

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

POST-EFFECTIVE AMENDMENT NO. 2
TO FORM S-1 ON FORM S-3REGISTRATION STATEMENT
UNDER THE SECURITIES ACT OF 1933CITIUS PHARMACEUTICALS, INC.
(Exact name of registrant as specified in its charter)

Nevada

(State or other jurisdiction of
incorporation or organization)

27-3425913

(I.R.S. Employer
Identification Number)11 Commerce Drive, First Floor
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(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

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Telephone: (919) 781-4000**Approximate date of commencement of proposed sale to the public:** From time to time after the effective date of this Registration Statement.If the only securities being registered on this Form are being offered pursuant to dividend or interest reinvestment plans, please check the following box. If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, other than securities offered only in connection with dividend or interest reinvestment plans, check the following box. If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. If this Form is a registration statement pursuant to General Instruction I.D. or a post-effective amendment thereto that shall become effective upon filing with the Commission pursuant to Rule 462(e) under the Securities Act, check the following box. If this Form is a post-effective amendment filed pursuant to General Instruction I.D. filed to register additional securities or additional classes of securities pursuant to Rule 413(b) under the Securities Act, check the following box.

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer", "accelerated filer", "smaller reporting company", and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer Accelerated filer Non-accelerated filer Smaller reporting company Emerging growth company If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 7(a)(2)(B) of the Securities Act. **The Registrant hereby amends this Registration Statement on such date or dates as may be necessary to delay its effective date until the Registrant shall file a further amendment which specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act or until the Registration Statement shall become effective on such date as the Securities and Exchange Commission, acting pursuant to said Section 8(a), may determine.**

EXPLANATORY NOTE

On May 12, 2017, we filed with the Securities and Exchange Commission, or the Commission, a registration statement on Form S-1 (File No. 333-217956), or the Registration Statement, which was amended by pre-effective amendments filed on July 3, 2017, July 13, 2017, July 24, 2017, and July 28, 2017, and by a post-effective amendment filed on January 12, 2018, to register the offer and sale of (i) 9,200,000 shares of common stock, \$0.001 par value per share, (ii) 92,000 warrants to purchase shares of common stock (the "Warrants"), (iii) the 9,200,000 shares of common stock underlying the Warrants, (iv) the underwriter warrants to purchase shares of common stock (the "Underwriter Warrants"), and (v) the 352,000 shares of common stock underlying the Underwriter Warrants. The Registration Statement was declared effective by the Commission on August 3, 2017. On August 8, 2017, we issued to investors an aggregate of 1,648,484 shares and Warrants to purchase up to an aggregate of 1,895,756 shares of common stock and issued Underwriter Warrants to purchase up to an aggregate of 65,940 shares of common stock. As of June 30, 2021, an aggregate of 272,767 Warrants had been exercised and Warrants to purchase up to 1,622,989 shares of common stock were outstanding. As of June 30, 2021, no Underwriter Warrants had been exercised.

This Post-Effective Amendment No. 2 to Form S-1 on Form S-3, or this Post-Effective Amendment, is being filed to (i) convert the Registration Statement to a registration statement on Form S-3 because we are eligible to use Form S-3, and (ii) maintain the registration of the 1,622,989 shares of common stock issuable upon exercise of the outstanding Warrants and the 65,940 shares of common stock issuable upon exercise of the Underwriter Warrants. All securities offered hereby are being offered on a delayed or continuous basis. We are not registering any additional securities under this Post-Effective Amendment. All filing fees payable in connection with the registration of these securities were previously paid by us in connection with the filing of the Registration Statement on Form S-1 prior to its effectiveness.

Registration of Common Stock Issuable Upon Exercise of the Warrants and Common Stock Issuable Upon Exercise of the Underwriter Warrants

This Post-Effective Amendment also contains an updated prospectus relating to (i) an aggregate of up to 1,622,989 shares of common stock issuable upon the exercise of the Warrants previously issued to investors on August 8, 2017, pursuant to a warrant agent agreement, dated as of August 3, 2017, between us and VStock Transfer, LLC, and (ii) the 65,940 shares of common stock issuable upon exercise of the Underwriter Warrants. This Post-Effective Amendment is being filed in compliance with Section 10(a)(3) of the Securities Act.

The information in this prospectus is not complete and may be changed. We may not sell these securities or accept an offer to buy these securities until the registration statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell these securities, and we are not soliciting an offer to buy these securities in any jurisdiction where the offer or sale is not permitted.

Subject to completion, dated July 2, 2021

PRELIMINARY PROSPECTUS



1,622,989 Shares of Common Stock Issuable upon Exercise of Warrants

65,940 Shares of Common Stock Issuable upon Exercise of Underwriter Warrants

This prospectus relates to the issuance of up to 1,622,989 shares of our common stock, \$0.001 par value per share, issuable upon the exercise of outstanding warrants, at an exercise price of \$4.125 per share, that were issued by us to investors on August 8, 2017 (referred to as the Warrants), pursuant to a master warrant agent agreement, dated as of August 3, 2017, or the Warrant Agreement, between us and VStock Transfer, LLC. The Warrants expire on August 2, 2022. This prospectus also relates to the issuance of 65,940 shares of common stock underlying the underwriter warrants issued by us on August 8, 2017 (referred to as the Underwriter Warrants), at an exercise price of \$4.5375 per share, all of which expire on August 2, 2022.

Investing in our securities involves a high degree of risk. See “Risk Factors” on page 8 of this prospectus to read about factors you should consider before investing in our securities. See “Where You Can Find More Information” and “Incorporation of Documents by Reference” for more information.

Our common stock is listed on the Nasdaq Capital Market under the symbol “CTXR”. The last reported sale price of our common stock on June 29, 2021 was \$3.51 per share. We recommend that you obtain current market quotations for our common stock prior to making an investment decision.

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

The date of this prospectus is _____, 2021

TABLE OF CONTENTS

About this Prospectus	i
Special Note Regarding Forward-Looking Statements and Industry Data	ii
The Company	1
The Offering	7
Risk Factors	8
Use of Proceeds	9
Plan of Distribution	10
Description of Our Capital Stock	10
Legal Matters	12
Experts	12
Where You Can Find Additional Information	12
Incorporation of Documents by Reference	13

ABOUT THIS PROSPECTUS

This prospectus is part of a post-effective amendment to a registration statement, originally on Form S-1 and now on Form S-3, that we filed with the Securities and Exchange Commission, or the SEC, using a “shelf” registration or continuous offering process. This prospectus relates to the offer and sale of up to 1,622,989 shares of our common stock to be offered from time to time upon exercise of the Warrants and up to 65,940 shares of our common stock to be offered from time to time upon exercise of the Underwriter Warrants.

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

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

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

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.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS AND INDUSTRY DATA

This prospectus and the documents incorporated by reference into this prospectus, contain 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. The statements contained in this prospectus and the documents incorporated by reference into this prospectus that are not purely historical are forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, or Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, or Exchange Act.

Forward-looking statements in this prospectus include, but are not limited to, statements about:

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

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 or incorporated by reference herein. 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 incorporate by reference in this prospectus and have filed with the SEC as exhibits to the registration statement, of which this prospectus is a part, 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 or incorporated herein by reference represent our views as of the date of this prospectus or the document incorporated by reference herein. We anticipate that subsequent events and developments will cause our views to change. However, while we may elect to update these forward-looking statements at some point in the future, we have no current

intention of doing so except to the extent required by applicable law. You should therefore not rely on these forward-looking statements as representing our views as of any date subsequent to the date of this prospectus.

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

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

THE 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 with a focus on anti-infective products in adjunct cancer care, unique prescription products and mesenchymal stem cell therapy. Our goal generally is to achieve leading market positions by providing therapeutic products that address unmet medical needs yet have a lower development risk than usually is associated with new chemical entities. New formulations of previously approved drugs with substantial existing safety and efficacy data are a core focus. We seek to reduce development and clinical risks associated with drug development, yet still focus on innovative applications. Our strategy centers on products that have intellectual property and regulatory exclusivity protection, while providing competitive advantages over other existing therapeutic approaches.

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 the Mino-Lok treatment. Thus, it has been demonstrated that the amount of either minocycline or edetate that leaks into the serum is very low or none at all.

Phase 2b Results

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

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

The main purpose of the study was to show that Mino-Lok therapy was at least as effective as the removal and replacement of CVCs when CRBSIs are present, and that the safety was better, that is, the complications of removing an infected catheter and replacing with a new one could be avoided. In addition to having a 100% efficacy rate with all CVCs being salvaged, Mino-Lok therapy had no significant adverse events (“SAEs”), compared to an 18% SAE rate in the matched cohort where patients had the infected CVCs removed and replaced with a fresh catheter. There were no overall complication rates in the Mino-Lok arm group compared to 11 patients with events (18%) in the control group. These events included bacterial relapse (5%) at four weeks post-intervention, and a number of complications associated with mechanical manipulation in the removal or replacement procedure for the catheter (10%) or development of deep-seated infections such as septic thrombophlebitis and osteomyelitis (8%). As footnoted, six patients had more than one complication in the control arm group.

Parameter	Mino-Lok Arm		Control Arm	
	N	(%)	N	(%)
Patients	30	(100)%	60	(100)%
Cancer type				
- Hematologic	20	(67)	48	(80)
- Solid tumor	10	(33)	12	(20)
ICU Admission	4	(13)	4	(7)

Mech. Ventilator	3	(10)	0	(0)
Bacteremia				
- Gram+	17	(57)*	32	(53)
- Gram-	14	(47)*	28	(47)
Neutropenia (<500)	19	(63)	36	(60)
Microbiologic Eradication	30	(100)	60	(100)
- Relapse	0	(0)	3	(5)
Complications	0	(0)	8	(13)
SAEs related to R&R	0	(0)	6	(10)
Overall Complication Rate	0	(0)%	11**	(18)%

* 1 polymicrobial patient had a Gram+ and a Gram- organism cultured

** 6 patients had > 1 complication

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

Phase 3 Trial

In November 2016, the Company initiated site recruitment for Phase 3 clinical trials. From initiation through the first quarter of 2017, the Company received input from several sites related to the control arm as being less than standard-of-care for some of the respective institutions. The Company worked closely with the U.S. Food and Drug Administration (“FDA”) with respect to the design of the Phase 3 trial and received feedback on August 17, 2017. The FDA stated that they recognized that there is an unmet medical need in salvaging infected catheters and agreed that an open label, superiority design would address the Company’s concerns and would be acceptable to meet the requirements of a new drug application. The Company amended the Phase 3 study design to remove the saline and heparin placebo control arm and to use an active control arm that conforms with today’s current standard-of-care. Patient enrollment commenced in February 2018.

The Mino-Lok Phase 3 trial was originally planned to enroll 700 patients in 50 participating institutions, all located in the U.S. There will be interim analyses at both the 50% and 75% points of the trial as measured by the number of patients treated. As of March 31, 2021, there are 25 active sites currently enrolling patients including such academic centers as MDACC, Henry Ford Health Center, Georgetown University Medical Center, and others. There is one additional medical center in startup mode. There are no other remaining sites in feasibility.

In September 2019, the Company announced that the FDA agreed to a new primary efficacy endpoint of “time to catheter failure” in comparing Mino-Lok to the antibiotic lock control arm. This change in the trial design reduced the required patient sample size of the trial from 700 subjects to approximately 144 available subjects to achieve the pre-specified 92 catheter failure events needed to conclude the trial. Additionally, the Company submitted a response to the FDA that it will implement this change in the primary endpoint and expected it to result in less than 150 subjects needed in its Phase 3 trial. The new primary endpoints require that the time to catheter failure be at least 38 days for Mino-Lok versus 21 days for the standard of care antibiotic locks.

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

In October 2019, the Company announced that the Phase 3 trial had reached the 40% completion triggering an interim futility analysis by the data monitoring committee (the “DMC”). The DMC is an independent panel of experts that review progress regarding the safety and efficacy of drugs in clinical trials, and to determine if the trial may be futile in achieving its endpoints or if the trial should be modified in any way.

In December 2019, the DMC convened and recommended that the trial continue with no changes because the analysis showed a positive outcome, as it met the prespecified interim futility analysis criteria.

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

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

In September 2020, we announced that another DMC meeting was held to review the data being generated and analyzed in the Mino-Lok Phase 3 trial based on progress to date, and to make recommendations to us as to any action that may be necessary regarding the study. After reviewing these data, the DMC members stated that they did not find any safety signals; and they also recommended continuing the trial without any modifications. The DMC further conducted an *ad hoc* meeting and agreed with the Company that a 75% interim analysis be conducted as planned in which superior efficacy is evaluated. Due to the COVID-19 pandemic, the interim analysis will be performed at the 65% threshold. To counter the impact of COVID-19, we have aggressively pursued outreach programs with webinars and other remote communications, and were able to add randomized patients bringing us closer to the number of events for the “superiority” analysis. We scheduled a meeting with the DMC for late June 2021.

On July 1, 2021, we announced that the DMC recommended proceeding with the trial as planned. The DMC did not identify any safety concerns and also recommended no modifications to the protocol-defined sample size or power to achieve the primary endpoint. We expect to file a New Drug Application, or NDA, in 2022.

In September 2020, the Company announced that the three registration batches for all components of Mino Lok were manufactured and that clinical sites were resupplied with registration product.

In November 2020, the Company announced that the three components of Mino-Lok, minocycline, disodium edetate (“EDTA”), and ethanol, were superior to EDTA and ethanol in their ability to eradicate resistant staphylococcal biofilms.

Fast Track Designation

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

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

Mino-Lok International Study

In October 2017, data from an international study on Mino-Lok was presented at the Infectious Disease Conference (“ID Week”) in San Diego, California. The 44-patient study was conducted in Brazil, Lebanon, and Japan and showed Mino-Lok therapy was an effective intervention to salvage long-term, infected CVCs in CRBSIs in patients who had cancer with limited vascular access. This study showed 95% effectiveness for Mino-Lok therapy in achieving microbiological eradication of the CVCs as compared to 83% for the control. The single failure in the Mino-Lok arm was due to a patient with *Burkholderia cepacia* that was resistant to all antibiotics tested.

Stability Patent Application for Mino-Lok

In October 2018, the U.S. Patent and Trademark Office (“USPTO”) issued U.S. Patent No. 10,086,114, entitled “Antimicrobial Solutions with Enhanced Stability.” This invention overcomes limitations in mixing antimicrobial solutions in which components have precipitated because of physical and/or chemical factors, thus limiting the stability of the post-mix solutions. The scientists and technologists at MDACC have been able to improve the stability of the post-mixed solutions through adjustments of the post-mixed pH of the solution. This may allow for longer storage time of the ready-to-use solution. Citius holds the exclusive worldwide license which provides access to this patented technology for development and commercialization of Mino-Lok.

On October 9, 2019, the European Patent Office (“EPO”) granted European Patent No. 3370794, entitled “Antimicrobial Solutions with Enhanced Stability.” The grant of this European patent strengthens the intellectual property protection for Mino-Lok through November of 2036. This invention overcomes limitations in mixing antimicrobial solutions, in which components have precipitated because of physical and/or chemical factors, thus limiting the stability of the post-mix solutions. The scientists and technologists at MDACC have been able to improve the stability of the post-mixed solutions through adjustments of the post-mixed pH of the solution. This may allow for longer storage time of the ready-to-use solution.

Mino-Wrap

On January 2, 2019, we entered into a patent and technology license agreement with the Board of Regents of the University of Texas System on behalf of MDACC, whereby we in-licensed exclusive worldwide rights to the patented technology for any and all uses relating to breast implants, specifically the Mino-Wrap technology. This includes rights to U.S. Patent No. 9,849,217, which was issued on December 16, 2017. We intend to develop Mino-Wrap as a liquefying, gel-based wrap containing minocycline and rifampin for the reduction of infections associated with breast implants following breast reconstructive surgeries. We are required to use commercially reasonable efforts to commercialize Mino-Wrap under several regulatory scenarios and achieve milestones associated with these regulatory options leading to an approval from the FDA. Mino-Wrap will require pre-clinical development prior to any regulatory pathway. In July 2019, we announced that we intend to pursue the FDA’s Investigational New Drug (“IND”) regulatory pathway for the development of Mino-Wrap. On August 4, 2020, we announced that we had submitted a briefing package to the FDA for a pre-IND consultation on Mino-Wrap. In December 2020, we reported the FDA response to the briefing package and commented that the FDA was in general agreement with our planned pre-clinical program and gave further guidance on our clinical plans. Following this guidance from the FDA, we are conducting *in vitro* experiments and product characterization studies for Mino-Wrap. Animal studies are underway.

Halo-Lido

Overview

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

Development of Hemorrhoids Drugs

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

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

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

Development Activities to Date

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

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

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

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

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

In June and July 2016, we engaged the Dominion Group, a leading provider of healthcare and pharmaceutical marketing research services. The primary market research was conducted to better understand the symptoms that are most bothersome to patients 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's impact on quality of life. The results of this survey are able to help us develop patient reported outcome evaluation tools. These tools can be used in clinical trials to evaluate the patients' conditions and to assess the performance of the test articles.

In March 2018, we announced that we had selected a higher potency corticosteroid in our steroid/anesthetic topical formulation program for the treatment of hemorrhoids. The original topical preparation, which we referred to as Hydro-Lido or CITI-001, which was used in the Phase 2a study, was a combination of hydrocortisone acetate and lidocaine hydrochloride. The new formulation, CITI-002, which we refer to as Halo-Lido, combines lidocaine with the higher potency corticosteroid halobetasol propionate for symptomatic relief of the pain and discomfort of hemorrhoids.

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

The FDA guided us to develop a novel patient-reported outcome, or PRO, instrument to assess clinical outcomes and efficacy of Halo-Lido. The PRO is currently being reviewed by the FDA. Pending feedback from the FDA, we expect to file an Investigational New Drug application, or IND, with the FDA and anticipate beginning a Phase 2b clinical study, both in the fourth quarter of 2021.

NoveCite

Overview

In October 2020, we, through our subsidiary, NoveCite, signed an exclusive agreement with Novellus Therapeutics Limited ("Novellus") to license iPSC-derived mesenchymal stem cells (iMSCs). Under this worldwide exclusive license, we will be focused on developing cellular therapies. Specifically, we will seek to develop and commercialize the NoveCite mesenchymal stem cells ("NC-iMSCs") to treat acute respiratory conditions with a near term focus on ARDS associated with COVID-19.

NC-iMSCs are the next generation mesenchymal stem cell therapy. They are believed to be differentiated and superior to donor-derived MSCs. Human donor-derived MSCs are sourced from human bone marrow, adipose tissue, placenta, umbilical tissue, etc. and have significant challenges (e.g., variable donor and tissue sources, limited supply, low potency, inefficient and expensive manufacturing). NC-iMSCs overcome these challenges because they:

- Are more potent and secrete exponentially higher levels of immunomodulatory proteins;
- Have practically unlimited supply for high doses and repeat doses;
- Are from a single donor and clonal so they are economically produced at scale with consistent quality and potency, as well as being footprint free (compared to viral reprogramming methods); and
- Have a significantly higher expansion capability.

Several cell therapy companies using donor-derived MSC therapies in treating ARDS have demonstrated that MSCs reduce inflammation, enhance clearance of pathogens and stimulate tissue repair in the lungs. Almost all these positive results are from early clinical trials or under the emergency authorization program.

In December 2020, the Company announced interim data from a proof-of-concept large animal study of its NC-iMSC therapy for acute inflammatory respiratory conditions including COVID-19 related ARDS. The available results of NC-iMSC therapy in the study show improvement in critical parameters, such as improved oxygenation, less systemic shock, and reduced lung injury, compared to the control group. The study was conducted in a widely accepted large animal model.

The Company expects to complete additional pre-clinical studies throughout 2021 and anticipates filing an IND by the end of the second quarter of 2022.

Corporate History and Information

We were founded as Citius Pharmaceuticals, LLC, a Massachusetts limited liability company, on January 23, 2007. On September 12, 2014, Citius Pharmaceuticals, LLC entered into a Share Exchange and Reorganization Agreement, with Citius Pharmaceuticals, Inc. (formerly Trail One, Inc.), a publicly traded company incorporated under the laws of the State of Nevada. Citius Pharmaceuticals, LLC became a wholly-owned subsidiary of Citius. On March 30, 2016, Citius acquired Leonard-Meron Biosciences, Inc. (“LMB”) as a wholly-owned subsidiary. LMB was a pharmaceutical company focused on the development and commercialization of critical care products with a concentration on anti-infectives. On September 11, 2020, we formed NoveCite, Inc. (“NoveCite”), a Delaware corporation, of which we own 75% of the issued and outstanding capital stock.

Our principal executive offices are located at 11 Commerce Drive, First Floor, Cranford, New Jersey 07016 and our telephone number is (908) 967-6677.

THE OFFERING

Common stock offered by us	Up to 1,622,989 shares of our common stock upon the exercise of Warrants and up to 65,940 shares of common stock upon the exercise of Underwriter Warrants. The Warrants have an exercise price of \$4.125 per share and expire on August 2, 2022. The Underwriter Warrants have an exercise price of \$4.5375 per share and expire on August 2, 2022.
Common stock to be outstanding immediately after this offering	136,390,148 shares, assuming the exercise in full of all Warrants and Underwriter Warrants for cash.
Use of proceeds	We may receive up to a total of approximately \$6,994,033 in gross proceeds if all of the Warrants and Underwriter Warrants are exercised for cash. We have not allocated any proceeds of such exercises to any particular purpose. See “Use of Proceeds” on page 9 for more information.
Risk Factors	You should read the “Risk Factors” section of this prospectus on page 8 for a discussion of factors to consider carefully before deciding to invest in shares of our common stock.
Nasdaq Capital Market trading symbol	“CTXR”

The number of shares of our common stock that will be outstanding immediately after this offering assumes the exercise in full of all of the Warrants and Underwriter Warrants and is based on 134,701,219 shares of our common stock outstanding as of March 31, 2021 and excludes:

- warrants for 51,569,059 shares of our common stock, with a weighted average exercise price of \$1.672 per share (subsequent to March 31, 2021, an aggregate of 10,208,210 shares of our common stock were issued upon the exercise of warrants for aggregate proceeds of \$15,187,567);
- options to purchase an aggregate of 4,615,171 shares of our common stock issued to our officers, directors and non-employee consultants under our 2014, 2018, and 2020 Stock Incentive Plans, with a weighted average exercise price of \$2.133 per share (subsequent to March 31, 2021, an aggregate of 70,000 shares of our common stock were issued upon the exercise of options for aggregate proceeds of \$82,634); and
- 1,240,000 shares of common stock available for future grants under our 2020 Stock Incentive Plan (subsequent to March 31, 2021, we issued options for the purchase of up to 110,000 shares of our common stock at an exercise price of \$2.50 per share).

On May 24, 2021, our stockholders approved the Citius Pharmaceuticals, Inc. 2021 Omnibus Stock Incentive Plan, which authorizes us to grant up to 8,740,000 shares of common stock, which consists of 7,500,000 shares of common stock reserved for the 2021 Omnibus Stock Incentive Plan and the 1,240,000 shares that remained available under the 2020 Omnibus Stock Incentive Plan on May 24, 2021. Upon approval of the 2021 Omnibus Stock Incentive Plan, the 2020 Omnibus Stock Incentive Plan was terminated.

RISK FACTORS

Investing in our securities involves a high degree of risk. You should consider carefully the risks and uncertainties described in “Risk Factors” in our most recently filed Annual Report on Form 10-K filed with the SEC, in each case as these risk factors are amended or supplemented by subsequent Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, or Current Reports on Form 8-K that have been or will be incorporated by reference in this prospectus. The risks incorporated herein by reference are those which we believe are the material risks that we face. The occurrence of any of such risks may materially and adversely affect our business, financial condition, results of operations and future prospects. In such an event, the market price of our common stock could decline, and you could lose part or all of your investment.

USE OF PROCEEDS

We may receive up to a total of approximately \$6,994,033 in gross proceeds if all of the Warrants and Underwriter Warrants are exercised for cash. However, as we are unable

to predict the timing or amount of potential exercises of the Warrants or the Underwriter 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 and the Underwriter Warrants, the Warrants and the Underwriter Warrants are exercisable under certain circumstances on a cashless basis, and should a holder elect to exercise on a cashless basis we will not receive any proceeds from the sale of common stock issued upon such cashless exercise.

We will incur all costs associated with this prospectus and the registration statement of which it is a part.

PLAN OF DISTRIBUTION

All of the securities offered by this prospectus are being offered and sold directly by us, without an underwriter. The holders of the Warrants and Underwriter Warrants may purchase the shares of our common stock directly from us by exercising their outstanding Warrants and Underwriter Warrants.

DESCRIPTION OF OUR CAPITAL STOCK

The following description summarizes the material terms of our 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 articles of incorporation and our bylaws, and to the provisions of applicable Nevada law.

General

Our authorized capital stock consists of (i) 400,000,000 shares of common stock, par value \$0.001, of which 134,701,219 shares were issued and outstanding as of March 31, 2021, and 144,979,429 shares were issued and outstanding as of June 25, 2021, and (ii) 10,000,000 shares of preferred stock, par value \$0.001, 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.

Common Stock

We are authorized to issue 400,000,000 shares of common stock, \$0.001 par value.

Each share of common stock has one vote per share for all purposes. The holders of a majority of the shares entitled to vote, present in person or represented by proxy, shall constitute a quorum at all meetings of our stockholders. Our common stock does not provide preemptive, subscription or conversion rights and there are no redemption or sinking fund provisions or rights. Our common stockholders 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 therefor as well as any distributions to the security holders. We have never paid cash dividends on our common stock, and do not expect to pay such dividends in the foreseeable future.

In the event of a liquidation, dissolution or winding up of our company, holders of common stock are entitled to share ratably in all of our assets remaining after payment of liabilities. Holders of common stock have no preemptive or other subscription or conversion rights.

Preferred Stock

We are authorized to issue 10,000,000 shares of preferred stock. Our Board of Directors is authorized to cause us to issue, from our authorized but unissued shares of preferred stock, one or more series of preferred stock, to establish from time to time the number of shares to be included in each such series, as well as to fix the designation and any preferences, conversion and other rights and limitations of such series. These rights and limitations may include voting powers, limitations as to dividends, and qualifications and terms and conditions of redemption of the shares of each such series.

Options

As of March 31, 2021, under the Company's 2014 Stock Incentive Plan, 2018 Omnibus Stock Incentive Plan, and 2020 Omnibus Stock Incentive Plan, we had outstanding options to purchase an aggregate of 4,615,171 shares of our common stock at a weighted average exercise price of \$2.133 per share. Of these, an aggregate of 1,968,804 options are exercisable. The remainder has vesting requirements. No more grants may be made under our 2014 Stock Incentive Plan, 2018 Omnibus Stock Incentive Plan or 2020 Omnibus Stock Incentive Plan.

On May 24, 2021, our stockholders approved the 2021 Omnibus Stock Incentive Plan which authorizes us to grant up to 8,740,000 shares of common stock, which consists of 7,500,000 shares of common stock reserved for the 2021 Omnibus Stock Incentive Plan and the 1,240,000 shares that remained available under the 2020 Omnibus Stock Incentive Plan on May 24, 2021. Upon approval of the 2021 Omnibus Stock Incentive Plan, the 2020 Omnibus Stock Incentive Plan was terminated.

Subsequent to March 31, 2021, 70,000 shares of our common stock were issued upon the exercise of options for aggregate proceeds of \$82,634, and we issued options to purchase up to an aggregate of 110,000 shares of our common stock to employees and advisors with an exercise price of \$2.50 per share.

Warrants

As of March 31, 2021, we had outstanding warrants to purchase an aggregate of 51,569,059 shares of our common stock at a weighted average price of \$1.672 per share, with a weighted average remaining life of 4.3 years. Subsequent to March 31, 2021, 10,208,210 shares of our common stock were issued upon the exercise of warrants for aggregate proceeds of \$15,187,567.

Trading Market

The shares of our common stock are currently listed on the Nasdaq Capital Market under the symbol "CTXR" and certain of our warrants issued in August 2017 are currently listed on the Nasdaq Capital Market under the symbol "CTXRW".

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 June 28, 2021, we had 95 record stockholders and did 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.

11

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

EXPERTS

The financial statements of Citius Pharmaceuticals, Inc. appearing in our Annual Report on Form 10-K for the fiscal year ended September 30, 2020, have been included herein by reference in reliance on the report of Wolf & Company, P.C., independent registered public accounting firm, given on the authority of such firm as experts in accounting and auditing.

WHERE YOU CAN FIND ADDITIONAL INFORMATION

We are subject to the reporting requirements of the Exchange Act 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, of which this prospectus is a part, over the Internet at the SEC's website at <http://www.sec.gov>. We also maintain a website at <http://www.citiuspharma.com>, at which you may access these materials free of charge as soon as reasonably practicable after they are electronically filed with, or furnished to, the SEC. The information contained in, or that can be accessed through, our website is not part of this prospectus. You may also request a copy of these filings, at no cost, by writing or telephoning us at: 11 Commerce Drive, First Floor, Cranford, New Jersey 07016, (908) 967-6677.

12

INCORPORATION OF DOCUMENTS BY REFERENCE

The SEC allows us to "incorporate by reference" information that we file with them. Incorporation by reference allows us to disclose important information to you by referring you to those other documents. The information incorporated by reference is an important part of this prospectus, and information that we file later with the SEC will

automatically update and supersede this information. We filed a registration statement on Form S-3 under the Securities Act with the SEC with respect to the securities being offered pursuant to this prospectus. 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 reference is made to the actual documents for complete information. Copies of all or any part of the registration statement, including the documents incorporated therein by reference or the exhibits, may be obtained upon payment of the prescribed rates at the offices of the SEC listed above in "Where You Can Find Additional Information." The documents we are incorporating by reference into this prospectus are:

- the description of our common stock contained in our Registration Statement on [Form 8-A](#), filed on July 28, 2017;
- our Annual Report on [Form 10-K](#) for the fiscal year ended September 30, 2020, filed with the SEC pursuant to Section 13 of the Exchange Act on December 16, 2020;
- our Quarterly Report on [Form 10-Q](#) for the quarter ended December 31, 2020, filed with the SEC pursuant to Section 13 of the Exchange Act on February 11, 2021;
- our Quarterly Report on [Form 10-Q](#) for the quarter ended March 31, 2021, filed with the SEC pursuant to Section 13 of the Exchange Act on May 13, 2021;
- our Current Reports on Form 8-K, filed with the SEC pursuant to Section 13 of the Exchange Act on [October 9](#), [October 26](#), [November 30](#), [December 8](#) and [December 9](#), 2020, and [January 11](#), [January 27](#), [February 9](#), [February 16](#) (but not Item 7.01), [February 19](#), [May 24](#), [June 7](#), [June 8](#), [June 22](#) (Form 8-K/A), and [July 1](#), 2021; and
- our definitive proxy statement on [Schedule 14A](#) for the annual meeting of stockholders held on February 9, 2021, filed with the SEC pursuant to Section 14 of the Exchange Act on December 21, 2020.

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

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 or any other subsequently filed document that is deemed to be incorporated by reference into 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 any or all of the documents incorporated by reference in the registration statement or this prospectus, including exhibits to these documents. You should direct any requests for documents to Citius Pharmaceuticals, Inc., Attention: Secretary, 11 Commerce Drive, 1st Floor, Cranford, New Jersey 07016, (908) 967-6677.

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

PART II

INFORMATION NOT REQUIRED IN PROSPECTUS

Item 14. Other Expenses of Issuance and Distribution.

The following table sets forth all costs and expenses paid or payable by us in connection with the sale of the common stock being registered. None of these costs or expenses will be borne by the selling stockholders.

SEC registration fee	\$ 2,184*
Legal fees and expenses	\$ 15,000**
Accounting fees and expenses	\$ 6,000**
Printing expenses	\$ 2,500**
Miscellaneous	\$ 1,316**
Total	<u>\$ 27,000**</u>

* Registration fees of \$2,184.02 were previously paid in connection with the filing of the original registration statement.

** Estimated, as permitted under Item 511 of Regulation S-K.

Item 15. Indemnification of Directors and Officers.

Neither our Articles of Incorporation nor Bylaws prevent us from indemnifying our officers, directors and agents to the extent permitted under the Nevada Revised Statute ("NRS"). NRS Section 78.751 provides that a corporation shall indemnify any director, officer, employee or agent of a corporation against expenses, including attorneys' fees, actually and reasonably incurred by him or her in connection with any the defense to the extent that a director, officer, employee or agent of a corporation has been successful on the merits or otherwise in defense of any action, suit or proceeding referred to in Section 78.751, or in defense of any claim, issue or matter therein.

NRS 78.7502(1) provides that a corporation may indemnify any person who was or is a party or is threatened to be made a party to any threatened, pending or completed action, suit or proceeding, whether civil, criminal, administrative or investigative, except an action by or in the right of the corporation, by reason of the fact that he or she is or was a director, officer, employee or agent of the corporation, or is or was serving at the request of the corporation as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise, against expenses, including attorneys' fees, judgments, fines and amounts paid in settlement actually and reasonably incurred by him or her in connection with the action, suit or proceeding if he or she: (a) is not liable pursuant to NRS 78.138; or (b) acted in good faith and in a manner which he or she reasonably believed to be in or not opposed to the best interests of the corporation, and, with respect to any criminal action or proceeding, had no reasonable cause to believe his or her conduct was unlawful.

NRS Section 78.7502(2) provides that a corporation may indemnify any person who was or is a party or is threatened to be made a party to any threatened, pending or completed action or suit by or in the right of the corporation to procure a judgment in its favor by reason of the fact that he or she is or was a director, officer, employee or agent of the corporation, or is or was serving at the request of the corporation as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other

enterprise against expenses, including amounts paid in settlement and attorneys' fees actually and reasonably incurred by him or her in connection with the defense or settlement of the action or suit if he or she: (a) is not liable pursuant to NRS 78.138; or (b) acted in good faith and in a manner which he or she reasonably believed to be in or not opposed to the best interests of the corporation. Indemnification may not be made for any claim, issue or matter as to which such a person has been adjudged by a court of competent jurisdiction, after exhaustion of all appeals therefrom, to be liable to the corporation or for amounts paid in settlement to the corporation, unless and only to the extent that the court in which the action or suit was brought or other court of competent jurisdiction determines upon application that in view of all the circumstances of the case, the person is fairly and reasonably entitled to indemnity for such expenses as the court deems proper.

NRS Section 78.747 provides that, except as otherwise specifically provided by statute or agreement, no director or officer of a corporation is individually liable for a debt or liability of the corporation, unless the director or officer acts as the alter ego of the corporation. The court as a matter of law must determine the question of whether a director or officer acts as the alter ego of a corporation.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers or persons controlling Citius pursuant to the foregoing provisions, we have 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. In the event that a claim for indemnification against such liabilities (other than the payment by us of expenses incurred or paid by a director, officer or controlling person of Citius in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, we will, unless in the opinion of our counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by us is against public policy as expressed hereby in the Securities Act and we will be governed by the final adjudication of such issue.

14

Item 16. Exhibits.

Exhibit Number	Description of Document	Registrant's Form	Dated	Exhibit Number	Filed Herewith
3.1	Amended and Restated Articles of Incorporation of Citius Pharmaceuticals, Inc.	8-K	9/18/2014	3.1	
3.2	Certificate of Amendment to the Amended and Restated Articles of Incorporation of Citius Pharmaceuticals, Inc., effective September 16, 2016.	8-K	9/21/2016	3.1	
3.3	Certificate of Amendment to the Amended and Restated Articles of Incorporation of Citius Pharmaceuticals, Inc., effective June 9, 2017.	8-K	6/8/2017	3.1	
3.4	Certificate of Amendment to the Amended and Restated Articles of Incorporation of Citius Pharmaceuticals, Inc., effective June 22, 2021.	8-K/A	6/22/2021	3.1	
3.5	Amended and Restated Bylaws of Citius Pharmaceuticals, Inc.	8-K	2/9/2018	3.1	
4.1	Form of Registration Rights Agreement between the Purchasers named therein and Citius Pharmaceuticals Holdings, Inc., dated September 12, 2014.	8-K	9/18/2014	10.2	
4.2	Form of Investor Warrant, dated September 12, 2014.	8-K	9/18/2014	10.3	
4.3	Warrant Agent Agreement dated August 3, 2017 between Citius Pharmaceuticals, Inc. and VStock Transfer, LLC.	8-K	8/04/2017	10.12	
4.4	Form of Common Stock Purchase Warrant, dated May 10, 2017.	10-Q	5/15/2017	10.4	
4.5	Form of Representative's Warrant, dated August 3, 2017.	8-K	8/4/2017	4.2	
4.6	Form of Investor Warrant, dated December 15, 2017.	8-K	12/19/2017	4.1	
4.7	Form of Placement Agent Warrant, dated December 15, 2017.	8-K	12/19/2017	4.2	
4.8	Form of Investor Warrant, dated March 28, 2018.	8-K	3/29/2018	4.1	
4.9	Form of Placement Agent Warrant, dated March 28, 2018.	8-K	3/29/2018	4.2	
4.10	Form of Common Stock Purchase Warrant, dated August 13, 2018.	8-K	8/13/2018	4.1	
4.11	Form of Pre-Funded Common Stock Purchase Warrant, dated August 13, 2018.	8-K	8/13/2018	4.2	

15

Exhibit Number	Description of Document	Registrant's Form	Dated	Exhibit Number	Filed Herewith
4.12	Form of Underwriter's Common Stock Purchase Warrant, dated August 13, 2018.	8-K	8/13/2018	4.3	
4.13	Form of Investor Warrant issued April 3, 2019.	8-K	4/03/2019	4.1	
4.14	Form of Placement Agent Warrant issued April 3, 2019.	8-K	4/03/2019	4.2	
4.15	Form of Common Stock Purchase Warrant issued September 27, 2019.	8-K	9/27/2019	4.1	
4.16	Form of Pre-Funded Common Stock Purchase Warrant issued September 27, 2019.	8-K	9/27/2019	4.2	
4.17	Form of Underwriters Common Stock Purchase Warrant issued September 27, 2019.	8-K	9/27/2019	4.3	
4.18	Form of Investor Warrant issued on February 19, 2020.	8-K	2/19/2020	4.1	
4.19	Form of Placement Agent Warrant issued on February 19, 2020.	8-K	2/19/2020	4.2	
4.20	Form of Investor Warrant issued May 18, 2020.	8-K	5/18/2020	4.1	
4.21	Form of Placement Agent Warrant issued May 18, 2020.	8-K	5/18/2020	4.2	
4.22	Form of Underwriter Warrant issued August 10, 2020.	8-K	8/10/2020	4.1	
4.23	Form of Investor Warrant issued January 27, 2021.	8-K	1/27/2021	4.1	
4.24	Form of Placement Agent Warrant issued January 27, 2021.	8-K	1/27/2021	4.2	
4.25	Registration Rights Agreement, dated January 24, 2021, by and among Citius Pharmaceuticals, Incl and the investors signatory thereto.	8-K	1/27/2021	4.3	
4.26	Form of Investor Warrant issued February 19, 2021.	8-K	2/19/2021	4.1	
4.27	Form of Placement Agent Warrant issued February 19, 2021.	8-K	2/19/2021	4.2	
5.1	Opinion of Wyrick Robbins Yates & Ponton, LLP.				X
23.1	Consent of Wolf & Company, P.C.				X
23.2	Consent of Wyrick Robbins Yates & Ponton LLP (included in Exhibit 5.1).				X
24.1	Power of Attorney (included on signature page).				X

16

Item 17. Undertakings

- (a) The undersigned registrant hereby undertakes:
- (1) To file, during any period in which offers or sales are being made, a post-effective amendment to this Registration Statement:
 - (i) To include any prospectus required by Section 10(a)(3) of the Securities Act of 1933;
 - (ii) To reflect in the prospectus any facts or events arising after the effective date of the registration statement (or the most recent post-effective amendment thereof) which, individually or in the aggregate, represent a fundamental change in the information set forth in the registration statement. Notwithstanding the foregoing, any increase or decrease in volume of securities offered (if the total dollar value of securities offered would not exceed that which was registered) and any deviation from the low or high end of the estimated maximum offering range may be reflected in the form of prospectus filed with the SEC pursuant to Rule 424(b) if, in the aggregate, the changes in volume and price represent no more than a 20% change in the maximum aggregate offering price set forth in the "Calculation of Registration Fee" table in the effective registration statement;
 - (iii) To include any material information with respect to the plan of distribution not previously disclosed in the registration statement or any material change to such information in the registration statement;
- provided, however,* that paragraphs (1)(i), (1)(ii) and (1)(iii) above do not apply if the information required to be included in a post-effective amendment by those paragraphs is contained in reports filed with or furnished to the Commission by registrant pursuant to Section 13 and Section 15(d) of the Securities Exchange Act of 1934 that are incorporated by reference in the registration statement, or is contained in a form of prospectus filed pursuant to Rule 424(b) that is part of the registration statement.
- (2) That, for the purpose of determining any liability under the Securities Act of 1933, each such post-effective amendment shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.
 - (3) To remove from registration by means of a post-effective amendment any of the securities being registered which remain unsold at the termination of the offering.
 - (5) That, for the purpose of determining liability under the Securities Act of 1933 to any purchaser:
 - (A) Each prospectus filed by the registrant pursuant to Rule 424(b)(3) shall be deemed to be part of the registration statement as of the date the filed prospectus was deemed part of and included in the registration statement; and
 - (B) Each prospectus required to be filed pursuant to Rule 424(b)(2), (b)(5) or (b)(7) as part of a registration statement in reliance on Rule 430B relating to an offering made pursuant to Rule 415(a)(1)(i), (vii) or (x) for the purpose of providing the information required by Section 10(a) of the Securities Act of 1933 shall be deemed to be part of and included in the registration statement as of the earlier of the date such form of prospectus is first used after effectiveness or the date of the first contract of sale of securities in the offering described in the prospectus. As provided in Rule 430B, for liability purposes of the issuer and any person that is at that date an underwriter, such date shall be deemed to be a new effective date of the registration statement relating to the securities in the registration statement to which that prospectus relates, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof. Provided, however, that no statement made in a registration statement or prospectus that is part of the registration statement or made in a document incorporated or deemed incorporated by reference into the registration statement or prospectus that is part of the registration statement will, as to a purchaser with a time of contract of sale prior to such effective date, supersede or modify any statement that was made in the registration statement or prospectus that was part of the registration statement or made in any such document immediately prior to such effective date.

17

- (b) The undersigned registrant hereby undertakes that, for purposes of determining any liability under the Securities Act of 1933, each filing of the registrant's annual report pursuant to Section 13(a) or Section 15(d) of the Securities Exchange Act of 1934 (and, where applicable, each filing of an employee benefit plan's annual report pursuant to Section 15(d) of the Securities Exchange Act of 1934) that is incorporated by reference in the registration statement shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.
 - (h) Insofar as indemnification for liabilities arising under the Securities Act of 1933 may be permitted to directors, officers and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Act and will be governed by the final adjudication of such issue.
- (i) The undersigned registrant hereby undertakes that:
- (1) For purposes of determining any liability under the Securities Act of 1933, the information omitted from the form of prospectus filed as part of this Registration Statement in reliance upon Rule 430A and contained in a form of prospectus filed by the registrant pursuant to Rule 424(b)(1) or (4) or 497(h) under the Securities Act shall be deemed to be part of this registration statement as of the time it was declared effective; and
 - (2) For the purpose of determining any liability under the Securities Act of 1933, each post-effective amendment that contains a form of prospectus shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

18

SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, the Registrant certifies that it has reasonable grounds to believe that it meets all of the requirements for filing on Form S-3 and has duly caused this Registration Statement on Form S-3 to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Cranford, State of New Jersey, on July 2, 2021.

CITIUS PHARMACEUTICALS, INC.

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

POWER OF ATTORNEY

KNOW ALL BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Myron Holubiak and Leonard Mazur as his or her true and lawful attorneys-in-fact and agents, each with the full power of substitution, for him or her and in his or her name, place or stead, in any and all capacities, to sign any and all amendments to this registration statement (including post-effective amendments), and any subsequent registration statement filed by the registrant pursuant to Rule 462(b) of the Securities Act of 1933, as amended, which relates to this registration statement, and to file the same, with exhibits thereto and other documents in connection therewith, with the SEC, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done in and about the premises, as fully to all intents and purposes as he or she might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, or their or his or her substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Act, this registration statement has been signed by the following persons in the capacities and on the dates indicated.

<u>Signature</u>	<u>Title</u>	<u>Date</u>
<u>/s/ Myron Holubiak</u> Myron Holubiak	President and Chief Executive Officer (Principal Executive Officer)	July 2, 2021
<u>/s/ Jaime Bartushak</u> Jaime Bartushak	Chief Financial Officer and Chief Accounting Officer (Principal Financial Officer and Principal Accounting Officer)	July 2, 2021
<u>/s/ Leonard Mazur</u> Leonard Mazur	Executive Chairman, Board of Directors	July 2, 2021
<u>/s/ Suren Dutia</u> Suren Dutia	Director	July 2, 2021
<u>/s/ Eugene Holuka</u> Dr. Eugene Holuka	Director	July 2, 2021
<u>/s/ William Kane</u> Dr. William Kane	Director	July 2, 2021
<u>/s/ Howard Safir</u> Howard Safir	Director	July 2, 2021
<u>/s/ Carol Webb</u> Carol Webb	Director	July 2, 2021

Wyrick Robbins Yates & Ponton LLP
4101 Lake Boone Trail, Suite 300
Raleigh, North Carolina 27607

July 2, 2021

Board of Directors
Citius Pharmaceuticals, Inc.
11 Commerce Drive, 1st Floor
Cranford, NJ 07016

Ladies and Gentlemen:

We have acted as counsel to Citius Pharmaceuticals, Inc., a Nevada corporation (the "Company"), in connection with the post-effective amendment on Form S-3 (the "Registration Statement") filed on the date hereof with the Securities and Exchange Commission (the "Commission") under the Securities Act of 1933, as amended (the "Act") to maintain the registration of (i) 1,622,989 shares issuable from time to time upon the exercise of warrants issued by the Company to investors on August 8, 2017 (the "Investor Warrants"), and (ii) 65,490 shares issuable from time to time upon the exercise of warrants issued by the Company to underwriter designees on August 8, 2017 (the "Underwriter Warrants," and together with the Investor Warrants, the "Warrants"). The shares issuable upon the exercise of the Investor Warrants and the Underwriter Warrants are referred to collectively as the "Warrant Shares". The Warrant Shares may be issued as set forth in the Registration Statement, any amendment thereto, and the prospectus contained therein filed pursuant to the rules and regulations promulgated under the Act.

This opinion is being furnished in accordance with the requirements of Item 16 of Form S-3 and Item 601(b)(5)(i) of Regulation S-K.

In connection with the foregoing, we have relied upon, among other things, our examination of such documents, records of the Company and certificates of its officers and public officials as we deemed necessary for purposes of the opinions expressed below. In our examination, we have assumed the genuineness of all signatures, the authenticity of all documents submitted to us as originals and the conformity with the original of all documents submitted to us as copies thereof.

Based upon the foregoing, we are of the opinion that (i) the Warrant Shares have been duly authorized for issuance, and (ii) when the Warrant Shares have been sold and issued as described in the Registration Statement and in accordance with the terms of the respective Warrants, will be validly issued, fully paid and non-assessable.

This opinion is limited to the existing applicable Nevada Revised Statutes and applicable judicial decisions interpreting these laws. We hereby consent to the filing of this opinion with the Commission as Exhibit 5.1 to the Registration Statement and reference to our firm under the heading "Legal Matters" in the prospectus included therein. In giving this consent, we do not admit that we are within the category of persons whose consent is required by Section 7 of the Act or the rules and regulations promulgated thereunder by the Commission.

Very truly yours,

/s/ Wyrick Robbins Yates & Ponton LLP

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in this Post-Effective Amendment No. 2 to the registration statement on Form S-1 (No. 333-217956), or the Registration Statement, on Form S-3 and related Prospectus of Citius Pharmaceuticals, Inc. of our report dated December 16, 2020, relating to the consolidated financial statements of Citius Pharmaceuticals, Inc., appearing in the Annual Report on Form 10-K for the year ended September 30, 2020.

We also consent to the reference to our Firm under the caption "Experts" in such Prospectus.

/s/ Wolf & Company, P.C.

Wolf & Company, P.C.
Boston, Massachusetts
July 2, 2021