

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549
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)

8731

(Primary Standard Industrial
Classification Code Number)

27-3425913

(I.R.S. Employer
Identification Number)11 Commerce Drive, First Floor
Cranford, New Jersey 07016
Telephone: (908) 967-6677

(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

Myron Holubiak
President and Chief Executive Officer
11 Commerce Drive, First Floor
Cranford, New Jersey 07016
Telephone: (908) 967-6677

(Name, address, including zip code, and telephone number, including area code, of agent for service)

*Copies to:*Alexander M. Donaldson
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Raleigh, North Carolina 27607
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.

CALCULATION OF REGISTRATION FEE

Title of Each Class of Securities to be Registered	Amount to be Registered (1)	Proposed Maximum Offering Price Per Unit or Share (1)	Proposed Maximum Aggregate Offering Price (1)	Amount of Registration Fee
Primary Offering:			\$ 100,000,000.00	\$ 12,980.00(2)
Common Stock, par value \$0.001 per share	(3)	(3)	(3)	(3)
Preferred Stock, par value \$0.001 per share	(3)	(3)	(3)	(3)
Debt Securities	(3)	(3)	(3)	(3)
Warrants	(3)	(3)	(3)	(3)
Units (4)	(3)	(3)	(3)	(3)
Rights	(3)	(3)	(3)	(3)
Secondary Offering by Selling Stockholders:				
Common Stock underlying warrants	641,166(5)	\$ 0.8264 (5)	\$ 529,859.58 (5)	\$ 68.78(5)
Total			\$ 100,529,859.58	\$ 13,048.78(6)

- (1) Pursuant to Rule 416 under the Securities Act, of 1933, as amended, or Securities Act, this registration statement shall also cover any additional shares of the registrant's securities that become issuable by reason of any stock splits, stock dividends or similar transactions.
- (2) Calculated pursuant to Rule 457(o) under the Securities Act.
- (3) The proposed maximum offering price per share will be determined, from time to time, by the Registrant in connection with the issuance by the Registrant of the securities registered hereunder and is not specified as to each class of security pursuant to General Instruction II.D. of Form S-3 under the Securities Act.
- (4) Each unit will be issued under a unit agreement and will be comprised of any combination of the Registrant's common stock, preferred stock, debt securities, warrants, and rights.
- (5) Pursuant to Rule 457(c) of the Securities Act, the offering price and registration fee are computed based on the average high and low prices for the Registrant's common stock reported on the Nasdaq Capital Market on September 8, 2020.
- (6) Pursuant to Rule 457(p) under the Securities Act, the Registrant hereby offsets the total registration fee due under this Registration Statement by the amount of the filing fee associated with the \$19,575,940.12 of unsold shares of common stock (the "Unsold Securities") previously registered on the Registrant's Form S-3 Registration Statement (SEC File No. 333-221492) declared effective by the Securities and Exchange Commission on December 15, 2017 (the "Prior Registration Statement"), to be sold by the Registrant. The associated filing fee of \$2,437.20 for the Unsold Securities under the Prior Registration Statement is hereby used to offset the current registration fee due, resulting in a registration fee in the amount of \$10,611.57 due in connection with the filing of this Registration Statement. To the extent that, after the filing date hereof and prior to the effectiveness of this Registration Statement, the Registrant sells any Unsold Securities pursuant to the Prior Registration Statement, the Registrant will identify in a pre-effective amendment to this Registration Statement the updated amount of Unsold Securities from the Prior Registration Statement to be included in this Registration Statement pursuant to Rule 415(a)(6) and the updated amount of securities to be registered on this Registration Statement. Pursuant to Rule 457(p) under the Securities Act, the offering of the Unsold Securities under the Prior Registration Statement will be deemed terminated as of the date of effectiveness of this Registration Statement.

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

This registration statement contains two prospectuses:

- Offering Prospectus: A base prospectus covering the offering, issuance and sale by us, pursuant to General Instruction I.B.1 or I.B.6, as applicable, to Form S-3, of up to \$100,000,000 of our common stock, preferred stock, debt securities, warrants, rights to purchase common stock, preferred stock, debt securities, or units for any combination of those securities; and
 - Resale Prospectus: A prospectus to be used for the resale by the selling stockholders, pursuant to General Instruction I.B.3 to Form S-3, of up to 641,166 shares of our common stock issuable upon exercise of warrants held by such selling stockholders.
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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 September 11, 2020

PROSPECTUS



**\$100,000,000
Common Stock
Preferred Stock
Debt Securities
Warrants
Units and/or
Rights**

We may offer and sell from time to time up to \$100,000,000 of our shares of common stock; shares of preferred stock; debt securities; warrants; rights to purchase common stock, preferred stock, debt securities, or units; or units that include any of these securities, in one or more offerings in amounts, at prices and on terms that we will determine at the time of offering.

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

As of September 11, 2020, the aggregate market value of our outstanding common stock held by non-affiliates, or the public float, was approximately \$55,686,569, which was calculated based on 43,167,883 shares of our outstanding common stock held by non-affiliates and on a price of \$1.29 per share, the last reported sale price for our common stock on August 4, 2020. Pursuant to General Instruction I.B.6 of Form S-3, in no event will we sell our common stock in a public primary offering with a value exceeding one-third of our public float in any 12-month period unless our public float subsequently rises to \$75.0 million or more. We have offered \$17,117,500.70 of securities pursuant to General Instruction I.B.6 of Form S-3 during the 12 calendar months prior to and including the date of this prospectus.

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

Our common stock is listed on the Nasdaq Capital Market under the symbol "CTXR". The last reported sale price of our common stock on September 9, 2020 was \$0.8748 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 , 2020

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ABOUT THIS PROSPECTUS

This prospectus is part of a Registration Statement on Form S-3 that we filed with the Securities and Exchange Commission, or the SEC, using a “shelf” registration process or continuous offering process. By using a shelf registration statement, we may from time to time, offer shares of our common stock; shares of our preferred stock; debt securities; warrants for such securities; rights to purchase common stock, preferred stock, debt securities or units; and units that include any of these securities, in one or more offerings, up to a total dollar amount of \$100,000,000.

This prospectus provides you with a general description of the securities we may offer. Each time we offer securities under this prospectus, we will provide a prospectus supplement that will contain specific information about the terms of that offering.

We may sell the securities (a) through agents; (b) through underwriters or dealers; (c) directly to one or more purchasers; or (d) through a combination of any of these methods of sale. See “Plan of Distribution” on page 7. A prospectus supplement (or pricing supplement), which we will provide to you each time we offer securities using this registration statement, will provide the names of any underwriters, dealers, or agents involved in the sale of the securities, and any applicable fee, commission or discount arrangements with them.

This prospectus does not contain all of the information included in the registration statement. For a more complete understanding of the offering of the securities, you should refer to the registration statement, including its exhibits. Prospectus supplements may also add, update or change information contained or incorporated by reference in this prospectus. However, no prospectus supplement will fundamentally change the terms that are set forth in this prospectus or offer a security that is not registered and described in this prospectus at the time of its effectiveness. This prospectus, together with any applicable prospectus supplements and the documents incorporated by reference into this prospectus or any prospectus supplement, will include material information relating to the offering. You should carefully read this prospectus, the applicable prospectus supplement, the information and documents incorporated herein by reference and the additional information under the heading “Where You Can Find Additional Information” before making an investment decision.

You should rely only on the information we have provided or incorporated by reference in this prospectus or any prospectus supplement. We have not authorized anyone to provide you with information different from that contained or incorporated by reference in this prospectus or any prospectus supplement. No dealer, salesperson or other person is authorized to give any information or to represent anything not contained or incorporated by reference in this prospectus or any prospectus supplement. You must not rely on any unauthorized information or representation. This prospectus is an offer to sell only the securities offered hereby, but only under circumstances and in jurisdictions where it is lawful to do so. You should assume that the information in this prospectus or any prospectus supplement is accurate only as of the date on the front of the document and that any information we have incorporated herein by reference is accurate only as of the date of the document incorporated by reference, regardless of the time of delivery of this prospectus and any prospectus supplement or any sale of a security.

To the extent there are inconsistencies between this prospectus, any prospectus supplement and any documents incorporated by reference, the document with the most recent date will control.

This prospectus may not be used to consummate sales of our securities, unless it is accompanied by a prospectus supplement.

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

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

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

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

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

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

THE COMPANY

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

Since our inception, we have devoted substantially all of our efforts to business planning, acquiring our proprietary technology, research and development, recruiting management and technical staff, and raising capital. We are developing three proprietary product candidates: Mino-Lok, an antibiotic lock solution used to treat patients with catheter-related bloodstream infections by salvaging the infected catheter; Mino-Wrap, a liquifying gel-based wrap for the reduction of tissue expander infections following breast reconstructive surgeries; and Halo-Lido, a corticosteroid-lidocaine topical formulation that is intended to provide anti-inflammatory and anesthetic relief to persons suffering from hemorrhoids. We believe these unique markets for our product candidates are large, growing and underserved by the current prescription products or procedures.

In March 2020, we entered into a six-month option agreement with a subsidiary of Novellus, Inc. (“Novellus”) whereby for the duration of the option we have the exclusive opportunity to in-license from Novellus on a worldwide basis, a novel cellular therapy for acute respiratory distress syndrome.

Corporate History and Information

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

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

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

PLAN OF DISTRIBUTION

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

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

In addition, we may issue the securities as a dividend or distribution or in a subscription rights offering to our existing security holders.

We may directly solicit offers to purchase securities, or agents may be designated to solicit such offers. In the prospectus supplement relating to such offering, we will name any agent that could be viewed as an underwriter under the Securities Act and describe any commissions that we must pay to any such agent. Any such agent will be acting on a best efforts basis for the period of its appointment or, if indicated in the applicable prospectus supplement, on a firm commitment basis. This prospectus may be used in connection with any offering of our securities through any of these methods or other methods described in the applicable prospectus supplement.

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

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

If any underwriters or agents are used in the sale of the securities in respect of which this prospectus is delivered, we will enter into an underwriting agreement, sales agreement or other agreement with them at the time of sale to them, and we will set forth in the prospectus supplement relating to such offering the names of the underwriters or agents and the terms of the related agreement with them.

In connection with the offering of securities, we may grant to the underwriters an option to purchase additional securities with an additional underwriting commission, as may be set forth in the accompanying prospectus supplement. If we grant any such option, the terms of such option will be set forth in the prospectus supplement for such securities.

If a dealer is used in the sale of the securities in respect of which the prospectus is delivered, we will sell such securities to the dealer, as principal. The dealer, who may be deemed to be an "underwriter" as that term is defined in the Securities Act, may then resell such securities to the public at varying prices to be determined by such dealer at the time of resale.

If we offer securities in a subscription rights offering to our existing security holders, we may enter into a standby underwriting agreement with dealers, acting as standby underwriters. We may pay the standby underwriters a commitment fee for the securities they commit to purchase on a standby basis. If we do not enter into a standby underwriting arrangement, we may retain a dealer-manager to manage a subscription rights offering for us.

Agents, underwriters, dealers and other persons may be entitled under agreements which they may enter into with us to indemnification by us against certain civil liabilities, including liabilities under the Securities Act, and may be customers of, engage in transactions with or perform services for us in the ordinary course of business.

If so indicated in the applicable prospectus supplement, we will authorize underwriters or other persons acting as our agents to solicit offers by certain institutions to purchase securities from us pursuant to delayed delivery contracts providing for payment and delivery on the date stated in the prospectus supplement. Each contract will be for an amount not less than, and the aggregate amount of securities sold pursuant to such contracts shall not be less nor more than, the respective amounts stated in the prospectus supplement. Institutions with whom the contracts, when authorized, may be made include commercial and savings banks, insurance companies, pension funds, investment companies, educational and charitable institutions and other institutions, but shall in all cases be subject to our approval. Delayed delivery contracts will not be subject to any conditions except that:

- the purchase by an institution of the securities covered under that contract shall not at the time of delivery be prohibited under the laws of the jurisdiction to which that institution is subject; and
- if the securities are also being sold to underwriters acting as principals for their own account, the underwriters shall have purchased such securities not sold for delayed delivery. The underwriters and other persons acting as our agents will not have any responsibility in respect of the validity or performance of delayed delivery contracts.

Offered securities may also be offered and sold, if so indicated in the prospectus supplement, in connection with a remarketing upon their purchase, in accordance with a redemption or repayment pursuant to their terms, or otherwise, by one or more remarketing firms, acting as principals for their own accounts or as agents for us. Any remarketing firm will be identified and the terms of its agreement, if any, with us and its compensation will be described in the applicable prospectus supplement. Remarketing firms may be deemed to be underwriters in connection with their remarketing of offered securities.

Certain agents, underwriters and dealers, and their associates and affiliates, may be customers of, have borrowing relationships with, engage in other transactions with, or perform services, including investment banking services, for us or one or more of our respective affiliates in the ordinary course of business.

In order to facilitate the offering of the securities, any underwriters may engage in transactions that stabilize, maintain or otherwise affect the price of the securities or any other securities the prices of which may be used to determine payments on such securities. Specifically, any underwriters may over allot in connection with the offering, creating a short position for their own accounts. In addition, to cover overallocments or to stabilize the price of the securities or of any such other securities, the underwriters may bid for, and purchase, the securities or any such other securities in the open market. Finally, in any offering of the securities through a syndicate of underwriters, the underwriting syndicate may reclaim selling concessions allowed to an underwriter or a dealer for distributing the securities in the offering if the syndicate repurchases previously distributed securities in transactions to cover syndicate short positions, in stabilization transactions or otherwise. Any of these activities may stabilize or maintain the market price of the securities above independent market levels. Any such underwriters are not required to engage in these activities and may end any of these activities at any time.

We may engage in at the market offerings into an existing trading market in accordance with Rule 415(a)(4) under the Securities Act. In addition, we may enter into derivative transactions with third parties, or sell securities not covered by this prospectus to third parties in privately negotiated transactions. If the applicable prospectus supplement so indicates, in connection with those derivatives, the third parties may sell securities covered by this prospectus and the applicable prospectus supplement, including in short sale transactions. If so, the third party may use securities pledged by us or borrowed from us or others to settle those sales or to close out any related open borrowings of stock, and may use securities received from us in settlement of those derivatives to close out any related open borrowings of stock. The third party in such sale transactions will be an underwriter and, if not identified in this prospectus, will be named in the applicable prospectus supplement (or a post-effective amendment). In addition, we may otherwise loan or pledge securities to a financial institution or other third party that in turn may sell the securities short using this prospectus and an applicable prospectus supplement. Such financial institution or other third party may transfer its economic short position to investors in our securities or in connection with a concurrent offering of other securities.

The securities may be new issues of securities and may have no established trading market. The securities may or may not be listed on a national securities exchange. We can make no assurance as to the liquidity of or the existence of trading markets for any of the securities.

The specific terms of any lock-up provisions in respect of any given offering will be described in the applicable prospectus supplement.

The underwriters, dealers and agents may engage in transactions with us, or perform services for us, in the ordinary course of business for which they receive compensation.

The anticipated date of delivery of offered securities will be set forth in the applicable prospectus supplement relating to each offer.

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 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 55,475,822 shares were issued and outstanding as of September 11, 2020, 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.

Common Stock

We are authorized to issue 200,000,000 shares of common stock, \$0.001 par value. Each share of common stock shall have one vote per share for all purposes. The holders of a majority of the shares entitled to vote, present in person or represented by proxy shall constitute a quorum at all meetings of our stockholders. Our common stock does not provide preemptive, subscription or conversion rights and there are no redemption or sinking fund provisions or rights. Our common 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.

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 June 30, 2020, 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 2,765,171 shares of our common stock at a weighted average exercise price of \$2.803 per share. Of these, an aggregate of 1,293,260 are exercisable. The remainder has vesting requirements. No more grants may be made under our 2014 Stock Incentive Plan or our 2018 Omnibus Stock Incentive Plan.

Unit Purchase Options

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

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

Warrants

As of June 30, 2020, we had outstanding warrants to purchase an aggregate of 25,285,479 shares of our common stock at a weighted average price of \$1.577 per share, with a weighted average remaining life of 3.75 years.

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 August 31, 2020, we had 96 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.

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

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

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

DESCRIPTION OF WARRANTS

The following description, together with the additional information we may include in any applicable prospectus supplement, summarizes the material terms and provisions of the warrants that we may offer under this prospectus and any related warrant agreement and warrant certificate. While the terms summarized below will apply generally to any warrants that we may offer, we will describe the specific terms of any series of warrants in more detail in the applicable prospectus supplement. If we indicate in the prospectus supplement, the terms of any warrants offered under that prospectus supplement may differ from the terms described below. Specific warrant agreements will contain additional important terms and provisions as follows and will be filed, along with a form of warrant certificate, as exhibits to the registration statement of which this prospectus is a part, or will be incorporated by reference from reports that we file with the SEC:

- the specific designation and aggregate number of, and the price at which we will issue, the warrants;
- the currency or currency units in which the offering price, if any, and the exercise price are payable;
- if applicable, the exercise price for shares of our common stock or preferred stock and the number of shares of common stock or preferred stock to be received upon exercise of the warrants;
- in the case of warrants to purchase debt securities, the principal amount of debt securities purchasable upon exercise of one warrant and the price at, and currency in which, this principal amount of debt securities may be purchased upon such exercise;
- the date on which the right to exercise the warrants will begin and the date on which that right will expire or, if warrant holders may not continuously exercise the warrants throughout that period, the specific date or dates on which the warrant holders may exercise the warrants;
- whether the warrants will be issued in fully registered form or bearer form, in definitive or global form or in any combination of these forms, although, in any case, the form of a warrant included in a unit will correspond to the form of the unit and of any security included in that unit;
- any applicable material U.S. federal income tax consequences;
- the identity of the warrant agent for the warrants and of any other depositaries, execution or paying agents, transfer agents, registrars or other agents;
- the proposed listing, if any, of the warrants or the common stock issuable upon exercise of the warrants on any securities exchange;
- if applicable, the date from and after which the warrants and the common stock or preferred stock will be separately transferable;
- if applicable, the minimum or maximum amount of the warrants that may be exercised at any one time;
- information with respect to book-entry procedures, if any;
- the anti-dilution provisions of the warrants, if any;
- the redemption or call provisions, if any;
- whether the warrants are to be sold separately or with other securities as parts of units; and
- any additional terms of the warrants, including terms, procedures and limitations relating to the exchange and exercise of the warrants.

Before exercising their warrants, holders of warrants will not have any of the rights of holders of the securities purchasable upon such exercise, including:

- in the case of warrants to purchase debt securities, the right to receive payments of principal of, or premium, if any, or interest on the debt securities purchasable upon exercise or to enforce covenants in the applicable indenture; or
- in the case of warrants to purchase common stock or preferred stock, the right to receive dividends, if any, or, payments upon our liquidation, dissolution or winding up or to exercise voting rights, if any.

Each warrant will entitle the holder of the warrant to purchase for cash, or via net exercise, an amount of securities at the exercise price set forth in the applicable prospectus supplement. Holders may exercise warrants at any time up to the close of business on the expiration date set forth in the applicable prospectus supplement. After the close of business on the expiration date, unexercised warrants will be void.

The transfer agent and registrar, if any, for any warrants will be set forth in the applicable prospectus supplement.

DESCRIPTION OF DEBT SECURITIES

The following description, together with the additional information we include in any applicable prospectus supplement, summarizes the material terms and provisions of any debt securities that we may offer under this prospectus. While the terms we have summarized below will apply generally to any future debt securities we offer, we will describe the particular terms of any debt securities that we may offer in more detail in the applicable prospectus supplement. The terms of any debt securities we may offer under a prospectus supplement may differ from the terms described below. For any debt securities that we offer, an indenture (and any relevant supplemental indenture), if required, will contain additional important terms and provisions, the form of which we filed as an exhibit to the registration statement of which this prospectus is a part and is incorporated therein by reference. We will file any definitive indenture as an exhibit to reports that we file with the SEC and incorporate by reference in this prospectus and the applicable prospectus supplement. Any indenture would be qualified under the Trust Indenture Act of 1939, as amended.

With respect to any debt securities that we issue, we will describe in each prospectus supplement the following terms relating to a series of debt securities:

- the title;
- the principal amount being offered, and if a series, the total amount authorized and the total amount outstanding;
- any limit on the amount that may be issued;
- whether or not we will issue the series of debt securities in global form, and if so, the terms and who the depository will be;
- the maturity date;
- the principal amount due at maturity;
- whether and under what circumstances, if any, we will pay additional amounts on any debt securities held by a person who is not a United States person for tax purposes, and whether we can redeem the debt securities if we have to pay such additional amounts;
- the annual interest rate, which may be fixed or variable, or the method for determining the rate and the date interest will begin to accrue, the dates interest will be payable and the regular record dates for interest payment dates or the method for determining such dates;
- whether or not the debt securities will be convertible into shares of our common stock or our preferred stock and, if so, the terms of such conversion;
- whether or not the debt securities will be secured or unsecured by some or all of our assets, and the terms of any secured debt;
- the terms of the subordination of any series of subordinated debt;
- the place where payments will be payable;
- restrictions on transfer, sale or other assignment, if any;
- our right, if any, to defer payment or interest and the maximum length of any such deferral period;
- the date, if any, after which and the conditions upon which, and the price at which, we may, at our option, redeem the series of debt securities pursuant to any optional or provisional redemption provisions and the terms of those redemption provisions;
- the date, if any, on which, and the price at which we are obligated, pursuant to any mandatory sinking fund or analogous fund provisions or otherwise, to redeem, or at the holder's option to purchase, the series of debt securities and the currency or currency unit in which the debt securities are payable;
- whether the indenture will restrict our ability to pay dividends, or will require us to maintain any asset ratios or reserves;
- whether we will be restricted from incurring any additional indebtedness, issuing additional securities, or entering into a merger, consolidation or sale of our business;
- a discussion of any material or special United States federal income tax considerations applicable to the debt securities;

- information describing any book-entry features;
- any provisions for payment of additional amounts for taxes;
- whether the debt securities are to be offered at a price such that they will be deemed to be offered at an “original issue discount” as defined in paragraph (a) of Section 1273 of the Internal Revenue Code of 1986, as amended;
- the denominations in which we will issue the series of debt securities, if other than denominations of \$1,000 and any integral multiple thereof;
- events of default;
- whether we and/or the indenture trustee may change an indenture without the consent of any holders;
- the form of debt security and how it may be exchanged and transferred;
- description of the indenture trustee and paying agent, and the method of payments; and
- any other specified terms, preferences, rights or limitations of, or restrictions on, the debt securities and any terms that may be required by us or advisable under applicable laws or regulations.

We summarize below the material terms of the form of indenture, if required, or indicate which material terms will be described in the applicable prospectus supplement. The indenture:

- does not limit the amount of debt securities that we may issue;
- allows us to issue debt securities in one or more series;
- does not require us to issue all of the debt securities of a series at the same time;
- allows us to reopen a series to issue additional debt securities without the consent of the holders of the debt securities of such series; and
- provides that the debt securities may be secured or unsecured, as may be set forth in the applicable prospectus supplement.

DESCRIPTION OF THE UNITS

We may issue units comprised of shares of common stock, shares of preferred stock, debt securities, warrants, or rights in any combination and in one or more series. Each unit will be issued so that the holder of the unit is also the holder of each security included in the unit. Thus, the holder of a unit will have the rights and obligations of a holder of each included security. The unit agreement under which a unit is issued may provide that the securities included in the unit may not be held or transferred separately, at any time or at any time before a specified date.

We may choose to evidence each series of units by unit certificates that we would issue under separate agreements. If we choose to evidence the units by unit certificate, we will enter into unit agreements with a unit agent and will indicate the name and address of the unit agent in the applicable prospectus supplement related to the particular series of units. We will file as exhibits to the registration statement of which this prospectus is a part, or will incorporate by reference from reports that we file with the SEC, the form of unit agreement, unit certificate, as may be applicable, and any supplemental agreements that describe the terms of the units we are offering before the issuance of the units.

DESCRIPTION OF THE RIGHTS

The following is a general description of the terms of the rights we may issue from time to time unless we provide otherwise in the applicable prospectus supplement. Particular terms of any rights we offer will be described in the prospectus supplement relating to such rights.

General

We may issue rights to purchase common stock, preferred stock, debt securities or units. Rights may be issued independently or together with other securities and may or may not be transferable by the person purchasing or receiving the rights. In connection with any rights offering to our stockholders, we may enter into a standby underwriting, backstop or other arrangements with one or more underwriters or other persons pursuant to which such underwriters or other persons would purchase any offered securities remaining unsubscribed for after such rights offering. In connection with a rights offering to our stockholders, we would distribute certificates evidencing the rights and a prospectus supplement to our stockholders on or about the record date that we set for receiving rights in such rights offering.

The applicable prospectus supplement will describe the following terms of any rights we may issue, including some or all of the following:

- the title and aggregate number of the rights;
- the subscription price or a formula for the determination of the subscription price for the rights and the currency or currencies in which the subscription price may be payable;
- if applicable, the designation and terms of the securities with which the rights are issued and the number of rights issued with each such security or each principal amount of such security;
- the number or a formula for the determination of the number of the rights issued to each stockholder;
- the extent to which the rights are transferable;
- in the case of rights to purchase debt securities, the principal amount of debt securities purchasable upon exercise of one right;
- in the case of rights to purchase common stock or preferred stock, the type of stock and number of shares of stock purchasable upon exercise of one right;
- in the case of rights to purchase units, the type and number of securities comprising the units, and the number of units purchasable upon exercise of one right;
- the date on which the right to exercise the rights will commence, and the date on which the rights will expire (subject to any extension);
- if applicable, the minimum or maximum amount of the rights that may be exercised at any one time;
- the extent to which such rights include an over-subscription privilege with respect to unsubscribed securities;
- if applicable, the procedures for adjusting the subscription price and number of shares of common stock or preferred stock purchasable upon the exercise of each right upon the occurrence of certain events, including stock splits, reverse stock splits, combinations, subdivisions or reclassifications of common stock or preferred stock;
- the effect on the rights of any merger, consolidation, sale or other disposition of our business;
- the terms of any rights to redeem or call the rights;
- information with respect to book-entry procedures, if any;

- the terms of the securities issuable upon exercise of the rights;
- if applicable, the material terms of any standby underwriting, backstop or other purchase arrangement that we may enter into in connection with the rights offering;
- if applicable, a discussion of material U.S. federal income tax considerations; and
- any other terms of the rights, including terms, procedures and limitations relating to the exchange and exercise of the rights.

We will file as exhibits to the registration statement of which this prospectus is a part, or will incorporate by reference from reports that we file with the SEC, the form of rights agreement and rights certificate that describe the terms of the rights we are offering before the issuance of rights.

Exercise of Rights

Each right will entitle the holder to purchase for cash or other consideration such shares of stock or principal amount of securities at the subscription price as shall in each case be set forth in, or be determinable as set forth in, the prospectus supplement relating to the rights offered thereby. Rights may be exercised as set forth in the applicable prospectus supplement beginning on the date specified therein and continuing until the close of business on the expiration date set forth in the prospectus supplement relating to the rights offered thereby. After the close of business on the expiration date, unexercised rights will become void.

Upon receipt of payment and a rights certificate properly completed and duly executed at the corporate trust office of the subscription agent or any other office indicated in the prospectus supplement, we will, as soon as practicable, forward the securities purchased upon such exercise. If less than all of the rights represented by such subscription certificate are exercised, a new subscription certificate will be issued for the remaining rights. If we so indicate in the applicable prospectus supplement, holders of the rights may surrender securities as all or part of the exercise price for rights.

We may determine to offer any unsubscribed offered securities directly to stockholders, to persons other than stockholders, to or through agents, underwriters or dealers or through a combination of such methods, including pursuant to standby underwriting, backstop or other arrangements, as described in the applicable prospectus supplement.

Prior to exercising their rights, holders of rights will not have any of the rights of holders of the securities purchasable upon subscription, including, in the case of rights to purchase common stock or preferred stock, the right to receive dividends, if any, or payments upon our liquidation, dissolution or winding up or to exercise any voting rights or, in the case of rights to purchase debt securities, the right to receive principal, premium, if any, or interest payments, on the debt securities purchasable upon exercise or to enforce covenants in the applicable indenture.

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, 2019, 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, over the Internet at the SEC's website at <http://www.sec.gov>. We also maintain a website at <http://www.citiuspharma.com>, at which you may access these materials free of charge as soon as reasonably practicable after they are electronically filed with, or furnished to, the SEC. The information contained in, or that can be accessed through, our website is not part of this prospectus. You may also request a copy of these filings, at no cost, by writing or telephoning us at: 11 Commerce Drive, First Floor, Cranford, New Jersey 07016, (908) 967-6677.

INCORPORATION OF DOCUMENTS BY REFERENCE

The SEC allows us to "incorporate by reference" information that we file with them. Incorporation by reference allows us to disclose important information to you by referring you to those other documents. The information incorporated by reference is an important part of this prospectus and any applicable accompanying prospectus, and information that we file later with the SEC will automatically update and supersede this information. We filed a registration statement on Form S-3 under the Securities Act with the SEC with respect to the securities being offered pursuant to this prospectus and any applicable accompanying prospectus. This prospectus omits certain information contained in the registration statement, as permitted by the SEC. You should refer to the registration statement, including the exhibits, for further information about us and the securities being offered pursuant to this prospectus and any applicable accompanying prospectus. Statements in this prospectus and any applicable accompanying prospectus regarding the provisions of certain documents filed with, or incorporated by reference in, the registration statement are not necessarily complete, and 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, 2019, filed with the SEC pursuant to Section 13 of the Exchange Act on December 16, 2019;
- our Quarterly Report on [Form 10-Q](#) for the quarter ended December 31, 2019, filed with the SEC pursuant to Section 13 of the Exchange Act on February 13, 2020;
- our Quarterly Report on [Form 10-Q](#) for the quarter ended March 31, 2020, filed with the SEC pursuant to Section 13 of the Exchange Act on May 14, 2020;
- our Quarterly Report on [Form 10-Q](#) for the quarter ended June 30, 2020, filed with the SEC pursuant to Section 13 of the Exchange Act on August 14, 2020;
- our Current Reports on Form 8-K, filed with the SEC pursuant to Section 13 of the Exchange Act on [October 7](#), [November 1](#), [November 5](#) and [December 19, 2019](#), and [January 22](#), [February 3](#), [February 4](#), [February 10](#), [February 14](#), [February 19](#), [February 25](#), [April 1](#), [April 7](#), [April 28](#), [April 29](#), [May 12](#), [May 18](#), [May 26](#), [June 2](#), [June 26](#), [July 10](#), [July 14](#), [August 4](#), [August 10](#), [August 26](#) and [August 26](#), 2020; and
- our definitive proxy statement on Schedule 14A for the annual meeting of stockholders held on February 12, 2020, filed with the SEC pursuant to Section 14 of the Exchange Act on [December 20, 2019](#).

In addition, all documents subsequently filed by us pursuant to Section 13(a), 13(c), 14 or 15(d) of the Exchange Act before the date any 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 and any applicable accompanying prospectus or in a document incorporated or deemed to be incorporated by reference into this prospectus and any applicable accompanying prospectus will be deemed to be modified or superseded for purposes of this prospectus and any applicable accompanying prospectus to the extent that a statement contained in this prospectus and any applicable accompanying prospectus or any other subsequently filed document that is deemed to be incorporated by reference into this prospectus and any applicable accompanying prospectus modifies or supersedes the statement. Any statement so modified or superseded will not be deemed, except as so modified or superseded, to constitute a part of this prospectus and any applicable accompanying prospectus.

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

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

The information in this prospectus is not complete and may be changed. The selling stockholders 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 September 11, 2020

PROSPECTUS



641,166 Shares of Common Stock Offered by Selling Stockholders

This prospectus relates to the sale or other disposition from time to time of up to 641,166 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 31. 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.

Investing in our securities involves a high degree of risk. See "Risk Factors" beginning on page 10 of this prospectus, in any accompanying prospectus supplement and in the documents incorporated by reference into this prospectus, to read about factors you should consider before investing in our securities.

Our common stock is listed on the Nasdaq Capital Market under the symbol "CTXR". The last reported sale price of our common stock on September 9, 2020 was \$0.8748 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 , 2020

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ABOUT THIS PROSPECTUS

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

We urge you to carefully read this prospectus and any prospectus supplement, together with the information incorporated herein by reference as described under the heading “Where You Can Find 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 contains forward-looking statements that are based on our management's belief and assumptions and on information currently available to our management. Although we believe that the expectations reflected in these forward-looking statements are reasonable, these statements relate to future events or our future financial performance, and involve known and unknown risks, uncertainties and other factors that may cause our actual results, levels of activity, performance or achievements to be materially different from any future results, levels of activity, performance or achievements expressed or implied by these forward-looking statements. Forward-looking statements in this prospectus include, but are not limited to, statements about:

- our need for, and ability to raise, additional capital;
- the number, designs, timing and results of our pre-clinical and clinical trials;
- the regulatory review process and any regulatory approvals that may be issued or denied by the FDA or other regulatory agencies;
- the commercial success and market acceptance of any of our product candidates that are approved for marketing in the United States or other countries;
- the accuracy of our estimates and of third-party estimates of the size and characteristics of the markets that may be addressed by our product candidates;
- our ability to manufacture sufficient amounts of our product candidates for clinical trials and, if approved, our products for commercialization activities;
- our need to secure collaborators to license, manufacture, market and sell any products for which we receive regulatory approval;
- our ability to protect our intellectual property and operate our business without infringing upon the intellectual property rights of others;
- the medical benefits, effectiveness and safety of our product candidates;
- the safety and efficacy of medicines or treatments introduced by competitors that are targeted to indications for which our product candidates are being developed;
- our current or prospective collaborators' compliance or non-compliance with their obligations under our agreements with them;
- the impact of the COVID-19 pandemic on our clinical trials, business and operations; 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. 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 or 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 and the documents incorporated by reference into this prospectus contain "forward-looking statements" that involve risks and uncertainties, as well as assumptions that, if they never materialize or prove incorrect, could cause our results to differ materially from those expressed or implied by such forward-looking statements. The statements contained in this prospectus and the documents incorporated by reference into this prospectus that are not purely historical are forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, or Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, or Exchange Act.

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

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

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

THE COMPANY

Overview

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

Since our inception, we have devoted substantially all of our efforts to business planning, acquiring our proprietary technology, research and development, recruiting management and technical staff, and raising capital. We are developing three proprietary product candidates: Mino-Lok, an antibiotic lock solution used to treat patients with catheter-related bloodstream infections by salvaging the infected catheter; Mino-Wrap, a liquifying gel-based wrap for the reduction of tissue expander infections following breast reconstructive surgeries; and Halo-Lido, a corticosteroid-lidocaine topical formulation that is intended to provide anti-inflammatory and anesthetic relief to persons suffering from hemorrhoids. We believe these unique markets for our product candidates are large, growing and underserved by the current prescription products or procedures.

In March 2020 we entered into a six-month option agreement with a subsidiary of Novellus, Inc. (“Novellus”) whereby for the duration of the option we have the exclusive opportunity to in-license from Novellus on a worldwide basis, a novel cellular therapy for acute respiratory distress syndrome.

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

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

Phase 2b Results

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

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

The main purpose of the study was to show that Mino-Lok therapy was at least as effective as the removal and replacement of CVCs when CRBSIs are present, and that the safety was better, that is, the complications of removing an infected catheter and replacing with a new one could be avoided. In addition to having a 100% efficacy rate with all CVCs being salvaged, Mino-Lok therapy had no significant adverse events (“SAEs”), compared to an 18% SAE rate in the matched cohort where patients had the infected CVCs removed and replaced (“R&R”) with a fresh catheter. There were no overall complication rates in the Mino-Lok arm group compared to 11 patients with events (18%) in the control group. These events included bacterial relapse (5%) at four weeks post-intervention, and a number of complications associated with mechanical manipulation in the removal or replacement procedure for the catheter (10%) or development of deep seated infections such as septic thrombophlebitis and osteomyelitis (8%). As footnoted, six patients had more than one (1) complication in the control arm group.

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

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

** 6 patients had > 1 complication

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

Phase 3 Initiation

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

The Mino-Lok phase 3 trial was originally planned to enroll 700 patients in 50 participating institutions, all located in the U.S. There will be interim analyses at both the 50% and 75% points of the trial as measured by the number of patients treated. As of July 31, 2020, there are 31 active sites currently enrolling patients including such academic centers as MDACC, Henry Ford Health Center, Georgetown University Medical Center, University of Chicago, and others. There is one additional medical center in startup mode. There are no other remaining sites in feasibility.

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

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

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

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

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

Fast Track Designation

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

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

Mino-Lok International Study

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

Stability Patent Application for Mino-Lok

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

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

Mino-Wrap

Overview

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

Halo-Lido

Overview

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

Development of Hemorrhoids Drugs

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

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

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

Development Activities to Date

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

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

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

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

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

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

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

We held a Type C meeting with the FDA in December 2017 to discuss the results of the Phase 2a study and to obtain the FDA's view on development plans to support the potential formulation change for the planned Phase 2b study. We also requested the FDA's feedback on our Phase 2b study design, including target patient population, inclusion/exclusion criteria, and efficacy endpoints. The pre-clinical and clinical development programs for CITI-002 are planned to be similar to those conducted for the development of CITI-001 to support the design for a planned Phase 3 clinical trial. We anticipate beginning a Phase 2b clinical study in the first half of 2021.

Citius/Novellus Program

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

Corporate History and Information

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

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

THE OFFERING
Up to 641,166 Shares of Common Stock

This prospectus relates to the resale by the selling stockholders identified in this prospectus of up to 641,166 shares of our common stock issuable upon exercise of warrants issued in August 2020 to the underwriter of our underwritten public offering, with an exercise price of \$1.3125 per share that expire on August 5, 2025.

Common stock offered by the selling stockholders	641,166 shares
Common stock outstanding before the offering ⁽¹⁾	55,475,822 shares
Common stock to be outstanding after the offering	56,116,988 shares
Common stock Nasdaq Capital Market Symbol	CTXR

⁽¹⁾ Based on the number of shares outstanding as of September 11, 2020.

Use of Proceeds

The 641,166 shares of common stock issuable upon the exercise of currently outstanding warrants 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 641,166 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 \$841,530 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.

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

Dividend Policy

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

Risk Factors

Investing in our common stock involves a high degree of risk. Please read the information contained under the heading "Risk Factors" beginning on page 10 of this prospectus and in any subsequent report incorporated by reference herein.

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 prospectus supplement relating to a particular offering of our securities may also discuss certain risks of investing in that offering. The risks set forth in any prospectus supplement and 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.

Risks related to our Business and our Industry

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

We were formed in 2007 and since our inception have incurred a net loss in each of our previous operating years. Our ability to become profitable depends upon our ability to obtain marketing approval for and generate revenues from sales of our product candidates. We have been focused on product development, have not received approval for any of our product candidates, and have not generated any revenues to date. We have incurred losses in each period of our operations, and we expect to continue to incur losses for the foreseeable future. These losses are likely to continue to adversely affect our working capital, total assets and stockholders' equity. The process of developing our product candidates requires significant clinical development, laboratory testing and clinical trials. In addition, commercialization of our product candidates will require that we obtain necessary regulatory approvals and establish sales, marketing and manufacturing capabilities, either through internal hiring or through contractual relationships with others. We expect to incur substantial losses for the foreseeable future as a result of anticipated increases in our research and development costs, including costs associated with conducting preclinical testing and clinical trials, and regulatory compliance activities. We incurred net losses of \$15,562,144, \$12,536,638 and \$10,384,953 for the years ended September 30, 2019, 2018 and 2017, respectively, and \$13,427,457 for the nine months ended June 30, 2020. At June 30, 2020, we had stockholders' equity of \$28,742,062 and an accumulated deficit of \$66,473,239. Our net cash used in operating activities was \$12,437,751, \$11,318,138 and \$7,971,205 for the years ended September 30, 2019, 2018 and 2017, respectively, and \$13,572,866 for the nine months ended June 30, 2020.

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

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

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

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

At June 30, 2020, without taking into account the proceeds from our common stock financing in August 2020, we expect that we have sufficient capital to continue our operations through January 2021. You should not rely on our consolidated balance sheet as an indication of the amount of proceeds that would be available to satisfy claims of creditors, and potentially be available for distribution to stockholders, in the event of liquidation.

Our audited consolidated financial statements included in this report have been prepared assuming that we will continue as a going concern and do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets, or the amounts and classification of liabilities that may result if we do not continue as a going concern. We have concluded that substantial doubt about our ability to continue as a going concern exists and our auditors have made reference to this in their audit report on our audited consolidated financial statements for the year ended September 30, 2019.

We need to secure additional financing in the near future to complete the development of our current product candidates and support our operations.

We anticipate that we will incur operating losses for the foreseeable future. We have received gross proceeds of approximately \$53.3 million from our public and private placement offerings through June 30, 2020. Additionally, in connection with the acquisition of LMB our Executive Chairman, Leonard Mazur, made an equity investment of \$3.0 million in March 2016. Mr. Mazur has also loaned us \$4,710,000 pursuant to convertible promissory notes. On August 8, 2017, these notes and accrued interest of \$76,240 were converted into 1,547,067 shares of common stock at a price of \$3.09 per share as part of an underwritten public offering which closed on the same date.

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

- the rate of progress and cost of our trials and other product development programs for our current product candidates;
- the costs and timing of obtaining licenses for additional product candidates, especially a license from Novellus for a possible ARDS treatment candidate, or acquiring other complementary technologies;
- the timing of any regulatory approvals of any of our product candidates;
- the costs of establishing or contracting for sales, marketing and distribution capabilities for our product candidates; and
- the status, terms and timing of any collaborative, licensing, co-promotion or other arrangements.

We will need to access the capital markets in the future for additional capital for research and development and for operations. Traditionally, pharmaceutical companies have funded their research and development expenditures through raising capital in the equity markets. Declines and uncertainties in these markets over the past several years have severely restricted raising new capital and have affected companies' ability to continue to expand or fund existing research and development efforts. The recent turmoil in the financial markets due to the COVID-19 pandemic could also adversely impact future fundraising activities. If the COVID-19 pandemic and related and/or other economic conditions continue or become worse, our future cost of equity or debt capital and access to the capital markets could be adversely affected. If we are not successful in securing additional financing, we may be required to significantly delay, reduce the scope of or eliminate one or more of our research or development programs, downsize our general and administrative infrastructure, or seek alternative measures to avoid insolvency, including arrangements with collaborative partners or others that may require us to relinquish rights to certain of our technologies or product candidates.

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

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

- successfully complete pre-clinical and clinical trials for our product candidates;
- receive marketing approvals from the FDA and similar foreign regulatory authorities for our product candidates;

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

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

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

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

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

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

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

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

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

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

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

We face significant risks in our product candidate development efforts.

Our business depends on the successful development and commercialization of our product candidates. We are not permitted to market any of our product candidates in the United States until we receive approval from the FDA, or in any foreign jurisdiction until we receive the requisite approvals from such jurisdiction. The process of developing new drugs and/or therapeutic products is inherently complex, unpredictable, time-consuming, expensive and uncertain. We must make long-term investments and commit significant resources before knowing whether our development programs will result in products that will receive regulatory approval and achieve market acceptance. Product candidates that appear to be promising at all stages of development may not reach the market for a number of reasons that may not be predictable based on results and data of the clinical program. Product candidates may be found ineffective or may cause harmful side effects during clinical trials, may take longer to progress through clinical trials than had been anticipated, may not be able to achieve the pre-defined clinical endpoints due to statistical anomalies even though clinical benefit may have been achieved, may fail to receive necessary regulatory approvals, may prove impracticable to manufacture in commercial quantities at reasonable cost and with acceptable quality, or may fail to achieve market acceptance.

We cannot predict whether or when we will obtain regulatory approval to commercialize our product candidates that are under development and we cannot, therefore, predict the timing of any future revenues from these product candidates, if any. The FDA has substantial discretion in the drug approval process, including the ability to delay, limit or deny approval of a product candidate for many reasons. For example, the FDA:

- could determine that we cannot rely on Section 505(b)(2) for Mino-Lok or Halo-Lido or any future product candidates;
- could determine that the information provided by us was inadequate, contained clinical deficiencies or otherwise failed to demonstrate the safety and effectiveness of any of our product candidates for any indication;
- may not find the data from clinical trials sufficient to support the submission of an NDA or to obtain marketing approval in the United States, including any findings that the clinical and other benefits of our product candidates outweigh their safety risks;
- may disagree with our trial design or our interpretation of data from preclinical studies or clinical trials, or may change the requirements for approval even after it has reviewed and commented on the design for our trials;
- may determine that we have identified the wrong reference listed drug or drugs or that approval of a Section 505(b)(2) application for any of our product candidates is blocked by patent or non-patent exclusivity of the reference listed drug or drugs;
- may identify deficiencies in the manufacturing processes or facilities of third-party manufacturers with which we enter into agreements for the manufacture of our product candidates;
- may approve our product candidates for fewer or more limited indications than we request, or may grant approval contingent on the performance of costly post-approval clinical trials;
- may change its approval policies or adopt new regulations that could adversely impact our product candidate development programs; or
- may not approve the labeling claims that we believe are necessary or desirable for the successful commercialization of our product candidates, or may require labeling claims that impair the potential market acceptance of our product candidates.

These same risks are generally applicable to the regulatory process in foreign countries. Any failure to obtain regulatory approval of our product candidates would significantly limit our ability to generate revenues, and any failure to obtain such approval for all of the indications and labeling claims we deem desirable could reduce our potential revenues.

While our business strategy generally is to focus on the development of late stage product candidates to lessen the development risk, there is still significant risk to successfully developing a product candidate.

Our goal in pursuing late stage therapeutic product candidates with what we believe is a promising pre-clinical and early clinical stage track record is to avoid the risk of failure at the pre-clinical and early clinical stages. However, there is still significant risk to obtaining regulatory approval and successfully commercializing any late stage product candidate that we pursue. All of the risks inherent in drug development of initial stage product candidates also apply to late stage candidates. We cannot assure you that our business strategy will be successful.

The results of pre-clinical studies and completed clinical trials are not necessarily predictive of future results, and our current product candidates may not have favorable results in later studies or trials.

Pre-clinical studies and Phase 1 and Phase 2 clinical trials are not primarily designed to test the efficacy of a product candidate in the general population, but rather to test initial safety, to study pharmacokinetics and pharmacodynamics, to study limited efficacy in a small number of study patients in a selected disease population, and to identify and attempt to understand the product candidate's side effects at various doses and dosing schedules. Success in pre-clinical studies or completed clinical trials does not ensure that later studies or trials, including continuing pre-clinical studies and large-scale clinical trials, will be successful nor does it predict future results. Favorable results in early studies or trials may not be repeated in later studies or trials, and product candidates in later stage trials may fail to show acceptable safety and efficacy despite having progressed through earlier trials. In addition, the placebo rate in larger studies may be higher than expected.

We may be required to demonstrate through large, long-term outcome trials that our product candidates are safe and effective for use in a broad population prior to obtaining regulatory approval.

There is typically a high rate of attrition from the failure of product candidates proceeding through clinical trials. In addition, certain subjects in our clinical trials may respond positively to placebo treatment - these subjects are commonly known as "placebo responders" - making it more difficult to demonstrate efficacy of the trial drug compared to placebo. This effect is likely to be observed in the treatment of hemorrhoids, which could negatively impact the development program for Halo-Lido.

If any of our product candidates fail to demonstrate sufficient safety and efficacy in any clinical trial, we will experience potentially significant delays and cost increases in, or may decide to abandon development of that product candidate. If we abandon or are delayed, or experience increased costs, in our development efforts related to any of our product candidates, we may not have sufficient resources to continue or complete development of that product candidate or any other product candidates. We may not be able to generate any revenues, continue our operations and clinical studies, or become profitable. Our reputation in the industry and in the investment community would likely be significantly damaged. Further, it might not be possible for us to raise funds in the public or private markets, and our stock price would likely decrease significantly.

If we are unable to file for approval of Mino-Lok or Halo-Lido under Section 505(b)(2) of the Federal Food, Drug and Cosmetic Act, or if we are required to generate additional data related to safety and efficacy in order to obtain approval of Mino-Lok or Halo-Lido under Section 505(b)(2), we may be unable to meet our anticipated development and commercialization timelines.

Our current plans for filing NDAs for our product candidates include efforts to minimize the data we will be required to generate in order to obtain marketing approval for certain of our product candidates and therefore possibly reduce the time and cost of development of a product candidate and obtain a shortened review period for the application. The timeline for filing and review of our planned NDA for each of Mino-Lok and Halo-Lido is based upon our plan to submit each such NDA under Section 505(b)(2) of the Federal Food, Drug and Cosmetic Act, wherein we will rely in part on data generated by third parties and that is in the public domain or elsewhere. Depending on the data that may be required by the FDA for approval, some of the data may be related to products already approved by the FDA. If the data relied upon is related to products already approved by the FDA and covered by third-party patents we would be required to certify that we do not infringe the listed patents or that such patents are invalid or unenforceable. As a result of the certification, the third party would have 45 days from notification of our certification to initiate an action against us. In the event that an action is brought in response to such a certification, the approval of our NDA could be subject to a stay of up to 30 months or more while we defend against such a suit. Approval of any product candidate under Section 505(b)(2) may therefore be delayed until patent exclusivity expires or until we successfully challenge the applicability of those patents applicable to our product candidates. Alternatively, we may elect to generate sufficient additional clinical data so that we no longer rely on data which triggers a potential stay of the approval of any product candidate. Even if no exclusivity periods apply to an application under Section 505(b)(2), the FDA has broad discretion to require us to generate additional data on the safety and efficacy of our product candidates to supplement third-party data on which we may be permitted to rely. In either event, we could be required, before obtaining marketing approval for such product candidate, to conduct substantial new research and development activities beyond those in which we currently plan to engage in order to obtain approval of that product candidate. Such additional new research and development activities would be costly and time consuming.

We may not be able to obtain shortened review of our applications where available, and in any event the FDA may not agree that any of our product candidates qualify for marketing approval. If we are required to generate additional data to support approval, we may be unable to meet our anticipated development and commercialization timelines, may be unable to generate the additional data at a reasonable cost, or at all, and may be unable to obtain marketing approval of that product candidate. In addition, notwithstanding the approval of many products by the FDA pursuant to Section 505(b)(2), over the last few years, some pharmaceutical companies and others have objected to the FDA's interpretation of Section 505(b)(2). If the FDA changes its interpretation of Section 505(b)(2), or if the FDA's interpretation is successfully challenged in court, this could delay or even prevent the FDA from approving any Section 505(b)(2) application that we submit.

Two of our product candidates, Mino-Lok and Halo-Lido, are combination products consisting of components that have each been separately approved by the FDA for other indications and which are commercially available and marketed by other companies. Our approval under Section 505(b)(2), if received, would not preclude physicians, pharmacists and patients from obtaining individual drug products and titrating the dosage of these drug products as close to our approved dose as possible.

Our Mino-Lok solution contains minocycline, disodium ethylenediaminetetraacetic acid (edetate), and ethyl alcohol, all of which have been separately approved by the FDA for other indications, or are used as excipients in other parenteral products. Assuming FDA approval and as a branded pharmaceutical product, we would need to obtain hospital formulary acceptance to generate sales of Mino-Lok. Additionally, we may encounter reluctance by the infectious disease physician community to vary from the existing standard of care to remove and replace an infected catheter. Currently, hospitals are reimbursed for the treatment of CRBSIs by the Center for Medicare and Medicare Services (“CMS”) through a Diagnosis Related Group (“DRG”) classification or code. Commercial insurance plans reimburse for CRBSIs in a similar manner. With Mino-Lok being priced as a branded FDA-approved pharmaceutical product, this could result in the participating hospital retaining a lower share of CMS or commercial reimbursement which may impact the acceptance and use of Mino-Lok by these institutions.

Our Halo-Lido product candidate for the treatment of hemorrhoids is a combination product consisting of two drugs, halobetasol propionate, a corticosteroid, and lidocaine, that have each been separately approved by the FDA for other indications and which are commercially available and marketed by other companies. Halobetasol propionate cream is available in a 0.05% strength, and lidocaine creams are also available in strengths up to 5%. From our market analysis and discussions with a limited number of physicians, we know that patients sometimes obtain two separate cream products and co-administer them as prescribed, giving them a combination treatment which could be very similar to what we intend to study and seek approval for. As a branded, FDA-approved product with safety and efficacy data, we intend to price our product substantially higher than the generically available individual creams. We will then have to convince third-party payers and pharmacy benefit managers of the advantages of our product and justify our premium pricing. We may encounter resistance from these entities and will then be dependent on patients’ willingness to pay the premium and not seek alternatives. In addition, pharmacists often suggest lower cost prescription treatment alternatives to both physicians and patients. If approved, our Section 505(b)(2) approval and the market exclusivity we may receive will not guarantee that such alternatives will not exist, that substitution will not occur, or that there will be immediate acceptance to our pricing by payer formularies.

Any fast track designation or grant of priority review status by the FDA may not actually lead to a faster development or regulatory review or approval process, nor will it assure FDA approval of our product candidates. Additionally, our product candidates may treat indications that do not qualify for priority review vouchers.

We have received fast track designation for Mino-Lok to treat and salvage infected central venous catheters in patients with CRBSIs. We may seek fast track designation for some of our other product candidates or priority review of applications for approval of our product candidates for certain indications. If a drug is intended for the treatment of a serious or life-threatening condition and the drug demonstrates the potential to address unmet medical needs for this condition, the drug sponsor may apply for FDA fast track designation. If a product candidate offers major advances in treatment, the FDA may designate it eligible for priority review. The FDA has broad discretion whether or not to grant these designations, so even if we believe a particular product candidate is eligible for these designations, we cannot assure you that the FDA would decide to grant them. Even with the fast track designation for Mino-Lok and if we do receive fast track designation or priority review for any other product candidate, we may not experience a faster development process, review or approval compared to conventional FDA procedures. The FDA may withdraw fast track designation from Mino-Lok or any other product candidate to be so designated if it believes that the designation is no longer supported by data from our clinical development program.

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

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

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

Even if one of our product candidates obtains regulatory approval, that product may not gain market acceptance among physicians, patients, healthcare payers or the medical community. The indication may be limited to a subset of the population or we may implement a distribution system and patient access program that is limited. Coverage and reimbursement of our product candidates by third-party payers, including government payers, generally is also necessary for commercial success. We believe that the degree of market acceptance and our ability to generate revenues from any approved product candidate or acquired approved product will depend on a number of factors, including:

- prevalence and severity of any side effects;
- results of any post-approval studies of the product;
- potential or perceived advantages or disadvantages over alternative treatments;
- availability of coverage and reimbursement from government and other third-party payers;
- the willingness of patients to pay out of pocket in the absence of government or third-party coverage;
- the relative convenience and ease of administration and dosing schedule;
- product labeling or product insert requirements of the FDA or other regulatory authorities;
- strength of sales, marketing and distribution support;
- price of any future products, if approved, both in absolute terms and relative to alternative treatments;
- the effectiveness of our or any future collaborators' sales and marketing strategies;
- the effect of current and future healthcare laws on our product candidates;
- patient access programs that require patients to provide certain information prior to receiving new and refill prescriptions; and
- requirements for prescribing physicians to complete certain educational programs for prescribing drugs.

If approved, any product candidate may fail to achieve market acceptance or generate significant revenue to achieve or sustain profitability. In addition, our efforts to educate the medical community and third-party payers on the benefits of any product candidate may require significant resources and may never be successful.

Even if approved for marketing by applicable regulatory bodies, we will not be able to create a market for any of our product candidates if we fail to establish marketing, sales and distribution capabilities, either on our own or through arrangements with third parties.

Our strategy with our product candidates is to outsource to third parties all or most aspects of the product development process, and possibly marketing, sales and distribution activities. Currently, we do not have any sales, marketing or distribution capabilities. In order to generate sales of any product candidates that receive regulatory approval, we must either acquire or develop an internal marketing and sales force with technical expertise and with supporting distribution capabilities or make arrangements with third parties to perform these services for us. The acquisition or development of a sales and distribution infrastructure would require substantial resources, which may divert the attention of our management and key personnel and defer our product development efforts. To the extent that we enter into marketing and sales arrangements with other companies, our revenues will depend on the efforts of others. These efforts may not be successful. If we fail to develop sales, marketing and distribution channels, or enter into arrangements for such with third parties, we will experience delays in product launch and sales and incur increased costs.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

In addition, before any of our collaborators can begin to commercially manufacture our product candidates, each must obtain regulatory approval of the manufacturing facility and process. Manufacturing of drugs for clinical and commercial purposes must comply with the FDA's Current Good Manufacturing Practices, or cGMP, and applicable non-U.S. regulatory requirements. The cGMP requirements govern quality control and documentation policies and procedures. Complying with cGMP and non-U.S. regulatory requirements will require that we expend time, money, and effort in production, recordkeeping, and quality control to assure that the product meets applicable specifications and other requirements. Our contracted manufacturing facilities must also pass a pre-approval inspection prior to FDA approval. Failure to pass a pre-approval inspection might significantly delay FDA approval of our product candidates. If any of our collaborators fails to comply with these requirements, we would be subject to possible regulatory action which could limit the jurisdictions in which we are permitted to sell our product candidates. As a result, our business, financial condition, and results of operations might be materially harmed.

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

- We might be unable to identify manufacturers for commercial supply on acceptable terms or at all because the number of potential manufacturers is limited and the FDA must approve any replacement contractor. This approval would generally require compliance inspections. In addition, a new manufacturer would have to be educated in, or develop substantially equivalent processes for, production of our product candidates after receipt of FDA approval, if any;
- Our third-party manufacturers might be unable to formulate and manufacture our product candidates in the volume and of the quality required to meet our clinical and commercial needs, if any;
- Our contract manufacturers might not perform as agreed or might not remain in the contract manufacturing business for the time required to supply our clinical trials or to successfully produce, store and distribute our product candidates for commercialization;
- Currently, our contract manufacturer for our clinical supplies is foreign, which increases the risk of shipping delays and adds the risk of import restrictions;
- Drug manufacturers are subject to ongoing periodic unannounced inspection by the FDA and corresponding state agencies to ensure strict compliance with cGMP and other government regulations and corresponding foreign standards. We do not have complete control over third-party manufacturers' compliance with these regulations and standards;
- If any third-party manufacturer makes improvements in the manufacturing process for our product candidates, we might not own, or might have to share, the intellectual property rights to the innovation with our licensors;
- Operations of our third-party manufacturers or suppliers could be disrupted by conditions unrelated to our business or operations, including a bankruptcy of the manufacturer or supplier or a natural disaster or a pandemic such as COVID-19; and
- We might compete with other companies for access to these manufacturers' facilities and might be subject to manufacturing delays if the manufacturers give other clients higher priority than us.

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

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

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

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

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

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

Our business strategy is based on the acquisition of additional product candidates. We might consider opportunities to acquire or invest in other technologies, products and businesses that might enhance our capabilities or complement our current product candidates. Potential and completed acquisitions and strategic investments involve numerous risks, including potential problems or issues associated with the following:

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

We have no current commitments with respect to any acquisition or investment in other technologies or businesses other than the option agreement that we have with Novellus to in-license a novel cellular therapy as a treatment for ARDS. We do not know if we will identify other suitable acquisitions, whether we will be able to successfully complete any acquisitions, or whether we will be able to successfully integrate any acquired product, technology or business into our business operations or retain key personnel, suppliers or collaborators.

Our ability to successfully develop our business through acquisitions would depend on our ability to identify, negotiate, complete and integrate suitable target businesses or technologies and obtain any necessary financing. These efforts could be expensive and time consuming and might disrupt our ongoing operations. If we are unable to efficiently integrate any acquired business, technology or product into our business operations, our business and financial condition might be adversely affected.

We rely on the significant experience and specialized expertise of our executive management and other key personnel and the loss of any of our executive management or key personnel or our inability to successfully hire their successors could harm our business.

Our performance is substantially dependent on the continued services and on the performance of our executive management and other key personnel, who have extensive experience and specialized expertise in our business. Our President and Chief Executive Officer, Myron Holubiak, our Executive Chairman, Leonard Mazur, and our Chief Medical Officer and Executive Vice President, Myron Czuczman, in particular have significant experience in the running of pharmaceutical companies and/or drug development itself. This depth of experience is of significant benefit to us, especially given the small size of our management team and company. The loss of the services of either Mr. Holubiak, Mr. Mazur or Dr. Czuczman, as well as any other member of our executive management or any key employees could harm our ability to attract capital and develop and commercialize our product candidates. We have no key man life insurance policies.

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

We utilize the services of a clinical management team on a part-time basis to assist us in managing our ongoing Phase 2 and Phase 3 trials and intend to do so for future preclinical and clinical trials. While we believe this will provide us with sufficient staffing for our current and future development efforts, we will need to hire or contract with additional qualified personnel with expertise in preclinical testing, clinical research and testing, government regulation, formulation and manufacturing and sales and marketing in connection with the continued development, regulatory approval and commercialization of our product candidates. We compete for qualified individuals with numerous pharmaceutical and biopharmaceutical companies, universities and other research institutions.

Competition for these individuals is intense, and we cannot be certain that our search for such personnel will be successful. Attracting and retaining qualified personnel will be critical to our success. In addition, we may be unable to attract and retain those qualified officers, directors and members of board committees required to provide for effective management. If we are unable to attract and retain qualified employees, officers and directors, the management and operation of our business could be adversely affected.

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

We will need to manage our anticipated growth and increased operational activity, including that which might result if we exercise our option with Novellus and in-license its novel cellular therapy for the treatment of ARDS. Our personnel, systems and facilities currently in place may not be adequate to support this future growth. Our need to effectively execute our growth strategy will require that we:

- manage our research and development activities and our regulatory trials effectively;
- attract and motivate sufficient numbers of talented employees or consultants;
- manage our internal development efforts effectively while complying with our contractual obligations to licensors, licensees, contractors, collaborators and other third parties;
- develop internal sales and marketing capabilities or establish collaborations with third parties with such capabilities;
- commercialize our product candidates; and
- improve our operational, financial and management controls, reporting systems and procedures.

This planned future growth could place a strain on our administrative and operational infrastructure and may require our management to divert a disproportionate amount of its attention away from our day-to-day activities. We may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel, which may result in weaknesses in our infrastructure, and give rise to operational mistakes, loss of business opportunities, loss of employees and consultants and reduced productivity among remaining employees and consultants. We may not be able to make improvements to our management information and control systems in an efficient or timely manner and may discover deficiencies in existing systems and controls. If our management is unable to effectively manage our expected growth, our expenses may increase more than expected, our ability to generate or increase our revenues could be reduced and we may not be able to implement our business strategy. Our future financial performance and our ability to compete effectively will depend, in part, on our ability to effectively manage any future growth.

Risks Related to Our Regulatory and Legal Environment

We are subject to extensive and costly government regulation.

Our product candidates are and any approved products will be subject to extensive and rigorous domestic government regulation including regulation by the FDA, the Centers for Medicare and Medicaid Services, other divisions of the U.S. Department of Health and Human Services, the U.S. Department of Justice, state and local governments, and their respective foreign equivalents. The FDA regulates the research, development, preclinical and clinical testing, manufacture, safety, effectiveness, record keeping, reporting, labeling, storage, approval, advertising, promotion, sale, distribution, import, and export of pharmaceutical products. If our product candidates are to be marketed abroad, they will also be subject to extensive regulation by foreign governments, whether or not they have obtained FDA approval. Such foreign regulation might be equally or more demanding than corresponding U.S. regulation. Government regulation substantially increases the cost and risk of researching, developing, manufacturing, and selling our product candidates. The regulatory review and approval process, which includes preclinical testing and clinical trials of each product candidate, is lengthy, expensive, and uncertain. We or our collaborators must obtain and maintain regulatory authorization to conduct clinical trials and approval for each product candidate we intend to market, and the manufacturing facilities used for the product candidates must be inspected and meet legal requirements. Securing regulatory approval requires submitting extensive preclinical and clinical data and other supporting information for each proposed product candidate in order to establish the product's safety and efficacy for each intended use. The development and approval process might take many years, requires substantial resources, and might never lead to the approval of a product. Further, the FDA or any foreign regulatory authority could change its established regulations that govern the drug development and approval process, which could negatively impact the regulatory review of our product candidates, including the anticipated timeline and cost of development and approval. Even if we are able to obtain regulatory approval for a particular product candidate, the approval might limit the indicated medical uses for the product, limit our ability to promote, sell, and distribute the product, require that we conduct costly post-marketing surveillance, and/or require that we conduct ongoing post-marketing studies. Material changes to an approved product, such as, for example, manufacturing changes or revised labeling, might require further regulatory review and approval. Once obtained, any approvals might be withdrawn, including, for example, if there is a later discovery of previously unknown problems with the product, such as a previously unknown safety issue.

If we, our collaborators or our contract manufacturers fail to comply with applicable regulatory requirements at any stage during the regulatory process, such noncompliance could result in, among other things: suspension or cessation of clinical trials; delays in the approval of applications or supplements to approved applications; refusal of a regulatory authority, including the FDA, to review pending market approval applications or supplements to approved applications; warning letters; fines; import and export restrictions; product recalls or seizures; injunctions; total or partial suspension of production; civil penalties; withdrawals of previously approved marketing applications or licenses; recommendations by the FDA or other regulatory authorities against governmental contracts; and/or criminal prosecutions.

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

We cannot assure you that we will receive the approvals necessary to commercialize for sale any product candidates we are currently developing or that we may acquire or seek to develop in the future. We will need FDA approval to commercialize our product candidates in the U.S. In order to obtain FDA approval of any product candidate, we must submit to the FDA an NDA demonstrating that the product candidate is safe for humans and effective for its intended use. This demonstration requires significant research, pre-clinical studies, and clinical trials. Satisfaction of the FDA's regulatory requirements typically takes many years, depends upon the type, complexity and novelty of the product candidate and requires substantial resources for research, development and testing. We cannot predict whether our research and clinical approaches will result in products that the FDA considers safe for humans and effective for their indicated uses. The FDA has substantial discretion in the product approval process and might require us to conduct additional pre-clinical and clinical testing, perform post-marketing studies or otherwise limit or impose conditions on any additional approvals we obtain. The approval process might also be delayed by changes in government regulation, future legislation or administrative action or changes in FDA policy that occur prior to or during our regulatory review. Delays in obtaining regulatory approvals might:

- delay commercialization of, and our ability to derive product revenues from, our product candidates;
- impose costly procedures on us; and
- diminish any competitive advantages that we might otherwise enjoy.

Even if we comply with all FDA requests, the FDA might ultimately reject one or more of our NDAs. We cannot be sure that we will ever obtain regulatory clearance for our product candidates. Failure to obtain FDA approval of our product candidates will severely undermine our business by leaving us without saleable products, and therefore without any potential sources of revenues, until another product candidate could be developed or obtained and successfully developed, approved and commercialized. Foreign jurisdictions impose similar regulatory approval processes and we will face the same risks if we seek foreign approval for any of our product candidates. There is no guarantee that we will ever be able to successfully develop or acquire any product candidate.

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

If one of our product candidates is approved by the FDA or by a foreign regulatory authority, we will be required to comply with extensive regulations for product manufacturing, labeling, packaging, adverse event reporting, storage, distribution, advertising, promotion and record keeping. Regulatory approvals may also be subject to significant limitations on the indicated uses or marketing of the products or to whom and how we may distribute an approved product. Even if U.S. regulatory approval is obtained, the FDA may still impose significant restrictions on a product's indicated uses or marketing or impose ongoing requirements for potentially costly post-approval studies. For example, the label ultimately approved for our product candidates, if any, may include restrictions on use. If so, we may be subject to ongoing regulatory obligations and restrictions, which may result in significant expense and limit our ability to commercialize our product candidates. The FDA could also require a registry to track the patients utilizing the product or implement a Risk Evaluation and Mitigation Strategy, or REMS, that could restrict access to the product, reduce our revenues and/or increase our costs. Potentially costly post-marketing clinical studies may be required as a condition of approval to further substantiate safety or efficacy, or to investigate specific issues of interest to the regulatory authority. Similar risks apply in foreign jurisdictions.

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

- issuance of Form 483 notices, warning letters and adverse publicity by the FDA or other regulatory agencies;
- imposition of fines and other civil penalties due to product liability or other issues;

- injunctions, suspensions or revocations of regulatory approvals;
- suspension of any ongoing pre-clinical and clinical trials;
- total or partial suspension of manufacturing;
- delays in commercialization;
- refusal by the FDA to approve pending applications or supplements to approved applications filed by us or our collaborators;
- refusals to permit medical products to be imported into or exported from the U.S.;
- restrictions on operations, including costly new manufacturing requirements;
- product recalls or seizures; and
- criminal prosecutions.

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

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

Post-approval marketing and promotion of products, standards and regulations for direct-to-consumer advertising, dissemination of off-label product information, industry-sponsored scientific and educational activities and promotional activities via the Internet are heavily scrutinized and regulated by the FDA. Products may only be marketed for approved indications and in accordance with provisions of the FDA approved labels. Failure to comply with such requirements may result in adverse publicity, warning letters issued by the FDA, and civil or criminal penalties.

In the event the FDA discovers post-approval violations, we could face penalties in the future including the FDA's issuance of a cease and desist order, impounding of our products, and civil or criminal penalties. As a follow-on to such governmental enforcement activities, consumers and other end-payers of the product may initiate action against us claiming, among other things, fraudulent misrepresentation, unfair competition, violation of various state consumer protection statutes and unjust enrichment. If the plaintiffs in such follow-on actions are successful, we could be subject to various damages, including compensatory damages, treble damages, punitive damages, restitution, disgorgement, prejudgment and post-judgment interest on any monetary award, and the reimbursement of the plaintiff's legal fees and costs, any of which could have an adverse effect on our revenue, business, financial condition and prospects.

We could be forced to pay substantial damage awards if product liability claims that may be brought against us are successful.

The use of any of our product candidates in pre-clinical and clinical trials, and the sale of any approved products, may expose us to liability claims and financial losses resulting from the use or sale of our product candidates. We have obtained limited product liability insurance coverage for our pre-clinical and clinical trials of \$5.0 million per occurrence and in the aggregate, subject to a deductible of \$25,000 per bodily injury and property damage occurrence and a medical expense each person limit of \$25,000. There can be no assurance that our existing insurance coverage will extend to any other product candidates in the future. Any product liability insurance coverage may not be sufficient to satisfy all liabilities resulting from product liability claims. A successful claim may prevent us from obtaining adequate product liability insurance in the future on commercially desirable terms, if at all. Even if a claim is not successful, defending such a claim would be time consuming and expensive, may damage that product's and our reputations in the marketplace, and would likely divert management's attention, any of which could have a material adverse effect on our company.

Risks Related to our Intellectual Property

Our business depends on protecting our intellectual property.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

The United States has enacted and is expected to continue to implement wide-ranging patent reform legislation. Further, recent United States Supreme Court rulings have either narrowed the scope of patent protection available in certain circumstances or weakened the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the scope and value of patents, once obtained.

In September 2011, the Leahy-Smith America Invents Act, also known as the America Invents Act, or AIA, was signed into law. The AIA includes a number of significant changes to U.S. patent law, including provisions that affect the way patent applications will be prosecuted and may also affect patent litigation. The USPTO is currently developing regulations and procedures to govern administration of the AIA, and many of the substantive changes to patent law associated with the AIA. It is not clear what other, if any, impact(s) the AIA will have on the operation of our business. Moreover, the AIA and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have an adverse effect on our business. One important change introduced by the AIA is that, as of March 16, 2013, the United States transitioned to a “first-to-file” system for deciding which party should be granted a patent when two or more patent applications are filed by different parties claiming the same invention. A third party who files a patent application with the USPTO after such date but prior to our filing may therefore be awarded a patent covering an invention of ours even if we were the first to invent. All of our U.S. patent applications were filed after March 16, 2013. This “first-inventor-to-file” system will require us both to remain cognizant, going forward, of the timing between invention and filing of a patent application.

Among some of the other changes introduced by the AIA are those that (i) limit where a patentee may file a patent infringement suit and (ii) provide opportunities for third parties to challenge any issued patent in the USPTO. Such changes apply to all of our U.S. patents. Because of a lower evidentiary standard in USPTO proceedings, as compared to the evidentiary standard applied in U.S. federal courts, necessary to invalidate a patent claim, a third party could potentially present evidence in a USPTO proceeding sufficient for the USPTO to find a claim invalid, notwithstanding that the same evidence would be insufficient to invalidate a claim first presented in a district court action. Accordingly, a third party may attempt opportunistically to use USPTO procedures to invalidate our patent claims.

Depending on decisions by the United States Congress, the U.S. federal courts, the USPTO or similar authorities in foreign jurisdictions, the laws and regulations governing patents could change in unpredictable ways that may weaken our and our licensors’ abilities to obtain new patents or to enforce existing patents we and our licensors or partners may obtain in the future.

Risks Related to Our Securities

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

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

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

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

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

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

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

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

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

We are subject to the reporting requirements of the Securities Exchange Act of 1934, as amended, or the Exchange Act, the Sarbanes-Oxley Act of 2002, or SOX, and Nasdaq rules and regulations. SOX requires, among other things, that we maintain effective disclosure controls and procedures and internal control over financial reporting. We perform system and process evaluation and testing of our internal controls over financial reporting to allow management to report on the effectiveness of our internal controls over financial reporting in our Annual Report on Form 10-K filing for each year, as required by Section 404 of SOX. We previously had identified material weaknesses in our internal control over financial reporting related to ineffective separation of duties due to our limited finance staff, our reliance on consultants to assist with the financial reporting function and a lack of documented policies and procedures, which weaknesses were reported in fiscal 2016 and 2017 (and prior to that by our predecessor company). While we remediated these material weaknesses as of September 30, 2018, such that management determined that our internal controls over financial reporting were effective as of that date, and as of June 30, 2020, we cannot assure that, in the future, a material weakness or significant deficiency will not exist or otherwise be discovered. If that were to happen, it could harm our operating results and cause stockholders to lose confidence in our reported financial information. Any such loss of confidence would have a negative effect on the trading price of our securities.

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

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

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

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

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

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

For the foreseeable future, to finance our operations, including possible acquisitions or strategic transactions, we expect to issue equity securities, resulting in the dilution of the ownership interests of our present stockholders. We are currently authorized to issue an aggregate of 200,000,000 shares of common stock and 10,000,000 shares of preferred stock. As of September 11, 2020, there were 55,475,822 shares of common stock outstanding, 26,285,479 shares underlying warrants with a weighted average exercise price of \$1.577 per share and 2,765,171 shares underlying options with a weighted average exercise price of \$2.803 per share. We may also issue additional shares of our common stock or other securities that are convertible into or exercisable for common stock in connection with hiring or retaining employees, or for other business purposes. The future issuance of any such additional shares of common stock or common stock equivalents may create downward pressure on the trading price of our common stock.

The common stock is controlled by insiders.

As of August 31, 2020, our executive officers and directors beneficially owned approximately 34.1% of our outstanding shares of common stock. Such concentrated control of our company may adversely affect the price of our common stock. If you acquire common stock, you may have no effective voice in the management of our company. Sales by our directors and executive officers or their affiliates, along with any other market transactions, could adversely affect the market price of our common stock.

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

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

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

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

USE OF PROCEEDS

The 641,166 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 641,166 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 \$841,530 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.

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

SELLING STOCKHOLDERS

The following table sets 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 August 31, 2020. The selling stockholders may offer the shares under this prospectus from time to time and may elect to sell under this prospectus some, all or none of the shares offered for resale by this prospectus. However, for the purposes of the table below, we have assumed that, after completion of the offering, none of the shares covered by this prospectus will be held by the selling stockholders. In addition, a selling stockholder may have sold, transferred or otherwise disposed of all or a portion of that holder's shares of common stock since the date on which the selling stockholder provided information for this table. We have not made independent inquiries about such transfers or dispositions. See the section entitled "Plan of Distribution" beginning on page 31.

Beneficial ownership is determined in accordance with Rule 13d-3(d) promulgated by the SEC under the Exchange Act. The percentage of shares beneficially owned prior to the offering is based on 55,475,822 shares of our common stock outstanding as of August 31, 2020.

Selling Stockholder	Number of Shares of Common Stock Beneficially Owned		Number of Share of Common Stock Offering	Shares of Common Stock Beneficially Owned After Sale of All Shares of Common Stock Pursuant to this Prospectus	
	Before Any Sale	% of Class		Number of Shares	% of Class
Noam Rubinstein ⁽¹⁾	988,035 ⁽²⁾	1.75%	201,967	786,068 ⁽²⁾	1.40%
Michael Vasinkevich ⁽¹⁾	1,962,304 ⁽²⁾	3.42%	411,148	1,551,156 ⁽²⁾	2.72%
Craig Schwabe ⁽¹⁾	53,196 ⁽²⁾	*	21,639	31,557 ⁽²⁾	*
Charles Worthman ⁽¹⁾	30,494 ⁽²⁾	*	6,412	24,082 ⁽²⁾	*
TOTAL	3,034,029	5.19%	641,166	2,392,863	4.13%

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

(1) The selling stockholder is an affiliate of a registered broker-dealer.

(2) Consists of warrants to purchase shares of common stock.

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

PLAN OF DISTRIBUTION

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

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

- ordinary brokerage transactions and transactions in which the broker-dealer solicits purchasers;
- block trades in which the broker-dealer will attempt to sell the shares as agent, but may position and resell a portion of the block as principal to facilitate the transaction;
- purchases by a broker-dealer as principal and resale by the broker-dealer for its account;
- an exchange distribution in accordance with the rules of the applicable exchange;

- privately negotiated transactions;
- short sales effected after the date the registration statement of which this prospectus is a part is declared effective by the SEC;
- through the writing or settlement of options or other hedging transactions, whether through an options exchange or otherwise;
- broker-dealers may agree with the selling stockholders to sell a specified number of such shares at a stipulated price per share;
- a combination of any such methods of sale; and
- any other method permitted by applicable law.

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

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

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

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

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

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

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

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

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

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 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 55,475,822 shares were issued and outstanding as of September 11, 2020, 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.

Common Stock

We are authorized to issue 200,000,000 shares of common stock, \$0.001 par value. Each share of common stock shall have one vote per share for all purposes. The holders of a majority of the shares entitled to vote, present in person or represented by proxy shall constitute a quorum at all meetings of our stockholders. Our common stock does not provide preemptive, subscription or conversion rights and there are no redemption or sinking fund provisions or rights. Our common 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 June 30, 2020, 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 2,765,171 shares of our common stock at a weighted average exercise price of \$2.803 per share. Of these, an aggregate of 1,293,260 are exercisable. The remainder has vesting requirements. No more grants may be made under our 2014 Stock Incentive Plan or our 2018 Omnibus Stock Incentive Plan.

Unit Purchase Options

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

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

Warrants

As of June 30, 2020, we had outstanding warrants to purchase an aggregate of 26,285,479 shares of our common stock at a weighted average price of \$1.577 per share, with a weighted average remaining life of 3.75 years.

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 August 31, 2020, we had 96 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.

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, 2019, 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, over the Internet at the SEC's website at <http://www.sec.gov>. We also maintain a website at <http://www.citiuspharma.com>, at which you may access these materials free of charge as soon as reasonably practicable after they are electronically filed with, or furnished to, the SEC. The information contained in, or that can be accessed through, our website is not part of this prospectus. You may also request a copy of these filings, at no cost, by writing or telephoning us at: 11 Commerce Drive, First Floor, Cranford, New Jersey 07016, (908) 967-6677.

INCORPORATION OF DOCUMENTS BY REFERENCE

The SEC allows us to "incorporate by reference" information that we file with them. Incorporation by reference allows us to disclose important information to you by referring you to those other documents. The information incorporated by reference is an important part of this prospectus and any applicable accompanying prospectus, and information that we file later with the SEC will automatically update and supersede this information. We filed a registration statement on Form S-3 under the Securities Act with the SEC with respect to the securities being offered pursuant to this prospectus and any applicable accompanying prospectus. This prospectus omits certain information contained in the registration statement, as permitted by the SEC. You should refer to the registration statement, including the exhibits, for further information about us and the securities being offered pursuant to this prospectus and any applicable accompanying prospectus. Statements in this prospectus and any applicable accompanying prospectus regarding the provisions of certain documents filed with, or incorporated by reference in, the registration statement are not necessarily complete, and 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, 2019, filed with the SEC pursuant to Section 13 of the Exchange Act on December 16, 2019;
- our Quarterly Report on [Form 10-Q](#) for the quarter ended December 31, 2019, filed with the SEC pursuant to Section 13 of the Exchange Act on February 13, 2020;
- our Quarterly Report on [Form 10-Q](#) for the quarter ended March 31, 2020, filed with the SEC pursuant to Section 13 of the Exchange Act on May 14, 2020;
- our Quarterly Report on [Form 10-Q](#) for the quarter ended June 30, 2020, filed with the SEC pursuant to Section 13 of the Exchange Act on August 14, 2020;
- our Current Reports on Form 8-K, filed with the SEC pursuant to Section 13 of the Exchange Act on [October 7](#), [November 1](#), [November 5](#) and [December 19, 2019](#), and [January 22](#), [February 3](#), [February 4](#), [February 10](#), [February 14](#), [February 19](#), [February 25](#), [April 1](#), [April 7](#), [April 28](#), [April 29](#), [May 12](#), [May 18](#), [May 26](#), [June 2](#), [June 26](#), [July 10](#), [July 14](#), [August 4](#), [August 10](#), [August 26](#) and [August 26](#), 2020; and
- our definitive proxy statement on Schedule 14A for the annual meeting of stockholders held on February 12, 2020, filed with the SEC pursuant to Section 14 of the Exchange Act on [December 20, 2019](#).

In addition, all documents subsequently filed by us pursuant to Section 13(a), 13(c), 14 or 15(d) of the Exchange Act before the date 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 and any applicable accompanying prospectus or in a document incorporated or deemed to be incorporated by reference into this prospectus and any applicable accompanying prospectus will be deemed to be modified or superseded for purposes of this prospectus and any applicable accompanying prospectus to the extent that a statement contained in this prospectus and any applicable accompanying prospectus or any other subsequently filed document that is deemed to be incorporated by reference into this prospectus and any applicable accompanying prospectus modifies or supersedes the statement. Any statement so modified or superseded will not be deemed, except as so modified or superseded, to constitute a part of this prospectus and any applicable accompanying prospectus.

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

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

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	\$	10,612
Legal fees and expenses	\$	15,000*
Accounting fees and expenses	\$	8,000*
Printing expenses	\$	1,500*
Miscellaneous	\$	4,888*
Total	\$	40,000*

* 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 78.7502 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 78.7502(1) or 78.7502(2), 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 provided by specific statute, 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.

Item 16. Exhibits.

Exhibit Number	Description of Document	Registrant's Form	Dated	Exhibit Number	Filed Herewith
1.1*	Form of Underwriting Agreement.	--	--	--	
3.1	Amended and Restated Articles of Incorporation of Citius Pharmaceuticals, Inc.	8-K	9/18/2014	3.1	
3.2	Certificate of Amendment to the Amended and Restated Articles of Incorporation of Citius Pharmaceuticals, Inc., effective September 16, 2016.	8-K	9/21/2016	3.1	
3.3	Certificate of Amendment to the Amended and Restated Articles of Incorporation of Citius Pharmaceuticals, Inc., effective June 9, 2017.	8-K	6/8/2017	3.1	
3.4	Amended and Restated Bylaws of Citius Pharmaceuticals, Inc.	8-K	2/9/2018	3.1	
4.1	Form of Registration Rights Agreement between the Purchasers named therein and Citius Pharmaceuticals Holdings, Inc., dated September 12, 2014.	8-K	9/18/2014	10.2	
4.2	Placement Agent's Unit Warrant in favor of Merriman Capital, Inc., dated September 12, 2014.	S-1/A	12/29/2015	10.12	
4.3	Form of Investor Warrant, dated September 12, 2014.	8-K	9/18/2014	10.3	
4.4	Form of Common Stock Purchase Warrant, dated May 10, 2017.	10-Q	5/15/2017	10.4	
4.5	Form of Representative's Warrant, dated August 3, 2017.	8-K	8/4/2017	4.2	
4.6	Form of Investor Warrant, dated December 15, 2017.	8-K	12/19/2017	4.1	
4.7	Form of Placement Agent Warrant, dated December 15, 2017.	8-K	12/19/2017	4.2	
4.8	Form of Investor Warrant, dated March 28, 2018.	8-K	3/29/2018	4.1	
4.9	Form of Placement Agent Warrant, dated March 28, 2018.	8-K	3/29/2018	4.2	
4.10	Form of Common Stock Purchase Warrant, dated August 13, 2018.	8-K	8/13/2018	4.1	
4.11	Form of Pre-Funded Common Stock Purchase Warrant, dated August 13, 2018.	8-K	8/13/2018	4.2	
4.12	Form of Underwriter's Common Stock Purchase Warrant, dated August 13, 2018.	8-K	8/13/2018	4.3	
4.13	Form of Investor Warrant issued April 3, 2019.	8-K	4/03/2019	4.1	
4.14	Form of Placement Agent Warrant issued April 3, 2019.	8-K	4/03/2019	4.2	
4.15	Form of Common Stock Purchase Warrant issued September 27, 2019.	8-K	9/27/2019	4.1	
4.16	Form of Pre-Funded Common Stock Purchase Warrant issued September 27, 2019.	8-K	9/27/2019	4.2	
4.17	Form of Underwriters Common Stock Purchase Warrant issued September 27, 2019.	8-K	9/27/2019	4.3	
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 Certificate of Amendment to Amended and Restated Articles of Incorporation of Citius Pharmaceuticals, Inc.	--	--	--	
4.24	Form of Indenture.				X
4.25*	Form of Note.	--	--	--	
4.26*	Form of Common Stock Warrant Agreement and Warrant Certificate.	--	--	--	
4.27*	Form of Preferred Stock Agreement and Warrant Certificate.	--	--	--	
4.28*	Form of Debt Securities Warrant Agreement and Warrant Certificate.	--	--	--	
4.29*	Form of Unit Agreement and Unit Certificate.	--	--	--	
4.30*	Form of Rights Agreement and Rights Certificate.	--	--	--	
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
25.1+	Statement of Eligibility of Trustee.				

* To be filed, if necessary, by amendment to the Registration Statement or as an exhibit to a report filed under the Exchange Act and incorporated by reference herein.

+ To be filed separately pursuant to Section 305(b)(2) of the Trust Indenture Act of 1939, as amended.

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.

(6) That, for the purpose of determining liability of the registrant under the Securities Act of 1933 to any purchaser in the initial distribution of the securities:

The undersigned registrant undertakes that in a primary offering of securities of the undersigned registrant pursuant to this Registration Statement, regardless of the underwriting method used to sell the securities to the purchaser, if the securities are offered or sold to such purchaser by means of any of the following communications, the undersigned registrant will be a seller to the purchaser and will be considered to offer or sell such securities to such purchaser:

- (i) Any preliminary prospectus or prospectus of the undersigned registrant relating to the offering required to be filed pursuant to Rule 424;
 - (ii) Any free writing prospectus relating to the offering prepared by or on behalf of the undersigned registrant or used or referred to by the undersigned registrant;
 - (iii) The portion of any other free writing prospectus relating to the offering containing material information about the undersigned registrant or its securities provided by or on behalf of the undersigned registrant; and
 - (iv) Any other communication that is an offer in the offering made by the undersigned registrant to the purchaser.
- (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.
- (j) The undersigned registrant hereby undertakes to file an application for the purpose of determining the eligibility of the trustee to act under subsection (a) of section 310 of the Trust Indenture Act ("Act") in accordance with the rules and regulations prescribed by the Commission under section 305(b)(2) of the Act.

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 September 11, 2020.

CITIUS PHARMACEUTICALS, INC.

By: /s/ Myron Holubiak
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)	September 11, 2020
<u>/s/ Jaime Bartushak</u> Jaime Bartushak	Chief Financial Officer and Chief Accounting Officer (Principal Accounting Officer)	September 11, 2020
<u>/s/ Leonard Mazur</u> Leonard Mazur	Executive Chairman, Board of Directors	September 11, 2020
<u>/s/ Suren Dutia</u> Suren Dutia	Director	September 11, 2020
<u>/s/ Dr. Eugene Holuka</u> Dr. Eugene Holuka	Director	September 11, 2020
<u>/s/ Dr. William Kane</u> Dr. William Kane	Director	September 11, 2020
<u>/s/ Howard Safir</u> Howard Safir	Director	September 11, 2020
<u>/s/ Carol Webb</u> Carol Webb	Director	September 11, 2020

CITIUS PHARMACEUTICALS, INC.

and

, as Trustee

INDENTURE

Dated as of _____, 20__

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INDENTURE, dated as of _____, 20____, by and between Citius Pharmaceuticals, Inc., a Nevada corporation, as Issuer (the "Company") and _____, a _____, organized under the laws of _____, as Trustee (the "Trustee").

RECITALS OF THE COMPANY

The Company has duly authorized the execution and delivery of this Indenture to provide for the issuance from time to time of its debentures, notes or other evidences of indebtedness to be issued in one or more series (the "Securities"), as herein provided, up to such principal amount as may from time to time be authorized in or pursuant to one or more resolutions of the Board of Directors or by supplemental indenture.

All things necessary to make this Indenture a valid agreement of the Company in accordance with its terms have been done, and the execution and delivery thereof have been in all respects duly authorized by the parties hereto.

NOW, THEREFORE, THIS INDENTURE WITNESSETH:

For and in consideration of the premises and the purchase of the Securities by the Holders thereof, it is mutually agreed, for the equal and proportionate benefit of all Holders of the Securities of a Series thereof, as follows:

ARTICLE 1

DEFINITIONS AND INCORPORATION BY REFERENCE

1.1. DEFINITIONS.

"Affiliate" of any specified Person means any other Person which, directly or indirectly through one or more intermediaries, controls, or is controlled by or is under common control with, such specified Person. For the purposes of this definition, "control" (including, with correlative meanings, the terms "controlling," "controlled by" and "under common control with"), as used with respect to any Person, means the possession, directly or indirectly, of the power to direct or cause the direction of the management or policies of such Person, whether through the ownership of voting securities, by agreement or otherwise.

"Agent" means any Registrar, Paying Agent, co-registrar or agent for service of notices and demands.

"Board of Directors" means the Board of Directors of the Company or any committee duly authorized to act therefor.

"Board Resolution" means a copy of a resolution certified pursuant to an Officers' Certificate to have been duly adopted by the Board of Directors of the Company and to be in full force and effect on the date of such certification which has been delivered to the Trustee.

"Capital Stock" means, with respect to any Person, any and all shares or other equivalents (however designated) of capital stock, partnership interests or any other participation, right or other interest in the nature of an equity interest in such Person or any option, warrant or other security convertible into any of the foregoing.

"Company" means the party named as such in the first paragraph of this Indenture until a successor replaces such party pursuant to Article 5 of this Indenture, and thereafter means the successor and any other primary obligor on the Securities.

"Company Order" means a written order signed in the name of the Company by two Officers, one of whom must be its Chief Executive Officer or its Chief Financial Officer.

“Company Request” means any written request signed in the name of the Company by its Chief Executive Officer, its President, any Vice President, its Chief Financial Officer or its Treasurer and attested to by its Secretary or any Assistant Secretary.

“Corporate Trust Office” means the office of the Trustee at which at any particular time its corporate trust business shall be principally administered.

“Default” means any event that is, or that with the passing of time or giving of notice or both would be, an Event of Default.

“Depository” means, with respect to the Securities of any Series issuable or issued in whole or in part in the form of one or more Global Securities, the Person designated as Depository for such Series by the Company, which Depository shall be a clearing agency registered under the Exchange Act, until a successor Depository shall have become such pursuant to the applicable provisions of this Indenture, and thereafter “Depository” shall mean each Person who is then a Depository hereunder, and if at any time there is more than one such Person, such Persons.

“Dollars” means the currency of the United States of America.

“Euro” means the single currency of participating member states of the economic and monetary union as contemplated in the Treaty on European Union.

“Exchange Act” means the Securities Exchange Act of 1934, as amended.

“Foreign Currency” means any currency or currency unit issued by a government other than the government of the United States of America.

“Foreign Government Obligations” means, with respect to Securities that are denominated in a Foreign Currency, (i) direct obligations of the government that issued or caused to be issued such currency for the payment of which obligations its full faith and credit is pledged or (ii) obligations of a Person controlled or supervised by, or acting as an agency or instrumentality of, such government, the timely payment of which is unconditionally guaranteed as a full faith and credit obligation by such government, which, in either case under clauses (i) and (ii), are not callable or redeemable at the option of the issuer thereof.

“GAAP” means generally accepted accounting principles consistently applied as in effect in the United States of America from time to time.

“Global Security” or “Global Securities” means a Security or Securities, as the case may be, in the form established pursuant to Section 2.2, evidencing all or part of a Series of Securities issued to the Depository for such Series or its nominee, and registered in the name of such Depository or nominee, and bearing the legend set forth in Section 2.15(c) (or such other legend(s) as may be applied to such Securities in accordance with Section 2.2(24)).

“Holder” or “Securityholder” means the Person in whose name a Security is registered on the Registrar’s books.

“Indebtedness” means (without duplication), with respect to any Person, any indebtedness at any time outstanding, secured or unsecured, contingent or otherwise, which is for borrowed money (whether or not the recourse of the lender is to the whole of the assets of such Person or only to a portion thereof), or evidenced by bonds, notes, debentures or similar instruments, or representing the balance deferred and unpaid of the purchase price of any property (excluding any balances that constitute accounts payable or trade payables, and other accrued liabilities arising in the ordinary course of business), if and to the extent any of the foregoing indebtedness would appear as a liability upon a balance sheet of such Person prepared in accordance with GAAP.

“Indenture” means this Indenture as amended, restated or supplemented from time to time.

“Interest Payment Date,” when used with respect to any Security, means the Stated Maturity of an installment of interest on such Security.

“Lien” means, with respect to any property or assets of any Person, any mortgage or deed of trust, pledge, hypothecation, assignment, deposit arrangement, security interest, lien, charge, easement, encumbrance, preference, priority or other security agreement or preferential arrangement of any kind or nature whatsoever on or with respect to such property or assets (including, without limitation, any capitalized lease obligation, conditional sales or other title retention agreement having substantially the same economic effect as any of the foregoing).

“Maturity,” when used with respect to any Security, means the date on which the principal of such Security, or an installment of principal, becomes due and payable as therein or herein provided, whether at the Stated Maturity or by declaration of acceleration, call for redemption, notice of option to elect payment or otherwise.

“Officer” means the Chief Executive Officer, the President, any Vice President, the Chief Financial Officer, the Treasurer or the Secretary of the Company, or any other officer designated by the Board of Directors, as the case may be.

“Officers’ Certificate” means, with respect to any Person, a certificate signed by the Chairman, Chief Executive Officer, President or any Senior or Executive Vice President and the Chief Financial Officer or any Treasurer of such Person, that shall comply with applicable provisions of this Indenture.

“Opinion of Counsel” means a written opinion from legal counsel, which counsel is reasonably acceptable to the Trustee. The counsel may be an employee of or counsel to the Company.

“Person” means any individual, corporation, limited liability company, partnership, joint venture, association, joint-stock company, trust, unincorporated organization or government (including any agency or political subdivision thereof).

“Redemption Date,” when used with respect to any Security to be redeemed, means the date fixed for such redemption pursuant to this Indenture.

“Responsible Officer,” when used with respect to the Trustee, means any officer within the corporate trust department or division of the Trustee (or any successor group of the Trustee) or any other officer of the Trustee customarily performing functions similar to those performed by any of the above designated officers, and also means, with respect to a particular corporate trust matter, any other officer to whom such matter is referred because of his knowledge of and familiarity with the particular subject.

“SEC” means the United States Securities and Exchange Commission as constituted from time to time, or any successor performing substantially the same functions.

“Securities” means the securities that are issued under this Indenture, as amended or supplemented from time to time pursuant to this Indenture.

“Securities Act” means the Securities Act of 1933, as amended.

“Series” or “Series of Securities” means each series of debentures, notes or other debt instruments of the Company created pursuant to Sections 2.1 and 2.2.

“Significant Subsidiary” means (i) any direct or indirect Subsidiary of the Company that would be a “significant subsidiary” as defined in Article 1, Rule 1-02 of Regulation S-X, promulgated pursuant to the Securities Act, as such regulation is in effect on the date hereof, or (ii) any group of direct or indirect Subsidiaries of the Company that, taken together as a group, would be a “significant subsidiary” as defined in Article 1, Rule 1-02 of Regulation S-X, promulgated pursuant to the Securities Act, as such regulation is in effect on the date hereof.

“Stated Maturity,” when used with respect to any Security or any installment of principal thereof or interest thereon, means the date specified in such Security as the fixed date on which the principal of such Security, or such installment of principal or interest, is due and payable, and when used with respect to any other Indebtedness, means the date specified in the instrument governing such Indebtedness as the fixed date on which the principal of such Indebtedness, or any installment of interest thereon, is due and payable.

“Subsidiary” of any specified Person means any corporation, limited liability company, partnership, joint venture, association or other business entity, whether now existing or hereafter organized or acquired, (i) in the case of a corporation, of which more than 50% of the total voting power of the Capital Stock entitled (without regard to the occurrence of any contingency) to vote in the election of directors thereof is held, directly or indirectly, by such Person or any of its Subsidiaries; or (ii) in the case of a partnership, joint venture, association or other business entity, with respect to which such Person or any of its Subsidiaries has the power to direct or cause the direction of the management and policies of such entity by contract or otherwise, or if in accordance with GAAP such entity is consolidated with such Person for financial statement purposes.

“TIA” means the Trust Indenture Act of 1939 (15 U.S. Code Section 77aaa-77bbb) as in effect on the date of this Indenture (except as provided in Section 8.3).

“Trustee” means the party named as such in this Indenture until a successor replaces it pursuant to this Indenture, and thereafter means the successor, and if at any time there is more than one such Person, “Trustee” as used with respect to the Securities of any Series shall mean the Trustee with respect to Securities of that Series.

“U.S. Government Obligations” means direct non-callable obligations of, or non-callable obligations guaranteed by, the United States of America for the payment of which obligation or guarantee the full faith and credit of the United States of America is pledged.

1.2. RESERVED.

1.3. INCORPORATION BY REFERENCE OF TRUST INDENTURE ACT.

Whenever this Indenture refers to a provision of the TIA, the portion of such provision required to be incorporated herein in order for this Indenture to be qualified under the TIA is incorporated by reference in and made a part of this Indenture. The following TIA terms used in this Indenture have the following meanings:

“Commission” means the SEC.

“indenture securities” means the Securities.

“indenture securityholder” means a Holder or Securityholder.

“indenture to be qualified” means this Indenture.

“indenture trustee” or “institutional trustee” means the Trustee.

“obligor on the indenture securities” means the Company.

All other terms used in this Indenture that are defined by the TIA, defined in the TIA by reference to another statute or defined by SEC rule have the meanings therein assigned to them.

1.4. RULES OF CONSTRUCTION.

Unless the context otherwise requires:

- (1) a term has the meaning assigned to it herein, whether defined expressly or by reference;
- (2) an accounting term not otherwise defined has the meaning assigned to it in accordance with GAAP;

(3) “or” is not exclusive;

(4) words in the singular include the plural, and in the plural include the singular;

(5) words used herein implying any gender shall apply to each gender; and

(6) the words “herein”, “hereof” and “hereunder” and other words of similar import refer to this Indenture as a whole and not to any particular Article, Section or other subdivision.

ARTICLE 2

THE SECURITIES

2.1. ISSUABLE IN SERIES.

The aggregate principal amount of Securities that may be authenticated and delivered under this Indenture is \$[]. The Securities may be issued in one or more Series. All Securities of a Series shall be identical except as may be set forth in a Board Resolution, a supplemental indenture or an Officers’ Certificate detailing the adoption of the terms thereof pursuant to the authority granted under a Board Resolution. In the case of Securities of a Series to be issued from time to time, the Board Resolution, Officers’ Certificate or supplemental indenture may provide for the method by which specified terms (such as interest rate, Stated Maturity, record date or date from which interest shall accrue) are to be determined. Securities may differ between Series in respect of any matters, PROVIDED, that all Series of Securities shall be equally and ratably entitled to the benefits of the Indenture.

2.2. ESTABLISHMENT OF TERMS OF SERIES OF SECURITIES.

At or prior to the issuance of any Securities within a Series, the following shall be established (as to the Series generally, in the case of Subsection 2.2(1) and either as to such Securities within the Series or as to the Series generally in the case of Subsections 2.2(2) through 2.2(24)) by a Board Resolution, a supplemental indenture or an Officers’ Certificate, in each case, pursuant to authority granted under a Board Resolution:

(1) the title of the Series (which shall distinguish the Securities of that particular Series from the Securities of any other Series);

(2) any limit upon the aggregate principal amount of the Securities of the Series which may be authenticated and delivered under this Indenture (except for Securities authenticated and delivered upon registration of transfer of, or in exchange for, or in lieu of, other Securities of the Series pursuant to Section 2.7, 2.8, 2.11, 3.6 or 8.5);

(3) the price or prices (expressed as a percentage of the principal amount thereof) at which the Securities of the Series will be issued;

(4) the date or dates on which the principal of the Securities of the Series is payable;

(5) the rate or rates (which may be fixed or variable) per annum or, if applicable, the method used to determine such rate or rates (including, but not limited to, any commodity, commodity index, stock exchange index or financial index) at which the Securities of the Series shall bear interest, if any, the date or dates from which such interest, if any, shall accrue, the date or dates on which such interest, if any, shall commence and be payable and any regular record date for the interest payable on any Interest Payment Date;

(6) the place or places where the principal of, and interest and premium, if any, on, the Securities of the Series shall be payable, or the method of such payment, if by wire transfer, mail or other means;

(7) if applicable, the period or periods within which, the price or prices at which and the terms and conditions upon which the Securities of the Series may be redeemed, in whole or in part, at the option of the Company;

(8) the obligation, if any, of the Company to redeem or purchase the Securities of the Series pursuant to any sinking fund or analogous provisions or at the option of a Holder thereof, and the period or periods within which, the price or prices at which and the terms and conditions upon which Securities of the Series shall be redeemed or purchased, in whole or in part, pursuant to such obligation;

(9) the dates, if any, on which and the price or prices at which the Securities of the Series will be repurchased by the Company at the option of the Holders thereof, and other detailed terms and provisions of such repurchase obligations;

(10) if other than denominations of \$1,000 and any integral multiple thereof, the denominations in which the Securities of the Series shall be issuable;

(11) the forms of the Securities of the Series in bearer (if to be issued outside of the United States of America) or fully registered form (and, if in fully registered form, whether the Securities will be issuable as Global Securities);

(12) if other than the principal amount thereof, the portion of the principal amount of the Securities of the Series that shall be payable upon declaration of acceleration of the Maturity thereof pursuant to Section 6.2;

(13) the currency of denomination of the Securities of the Series, which may be Dollars or any Foreign Currency, including, but not limited to, the Euro, and, if such currency of denomination is a composite currency other than the Euro, the agency or organization, if any, responsible for overseeing such composite currency;

(14) the designation of the currency, currencies or currency units in which payment of the principal of, and interest and premium, if any, on, the Securities of the Series will be made;

(15) if payments of principal of, or interest or premium, if any, on, the Securities of the Series are to be made in one or more currencies or currency units other than that or those in which such Securities are denominated, the manner in which the exchange rate with respect to such payments will be determined;

(16) the manner in which the amounts of payment of principal of, or interest and premium, if any, on, the Securities of the Series will be determined, if such amounts may be determined by reference to an index based on a currency or currencies or by reference to a commodity, commodity index, stock exchange index or financial index;

(17) the provisions, if any, relating to any collateral provided for the Securities of the Series;

(18) any addition to or change in the covenants set forth in Articles 4 or 5 that applies to Securities of the Series;

(19) any addition to or change in the Events of Default which applies to any Securities of the Series, and any change in the right of the Trustee or the requisite Holders of such Securities to declare the principal amount thereof due and payable pursuant to Section 6.2;

(20) the terms and conditions, if any, for conversion of the Securities into or exchange of the Securities for shares of common stock or preferred stock of the Company that apply to Securities of the Series;

(21) any depositories, interest rate calculation agents, exchange rate calculation agents or other agents with respect to Securities of such Series if other than those appointed herein;

(22) the terms and conditions, if any, upon which the Securities shall be subordinated in right of payment to other Indebtedness of the Company;

(23) if applicable, that the Securities of the Series, in whole or any specified part, shall be defeasible pursuant to Article 9; and

(24) any other terms of the Securities of the Series (which terms shall not be inconsistent with the provisions of this Indenture, except as permitted by Section 8.1, but which may modify or delete any provision of this Indenture insofar as it applies to such Series).

All Securities of any one Series need not be issued at the same time, and may be issued from time to time, consistent with the terms of this Indenture, if so provided by or pursuant to the Board Resolution, supplemental indenture or Officers' Certificate referred to above, however, the authorized principal amount of any Series may not be increased to provide for issuances of additional Securities of such Series, unless otherwise provided in such Board Resolution, supplemental indenture or Officers' Certificate.

2.3. EXECUTION AND AUTHENTICATION.

The Securities shall be executed on behalf of the Company by two Officers of the Company or an Officer and an Assistant Secretary of the Company. Each such signature may be either manual or facsimile. The Company's seal, if any, may be impressed, affixed, imprinted or reproduced on the Securities and may be in facsimile form.

If an Officer whose signature is on a Security no longer holds that office at the time the Security is authenticated, the Security shall nevertheless be valid.

A Security shall not be valid until authenticated by the manual signature of the Trustee or an authenticating agent. The signature shall be conclusive evidence that the Security has been authenticated under this Indenture. The Trustee shall at any time, and from time to time, authenticate Securities for original issue in the principal amount provided in the Board Resolution, supplemental indenture hereto or Officers' Certificate, upon receipt by the Trustee of a Company Order. Such Company Order may authorize authentication and delivery pursuant to oral or electronic instructions from the Company or its duly authorized agent or agents, which oral instructions shall be promptly confirmed in writing. Each Security shall be dated the date of its authentication.

The aggregate principal amount of Securities of any Series outstanding at any time may not exceed any limit upon the maximum principal amount for such Series set forth in the Board Resolution, supplemental indenture hereto or Officers' Certificate delivered pursuant to Section 2.2, except as provided in Section 2.8.

Prior to the issuance of Securities of any Series, the Trustee shall have received and (subject to Section 7.1) shall be fully protected in relying on: (a) the Board Resolution, supplemental indenture hereto or Officers' Certificate establishing the form of the Securities of that Series or of Securities within that Series and the terms of the Securities of that Series or of Securities within that Series, (b) an Officers' Certificate complying with Section 10.4, and (c) an Opinion of Counsel complying with Section 10.4.

The Trustee shall have the right to decline to authenticate and deliver any Securities of any Series: (a) if the Trustee, being advised in writing by outside counsel, determines that such action may not lawfully be taken; or (b) if the Trustee in good faith by its board of directors or trustees, executive committee or a trust committee of directors and/or vice-presidents shall reasonably determine that such action would expose the Trustee to personal liability, or cause it to have a conflict of interest with respect to Holders of any then outstanding Series of Securities.

The Trustee may appoint an authenticating agent acceptable to the Company to authenticate Securities. An authenticating agent may authenticate Securities whenever the Trustee may do so. Any appointment shall be evidenced by an instrument signed by an authorized officer of the Trustee, a copy of which shall be furnished to the Company. Each reference in this Indenture to authentication by the Trustee includes authentication by such agent. An authenticating agent has the same rights as an Agent to deal with the Company or an Affiliate of the Company.

2.4. REGISTRAR AND PAYING AGENT.

The Company shall maintain in each Place of Payment for any Series of Securities (i) an office or agency where such Securities may be presented for registration of transfer or for exchange (“Registrar”), (ii) an office or agency where such Securities may be presented for payment (“Paying Agent”) (PROVIDED that the Company shall at all times maintain a Paying Agent in the Borough of Manhattan, City of New York, State of New York (the “New York Paying Agent”), and PROVIDED, FURTHER, that at the option of the Company payment of interest may be made by check mailed to the address of the Person entitled thereto as such address shall appear in the register for the Securities maintained by the Registrar), and (iii) an office or agency where notices and demands to or upon the Company in respect of the Securities and this Indenture may be served (“Service Agent”). The Registrar shall keep a register of the Securities and of their transfer and exchange. The Company may have one or more co-registrars and one or more additional paying agents. The Company shall give prompt written notice to the Trustee of the location, and any change in the location, of such office or agency. If at any time the Company shall fail to maintain any such required office, or to furnish the Trustee with the address thereof, such presentations, surrenders, notices and demands may be made or served at the address of the Trustee as set forth in Section 10.2. If the Company acts as Paying Agent, it shall segregate the money held by it for the payment of principal of, and interest and premium, if any, on, the Securities and hold it as a separate trust fund. The Company may change any Paying Agent, Registrar, co-registrar or any other Agent without notice to any Securityholder.

The Company may also from time to time designate one or more other offices or agencies where the Securities may be presented or surrendered for any or all such purposes, and may from time to time rescind such designations; PROVIDED, HOWEVER, that no such designation or rescission shall in any manner relieve the Company of its obligation to maintain an office or agency in each Place of Payment for Securities of any Series for such purposes. The Company hereby initially designates the Corporate Trust Office of the Trustee as such office of the Company. The Company shall give prompt written notice to the Trustee of such designation or rescission, and of any change in the location of any such other office or agency.

The Company shall enter into an appropriate agency agreement with any Registrar or Paying Agent not a party to this Indenture. The agreement shall implement the provisions of this Indenture that relate to such Agent. The Company shall notify the Trustee of the name and address of any such Agent. If the Company fails to maintain a Registrar or Paying Agent, or agent for service of notices and demands, or fails to give the foregoing notice, the Trustee shall act as such. The Company hereby appoints the Trustee as the initial Registrar, Paying Agent and Service Agent for each Series unless another Registrar, Paying Agent or Service Agent, as the case may be, is appointed prior to the time Securities of that Series are first issued. The Company designates _____, as the New York Paying Agent, with offices at _____.

2.5. PAYING AGENT TO HOLD ASSETS IN TRUST.

The Trustee as Paying Agent shall, and the Company shall require each Paying Agent other than the Trustee to agree in writing that each Paying Agent shall, hold in trust for the benefit of the Holders of any Series of Securities or the Trustee all assets held by the Paying Agent for the payment of principal of, or interest or premium, if any, on, such Series of Securities (whether such assets have been distributed to it by the Company or any other obligor on such Series of Securities), and the Company and the Paying Agent shall notify the Trustee in writing of any Default by the Company (or any other obligor on such Series of Securities) in making any such payment. The Company at any time may require a Paying Agent to distribute all assets held by it to the Trustee and account for any assets disbursed, and the Trustee may, at any time during the continuance of any payment default with respect to any Series of Securities, upon written request to a Paying Agent, require such Paying Agent to distribute all assets held by it to the Trustee and to account for any assets distributed. Upon distribution to the Trustee of all assets that shall have been delivered by the Company to the Paying Agent, the Paying Agent shall have no further liability for such assets.

2.6. SECURITYHOLDER LISTS.

The Trustee shall preserve in as current a form as is reasonably practicable the most recent list available to it of the names and addresses of Securityholders of each Series of Securities. If the Trustee is not the Registrar, the Company shall furnish to the Trustee as of each regular record date for the payment of interest on the Securities of a Series and before each related Interest Payment Date, and at such other times as the Trustee may request in writing, a list in such form and as of such date as the Trustee may reasonably require of the names and addresses of Securityholders of each Series of Securities.

2.7. TRANSFER AND EXCHANGE.

When Securities of a Series are presented to the Registrar with a request to register the transfer thereof, the Registrar shall register the transfer as requested if the requirements of applicable law are met, and when such Securities of a Series are presented to the Registrar with a request to exchange them for an equal principal amount of other authorized denominations of Securities of the same Series, the Registrar shall make the exchange as requested. To permit transfers and exchanges, upon surrender of any Security for registration of transfer at the office or agency maintained pursuant to Section 2.4, the Company shall execute and the Trustee shall authenticate Securities at the Registrar's request.

If Securities are issued as Global Securities, the provisions of Section 2.15 shall apply.

All Securities issued upon any registration of transfer or exchange of Securities shall be the valid obligations of the Company, evidencing the same debt, and entitled to the same benefits under this Indenture, as the Securities surrendered upon such registration of transfer or exchange.

Every Security presented or surrendered for registration of transfer or for exchange shall (if so required by the Company or the Registrar or a co-registrar) be duly endorsed, or be accompanied by a written instrument of transfer in form satisfactory to the Company and the Registrar or a co-registrar, duly executed by the Holder thereof or his attorney duly authorized in writing.

Any exchange or transfer shall be without charge, except that the Company may require payment by the Holder of a sum sufficient to cover any tax or other governmental charge that may be imposed in relation to a transfer or exchange, but this provision shall not apply to any exchange pursuant to Section 2.11, 3.6 or 8.5. The Trustee shall not be required to register transfers of Securities of any Series, or to exchange Securities of any Series, for a period of 15 days before the record date for selection for redemption of such Securities. The Trustee shall not be required to exchange or register transfers of Securities of any Series called or being called for redemption in whole or in part, except the unredeemed portion of such Security being redeemed in part.

2.8. REPLACEMENT SECURITIES.

If a mutilated Security is surrendered to the Trustee, or if the Holder of a Security presents evidence to the satisfaction of the Company and the Trustee that the Security has been lost, destroyed or wrongfully taken, the Company shall issue and the Trustee shall authenticate a replacement Security of the same Series and of like tenor and principal amount and bearing a number not contemporaneously outstanding. An indemnity bond may be required by the Company or the Trustee that is sufficient in the reasonable judgment of the Company or the Trustee, as the case may be, to protect the Company, the Trustee or any Agent from any loss which any of them may suffer if a Security is replaced. The Company may charge such Holder for the Company's out-of-pocket expenses in replacing a Security, including the fees and expenses of the Trustee. Every replacement Security shall constitute an original additional obligation of the Company, whether or not the destroyed, lost or stolen Security shall be at any time enforceable by anyone, and shall be entitled to all the benefits of this Indenture equally and proportionately with any and all other Securities of that Series duly issued hereunder.

2.9. OUTSTANDING SECURITIES.

Securities outstanding at any time are all Securities authenticated by the Trustee, except for those canceled by it, those delivered to it for cancellation and those described in this Section 2.9 as not outstanding.

If a Security is replaced pursuant to Section 2.8 (other than a mutilated Security surrendered for replacement), it ceases to be outstanding until the Company and the Trustee receive proof satisfactory to each of them that the replaced Security is held by a bona fide purchaser. A mutilated Security ceases to be outstanding upon surrender of such Security and replacement thereof pursuant to Section 2.8.

If a Paying Agent holds on a Redemption Date or the Stated Maturity money sufficient to pay the principal of, premium, if any, and accrued interest on, Securities payable on that date, and is not prohibited from paying such money to the Holders thereof pursuant to the terms of this Indenture (PROVIDED, that if such Securities are to be redeemed, notice of such redemption has been duly given pursuant to this Indenture or provision therefor satisfactory to the Trustee has been made), then on and after that date such Securities cease to be outstanding and interest on them ceases to accrue.

A Security does not cease to be outstanding solely because the Company or an Affiliate holds the Security.

2.10. WHEN TREASURY SECURITIES DISREGARDED; DETERMINATION OF HOLDERS' ACTION.

In determining whether the Holders of the required aggregate principal amount of the Securities of any Series have concurred in any direction, waiver or consent, the Securities of any Series owned by the Company or any other obligor on such Securities, or by any Affiliate of any of them, shall be disregarded, except that for the purposes of determining whether the Trustee shall be protected in relying on any such direction, waiver or consent, only Securities of such Series which the Trustee actually knows are so owned shall be so disregarded. Securities of such Series so owned which have been pledged in good faith shall not be disregarded if the pledgee establishes to the satisfaction of the Trustee the pledgee's right so to act with respect to the Securities of such Series and that the pledgee is not the Company or any other obligor on the Securities of such Series, or an Affiliate of any of them.

2.11. TEMPORARY SECURITIES.

Until definitive Securities are ready for delivery, the Company may prepare and execute, and the Trustee shall authenticate, temporary Securities. Temporary Securities shall be substantially in the form, and shall carry all rights, of definitive Securities, but may have variations that the Company considers appropriate for temporary Securities. Without unreasonable delay, the Company shall prepare and execute, and the Trustee shall authenticate, definitive Securities in exchange for temporary Securities without charge to the Holder.

2.12. CANCELLATION.

All Securities surrendered for payment, redemption or registration of transfer or exchange, or for credit against any sinking fund payment, shall, if surrendered to any Person other than the Trustee, be delivered to the Trustee for cancellation. The Company may at any time deliver to the Trustee for cancellation any Securities previously authenticated and delivered hereunder which the Company may have acquired in any manner whatsoever, and may deliver to the Trustee (or to any other Person for delivery to the Trustee) for cancellation any Securities previously authenticated hereunder which the Company has not issued and sold. The Registrar and the Paying Agent shall forward to the Trustee any Securities surrendered to them for transfer, exchange or payment. The Trustee or, at the direction of the Trustee, the Registrar or the Paying Agent, and no one else, shall cancel, and at the written request of the Company shall dispose of, all Securities surrendered for transfer, exchange, payment or cancellation. If the Company shall acquire any of the Securities, such acquisition shall not operate as a redemption or satisfaction of the Indebtedness represented by such Securities unless and until the same are surrendered to the Trustee for cancellation pursuant to this Section 2.12. No Securities shall be authenticated in lieu of or in exchange for any Securities cancelled as provided in this Section 2.12, except as expressly permitted by this Indenture.

2.13. PAYMENT OF INTEREST; DEFAULTED INTEREST; COMPUTATION OF INTEREST.

Except as otherwise provided as contemplated by Section 2.2 with respect to any Series of Securities, interest on any Security which is payable, and is punctually paid or duly provided for, on any Interest Payment Date shall be paid to the Person in whose name that Security is registered at the close of business on the regular record date for such interest, as provided in the Board Resolution, supplemental indenture hereto or Officers' Certificate establishing the terms of such Series.

If the Company defaults in a payment of interest on the Securities, it shall pay the defaulted amounts, plus any interest payable on defaulted amounts pursuant to Section 4.1, to the Persons who are Securityholders on a subsequent special record date, which date shall be the 15th day next preceding the date fixed by the Company for the payment of defaulted interest, or the next succeeding Business Day if such date is not a Business Day. At least 15 days before the special record date, the Company shall mail or cause to be mailed to each Securityholder, with a copy to the Trustee, a notice that states the special record date, the payment date and the amount of defaulted interest, and interest payable on such defaulted interest, if any, to be paid.

Except as otherwise specified as contemplated by Section 2.2 for Securities of any Series, interest on the Securities of each Series shall be computed on the basis of a 360-day year of twelve 30-day months.

2.14. CUSIP NUMBER.

The Company in issuing the Securities may use one or more "CUSIP" numbers, and, if the Company does so, the Trustee shall use the CUSIP number(s) in notices of redemption or exchange as a convenience to Holders, PROVIDED, that any such notice may state that no representation is made as to the correctness or accuracy of the CUSIP number(s) printed in the notice or on the Securities, and that reliance may be placed only on the other identification numbers printed on the Securities, and that any such redemption or exchange shall not be affected by any defect in or omission of any such numbers.

2.15. PROVISIONS FOR GLOBAL SECURITIES.

(a) A Board Resolution, a supplemental indenture hereto or an Officers' Certificate shall establish whether the Securities of a Series shall be issued in whole or in part in the form of one or more Global Securities, and the Depository for such Global Securities or Securities.

(b) Notwithstanding any provisions to the contrary contained in Section 2.7 and in addition thereto, if, and only if the Depository (i) at any time is unwilling or unable to continue as Depository for such Global Security or ceases to be a clearing agency registered under the Exchange Act and (ii) a successor Depository is not appointed by the Company within 90 days after the date the Company is so informed in writing or becomes aware of the same, the Company promptly will execute and deliver to the Trustee definitive Securities, and the Trustee, upon receipt of a Company Request for the authentication and delivery of such definitive Securities (which the Company will promptly execute and deliver to the Trustee) and an Officers' Certificate to the effect that such Global Security shall be so exchangeable, will authenticate and deliver definitive Securities, without charge, registered in such names and in such authorized denominations as the Depository shall direct in writing (pursuant to instructions from its direct and indirect participants or otherwise) in an aggregate principal amount equal to the principal amount of the Global Security with like tenor and terms. Upon the exchange of a Global Security for definitive Securities, such Global Security shall be canceled by the Trustee. Unless and until it is exchanged in whole or in part for definitive Securities, as provided in this Section 2.15(b), a Global Security may not be transferred except as a whole by the Depository with respect to such Global Security to a nominee of such Depository, by a nominee of such Depository to such Depository or another nominee of such Depository or by the Depository or any such nominee to a successor Depository or a nominee of such a successor Depository.

(c) Any Global Security issued hereunder shall bear a legend in substantially the following form:

"This Security is a Global Security within the meaning of the Indenture hereinafter referred to, and is registered in the name of the Depository or a nominee of the Depository. This Security is exchangeable for Securities registered in the name of a Person other than the Depository or its nominee only in the limited circumstances described in the Indenture, and may not be transferred except as a whole by the Depository to a nominee of the Depository, by a nominee of the Depository to the Depository or another nominee of the Depository or by the Depository or any such nominee to a successor Depository or a nominee of such a successor Depository."

(d) The Depository, as a Holder, may appoint agents and otherwise authorize participants to give or take any request, demand, authorization, direction, notice, consent, waiver or other action which a Holder is entitled to give or take under the Indenture.

(e) Notwithstanding the other provisions of this Indenture, unless otherwise specified as contemplated by Section 2.2, payment of the principal of, and interest and premium, if any, on, any Global Security shall be made to the Depository or its nominee in its capacity as the Holder thereof.

(f) Except as provided in Section 2.15(e) above, the Company, the Trustee and any Agent shall treat a Person as the Holder of such principal amount of outstanding Securities of any Series represented by a Global Security as shall be specified in a written statement of the Depository (which may be in the form of a participants' list for such Series) with respect to such Global Security, for purposes of obtaining any consents, declarations, waivers or directions required to be given by the Holders pursuant to this Indenture, PROVIDED, that until the Trustee is so provided with a written statement, it may treat the Depository or any other Person in whose name a Global Security is registered as the owner of such Global Security for the purpose of receiving payment of the principal of, and any premium and (subject to Section 2.13) any interest on, such Global Security and for all other purposes whatsoever, and none of the Company, the Trustee or any agent of the Company or the Trustee shall be affected by notice to the contrary.

2.16. PERSONS DEEMED OWNERS.

Prior to due presentment of a Security for registration of transfer, the Company, the Trustee, the Registrar and any agent of the Company, the Registrar or the Trustee may treat the Person in whose name such Security is registered as the owner of such Security for the purpose of receiving payment of the principal of, and any premium and (subject to Section 2.13) any interest on, such Security and for all other purposes whatsoever, and none of the Company, the Trustee, the Registrar or any agent of the Company, the Trustee or the Registrar shall be affected by notice to the contrary.

ARTICLE 3

REDEMPTION

3.1. NOTICES TO TRUSTEE.

The Company may, with respect to any Series of Securities, reserve the right to redeem and pay the Series of Securities, or may covenant to redeem and pay the Series of Securities or any part thereof, prior to the Stated Maturity thereof at such time and on such terms as provided for in such Securities or the related Board Resolution, supplemental indenture or Officers' Certificate. If a Series of Securities is redeemable and the Company elects to redeem all or part of such Series of Securities, it shall notify the Trustee of the Redemption Date and the principal amount of Securities to be redeemed at least 45 days (unless a shorter notice shall be satisfactory to the Trustee) before the Redemption Date. Any such notice may be canceled at any time prior to notice of such redemption being mailed to any Holder, and shall thereby be void and of no effect.

3.2. SELECTION BY TRUSTEE OF SECURITIES TO BE REDEEMED.

Unless otherwise indicated for a particular Series of Securities by a Board Resolution, a supplemental indenture or an Officers' Certificate, if fewer than all of the Securities of a Series are to be redeemed, the Trustee shall select the Securities of a Series to be redeemed pro rata, by lot or by any other method that the Trustee considers fair and appropriate (unless the Company specifically directs the Trustee otherwise) and, if such Securities are listed on any securities exchange, by a method that complies with the requirements of such exchange.

The Trustee shall make the selection from Securities of a Series outstanding and not previously called for redemption, and shall promptly notify the Company in writing of the Securities selected for redemption and, in the case of any Security selected for partial redemption, the principal amount thereof to be redeemed at least 35 but not more than 60 days before the Redemption Date. Securities of a Series in denominations of \$1,000 may be redeemed only in whole. The Trustee may select for redemption portions of the principal of Securities of a Series that have denominations larger than \$1,000. Securities of a Series and portions of them it selects shall be in amounts of \$1,000 or, with respect to Securities of any Series issuable in other denominations pursuant to Section 2.2(10), the minimum principal denomination for each Series and integral multiples thereof. Provisions of this Indenture that apply to Securities called for redemption also apply to portions of Securities called for redemption.

3.3. NOTICE OF REDEMPTION.

Unless otherwise indicated for a particular Series by Board Resolution, a supplemental indenture hereto or an Officers' Certificate, at least 30 days, and no more than 60 days, before a Redemption Date, the Company shall mail, or cause to be mailed, a notice of redemption by first-class mail to each Holder of Securities to be redeemed at his or her last address as the same appears on the registry books maintained by the Registrar. The notice shall identify the Securities to be redeemed and shall state:

- (1) the Redemption Date;
- (2) the redemption price, and that such redemption price shall become due and payable on the Redemption Date;
- (3) if any Security of a Series is being redeemed in part, the portion of the principal amount of such Security of a Series to be redeemed and that, after the Redemption Date and upon surrender of such Security of a Series, a new Security or Securities in principal amount equal to the unredeemed portion will be issued;
- (4) the name and address of the Paying Agent;
- (5) that Securities of a Series called for redemption must be surrendered to the Paying Agent to collect the redemption price, and the place or places where each such Security is to be surrendered for such payment;
- (6) that, unless the Company defaults in making the redemption payment, interest on the Securities of a Series called for redemption ceases to accrue on the Redemption Date, and the only remaining right of the Holders of such Securities is to receive payment of the redemption price upon surrender to the Paying Agent of the Securities redeemed;
- (7) if fewer than all of the Securities of a Series are to be redeemed, the identification of the particular Securities of a Series (or portion thereof) to be redeemed, as well as the aggregate principal amount of Securities of a Series to be redeemed and the aggregate principal amount of Securities of a Series to be outstanding after such partial redemption;
- (8) the CUSIP number, if any, printed on the Securities being redeemed; and
- (9) that no representation is made as to the correctness or accuracy of the CUSIP number, if any, listed in such notice or printed on the Securities.

At the Company's request, the Trustee shall give the notice of redemption in the Company's name and at the Company's sole expense.

3.4. EFFECT OF NOTICE OF REDEMPTION.

Once the notice of redemption described in Section 3.3 is mailed, Securities of a Series called for redemption become due and payable on the Redemption Date and at the redemption price, plus interest, if any, accrued to the Redemption Date. Upon surrender to the Trustee or Paying Agent, such Securities of a Series shall be paid at the redemption price, plus accrued interest, if any, to the Redemption Date; PROVIDED, that if the Redemption Date is after a regular interest payment record date and on or prior to the next Interest Payment Date, the accrued interest shall be payable to the Holder of the redeemed Securities registered on the relevant record date, as specified by the Company in the notice to the Trustee pursuant to Section 3.1.

3.5. DEPOSIT OF REDEMPTION PRICE.

On or prior to the Redemption Date (but no later than 11:00 A.M. Eastern Time on such date), the Company shall deposit with the Paying Agent money sufficient to pay the redemption price of and accrued interest, if any, on all Securities to be redeemed on that date other than Securities or portions thereof called for redemption on that date which have been delivered by the Company to the Trustee for cancellation.

On and after any Redemption Date, if money sufficient to pay the redemption price of, and accrued interest on, Securities called for redemption shall have been made available in accordance with the preceding paragraph and the Company and the Paying Agent are not prohibited from paying such moneys to Holders, the Securities called for redemption will cease to accrue interest and the only right of the Holders of such Securities will be to receive payment of the redemption price of and, subject to the proviso in Section 3.4, accrued and unpaid interest on such Securities to the Redemption Date. If any Security called for redemption shall not be so paid, interest will be paid, from the Redemption Date until such redemption payment is made, on the unpaid principal of the Security and any interest or premium, if any, not paid on such unpaid principal, in each case, at the rate and in the manner provided in the Securities.

3.6. SECURITIES REDEEMED IN PART.

Upon surrender of a Security of a Series that is redeemed in part, the Company shall execute, and the Trustee shall authenticate, for a Holder a new Security of the same Series equal in principal amount to the unredeemed portion of the Security surrendered.

ARTICLE 4

COVENANTS

4.1. PAYMENT OF SECURITIES.

The Company shall pay the principal of, and interest and premium, if any, on, each Series of Securities on the dates and in the manner provided in such Securities and this Indenture.

An installment of principal or interest shall be considered paid on the date it is due if the Trustee or Paying Agent holds on that date money designated for and sufficient to pay such installment and is not prohibited from paying such money to the Holders pursuant to the terms of this Indenture or otherwise.

The Company shall pay interest on overdue principal, and overdue interest, to the extent lawful, at the rate specified in the Series of Securities.

4.2. SEC REPORTS.

The Company will deliver to the Trustee within 15 days after the filing of the same with the SEC, copies of the quarterly and annual reports and of the information, documents and other reports, if any, which the Company is required to file with the SEC pursuant to Section 13 or 15(d) of the Exchange Act; PROVIDED, HOWEVER, that each such report or document will be deemed to be so delivered to the Trustee if the Company files such report or document with the SEC through the SEC's EDGAR database no later than the time such report or document is required to be filed with the SEC pursuant to the Exchange Act. Notwithstanding that the Company may not be subject to the reporting requirements of Section 13 or 15(d) of the Exchange Act, the Company will file with the SEC, to the extent permitted, and provide the Trustee with, such quarterly and annual reports and such information, documents and other reports specified in Sections 13 and 15(d) of the Exchange Act. The Company will also comply with the other provisions of TIA Section 314(a).

4.3. WAIVER OF STAY, EXTENSION OR USURY LAWS.

The Company covenants (to the extent that it may lawfully do so) that it will not at any time insist upon, or plead (as a defense or otherwise) or in any manner whatsoever claim or take the benefit or advantage of, any stay, extension, usury or other law which would prohibit or forgive the Company from paying all or any portion of the principal of, and/or interest and premium, if any, on, the Securities as contemplated herein, wherever enacted, now or at any time hereafter in force, or which may affect the covenants or the performance of this Indenture; and the Company hereby expressly waives (to the extent that they may lawfully do so) all benefit or advantage of any such law, and covenants that it will not hinder, delay or impede the execution of any power herein granted to the Trustee, but will suffer and permit the execution of every such power as though no such law had been enacted.

4.4. COMPLIANCE CERTIFICATE.

(a) The Company shall deliver to the Trustee, within 120 days after the end of each fiscal year of the Company, an Officers' Certificate which complies with TIA Section 314(a)(4) stating that a review of the activities of the Company and its Subsidiaries during such fiscal year has been made under the supervision of the signing Officers with a view to determining whether the Company has kept, observed, performed and fulfilled its obligations under this Indenture, and further stating, as to each such Officer signing such certificate, that to the best of his or her knowledge the Company has kept, observed, performed and fulfilled each and every covenant contained in this Indenture and that there is no default in the performance or observance of any of the terms, provisions and conditions hereof (or, if a Default or Event of Default shall have occurred, describing all such Defaults or Events of Default of which he or she may have knowledge and what action the Company is taking or proposes to take with respect thereto) and that to the best of his or her knowledge no event has occurred and remains in existence by reason of which payments on account of the principal of, or interest or premium, if any, on, the Securities is prohibited, or if such event has occurred, a description of the event and what action the Company is taking or proposes to take with respect thereto.

(b) (i) If any Default or Event of Default has occurred and is continuing or (ii) if any Holder seeks to exercise any remedy hereunder with respect to a claimed Default under this Indenture or the Securities, within five Business Days after the Company becoming aware of such occurrence the Company shall deliver to the Trustee an Officers' Certificate specifying such event, notice or other action and what action the Company is taking or proposes to take with respect thereto.

4.5. CORPORATE EXISTENCE.

Subject to Article 5, the Company shall do or cause to be done all things necessary to preserve and keep in full force and effect its corporate existence, in accordance with the organizational documents (as the same may be amended from time to time) of the Company and the rights (charter and statutory), licenses and franchises of the Company; PROVIDED, HOWEVER, that the Company shall not be required to preserve any such right, license or franchise, or its corporate existence, if the Board of Directors shall determine that the preservation thereof is no longer desirable in the conduct of the business of the Company and that the loss thereof is not adverse in any material respect to the Holders.

ARTICLE 5

SUCCESSOR CORPORATION

5.1. LIMITATION ON CONSOLIDATION, MERGER AND SALE OF ASSETS.

(a) The Company will not, in any transaction or series of transactions, merge or consolidate with or into, or sell, assign, convey, transfer, lease or otherwise dispose of all or substantially all of its properties and assets (as an entirety or substantially as an entirety in one transaction or a series of related transactions), to any Person or Persons, unless at the time of and after giving effect thereto (i) either (A) if the transaction or series of transactions is a merger or consolidation, the Company shall be the surviving Person of such merger or consolidation, or (B) the Person formed by such consolidation or into which the Company is merged or to which the properties and assets of the Company are transferred (any such surviving Person or transferee Person being the "Surviving Entity") shall be a corporation organized and existing under the laws of the United States of America, any state thereof or the District of Columbia, or a corporation or comparable legal entity organized under the laws of a foreign jurisdiction and shall expressly assume by a supplemental indenture executed and delivered to the Trustee, in form reasonably satisfactory to the Trustee, all of the obligations of the Company (including, without limitation, the obligation to pay the principal of, and premium and interest, if any, on, the Securities and the performance of the other covenants) under the Securities of each Series and this Indenture, and in each case, this Indenture shall remain in full force and effect; and (ii) immediately before and immediately after giving effect to such transaction or series of transactions on a pro forma basis (including, without limitation, any Indebtedness incurred or anticipated to be incurred in connection with or in respect of such transaction or series of transactions), no Default or Event of Default shall have occurred and be continuing.

(b) In connection with any consolidation, merger or transfer of assets contemplated by this Section 5.1, the Company shall deliver, or cause to be delivered, to the Trustee, in form and substance reasonably satisfactory to the Trustee, an Officers' Certificate and an Opinion of Counsel, each stating that such consolidation, merger or transfer, and the supplemental indenture in respect thereto, comply with this Section 5.1, and that all conditions precedent herein provided for relating to such transaction or transactions have been complied with.

5.2. SUCCESSOR PERSON SUBSTITUTED.

Upon any consolidation, merger or transfer of all or substantially all of the assets of the Company in accordance with Section 5.1 above, the successor corporation formed by such consolidation, or into which the Company is merged or to which such transfer is made, shall succeed to, and be substituted for, and may exercise every right and power of, the Company under this Indenture with the same effect as if such successor corporation had been named as the Company herein, and thereafter (except with respect to any such transfer which is a lease) the predecessor corporation shall be relieved of all obligations and covenants under this Indenture and the Securities.

ARTICLE 6

DEFAULTS AND REMEDIES

6.1. EVENTS OF DEFAULT.

"Events of Default," wherever used herein with respect to Securities of any Series, means any one of the following events, unless in the establishing Board Resolution, supplemental indenture or Officers' Certificate, it is provided that such Series shall not have the benefit of said Event of Default:

- (1) there is a default in the payment of any principal of, or premium, if any, on, the Securities when the same becomes due and payable at Maturity, upon acceleration, redemption or otherwise;
- (2) there is a default in the payment of any interest on any Security of a Series when the same becomes due and payable, and the Default continues for a period of 30 days;
- (3) the Company defaults in the observance or performance of any other covenant in the Securities of a Series or in this Indenture for 60 days after written notice from the Trustee or the Holders of not less than 25% in the aggregate principal amount of the Securities of such Series then outstanding, which notice must specify the Default, demand that it be remedied and state that the notice is a "Notice of Default";
- (4) the Company or any Significant Subsidiary pursuant to or within the meaning of any Bankruptcy Law:
 - (A) commences a voluntary case,

- (B) consents to the entry of an order for relief against it in an involuntary case,
- (C) consents to the appointment of a Custodian of it or for all or substantially all of its property,
- (D) makes a general assignment for the benefit of its creditors, or
- (E) generally is not paying its debts as they become due;

(5) a court of competent jurisdiction enters an order or decree under any Bankruptcy Law that:

- (A) is for relief against the Company or any Significant Subsidiary in an involuntary case,
 - (B) appoints a Custodian of the Company or any Significant Subsidiary, or for all or substantially all of the property of the Company or any Significant Subsidiary, or
 - (C) orders the liquidation of the Company or any Significant Subsidiary, and the order or decree remains unstayed and in effect for 90 consecutive days;
- or

(6) any other Event of Default provided with respect to Securities of that Series, which is specified in a Board Resolution, a supplemental indenture hereto or an Officers' Certificate, in accordance with Section 2.2(19).

The term "Bankruptcy Law" means Title 11, U.S. Code, or any similar federal or state law for the relief of debtors. The term "Custodian" means any receiver, trustee, assignee, liquidator or similar official under any Bankruptcy Law.

The Trustee may withhold notice of any Default (except in the payment of the principal of, or interest or premium, if any, on, the Securities) to the Holders of the Securities of any Series in accordance with Section 7.5. When a Default is cured, it ceases to exist.

6.2. ACCELERATION.

If an Event of Default with respect to Securities of any Series at the time outstanding (other than an Event of Default arising under Section 6.1(4) or (5)) occurs and is continuing, the Trustee by written notice to the Company, or the Holders of not less than 25% in aggregate principal amount of the Securities of that Series then outstanding by written notice to the Company and the Trustee, may declare that the entire principal amount of all the Securities of that Series then outstanding plus accrued and unpaid interest to the date of acceleration are immediately due and payable, in which case such amounts shall become immediately due and payable; PROVIDED, HOWEVER, that after such acceleration but before a judgment or decree based on such acceleration is obtained by the Trustee, the Holders of a majority in aggregate principal amount of the outstanding Securities of that Series may rescind and annul such acceleration and its consequences if (i) all existing Events of Default, other than the nonpayment of accelerated principal, interest or premium, if any, that has become due solely because of the acceleration, have been cured or waived, (ii) to the extent the payment of such interest is lawful, interest on overdue installments of interest and overdue principal, which has become due otherwise than by such declaration of acceleration, has been paid and (iii) the rescission would not conflict with any judgment or decree. No such rescission shall affect any subsequent Default or impair any right consequent thereto. In case an Event of Default specified in Section 6.1(4) or (5) with respect to the Company occurs, such principal, premium, if any, and interest amount with respect to all of the Securities of that Series shall be due and payable immediately without any declaration or other act on the part of the Trustee or the Holders of the Securities of that Series.

6.3. REMEDIES.

If an Event of Default with respect to Securities of any Series at the time outstanding occurs and is continuing, the Trustee may pursue any available remedy by proceeding at law or in equity to collect the payment of the principal of, or interest and premium, if any, on, the Securities of that Series, or to enforce the performance of any provision of the Securities of that Series or this Indenture.

The Trustee may maintain a proceeding even if it does not possess any of the Securities of that Series or does not produce any of them in the proceeding. A delay or omission by the Trustee or any Securityholder in exercising any right or remedy accruing upon an Event of Default shall not impair the right or remedy or constitute a waiver of or acquiescence in the Event of Default. No remedy is exclusive of any other remedy. All available remedies are cumulative to the extent permitted by law.

6.4. WAIVER OF PAST DEFAULTS AND EVENTS OF DEFAULT.

Subject to Sections 6.2, 6.7 and 8.2, the Holders of a majority in principal amount of the Securities of any Series then outstanding have the right to waive any existing Default or Event of Default with respect to such Series or compliance with any provision of this Indenture (with respect to such Series) or the Securities of such Series. Upon any such waiver, such Default with respect to such Series shall cease to exist, and any Event of Default with respect to such Series arising therefrom shall be deemed to have been cured for every purpose of this Indenture; but no such waiver shall extend to any subsequent or other Default or Event of Default or impair any right consequent thereto. This Section 6.4 shall be in lieu of TIA Section 316(a)(1)(B), and TIA Section 316(a)(1)(B) is hereby expressly excluded from this Indenture and Section as permitted by the TIA.

6.5. CONTROL BY MAJORITY.

Subject to Sections 6.2, 6.7 and 8.2, the Holders of a majority in principal amount of the Securities of any Series then outstanding may direct the time, method and place of conducting any proceeding for any remedy available to the Trustee or exercising any trust or power conferred on the Trustee by this Indenture with respect to such Series. The Trustee, however, may refuse to follow any direction that conflicts with law or this Indenture, or that the Trustee determines may be unduly prejudicial to the rights of another Securityholder, or that may involve the Trustee in personal liability; PROVIDED, that the Trustee may take any other action deemed proper by the Trustee which is not inconsistent with such direction. This Section 6.5 shall be in lieu of TIA Section 316(a)(1)(A), and TIA Section 316(a)(1)(A) is hereby expressly excluded from this Indenture and Section as permitted by the TIA.

6.6. LIMITATION ON SUITS.

Subject to Section 6.7, a Securityholder may not institute any proceeding or pursue any remedy with respect to this Indenture or the Securities of a Series unless:

- (1) the Holder gives to the Trustee written notice of a continuing Event of Default with respect to the Securities of that Series;
- (2) the Holders of at least 25% in aggregate principal amount of the Securities of such Series then outstanding make a written request to the Trustee to pursue the remedy;
- (3) such Holder or Holders offer to the Trustee indemnity reasonably satisfactory to the Trustee against any loss, liability or expense to be incurred in compliance with such request;
- (4) the Trustee does not comply with the request within 60 days after receipt of the request and the offer of indemnity; and
- (5) no direction inconsistent with such written request has been given to the Trustee during such 60-day period by the Holders of a majority in aggregate principal amount of the Securities of such Series then outstanding.

A Securityholder may not use this Indenture to prejudice the rights of another Securityholder, or to obtain a preference or priority over another Securityholder.

6.7. RIGHTS OF HOLDERS TO RECEIVE PAYMENT.

Notwithstanding any other provision of this Indenture, the right of any Holder of a Security of a Series to receive payment of the principal of, and interest and premium, if any, on, the Security of such Series on or after the respective due dates expressed in the Security of such Series, or to bring suit for the enforcement of any such payment on or after such respective dates, is absolute and unconditional, and shall not be impaired or affected without the consent of the Holder.

6.8. COLLECTION SUIT BY TRUSTEE.

If an Event of Default in payment of principal, interest or premium, if any, specified in Section 6.1(1) or (2) with respect to Securities of any Series at the time outstanding occurs and is continuing, the Trustee may recover judgment in its own name and as trustee of an express trust against the Company (or any other obligor on the Securities of that Series) for the whole amount of unpaid principal and premium, if any, and accrued interest remaining unpaid, together with interest on overdue principal and premium, if any, and, to the extent that payment of such interest is lawful, interest on overdue installments of interest, in each case at the rate then borne by the Securities of that Series, and such further amounts as shall be sufficient to cover the costs and expenses of collection, including the reasonable compensation, expenses, disbursements and advances of the Trustee, its agents and counsel, as set forth in Section 7.7.

6.9. TRUSTEE MAY FILE PROOFS OF CLAIM.

The Trustee may file such proofs of claim and other papers or documents, and take other actions (including sitting on a committee of creditors), as may be necessary or advisable in order to have the claims of the Trustee (including any claim for the reasonable compensation, expenses, disbursements and advances of the Trustee, its agents and counsel) and the Securityholders allowed in any judicial proceedings relative to the Company (or any other obligor on the Securities), any of their respective creditors or any of their respective property, and the Trustee shall be entitled and empowered to collect and receive any monies or other property payable or deliverable on any such claims, and to distribute the same after deduction of its charges and expenses to the extent that any such charges and expenses are not paid out of the estate in any such proceedings, and any custodian in any such judicial proceeding is hereby authorized by each Securityholder to make such payments to the Trustee, and in the event that the Trustee shall consent to the making of such payments directly to the Securityholders, to pay to the Trustee any amount due to it for the reasonable compensation, expenses, disbursements and advances of the Trustee, its agents and counsel, and any other amounts due the Trustee under Section 7.7.

Nothing herein contained shall be deemed to authorize the Trustee to authorize or consent to, or accept or adopt on behalf of any Securityholder, any plan of reorganization, arrangement, adjustment or composition affecting the Securities of a Series or the rights of any Holder thereof, or to authorize the Trustee to vote in respect of the claim of any Securityholder in any such proceedings.

6.10. PRIORITIES.

If the Trustee collects any money pursuant to this Article 6, it shall pay out the money in the following order:

FIRST: to the Trustee for amounts due under Section 7.7;

SECOND: to Securityholders for amounts then due and unpaid for the principal of, and interest and premium, if any, on, the Securities in respect of which, or for the benefit of which, such money has been collected, ratably, without preference or priority of any kind, according to the amounts due and payable on such Securities; for principal and any premium and interest, respectively; and

THIRD: to the Company.

The Trustee may fix a record date and payment date for any payment to Securityholders pursuant to this Section 6.10. At least 15 days before such record date, the Trustee shall mail to each Securityholder a notice that states the record date, the payment date and amount to be paid.

6.11. UNDERTAKING FOR COSTS.

In any suit for the enforcement of any right or remedy under this Indenture, or in any suit against the Trustee for any action taken or omitted by it as Trustee, a court in its discretion may require the filing by any party litigant in the suit of an undertaking to pay the costs of the suit, and the court in its discretion may assess reasonable costs, including reasonable attorneys' fees, against any party litigant in the suit, having due regard to the merits and good faith of the claims or defenses made by the party litigant. This Section 6.11 does not apply to a suit by the Trustee, a suit by a Holder pursuant to Section 6.7 or a suit by Holders of more than 10% in principal amount of the Securities of a Series then outstanding.

ARTICLE 7

TRUSTEE

7.1. DUTIES OF TRUSTEE.

(a) If an Event of Default has occurred and is continuing, the Trustee shall exercise such of the rights and powers vested in it by this Indenture and use the same degree of care and skill in their exercise as a prudent Person would exercise or use under the same circumstances in the conduct of his own affairs.

(b) Except during the continuance of an Event of Default:

(1) The Trustee need perform only those duties that are specifically set forth in this Indenture, and no covenants or obligations shall be implied in this Indenture against the Trustee.

(2) In the absence of bad faith on its part, the Trustee may conclusively rely, as to the truth of the statements and the correctness of the opinions expressed therein, upon certificates or opinions furnished to the Trustee and conforming to the requirements of this Indenture, but, in the case of any such certificates or opinions which by any provision hereof are specifically required to be furnished to the Trustee, the Trustee shall be under a duty to examine the same to determine whether or not they conform to the requirements of this Indenture.

(c) The Trustee may not be relieved from liability for its own negligent action, its own negligent failure to act or its own willful misconduct, except that:

(1) This paragraph does not limit the effect of paragraph (b) of this Section 7.1.

(2) The Trustee shall not be liable for any error of judgment made in good faith by a Responsible Officer, unless it is proved that the Trustee was negligent in ascertaining the pertinent facts.

(3) The Trustee shall not be liable with respect to any action it takes or omits to take in good faith in accordance with a direction received by it pursuant to Sections 6.2 and 6.5.

(d) No provision of this Indenture shall require the Trustee to expend or risk its own funds, or otherwise incur any financial liability, in the performance of any of its rights or powers if it shall have reasonable grounds for believing that repayment of such funds or adequate indemnity satisfactory to it against such risk or liability is not reasonably assured to it.

(e) Whether or not therein expressly so provided, paragraphs (a), (b), (c) and (d) of this Section 7.1 shall govern every provision of this Indenture that in any way relates to the Trustee.

(f) The Trustee and Paying Agent shall not be liable for interest on any money received by either of them, except as the Trustee and Paying Agent may agree in writing with the Company. Money held in trust by the Trustee need not be segregated from other funds except to the extent required by the law.

(g) The Paying Agent, the Registrar and any authenticating agent shall be entitled to the protections, immunities and standard of care set forth in paragraphs (a), (b), (c), (d) and (f) of this Section 7.1 and in Section 7.2 with respect to the Trustee.

7.2. RIGHTS OF TRUSTEE.

(a) Subject to Section 7.1:

(1) The Trustee may rely on, and shall be protected in acting or refraining from acting upon, any document reasonably believed by it to be genuine and to have been signed or presented by the proper Person. The Trustee need not investigate any fact or matter stated in the document.

(2) Before the Trustee acts or refrains from acting, it may require an Officers' Certificate or an Opinion of Counsel, or both, which shall conform to the provisions of Section 10.5. The Trustee shall be protected and shall not be liable for any action it takes or omits to take in good faith in reliance on such certificate or opinion.

(3) The Trustee may act through agents and attorneys, and shall not be responsible for the misconduct or negligence of any agent appointed by it with due care.

(4) The Trustee shall not be liable for any action it takes or omits to take in good faith which it reasonably believes to be authorized or within its rights or powers.

(5) The Trustee may consult with counsel reasonably acceptable to the Trustee, which may be counsel to the Company, and the advice or opinion of such counsel as to matters of law shall be full and complete authorization and protection from liability in respect of any action taken, omitted or suffered by it hereunder in good faith and in accordance with the advice or opinion of such counsel.

(6) The Trustee shall be under no obligation to exercise any of the rights or powers vested in it by this Indenture at the request, order or direction of any of the Holders pursuant to the provisions of this Indenture, unless such Holders shall have offered to the Trustee reasonable security or indemnity against the costs, expenses and liabilities which may be incurred therein or thereby.

(7) The Trustee shall not be deemed to have knowledge of any fact or matter (including, without limitation, a Default or Event of Default) unless such fact or matter is known to a Responsible Officer of the Trustee.

(8) Unless otherwise expressly provided herein or in the Securities of a Series or the related Board Resolution, supplemental indenture or Officers' Certificate, the Trustee shall not have any responsibility with respect to reports, notices, certificates or other documents filed with it hereunder, except to make them available for inspection, at reasonable times, by Securityholders, it being understood that delivery of such reports, information and documents to the Trustee is for informational purposes only and the Trustee's receipt of such shall not constitute constructive notice of any information contained therein or determinable from information contained therein, including the Company's compliance with any of its covenants hereunder (except as set forth in Section 4.4).

7.3. INDIVIDUAL RIGHTS OF TRUSTEE.

The Trustee in its individual or any other capacity may become the owner or pledgee of Securities, and may make loans to, accept deposits from, perform services for or otherwise deal with the Company, or any Affiliate thereof, with the same rights it would have if it were not Trustee. Any Agent may do the same with like rights. The Trustee, however, shall be subject to Sections 7.10 and 7.11.

7.4. TRUSTEE'S DISCLAIMER.

The Trustee makes no representation as to the validity or adequacy of this Indenture or the Securities (except that the Trustee represents that it is duly authorized to execute and deliver this Indenture and authenticate the Securities and perform its obligations hereunder), and the Trustee shall not be accountable for the Company's use of the proceeds from the sale of Securities or any money paid to the Company pursuant to the terms of this Indenture, and the Trustee shall not be responsible for any statement in the Securities other than its certificates of authentication.

7.5. NOTICE OF DEFAULT.

If a Default or an Event of Default occurs and is continuing with respect to the Securities of any Series, and if it is known to the Trustee, the Trustee shall mail to each Securityholder of the Securities of that Series notice of the Default or the Event of Default, as the case may be, within 90 days after it occurs or, if later, after a Responsible Officer of the Trustee has knowledge of such Default or Event of Default (except if such Default or Event of Default has been validly cured or waived before the giving of such notice). Except in the case of a Default or an Event of Default in payment of the principal of, or interest or premium, if any, on, any Security of any Series, the Trustee may withhold the notice if and so long as the Board of Directors of the Trustee, the executive committee or any trust committee of such board and/or its Responsible Officers in good faith determine(s) that withholding the notice is in the interests of the Securityholders of that Series.

7.6. REPORTS BY TRUSTEE TO HOLDERS.

If and to the extent required by the TIA, within 60 days after April 1 of each year, commencing the April 1 following the date of this Indenture, the Trustee shall mail to each Securityholder a brief report dated as of such April 1 that complies with TIA Section 313(a). The Trustee also shall comply with TIA Sections 313(b) and 313(c).

A copy of each report at the time of its mailing to Securityholders shall be filed with the SEC and any stock exchange on which the Securities of that Series are listed. The Company shall promptly notify the Trustee when the Securities of any Series are listed on any stock exchange or any delisting thereof, and the Trustee shall comply with TIA Section 313(d).

7.7. COMPENSATION AND INDEMNITY.

The Company shall pay to the Trustee from time to time reasonable compensation for its services. The Trustee's compensation shall not be limited by any provision of law on compensation of a trustee of an express trust. The Company shall reimburse the Trustee within 45 days after receipt of request for all reasonable out-of-pocket disbursements and expenses incurred or made by it in connection with its duties under this Indenture, including the reasonable compensation, disbursements and expenses of the Trustee's agents and counsel.

The Company shall indemnify the Trustee for, and hold it harmless against, any and all loss or liability incurred by it in connection with the acceptance or performance of its duties under this Indenture including the reasonable costs and expenses of defending itself against any claim or liability in connection with the exercise or performance of any of its powers or duties hereunder. The Trustee shall notify the Company promptly of any claim asserted against the Trustee for which it may seek indemnity.

The failure by the Trustee to so notify the Company shall not however relieve the Company of its obligations. Notwithstanding the foregoing, the Company need not reimburse the Trustee for any expense or indemnify it against any loss or liability incurred by the Trustee through its negligence or bad faith. To secure the payment obligations of the Company in this Section 7.7, the Trustee shall have a lien prior to the Securities of any Series on all money or property held or collected by the Trustee except such money or property held in trust to pay the principal of, interest and premium, if any, on particular Securities of that Series.

When the Trustee incurs expenses or renders services after an Event of Default specified in Section 6.1(4) or (5) occurs, the expenses and the compensation for the services are intended to constitute expenses of administration under any Bankruptcy Law.

For purposes of this Section 7.7, the term "Trustee" shall include any trustee appointed pursuant to this Article 7.

7.8. REPLACEMENT OF TRUSTEE.

The Trustee may resign with respect to the Securities of one or more Series by so notifying the Company in writing at least 90 days in advance of such resignation.

The Holders of a majority in principal amount of the outstanding Securities of any Series may remove the Trustee with respect to that Series by notifying the removed Trustee in writing and may appoint a successor Trustee with respect to that Series with the consent of the Company, which consent shall not be unreasonably withheld. The Company may remove the Trustee with respect to that Series at its election if:

- (1) the Trustee fails to comply with, or ceases to be eligible under, Section 7.10;
- (2) the Trustee is adjudged a bankrupt or an insolvent, or an order for relief is entered with respect to the Trustee, under any Bankruptcy Law;
- (3) a Custodian or other public officer takes charge of the Trustee or its property; or
- (4) the Trustee otherwise becomes incapable of acting.

If the Trustee resigns or is removed, or if a vacancy exists in the office of Trustee, with respect to any Series of Securities for any reason, the Company shall promptly appoint, by Board Resolution, a successor Trustee.

If a successor Trustee with respect to the Securities of one or more Series does not take office within 60 days after the retiring Trustee resigns or is removed, the retiring Trustee, the Company or the Holders of at least 10% in principal amount of the outstanding Securities of the applicable Series may petition any court of competent jurisdiction for the appointment of a successor Trustee.

If the Trustee with respect to the Securities of one or more Series fails to comply with Section 7.10, any Securityholder of the applicable Series may petition any court of competent jurisdiction for the removal of the Trustee and the appointment of a successor Trustee.

A successor Trustee shall deliver a written acceptance of its appointment to the retiring Trustee and to the Company. Immediately following such delivery, (i) the retiring Trustee with respect to one or more Series shall, subject to its rights under Section 7.7, transfer all property held by it as Trustee with respect to such Series to the successor Trustee, (ii) the resignation or removal of the retiring Trustee shall become effective and (iii) the successor Trustee with respect to such Series shall have all the rights, powers and duties of the Trustee under this Indenture. A successor Trustee with respect to the Securities of one or more Series shall mail notice of its succession to each Securityholder of such Series.

7.9. SUCCESSOR TRUSTEE BY CONSOLIDATION, MERGER OR CONVERSION.

If the Trustee, or any Agent, consolidates with, merges or converts into, or transfers all or substantially all of its corporate trust assets to, another corporation, subject to Section 7.10, the successor corporation without any further act shall be the successor Trustee or Agent, as the case may be.

7.10. ELIGIBILITY; DISQUALIFICATION.

This Indenture shall always have a Trustee who satisfies the requirements of TIA Sections 310(a)(1), (2) and (5) in every respect. The Trustee (or in the case of a Trustee that is a Person included in a bank holding company system, the related bank holding company) shall have a combined capital and surplus of at least \$100,000,000 as set forth in its most recent published annual report of condition. The Trustee shall comply with TIA Section 310(b), including the provision in Section 310(b)(1). In addition, if the Trustee is a Person included in a bank holding company system, the Trustee, independently of such bank holding company, shall meet the capital requirements of TIA Section 310(a)(2). If at any time the Trustee shall cease to be eligible in accordance with the provisions of this Section 7.10, it shall resign immediately in the manner and with the effect specified in this Article 7.

7.11. PREFERENTIAL COLLECTION OF CLAIMS AGAINST COMPANY.

The Trustee shall comply with TIA Section 311(a), excluding any creditor relationship listed in TIA Section 311(b). A Trustee who has resigned or been removed shall be subject to TIA Section 311(a) to the extent indicated therein.

7.12. PAYING AGENTS.

The Company shall cause each Paying Agent other than the Trustee to execute and deliver to it and the Trustee an instrument in which such agent shall agree with the Trustee, subject to the provisions of this Section 7.12:

(1) that it will hold all sums held by it as agent for the payment of the principal of, or interest or premium, if any, on, the Securities (whether such sums have been paid to it by the Company or by any obligor on the Securities) in trust for the benefit of Holders of the Securities or the Trustee;

(2) that it will at any time during the continuance of any Event of Default, upon written request from the Trustee, deliver to the Trustee all sums so held in trust by it together with a full accounting thereof; and

(3) that it will give the Trustee written notice within three Business Days after any failure of the Company (or by any obligor on the Securities) in the payment of any installment of the principal of, or interest or premium, if any, on, the Securities when the same shall be due and payable.

ARTICLE 8

AMENDMENTS, SUPPLEMENTS AND WAIVERS

8.1. WITHOUT CONSENT OF HOLDERS.

The Company, when authorized by a Board Resolution, and the Trustee may amend or supplement this Indenture or the Securities of one or more Series without notice to or consent of any Securityholder:

(1) to comply with Section 5.1;

(2) to provide for certificated Securities in addition to uncertificated Securities;

(3) to comply with any requirements of the SEC under the TIA;

(4) to cure any ambiguity, defect or inconsistency, or to make any other change herein or in the Securities that does not materially and adversely affect the rights of any Securityholder;

(5) to provide for the issuance of, and establish the form and terms and conditions of, Securities of any Series as permitted by this Indenture; or

(6) to evidence and provide for the acceptance of appointment hereunder by a successor Trustee with respect to the Securities of one or more Series, and to add to or change any of the provisions of this Indenture as shall be necessary to provide for or facilitate the administration of the trusts hereunder by more than one Trustee.

The Trustee is hereby authorized to join with the Company in the execution of any supplemental indenture authorized or permitted by the terms of this Indenture, and to make any further appropriate agreements and stipulations which may be therein contained, but the Trustee shall not be obligated to enter into any such supplemental indenture which adversely affects its own rights, duties or immunities under this Indenture.

8.2. WITH CONSENT OF HOLDERS.

(a) The Company, when authorized by a Board Resolution, and the Trustee may amend or supplement this Indenture or the Securities of one or more Series with the written consent of the Holders of not less than a majority in aggregate principal amount of the outstanding Securities of such Series affected by such amendment or supplement without notice to any Securityholder. The Holders of not less than a majority in aggregate principal amount of the outstanding Securities of each such Series affected by such amendment or supplement may waive compliance by the Company in a particular instance with any provision of this Indenture or the Securities of such Series without notice to any Securityholder. Subject to Section 8.4, without the consent of each Securityholder affected, however, an amendment, supplement or waiver may not:

(1) reduce the amount of Securities whose Holders must consent to an amendment, supplement or waiver to this Indenture or the Securities;

(2) reduce the rate of, or change the time for payment of, interest on any Security;

(3) reduce the principal, or change the Stated Maturity, of any Security, or reduce the amount of, or postpone the date fixed for, the payment of any sinking fund or analogous obligation;

(4) make any Security payable in money other than that stated in the Security;

(5) change the amount or time of any payment required by the Securities, or reduce the premium payable upon any redemption of the Securities, or change the time before which no such redemption may be made;

(6) waive a Default or Event of Default in the payment of the principal of, or interest or premium, if any, on, any Security (except a rescission of acceleration of the Securities of any Series by the Holders of at least a majority in principal amount of the outstanding Securities of such Series and a waiver of the payment default that resulted from such acceleration);

(7) waive a redemption payment with respect to any Security, or change any of the provisions with respect to the redemption of any Securities;

(8) make any changes in Section 6.6 or this Section 8.2, except to increase any percentage of Securities the Holders of which must consent to any matter; or

(9) take any other action otherwise prohibited by this Indenture to be taken without the consent of each Holder affected thereby.

(b) Upon the request of the Company, accompanied by a Board Resolution authorizing the execution of any such supplemental indenture, and upon the receipt by the Trustee of evidence reasonably satisfactory to the Trustee of the consent of the Securityholders as aforesaid and of the documents described in Section 8.6, the Trustee shall join with the Company in the execution of such supplemental indenture, unless such supplemental indenture affects the Trustee's own rights, duties or immunities under this Indenture, in which case the Trustee may in its discretion, but shall not be obligated to, enter into such supplemental indenture.

(c) It shall not be necessary for the consent of the Holders under this section to approve the particular form of any proposed amendment, supplement or waiver, but it shall be sufficient if such consent approves the substance thereof.

After an amendment or supplement under this Section becomes effective, the Company shall mail to Securityholders a notice briefly describing the amendment or supplement. Any failure of the Company to mail any such notice, or any defect therein, shall not, however, in any way impair or affect the validity of any supplemental indenture.

8.3. COMPLIANCE WITH TRUST INDENTURE ACT.

Every amendment to, or supplement of, this Indenture or the Securities shall comply with the TIA as then in effect.

8.4. REVOCATION AND EFFECT OF CONSENTS.

Until an amendment, supplement, waiver or other action becomes effective, a consent to it by a Holder of a Security is a continuing consent conclusive and binding upon such Holder and every subsequent Holder of the same Security or portion thereof, and of any Security issued upon the transfer thereof or in exchange therefor or in place thereof, even if notation of the consent is not made on any such Security. Any such Holder or subsequent Holder, however, may revoke the consent as to his Security or portion of a Security, if the Trustee receives the notice of revocation before the date the amendment, supplement, waiver or other action becomes effective.

The Company may, but shall not be obligated to, fix a record date for the purpose of determining the Holders entitled to consent to any amendment, supplement or waiver, which record date shall be at least 30 days prior to the first solicitation of such consent. If a record date is fixed, then, notwithstanding the preceding paragraph, those Persons who were Holders at such record date (or their duly designated proxies), and only such Persons, shall be entitled to consent to such amendment, supplement or waiver, or to revoke any consent previously given, whether or not such Persons continue to be Holders after such record date.

After an amendment, supplement, waiver or other action becomes effective, it shall bind every Securityholder, unless it makes a change described in any of clauses (1) through (9) of Section 8.2. In that case, the amendment, supplement, waiver or other action shall bind each Holder of a Security who has consented to it and every subsequent Holder of a Security or portion of a Security that evidences the same debt as the consenting Holder's Security; PROVIDED, that any such waiver shall not impair or affect the right of any Holder to receive payment of the principal of, and interest and premium, if any, on, a Security, on or after the respective due dates expressed in such Security, or to bring suit for the enforcement of any such payment on or after such respective dates without the consent of such Holder.

8.5. NOTATION ON OR EXCHANGE OF SECURITIES.

If an amendment, supplement or waiver changes the terms of a Security of any Series, the Trustee may request the Holder of such Security to deliver it to the Trustee. In such case, the Trustee shall place an appropriate notation on such Security about the changed terms and return it to the Holder. Alternatively, the Company, in exchange for such Security, may issue, and the Trustee shall authenticate, a new security that reflects the changed terms. Failure to make the appropriate notation or issue a new Security shall not affect the validity and effect of such amendment, supplement or waiver.

8.6. TRUSTEE TO SIGN AMENDMENTS, ETC.

The Trustee shall sign any amendment, supplement or waiver authorized pursuant to this Article 8 if the amendment, supplement or waiver does not adversely affect the rights, duties, liabilities or immunities of the Trustee. If it does, the Trustee may, but need not, sign it. In signing or refusing to sign such amendment, supplement or waiver the Trustee shall be entitled to receive and, subject to Section 7.1, shall be fully protected in relying upon an Officers' Certificate and an Opinion of Counsel stating that such amendment, supplement or waiver is authorized or permitted by this Indenture. The Company may not sign an amendment or supplement until the Board of Directors of the Company approves it.

ARTICLE 9

DISCHARGE OF INDENTURE; DEFEASANCE

9.1. DISCHARGE OF INDENTURE.

The Company may terminate its obligations under the Securities of any Series and this Indenture with respect to such Series, except the obligations referred to in the last paragraph of this Section 9.1, if there shall have been canceled by the Trustee, or delivered to the Trustee for cancellation, all Securities of such Series theretofore authenticated and delivered (other than any Securities of such Series that are asserted to have been destroyed, lost or stolen and that shall have been replaced as provided in Section 2.8) and the Company has paid all sums payable by it hereunder or deposited all required sums with the Trustee.

After such delivery the Trustee upon request shall acknowledge in a writing prepared by or on behalf of the Company the discharge of the Company's obligations under the Securities of such Series and this Indenture, except for those surviving obligations specified below.

Notwithstanding the satisfaction and discharge of this Indenture, the obligations of the Company in Sections 7.7, 9.5 and 9.6 shall survive.

9.2. LEGAL DEFEASANCE.

The Company may at its option, by Board Resolution, be discharged from its obligations with respect to the Securities of any Series on the date upon which the conditions set forth in Section 9.4 below are satisfied (hereinafter, "Legal Defeasance"). For this purpose, such Legal Defeasance means that the Company shall be deemed to have paid and discharged the entire indebtedness represented by the Securities of such Series and to have satisfied all its other obligations under such Securities and this Indenture insofar as such Securities are concerned (and the Trustee, at the expense of the Company, shall, subject to Section 9.6, execute proper instruments acknowledging the same, as are delivered to it by the Company), except for the following, which shall survive until otherwise terminated or discharged hereunder: (A) the rights of Holders of outstanding Securities of such Series to receive solely from the trust funds described in Section 9.4 and as more fully set forth in such section, payments in respect of the principal of, and interest and premium, if any, on, the Securities of such Series when such payments are due, (B) the Company's obligations with respect to the Securities of such Series under Sections 2.4, 2.5, 2.6, 2.7, 2.8 and 2.9, (C) the rights, powers, trusts, duties and immunities of the Trustee hereunder (including claims of, or payments to, the Trustee under or pursuant to Section 7.7) and (D) this Article 9. Subject to compliance with this Article 9, the Company may exercise its option under this Section 9.2 with respect to the Securities of any Series notwithstanding the prior exercise of its option under Section 9.3 below with respect to the Securities of such Series.

9.3. COVENANT DEFEASANCE.

At the option of the Company, pursuant to a Board Resolution, the Company shall be released from its obligations with respect to the outstanding Securities of any Series under Sections 4.2 through 4.5, inclusive, and Section 5.1, with respect to the outstanding Securities of such Series, on and after the date the conditions set forth in Section 9.4 are satisfied (hereinafter, "Covenant Defeasance"). For this purpose, such Covenant Defeasance means that the Company may omit to comply with and shall have no liability in respect of any term, condition or limitation set forth in any such specified section or portion thereof, whether directly or indirectly by reason of any reference elsewhere herein to any such specified Section or portion thereof or by reason of any reference in any such specified section or portion thereof to any other provision herein or in any other document, but the remainder of this Indenture and the Securities of any Series shall be unaffected thereby.

9.4. CONDITIONS TO LEGAL DEFEASANCE OR COVENANT DEFEASANCE.

The following shall be the conditions to application of Section 9.2 or Section 9.3 to the outstanding Securities of a Series:

(1) the Company shall irrevocably have deposited or caused to be deposited with the Trustee (or another trustee satisfying the requirements of Section 7.10 who shall agree to comply with the provisions of this Article 9 applicable to it) as funds in trust for the purpose of making the following payments, specifically pledged as security for, and dedicated solely to, the benefit of the Holders of the Securities, (A) money in an amount, or (B) U.S. Government Obligations or Foreign Government Obligations which through the scheduled payment of principal and interest in respect thereof in accordance with their terms will provide, not later than the due date of any payment, money in an amount, or (C) a combination thereof, sufficient, in the opinion of a nationally recognized firm of independent public accountants expressed in a written certification thereof delivered to the Trustee, to pay and discharge, and which shall be applied by the Trustee (or other qualifying trustee) to pay and discharge, the principal of, and accrued interest and premium, if any, on, the outstanding Securities of such Series at the Stated Maturity of such principal, interest or premium, if any, or on dates for payment and redemption of such principal, interest and premium, if any, selected in accordance with the terms of this Indenture and of the Securities of such Series;

(2) no Event of Default or Default with respect to the Securities of such Series shall have occurred and be continuing on the date of such deposit, or shall have occurred and be continuing at any time during the period ending on the 91st day after the date of such deposit or, if longer, ending on the day following the expiration of the longest preference period under any Bankruptcy Law applicable to the Company in respect of such deposit as specified in the Opinion of Counsel identified in paragraph (8) below (it being understood that this condition shall not be deemed satisfied until the expiration of such period);

(3) such Legal Defeasance or Covenant Defeasance shall not cause the Trustee to have a conflicting interest for purposes of the TIA with respect to any securities of the Company;

(4) such Legal Defeasance or Covenant Defeasance shall not result in a breach or violation of, or constitute default under, any other agreement or instrument to which the Company is a party or by which it is bound;

(5) the Company shall have delivered to the Trustee an Opinion of Counsel stating that, as a result of such Legal Defeasance or Covenant Defeasance, neither the trust nor the Trustee will be required to register as an investment company under the Investment Company Act of 1940, as amended;

(6) in the case of an election under Section 9.2, the Company shall have delivered to the Trustee an Opinion of Counsel stating that (i) the Company has received from, or there has been published by, the Internal Revenue Service a ruling to the effect that or (ii) there has been a change in any applicable Federal income tax law with the effect that, and such opinion shall confirm that, the Holders of the outstanding Securities of such Series or Persons in their positions will not recognize income, gain or loss for Federal income tax purposes solely as a result of such Legal Defeasance and will be subject to Federal income tax on the same amounts, in the same manner, including as a result of prepayment, and at the same times as would have been the case if such Legal Defeasance had not occurred;

(7) in the case of an election under Section 9.3, the Company shall have delivered to the Trustee an Opinion of Counsel to the effect that the Holders of the outstanding Securities of such Series will not recognize income, gain or loss for Federal income tax purposes as a result of such Covenant Defeasance, and will be subject to Federal income tax on the same amounts, in the same manner and at the same times as would have been the case if such Covenant Defeasance had not occurred;

(8) the Company shall have delivered to the Trustee an Officers' Certificate and an Opinion of Counsel, each stating that all conditions precedent provided for in this Article 9 relating to either the Legal Defeasance under Section 9.2 or the Covenant Defeasance under Section 9.3 (as the case may be) have been complied with;

(9) the Company shall have delivered to the Trustee an Officers' Certificate stating that the deposit under clause (1) was not made by the Company with the intent of defeating, hindering, delaying or defrauding any creditors of the Company or others; and

(10) the Company shall have paid, or duly provided for payment under terms mutually satisfactory to the Company and the Trustee, all amounts then due to the Trustee pursuant to Section 7.7.

9.5. DEPOSITED MONEY AND U.S. AND FOREIGN GOVERNMENT OBLIGATIONS TO BE HELD IN TRUST; OTHER MISCELLANEOUS PROVISIONS.

All money, U.S. Government Obligations and Foreign Government Obligations (including the proceeds thereof) deposited with the Trustee pursuant to Section 9.4 in respect of the outstanding Securities shall be held in trust and applied by the Trustee, in accordance with the provisions of such Securities and this Indenture, to the payment, either directly or through any Paying Agent as the Trustee may determine, to the Holders of such Securities, of all sums due and to become due thereon in respect of principal, accrued interest and premium, if any, but such money need not be segregated from other funds except to the extent required by law.

The Company shall pay and indemnify the Trustee against any tax, fee or other charge imposed on or assessed against the U.S. Government Obligations and Foreign Government Obligations deposited pursuant to Section 9.4 or the principal, interest and premium, if any, received in respect thereof other than any such tax, fee or other charge which by law is for the account of the Holders of the outstanding Securities.

Anything in this Article 9 to the contrary notwithstanding, but subject to payment of any of its outstanding fees and expenses, the Trustee shall deliver or pay to the Company from time to time upon Company Request any money, U.S. Government Obligations or Foreign Government Obligations held by the Trustee as provided in Section 9.4 which, in the opinion of a nationally-recognized firm of independent public accountants expressed in a written certification thereof delivered to the Trustee, are in excess of the amount thereof which would then be required to be deposited to effect an equivalent Legal Defeasance or Covenant Defeasance.

9.6. REINSTATEMENT.

If the Trustee or Paying Agent is unable to apply any money, U.S. Government Obligations or Foreign Government Obligations in accordance with Section 9.1, 9.2, 9.3 or 9.4 by reason of any legal proceeding or by reason of any order or judgment of any court or governmental authority enjoining, restraining or otherwise prohibiting such application, the Company's obligations under this Indenture and the Securities shall be revived and reinstated as though no deposit had occurred pursuant to this Article 9 until such time as the Trustee or Paying Agent is permitted to apply all such money, U.S. Government Obligations or Foreign Government Obligations, as the case may be, in accordance with Section 9.1, 9.2, 9.3 or 9.4; PROVIDED, HOWEVER, that if the Company has made any payment of principal of, or accrued interest or premium, if any, on, any Securities because of the reinstatement of its obligations, the Company shall be subrogated to the rights of the Holders of such Securities to receive such payment from the money, U.S. Government Obligations or Foreign Government Obligations held by the Trustee or Paying Agent.

9.7. MONEYS HELD BY PAYING AGENT.

In connection with the satisfaction and discharge of this Indenture, all moneys then held by any Paying Agent under the provisions of this Indenture shall, upon demand of the Company, be paid to the Trustee, or, if sufficient moneys have been deposited pursuant to Section 9.1, to the Company, and thereupon such Paying Agent shall be released from all further liability with respect to such moneys.

9.8. MONEYS HELD BY TRUSTEE.

Any moneys deposited with the Trustee or any Paying Agent or then held by the Company in trust for the payment of the principal of, or interest or premium, if any, on, any Security that are not applied but remain unclaimed by the Holder of such Security for two years after the date upon which the principal of, or interest or premium, if any, on, such Security shall have respectively become due and payable shall be repaid to the Company upon Company Request, or if such moneys are then held by the Company in trust, such moneys shall be released from such trust; and the Holder of such Security entitled to receive such payment shall thereafter, as an unsecured general creditor, look only to the Company for the payment thereof, and all liability of the Trustee or such Paying Agent with respect to such trust money shall thereupon cease; PROVIDED, HOWEVER, that the Trustee or any such Paying Agent, before being required to make any such repayment, may, at the expense of the Company, either mail to each Securityholder affected, at the address shown in the register of the Securities maintained by the Registrar, or cause to be published once a week for two successive weeks, in a newspaper published in the English language, customarily published each Business Day and of general circulation in the City of New York, New York, a notice that such money remains unclaimed and that, after a date specified therein, which shall not be less than 30 days from the date of such mailing or publication, any unclaimed balance of such moneys then remaining will be repaid to the Company. After payment to the Company or the release of any money held in trust by the Company, Securityholders entitled to the money must look only to the Company for payment as general creditors, unless applicable abandoned property law designates another Person.

ARTICLE 10

MISCELLANEOUS

10.1. TRUST INDENTURE ACT CONTROLS.

If any provision of this Indenture limits, qualifies or conflicts with another provision which is required to be included in this Indenture by the TIA, the required provision shall control. If any provision of this Indenture modifies or excludes any provision of the TIA which may be so modified or excluded, the latter provision shall be deemed to apply to this Indenture as so modified or to be excluded, as the case may be.

10.2. NOTICES.

Any notice or communication shall be given in writing and delivered in Person, sent by facsimile (and receipt confirmed by telephone or electronic transmission report), delivered by commercial courier service or mailed by first-class mail, postage prepaid, addressed as follows:

If to the Company:

Citius Pharmaceuticals, Inc.
11 Commerce Drive, First Floor
Cranford, New Jersey 07016
Attention: Chief Executive Officer

Copy to:

Wyrick Robbins Yates & Ponton LLP
4101 Lake Boone Trail, Suite 300
Raleigh, NC 27607
Fax: (919) 781-4000
Attention: Alexander M. Donaldson, Esq.

If to the Trustee:

The Company or the Trustee by written notice to the other may designate additional or different addresses for subsequent notices or communications. Any notice or communication to the Company or the Trustee shall be deemed to have been given or made as of the date so delivered if personally delivered; when receipt is confirmed by telephone or electronic transmission report, if sent by facsimile; and three Business Days after mailing if sent by registered or certified mail, postage prepaid (except that a notice of change of address shall not be deemed to have been given until actually received by the addressee).

Any notice or communication mailed to a Securityholder shall be mailed to such Securityholder by first-class mail, postage prepaid, at such Securityholder's address shown on the register kept by the Registrar.

Failure to mail, or any defect in, a notice or communication to a Securityholder shall not affect its sufficiency with respect to other Securityholders. If a notice or communication to a Securityholder is mailed in the manner provided above, it shall be deemed duly given, three Business Days after such mailing, whether or not the addressee receives it.

In case by reason of the suspension of regular mail service, or by reason of any other cause, it shall be impossible to mail any notice as required by this Indenture, then such method of notification as shall be made with the approval of the Trustee shall constitute a sufficient mailing of such notice.

In the case of Global Securities, notices or communications to be given to Securityholders shall be given to the Depository, in accordance with its applicable policies as in effect from time to time.

In addition to the manner provided for in the foregoing provisions, notices or communications to Securityholders shall be given by the Company by release made to Reuters Economic Services and Bloomberg Business News.

10.3. COMMUNICATIONS BY HOLDERS WITH OTHER HOLDERS.

Securityholders of any Series may communicate pursuant to TIA Section 312(b) with other Securityholders of that Series or any other Series with respect to their rights under this Indenture or the Securities of that Series or any other Series. The Company, the Trustee, the Registrar and any other Person shall have the protection of TIA Section 312(c).

10.4. CERTIFICATE AND OPINION AS TO CONDITIONS PRECEDENT.

Upon any request or application by the Company to the Trustee to take any action under this Indenture, the Company shall furnish to the Trustee:

(1) an Officers' Certificate (which shall include the statements set forth in Section 10.5 below) stating that, in the opinion of the signers, all conditions precedent, if any, provided for in this Indenture relating to the proposed action have been complied with; and

(2) an Opinion of Counsel (which shall include the statements set forth in Section 10.5 below) stating that, in the opinion of such counsel, all such conditions precedent have been complied with.

10.5. STATEMENT REQUIRED IN CERTIFICATE AND OPINION.

Each certificate and opinion with respect to compliance with a condition or covenant provided for in this Indenture (other than pursuant to Section 4.4) shall include:

(1) a statement that the Person making such certificate or opinion has read such covenant or condition;

(2) a brief statement as to the nature and scope of the examination or investigation upon which the statements or opinions contained in such certificate or opinion are based;

(3) a statement that, in the opinion of such Person, it or he has made such examination or investigation as is necessary to enable it or him to express an informed opinion as to whether or not such covenant or condition has been complied with; and

(4) a statement as to whether or not, in the opinion of such Person, such covenant or condition has been complied with.

10.6. RULES BY TRUSTEE AND AGENTS.

The Trustee may make reasonable rules for action by or at meetings of Securityholders. The Registrar and Paying Agent may make reasonable rules for their functions.

10.7. BUSINESS DAYS; LEGAL HOLIDAYS; PLACE OF PAYMENT.

A "Business Day" is a day that is not a Legal Holiday. A "Legal Holiday" is a Saturday, a Sunday, a federally-recognized holiday or a day on which banking institutions are not authorized or required by law, regulation or executive order to be open in the State of New York.

If a payment date is a Legal Holiday at a Place of Payment, payment may be made at that place on the next succeeding day that is not a Legal Holiday, and no interest shall accrue for the intervening period. "Place of Payment" means the place or places where the principal of, and interest and premium, if any, on, the Securities of a Series are payable as specified as contemplated by Section 2.2. If the regular record date is a Legal Holiday, the record date shall not be affected.

10.8. GOVERNING LAW.

THIS INDENTURE AND THE SECURITIES SHALL BE GOVERNED BY AND CONSTRUED IN ACCORDANCE WITH THE LAWS OF THE STATE OF NEW YORK, AS APPLIED TO CONTRACTS MADE AND PERFORMED WITHIN THE STATE OF NEW YORK WITHOUT REGARD TO PRINCIPLES OF CONFLICTS OF LAW.

10.9. NO ADVERSE INTERPRETATION OF OTHER AGREEMENTS.

This Indenture may not be used to interpret another indenture, loan, security or debt agreement of the Company or any Subsidiary thereof. No such indenture, loan, security or debt agreement may be used to interpret this Indenture.

10.10. NO RECOURSE AGAINST OTHERS.

A director, officer, employee, stockholder or incorporator, as such, of the Company shall not have any liability for any obligations of the Company under the Securities or the Indenture. Each Securityholder by accepting a Security waives and releases all such liability. Such waiver and release are part of the consideration for the issuance of the Securities.

10.11. SUCCESSORS.

All covenants and agreements of the Company in this Indenture and the Securities shall bind the Company's successors and assigns, whether so expressed or not. All agreements of the Trustee, any additional trustee and any Paying Agents in this Indenture shall bind their respective successors and assigns.

10.12. MULTIPLE COUNTERPARTS.

The parties may sign multiple counterparts of this Indenture. Each signed counterpart shall be deemed an original, but all of them together represent one and the same agreement.

10.13. TABLE OF CONTENTS, HEADINGS, ETC.

The table of contents, cross-reference sheet and headings of the Articles and Sections of this Indenture have been inserted for convenience of reference only, are not to be considered a part hereof, and shall in no way modify or restrict any of the terms or provisions hereof.

10.14. SEVERABILITY.

Each provision of this Indenture shall be considered separable, and if for any reason any provision which is not essential to the effectuation of the basic purpose of this Indenture or the Securities shall be invalid, illegal or unenforceable, the validity, legality and enforceability of the remaining provisions shall not in any way be affected or impaired thereby, and a Holder shall have no claim therefor against any party hereto.

10.15. SECURITIES IN A FOREIGN CURRENCY OR IN EUROS.

Unless otherwise specified in a Board Resolution, a supplemental indenture hereto or an Officers' Certificate delivered pursuant to Section 2.2 with respect to a particular Series of Securities, whenever for purposes of this Indenture any action may be taken by the Holders of a specified percentage in aggregate principal amount of Securities of all Series or all Series affected by a particular action at the time outstanding and, at such time, there are outstanding Securities of any Series which are denominated in a coin or currency other than Dollars (including Euros), then the principal amount of Securities of such Series which shall be deemed to be outstanding for the purpose of taking such action shall be that amount of Dollars that could be obtained for such amount at the Market Exchange Rate at such time. For purposes of this Section 10.15, "Market Exchange Rate" shall mean the noon Dollar buying rate in New York City for cable transfers of that currency as published by the Federal Reserve Bank of New York; PROVIDED, HOWEVER, in the case of Euros, Market Exchange Rate shall mean the rate of exchange determined by the Commission of the European Union (or any successor thereto) as published in the Official Journal of the European Union (such publication or any successor publication, the "Journal"). If such Market Exchange Rate is not available for any reason with respect to such currency, the Trustee shall use, in its sole discretion and without liability on its part, such quotation of the Federal Reserve Bank of New York or, in the case of Euros, the rate of exchange as published in the Journal, as of the most recent available date, or quotations or, in the case of Euros, rates of exchange from one or more major banks in New York City or in the country of issue of the currency in question or, in the case of Euros, in Luxembourg or such other quotations or, in the case of Euros, rates of exchange as the Trustee, upon consultation with the Company, shall deem appropriate. The provisions of this paragraph shall apply in determining the equivalent principal amount in respect of Securities of a Series denominated in currency other than Dollars in connection with any action taken by Holders of Securities pursuant to the terms of this Indenture.

All decisions and determinations of the Trustee regarding the Market Exchange Rate or any alternative determination provided for in the preceding paragraph shall be in the Trustee's sole discretion, and shall, in the absence of manifest error, be conclusive to the extent permitted by law for all purposes and irrevocably binding upon the Company and all Holders.

10.16. JUDGMENT CURRENCY.

The Company agrees, to the fullest extent that it may effectively do so under applicable law, that (a) if for the purpose of obtaining judgment in any court it is necessary to convert the sum due in respect of the principal of, or interest or premium, if any, or other amount on, the Securities of any Series (the "Required Currency") into a currency in which a judgment will be rendered (the "Judgment Currency"), the rate of exchange used shall be the rate at which, in accordance with normal banking procedures, the Trustee could purchase in The City of New York the Required Currency with the Judgment Currency on the day on which final unappealable judgment is entered, unless such day is not a Business Day, in which instance, the rate of exchange used shall be the rate at which, in accordance with normal banking procedures, the Trustee could purchase in The City of New York the Required Currency with the Judgment Currency on the Business Day preceding the day on which final unappealable judgment is entered and (b) its obligations under this Indenture to make payments in the Required Currency (i) shall not be discharged or satisfied by any tender or any recovery pursuant to any judgment (whether or not entered in accordance with subsection (a)) in any currency other than the Required Currency, except to the extent that such tender or recovery shall result in the actual receipt, by the payee, of the full amount of the Required Currency expressed to be payable in respect of such payments, (ii) shall be enforceable as an alternative or additional cause of action for the purpose of recovering in the Required Currency the amount, if any, by which such actual receipt shall fall short of the full amount of the Required Currency so expressed to be payable and (iii) shall not be affected by judgment being obtained for any other sum due under this Indenture.

IN WITNESS WHEREOF, the parties hereto have caused this Indenture to be duly executed, and their respective corporate seals to be hereunto affixed and attested, all as of the day and year first above written.

CITIUS PHARMACEUTICALS, INC.

By: _____
Name: _____
Title: _____

[Name of Trustee]

By: _____
Name: _____
Title: _____

By: _____
Name: _____
Title: _____



Wyrick Robbins Yates & Ponton LLP
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September 11, 2020

Board of Directors
Citius Pharmaceuticals, Inc.
11 Commerce Drive, First Floor
Cranford, New Jersey 07016

Re: Shelf Registration Statement on Form S-3

Ladies and Gentlemen:

We have acted as counsel to Citius Pharmaceuticals, Inc., a Nevada corporation (the "Company"), in connection with its registration statement on Form S-3 (the "Registration Statement") filed on even date herewith with the Securities and Exchange Commission (the "Commission") under the Securities Act of 1933, as amended (the "Act"). The Registration Statement relates to the proposed issuance and sale from time to time of up to \$100,000,000 of one or more of the following securities by the Company pursuant to Rule 415 under the Act: (i) shares of common stock, par value \$0.001 per share, of the Company, which may include shares of common stock that constitute a part of or that are issuable upon the conversion or exercise of other Securities (as defined herein) in the Registration Statement ("Common Stock"); (ii) preferred stock, par value \$0.001 per share, of the Company, which may include shares of preferred stock that constitute a part of or that are issuable upon the conversion or exercise of other Securities in the Registration Statement ("Preferred Stock" and together with Common Stock, "Equity Securities"); (iii) warrants covering Equity Securities and/or Debt Securities (as defined below), which may include warrants that constitute a part of or that are issuable upon the conversion or exercise of other Securities in the Registration Statement ("Warrants"); (iv) one or more series of debt securities of the Company and/or convertible debt securities of the Company, which may include convertible debt securities of the Company that constitute a part of or that are issuable upon the conversion or exercise of other Securities in the Registration Statement ("Debt Securities"); (v) rights to purchase shares of Equity Securities, and rights to purchase Debt Securities and/or Units (as defined below) ("Rights"); and (vi) units consisting of Equity Securities, Warrants, Debt Securities and/or Rights ("Units"). Such Equity Securities, Warrants, Debt Securities, Rights and Units are referred to collectively in this opinion as "Securities." Additionally, the Registration Statement registers for resale an aggregate of 641,166 shares of Common Stock from time to time upon exercise of warrants held by the selling stockholders (the "Shares"), issuable from time to time upon exercise of warrants held by the selling stockholders. The Shares may be resold 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 of documents for purposes of this opinion, we have assumed, and express no opinion as to, the authenticity and completeness of all documents submitted to us as originals, the conformity to originals and completeness of all documents submitted to us as copies, the legal capacity of all persons or entities executing the same, the genuineness of all signatures, the lack of any undisclosed termination, modification, waiver, or amendment to any document reviewed by us, and the due authorization, execution, and delivery of all documents by the Company's shareholders where due authorization, execution, and delivery are prerequisites to the effectiveness thereof.

In expressing the opinions set forth below, we also have assumed the following:

- (1) Prior to the issuance of (a) any Equity Securities that are not outstanding as of the date hereof or (b) any Warrants covering the Equity Securities, the Company will have available for issuance, under its Articles of Incorporation, as amended, and as may be further amended from time to time and as in effect at the time thereof, the requisite number of authorized but unissued shares of Common Stock and/or Preferred Stock;
- (2) At the time of the issuance, sale, and delivery, as applicable, of any Debt Securities, Warrants, Rights or Units: (a) the execution, delivery and performance by the Company of the indenture in substantially the form of Exhibit 4.24 to the Registration Statement and any supplemental indenture thereto (any such indenture, together with any applicable supplemental indenture, the "Indenture"), warrant agreement, rights agreement or unit agreement (collectively, the "Documents"), as applicable, and all actions necessary for the issuance of the applicable Securities, and the form and terms thereof, will comply with all requirements and restrictions, if any, applicable to the Company, whether imposed by any agreement or instrument to which the Company is a party or by which it is bound or any court or other governmental or regulatory body having jurisdiction over the Company; (b) the Company will have duly authorized, executed, and delivered any such Document and will have duly authorized the issuance of any such Security, and none of such authorizations will have been modified or rescinded, and there will not have occurred any change in law affecting the validity, legally binding character, or enforceability thereof; and (c) with respect to any Document executed or to be executed by any party other than the Company, such party has, or will have, duly authorized, executed, and delivered the Documents to which it is a party and each such Document is, or will be, the valid and binding obligation of such party, enforceable against it in accordance with its terms;
- (3) The Registration Statement and any additional amendments thereto (including post-effective amendments) will have become effective, will be effective, and will comply with all applicable laws at the time the Securities or Shares are offered or issued as contemplated by the Registration Statement;
- (4) A prospectus supplement will have been prepared and filed with the Commission describing the Securities or, if required, the Shares offered thereby and will comply with all applicable laws;
- (5) Any Securities or Shares being offered pursuant to a prospectus supplement will be issued and sold as contemplated in the Registration Statement and such prospectus supplement;
- (6) There shall not have occurred any change in law affecting the validity of the Securities or Shares; and
- (7) The Company will remain duly organized, validly existing, and in good standing under the laws of the State of Nevada.

We render this opinion only with respect to, and express no opinion herein concerning the application or effect of, the laws of any jurisdiction other than the existing laws of the State of Nevada and reported judicial decisions relating thereto.

Based upon and subject to the foregoing and the additional limitations, qualifications, exceptions and assumptions set forth below, it is our opinion that:

- (1) With respect to the Equity Securities: (a) when the Company's board of directors or any duly designated committee thereof has adopted resolutions approving the issuance and sale of Equity Securities at a specified price or pursuant to a specified pricing mechanism; (b) if Equity Securities are to be sold in a firm commitment underwritten offering or in a best efforts placement offering, an underwriting agreement or placement agency agreement with respect to such Equity Securities has been duly authorized, executed, and delivered by the Company and the other parties thereto; (c) any legally required consents, approvals, authorizations and other orders of the Commission and any other regulatory authorities have been obtained; (d) when a Certificate of Amendment to the Company's Articles of Incorporation, as amended, relating to any Preferred Stock has been duly executed and filed with the Office of the Secretary of State of the State of Nevada; (e) when certificates representing the Equity Securities have been duly executed by appropriate officers of the Company or appropriate book entries have been made in the records of the Company; and (f) when the Equity Securities have been duly and properly sold, paid for, and delivered as contemplated in the Registration Statement, any prospectus supplement relating thereto and, if applicable, in accordance with the applicable underwriting or other purchase agreement, then the Equity Securities will be validly issued, fully paid, and nonassessable.
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- (2) With respect to the Warrants: (a) when the Company's board of directors or any duly designated committee thereof has adopted resolutions approving the issuance and sale of Warrants at a specified price or pursuant to a specified pricing mechanism; (b) if the Warrants are to be sold in a firm commitment underwritten offering or in a best efforts placement offering, an underwriting agreement or placement agency agreement with respect to such Warrants has been duly authorized, executed, and delivered by the Company and the other parties thereto; (c) any legally required consents, approvals, authorizations and other orders of the Commission and any other regulatory authorities have been obtained; (d) any shares of Equity Securities or any Debt Securities purchasable upon exercise of the Warrants, as applicable, have been duly and validly authorized and reserved for issuance and sale; (e) when a Certificate of Amendment to the Company's Articles of Incorporation, as amended, relating to any Preferred Stock has been duly executed and filed with the Office of the Secretary of State of the State of Nevada; and (f) the warrant agreements have been duly executed and the Warrants duly sold by the Company against payment therefor in accordance with any applicable warrant agreement, and in accordance with such corporate action and applicable law and as contemplated in the Registration Statement and the prospectus supplement setting forth the terms of the Warrants and the plan of distribution, then, upon the happening of such events, the Warrants will constitute valid and binding obligations of the Company, enforceable against the Company in accordance with their terms, except as enforcement thereof may be limited by applicable bankruptcy, insolvency, reorganization, arrangement, moratorium or other similar laws affecting creditors' rights, and subject to general equity principles and to limitations on availability of equitable relief, including specific performance.
- (3) With respect to the Debt Securities: (a) when the Company's board of directors or any duly designated committee thereof has adopted resolutions approving the issuance and sale of Debt Securities at a specified price or pursuant to a specified pricing mechanism; (b) if the Debt Securities are to be sold in a firm commitment underwritten offering or in a best efforts placement offering, an underwriting agreement or placement agency agreement with respect to such Debt Securities has been duly authorized, executed, and delivered by the Company and the other parties thereto; (c) the Indenture has been duly executed and delivered on behalf of the Company and a trustee qualified to act as such under applicable law and such Indenture has been duly qualified under the Trust Indenture Act of 1939, as amended; (d) all necessary corporate action has been taken by the Company to authorize the form, terms, execution, and delivery of the Debt Securities; (e) any legally required consents, approvals, authorizations and other orders of the Commission and any other regulatory authorities have been obtained; and (f) such Debt Securities have been duly executed by the Company and authenticated by the applicable trustee in accordance with the Indenture and have been duly issued and delivered against payment therefor in accordance with such corporate action and applicable law and as contemplated in the Registration Statement and the prospectus supplement setting forth the terms of the Debt Securities and the plan of distribution, then, upon the happening of such events, such Debt Securities will constitute the valid and binding obligations of the Company, enforceable against the Company in accordance with their terms, except as enforcement thereof may be limited by applicable bankruptcy, insolvency, reorganization, arrangement, moratorium or other similar laws affecting creditors' rights, and subject to general equity principles and to limitations on availability of equitable relief, including specific performance.
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- (4) With respect to the Rights: (a) when the Company's board of directors or any duly designated committee thereof has adopted resolutions approving the issuance and sale of Rights at a specified price or pursuant to a specified pricing mechanism; (b) if the Rights are to be sold in a firm commitment underwritten offering or in a best efforts placement offering, an underwriting agreement or placement agency agreement with respect to such Rights has been duly authorized, executed, and delivered by the Company and the other parties thereto; (c) any legally required consents, approvals, authorizations, and other orders of the Commission and any other regulatory authorities have been obtained; (d) any shares of Equity Securities, and any Debt Securities and/or Units to be issued pursuant to such Rights have been duly and validly authorized and reserved for issuance and sale; and (e) the rights agreements have been duly executed and the Rights duly sold by the Company against payment therefor in accordance with any applicable rights agreement, and in accordance with such corporate action and applicable law and as contemplated in the Registration Statement and the prospectus supplement setting forth the terms of the Rights and the plan of distribution, then, upon the happening of such events, the Rights will constitute the valid and binding obligations of the Company, enforceable against the Company in accordance with their terms, except as enforcement thereof may be limited by applicable bankruptcy, insolvency, reorganization, arrangement, moratorium or other similar laws affecting creditors' rights, and subject to general equity principles and to limitations on availability of equitable relief, including specific performance.
- (5) With respect to the Units: (a) when the Company's board of directors or any duly designated committee thereof has adopted resolutions approving the issuance and sale of Units at a specified price or pursuant to a specified pricing mechanism; (b) if the Units are to be sold in a firm commitment underwritten offering or in a best efforts placement offering, an underwriting agreement or placement agency agreement with respect to such Units has been duly authorized, executed, and delivered by the Company and the other parties thereto; (c) any legally required consents, approvals, authorizations, and other orders of the Commission and any other regulatory authorities have been obtained; (d) any shares of Equity Securities, and any Debt Securities, Warrants and/or Rights to be issued pursuant to such Units have been duly and validly authorized and reserved for issuance and sale; and (e) the unit agreements have been duly executed and the Units duly sold by the Company against payment therefor in accordance with the unit agreements, and in accordance with such corporate action and applicable law and as contemplated in the Registration Statement and the prospectus supplement setting forth the terms of the Units and the plan of distribution, then, upon the happening of such events, the Units will constitute the valid and binding obligations of the Company, enforceable against the Company in accordance with their terms, except as enforcement thereof may be limited by applicable bankruptcy, insolvency, reorganization, arrangement, moratorium or other similar laws affecting creditors' rights, and subject to general equity principles and to limitations on availability of equitable relief, including specific performance.
- (6) With respect to the Shares: we are of the opinion that the Shares have been duly authorized for issuance and, when the Shares have been issued and sold as described in the Registration Statement, will be duly authorized, validly issued, fully paid and non-assessable.

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 prospectuses 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.

This opinion is intended solely for use in connection with sale of the Securities and the Shares subject to the Registration Statement and is not to be relied upon for any other purpose. This opinion is rendered as of the date first written above and based solely on our understanding of facts in existence as of such date after the aforementioned examination.

We assume no obligation to advise you of any fact, circumstance, event or change in the law or the facts that may hereafter be brought to our attention whether or not such occurrence would affect or modify any of the opinions expressed herein.

Sincerely,

/s/ Wyrick Robbins Yates & Ponton LLP

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in this Registration Statement on Form S-3 and related Prospectus of Citius Pharmaceuticals, Inc. of our report dated December 16, 2019, relating to the consolidated financial statements of Citius Pharmaceuticals, Inc., appearing in the Annual Report on Form 10-K for the year ended September 30, 2019.

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
September 11, 2020