius Pharmaceuticals, Inc. incorporated by reference into this prospectus at September 30, 2017 and 2016, and for each of the three years in the period ended September 30, 2017, have been audited by Wolf & Company, P.C., independent registered public accounting firm, as set forth in their report thereon appearing elsewhere herein, and are included in reliance upon such report given on the authority of such firm as experts in accounting and auditing.

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

INCORPORATION OF 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." The document we are incorporating by reference is:

- our Annual Report on Form 10-K for the fiscal year ended September 30, 2017, filed with the SEC on December 13, 2017;
- our definitive proxy statement on schedule 14A for our 2018 annual meeting filed with the SEC on December 13, 2017; and
- our Current Reports on Form 8-K filed with the SEC on October 10, October 24, October 31, November 7 (two Forms 8-K), November 9, December 1 (except Item 7.01) and December 19, 2017.

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

We will furnish without charge to you, on written or oral request, a copy of the Annual 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.

DISCLOSURE OF COMMISSION POSITION ON INDEMNIFICATION FOR SECURITIES ACT LIABILITY

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers or persons controlling the registrant pursuant to the foregoing provisions, the registrant has been informed that in the opinion of the SEC such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable.