U.S. SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-Q

(Mark One)

☒ QUARTERLY REPORT UNDER SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended: **June 30, 2017**

OR

☐ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from _____ to _____

Commission File Number 333-170781

Citius Pharmaceuticals, Inc.

(Exact name of registrant as specified in its charter)

Nevada	**27-3425913**
(*State or other jurisdiction of incorporation or organization*)	(*IRS Employer Identification No.*)

11 Commerce Drive, First Floor, Cranford, NJ 07016
(*Address of principal executive offices and zip code*)

(908) 967-6677
(*Registrant's telephone number, including area code*)

_____
(*Former name, former address and former fiscal year, if changed since last report*)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to filed such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (Section 232.405 of this chapter) during the preceding 12 months (or such shorter period that the registrant was required to submit and post such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company or an emerging growth company.

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 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

As of August 8, 2017, there were 8,252,798 shares of common stock, $0.001 par value, of the registrant issued and outstanding.

Citius Pharmaceuticals, Inc.
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EXPLANATORY NOTE

In this Quarterly Report on Form 10-Q, and unless the context otherwise requires the "Company," "we," "us" and "our" refer to Citius Pharmaceuticals, Inc. and its wholly owned subsidiaries, Citius Pharmaceuticals, LLC and Leonard-Meron Biosciences, Inc., taken as a whole.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains "forward-looking statements." Forward-looking statements include, but are not limited to, statements that express our intentions, beliefs, expectations, strategies, predictions or any other statements relating to our future activities or other future events or conditions. These statements are based on current expectations, estimates and projections about our business based, in part, on assumptions made by management. These statements are not guarantees of future performance and involve risks, uncertainties and assumptions that are difficult to predict. Therefore, actual outcomes and results may, and are likely to, differ materially from what is expressed or forecasted in the forward-looking statements due to numerous factors discussed from time to time in this report and in other documents which we file with the Securities and Exchange Commission. In addition, such statements could be affected by risks and uncertainties related to:

- our ability to raise funds for general corporate purposes and operations, including our clinical trials;
- the commercial feasibility and success of our technology;
- our ability to recruit qualified management and technical personnel;
- the success of our clinical trials;
- our ability to obtain and maintain required regulatory approvals for our products; and
- the other factors discussed in the "Risk Factors" section and elsewhere in this report.

The foregoing list does not contain all of the risks and uncertainties. Any forward-looking statements speak only as of the date on which they are made, and except as may be required under applicable securities laws; we do not undertake any obligation to update any forward-looking statement to reflect events or circumstances after the filing date of this report.

PART I - FINANCIAL INFORMATION

Item 1. Financial Statements

CITIUS PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(Unaudited)

	June 30, 2017	September 30, 2016
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 198,728	$ 294,351
Prepaid expenses	357,807	598,484
Total Current Assets	556,535	892,835
Property and Equipment, Net of Accumulated Depreciation of $6,795 and $4,780	1,727	3,742
Other Assets:		
Deposits	2,167	2,167
Deferred offering costs	20,000	64,801
In-process research and development	19,400,000	19,400,000
Goodwill	1,586,796	1,586,796
Total Other Assets	21,008,963	21,053,764
Total Assets	$ 21,567,225	$ 21,950,341
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	$ 1,977,522	$ 909,156
Accrued expenses	654,952	958,101
Accrued compensation	1,218,365	903,250
Accrued interest	97,350	30,871
Notes payable – related parties	5,416,303	672,970
Derivative warrant liability	581,164	1,681,973
Due to related party	27,637	27,637
Total Current Liabilities	9,973,293	5,183,958
Commitments and Contingencies		
Stockholders' Equity:		
Preferred stock – $0.001 par value; 10,000,000 shares authorized; no shares issued and outstanding	—	—
Common stock – $0.001 par value; 200,000,000 shares authorized; 5,057,247 and 4,875,871 shares issued and outstanding at June 30, 2017 and September 30, 2016, respectively	5,057	4,876
Additional paid-in capital	36,266,804	34,097,754
Accumulated deficit	(24,677,929)	(17,336,247)
Total Stockholders' Equity	11,593,932	16,766,383
Total Liabilities and Stockholders' Equity	$ 21,567,225	$ 21,950,341

See notes to unaudited condensed consolidated financial statements.

Reflects a 1-for-15 reverse stock split effective June 9, 2017

CITIUS PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
FOR THE THREE AND NINE MONTHS ENDED JUNE 30, 2017 AND 2016
(Unaudited)

	Three Months Ended		Nine Months Ended	
	June 30, 2017	June 30, 2016	June 30, 2017	June 30, 2016
Revenues	$ —	$ —	$ —	$ —
Operating Expenses				
Research and development	190,648	381,119	2,461,722	1,009,975
General and administrative	1,797,749	1,464,551	4,313,703	2,515,069
Stock-based compensation – general and administrative	266,812	280,764	808,356	517,677
Total Operating Expenses	2,255,209	2,126,434	7,583,781	4,042,721
Operating Loss	(2,255,209)	(2,126,434)	(7,583,781)	(4,042,721)
Other Income (Expense), Net				
Interest income	—	782	—	800
Gain (loss) on revaluation of derivative warrant liability	(133,512)	(1,485,832)	308,878	(1,659,738)
Interest expense	(33,700)	(4,445)	(66,779)	(4,445)
Total Other Income (Expense), Net	(167,212)	(1,489,495)	242,099	(1,663,383)
Loss before Income Taxes	(2,422,421)	(3,615,929)	(7,341,682)	(5,706,104)
Income tax benefit	—	—	—	—
Net Loss	$(2,422,421)	$(3,615,929)	$(7,341,682)	$(5,706,104)
Net Loss Per Share - Basic and Diluted	$ (0.49)	$ (0.75)	$ (1.45)	$ (1.78)
Weighted Average Common Shares Outstanding				
Basic and diluted	4,952,558	4,844,235	5,047,593	3,203,822

See notes to unaudited condensed consolidated financial statements.

Reflects a 1-for-15 reverse stock split effective June 9, 2017

CITIUS PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED STATEMENT OF CHANGES IN STOCKHOLDERS' EQUITY
FOR THE NINE MONTHS ENDED JUNE 30, 2017
(Unaudited)

	Preferred Stock	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Equity
		Shares	Amount			
Balance, September 30, 2016	$ —	4,875,871	$ 4,876	$34,097,754	$ (17,336,247)	$ 16,766,383
Issuance of common stock in private placements, net of costs	—	128,016	128	491,223	—	491,351
Issuance of common stock for services and release agreements	—	47,797	48	421,950	—	421,998
Issuance of fractional shares for 1-for-15 reverse stock split		734	—	—	—	—
Stock options exercised	—	4,829	5	35	—	40
Premium on convertible promissory notes – related party	—	—	—	(833,333)	—	(833,333)
Issuance of unit purchase options	—	—	—	297,998	—	297,998
Issuance of warrants in settlement of liabilities	—	—	—	190,890	—	190,890
Reclassification of derivative warrant liability to additional paid-in capital, net	—	—	—	791,931	—	791,931
Stock-based compensation	—	—	—	808,356	—	808,356
Net loss	—	—	—	—	(7,341,682)	(7,341,682)
Balance, June 30, 2017	$ —	5,057,247	$ 5,057	$36,266,804	$ (24,677,929)	$ 11,593,932

See notes to unaudited condensed consolidated financial statements.

Reflects a 1-for-15 reverse stock split effective June 9, 2017

CITIUS PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
FOR THE NINE MONTHS ENDED JUNE 30, 2017 AND 2016
(Unaudited)

	2017	2016
Cash Flows From Operating Activities:		
Net loss	$(7,341,682)	$(5,706,104)
Adjustments to reconcile net loss to net cash used in operating activities:		
Loss (gain) on revaluation of derivative warrant liability	(308,878)	1,659,738
Stock-based compensation expense	808,356	517,677
Fair value of stock issued for services and release agreements	421,998	90,000
Fair value of options issued to purchase units of common stock	104,138	—
Warrants issued and repriced in settlement agreements	190,890	—
Depreciation	2,015	671
Write-off of abandoned trademarks	—	5,401
Changes in operating assets and liabilities:		
Prepaid expenses	434,537	(313,884)
Accounts payable	1,068,366	(494,752)
Accrued expenses	(303,149)	(21,891)
Accrued compensation	315,115	160,000
Accrued interest	66,479	2,460
Due to related party	—	(32,749)
Net Cash Used In Operating Activities	(4,541,815)	(4,133,433)
Cash Flows From Investing Activities:		
Cash acquired in acquisition	—	255,748
Net Cash Provided By Investing Activities	—	255,748
Cash Flows From Financing Activities:		
Deferred offering costs	(20,000)	—
Proceeds from notes payable - related parties	3,910,000	—
Repayment of notes payable – related parties	—	(600,000)
Proceeds from stock option exercise	40	—
Net proceeds from private placements	556,152	5,427,688
Net Cash Provided By Financing Activities	4,446,192	4,827,688
Net Change in Cash and Cash Equivalents	(95,623)	950,003
Cash and Cash Equivalents - Beginning of Period	294,351	676,137
Cash and Cash Equivalents - End of Period	$ 198,728	$ 1,626,140
Supplemental Disclosures Of Cash Flow Information and Non-cash Transactions:		
Interest paid	$ 300	$ 1,985
Income taxes paid	$ —	$ —
Premium on convertible promissory notes – related party	$ 833,333	—
Fair value of unit purchase option issued for future services	$ 193,860	$ —
Fair value of warrants recorded as derivative warrant liability	$ 641,385	$ 1,198,564
Reclassification of derivative warrant liability to additional paid-in capital	$ 1,433,316	$ 649,656

See Note 1 for supplemental cash flow information related to the acquisition of Leonard-Meron Biosciences, Inc.

See notes to unaudited condensed consolidated financial statements.

CITIUS PHARMACEUTICALS, INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
FOR THE NINE MONTHS ENDED JUNE 30, 2017 AND 2016
(Unaudited)

1. NATURE OF OPERATIONS, BASIS OF PRESENTATION AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Business

Citius Pharmaceuticals, Inc. ("Citius" or the "Company") is a specialty pharmaceutical company dedicated to the development and commercialization of critical care products targeting unmet needs with a focus on anti-infectives, cancer care and unique prescription products. The Company was founded as Citius Pharmaceuticals, LLC, a Massachusetts limited liability company, on January 23, 2007. On September 12, 2014, Citius Pharmaceuticals, LLC entered into a Share Exchange and Reorganization Agreement with Citius Pharmaceuticals, Inc. (formerly Trail One, Inc.), a publicly traded company incorporated under the laws of the State of Nevada. Citius Pharmaceuticals, LLC became a wholly-owned subsidiary of Citius.

On March 30, 2016, Citius acquired Leonard-Meron Biosciences, Inc. ("LMB") as a wholly-owned subsidiary (see "Acquisition of Leonard-Meron Biosciences, Inc." below).

The Company had one approved product, Suprenza (phentermine hydrochloride), which it licensed out for promotion in the United States, Canada and Mexico. On July 1, 2016, the Company announced that it was discontinuing Suprenza. Since its inception, the Company has devoted substantially all of its efforts to business planning, research and development, recruiting management and technical staff, and raising capital.

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

Reverse Stock Split

On June 9, 2017, the Company affected a 1-for-15 reverse stock split of its issued and outstanding shares of common stock, $0.001 par value. Under the terms of the reverse stock split, fractional shares issuable to stockholders were rounded up to the nearest whole share, resulting in a reverse split slightly less than 1-for-15 in the aggregate. All per share amounts and number of shares (other than authorized shares) in these condensed consolidated financial statements and related notes have been retroactively restated to reflect the reverse stock split.

Acquisition of Leonard-Meron Biosciences, Inc.

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

The Company acquired tangible assets consisting of cash of $255,748, prepaid expenses of $20,544, property and equipment of $5,085, deposits of $2,167, and identifiable intangible assets of $19,400,000 related to in-process research and development. The Company assumed accounts payable of $244,776, accrued expenses of $598,659, accrued compensation of $615,000, accrued interest of $23,862, and notes payable of $772,970. Accordingly, the net assets acquired amounted to $17,428,277.

The fair value of LMB's net assets acquired on the date of the acquisition, based on management's analysis of the fair value of the 1,942,456 shares of the Company's common stock issued for LMB's outstanding stock, the 243,020 Company common stock warrants issued for LMB's outstanding common stock warrants, and the vested portion of the 77,252 Company common stock options issued for LMB's outstanding common stock options was $19,015,073. The fair value of the common stock issued was estimated at $17,482,093, the fair value of the warrants issued was estimated at $1,071,172 and the fair value of the vested options was estimated at $461,808.

The Company recorded goodwill of $1,586,796 for the excess of the purchase price of $19,015,073 over the net assets acquired of $17,428,277.

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

Unaudited pro forma operating results for the nine months ended June 30, 2016, assuming the acquisition of LMB had been made as of October 1, 2015, are as follows:

	2016
Revenues	$ —
Net loss	$(8,959,053)
Net loss per share – basic and diluted	$ (2.00)

Basis of Presentation and Summary of Significant Accounting Policies

Basis of Preparation — The accompanying consolidated financial statements include the operations of Citius Pharmaceuticals, Inc., and its wholly-owned subsidiaries, Citius Pharmaceuticals, LLC, and LMB since the March 30, 2016 acquisition. All significant inter-company balances and transactions have been eliminated in consolidation.

The accompanying unaudited consolidated financial statements of the Company have been prepared in accordance with accounting principles generally accepted in the United States of America for interim financial information, without being audited, pursuant to the rules and regulations of the Securities and Exchange Commission. Accordingly, they do not include all of the information and footnotes required by accounting principles generally accepted in the United States of America for complete financial statements. In the opinion of management, all adjustments considered necessary to make the financial statements not misleading have been included. Operating results for the nine months ended June 30, 2017 are not necessarily indicative of the results that may be expected for the year ending September 30, 2017. The unaudited consolidated financial statements should be read in conjunction with the audited consolidated financial statements and notes thereto included in the Company's Annual Report on Form 10-K for the year ended September 30, 2016 filed with the Securities and Exchange Commission.

Reverse Stock Split — On June 9, 2017, the Company affected a 1-for-15 reverse stock split of its issued and outstanding shares of common stock, $0.001 par value. Under the terms of the reverse stock split, fractional shares issuable to stockholders were rounded up to the nearest whole share, resulting in a reverse split slightly less than 1-for-15 in the aggregate. All per share amounts and number of shares (other than authorized shares) in these condensed consolidated financial statements and related notes have been retroactively restated to reflect the reverse stock split.

Use of Estimates — Our accounting principles require our management to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of assets and liabilities at the date of the financial statements, and reported amounts of revenues and expenses during the reporting period. Estimates having relatively higher significance include the accounting for acquisitions, stock-based compensation, valuation of warrants, and income taxes. Actual results could differ from those estimates and changes in estimates may occur.

Basic and Diluted Net Loss per Common Share — Basic and diluted net loss per common share is computed by dividing net loss in each period by the weighted average number of shares of common stock outstanding during such period. For the periods presented, common stock equivalents, consisting of options, warrants and convertible securities were not included in the calculation of the diluted loss per share because they were anti-dilutive.

Recent Accounting Pronouncements

In May 2017, the FASB issued ASU No. 2017-09, *Compensation - Stock Compensation (Topic 718): Scope of Modification Accounting*, which clarifies when changes to the terms or conditions of a share-based payment award must be accounted for as modifications. The new guidance will reduce diversity in practice and result in fewer changes to the terms of an award being accounted for as modifications. Under ASU 2017-09, an entity will not apply modification accounting to a share-based payment award if the award's fair value, vesting conditions and classification as an equity or liability instrument are the same immediately before and after the change. ASU 2017-09 will be applied prospectively to awards modified on or after the adoption date. The guidance is effective for annual periods, and interim periods within those annual periods, beginning after December 15, 2017. Early adoption is permitted. The Company is evaluating the impact of the adoption of this guidance on its financial statements but does not expect it to have a material impact.

In July 2017, FASB issued ASU No. 2017-11, *Earnings Per Share (Topic 260); Distinguishing Liabilities from Equity (Topic 480); Derivatives and Hedging (Topic 815): (Part I) Accounting for Certain Financial Instruments with Down Round Features, (Part II) Replacement of the Indefinite Deferral for Mandatorily Redeemable Financial Instruments of Certain Nonpublic Entities and Certain Mandatorily Redeemable Non-controlling Interests with a Scope Exception.* Part I of this Update addresses the complexity of accounting for certain financial instruments with down round features by simplifying the accounting for these instruments. This Update requires companies to disregard the down round feature when assessing whether an instrument, such as a warrant, is indexed to its own stock, for purposes of determining liability or equity classification. This will change the classification of certain warrants with down round features from a liability to equity. Also, entities must adjust their basic EPS calculation for the effect of the down round provision when triggered (that is, when the exercise price of the related equity-linked financial instrument is adjusted downward because of the down round feature). That effect is treated as a dividend and as a reduction of income available to common shareholders in basic EPS. An entity will also recognize the effect of the trigger within equity. The guidance is effective for annual periods, and interim periods within those annual periods, beginning after December 15, 2017. Early adoption is permitted. The Company is evaluating the impact of the adoption of this guidance on its financial statements and expects it to have a material impact as it would reclassify the derivative warrant liability into additional paid-in capital. Part II of this Update

addresses the difficulty of navigating Topic 480, Distinguishing Liabilities from Equity, because of the existence of extensive pending content in the FASB Accounting Standards Codification. The amendments in Part II of this Update re-characterize the indefinite deferral of certain provisions of Topic 480, Distinguishing Liabilities from Equity that previously were presented as pending content in the Codification, to a scope exception, and do not have any accounting effect.

2. GOING CONCERN UNCERTAINTY AND MANAGEMENT'S PLAN

The accompanying condensed consolidated financial statements have been prepared on a going concern basis, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. The Company experienced negative cash flows from operations of $4,541,815 for the nine months ended June 30, 2017. At June 30, 2017, the Company had a working capital deficit of $9,416,758. The Company has no revenue and has relied on proceeds from equity transactions and debt to finance its operations. At June 30, 2017, the Company had limited capital to fund its operations. This raises substantial doubt about the Company's ability to continue as a going concern.

The Company plans to raise capital through equity financings from outside investors as well as raise additional funds from existing investors and continued borrowings under related party debt agreements (see Notes 6 and 9). There is no assurance, however, that the Company will be successful in raising the needed capital and, if funding is available, that it will be available on terms acceptable to the Company.

The accompanying condensed consolidated financial statements do not include any adjustments that might result from the outcome of the above uncertainty.

3. BUSINESS AGREEMENTS

Alpex Pharma S.A.

On June 12, 2008, the Company entered into a collaboration and license agreement (the "Alpex Agreement") with Alpex Pharma S.A. ("Alpex"), in which Alpex granted the Company an exclusive right and license to use certain Alpex intellectual property in order to develop and commercialize orally disintegrating tablet formulations of pharmaceutical products in United States, Canada and Mexico. In addition, Alpex manufactures Suprenza, the Company's commercialized pharmaceutical product, on a contract basis. The agreement was amended on November 15, 2011 as part of an Amendment and Coordination Agreement (see the "Three-Party Agreement" below).

Under the terms of the Alpex Agreement, as amended by the Three-Party Agreement dated November 15, 2011 (see below), Alpex is entitled to a payment per tablet manufactured and a percentage of all milestone, royalty and other payments received by the Company from Prenzamax, LLC, pursuant to a sublicense agreement (see below). In addition, under the terms of the Alpex Agreement, Alpex retained the right to use the clinical data generated by the Company to file for regulatory approval and market Suprenza in the rest of the world. In the event that Alpex has such sales, Alpex will pay the Company a percentage royalty on net sales, as defined ("Alpex Revenue"). No milestone, royalty or other payments were earned or received by the Company except for the reimbursement of certain regulatory fees under the Three-Party Agreement.

On July 1, 2016, the Company announced that it notified the Food and Drug Administration ("FDA") and Alpex that it was discontinuing Suprenza.

Prenzamax, LLC

On November 15, 2011, the Company entered into an exclusive license agreement (the "Sublicense Agreement") with Prenzamax, LLC ("Prenzamax"), in which the Company granted Prenzamax and its affiliates the exclusive right to commercialize Suprenza in the United States. Prenzamax is an affiliate of Akrimax, a related party (see Note 7) and was formed for the specific purpose of managing the Sublicense Agreement. Under the terms of the Sublicense Agreement, Prenzamax is to pay the Company a percentage of the product's EBITDA, as defined ("Profit Share Payments"). In addition, Prenzamax is to reimburse the Company directly for certain development costs. These payments are to commence once Prenzamax has achieved profitability, as defined in the Sublicense Agreement. Further, under the terms of the Sublicense Agreement, Prenzamax is required to share in the royalty payment due to Alpex under the Alpex Agreement. In addition, Prenzamax is entitled to a percentage of the Alpex Revenue received by the Company. The Company has not been reimbursed for any development costs nor has it earned any Profit Share Payments.

On July 1, 2016, the Company announced that it notified Prenzamax that it was discontinuing Suprenza.

Three-Party Agreement

On November 15, 2011, the Company, Alpex and Prenzamax entered into the Three-Party Agreement wherein the terms of the Alpex Agreement were modified and Prenzamax and the Company agreed to each pay a portion of certain regulatory filing fees for as long as Prenzamax is purchasing Suprenza from Alpex pursuant to the Three-Party Agreement.

On July 1, 2016, the Company announced that it notified Alpex and Prenzamax that it was discontinuing Suprenza.

Patent and Technology License Agreement

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

4. NOTES PAYABLE – RELATED PARTIES

A summary of notes payable outstanding is as follows:

	June 30, 2017	September 30, 2016
Demand notes payable – Leonard Mazur	$ 160,470	$ 160,470
Demand notes payable – Myron Holubiak	12,500	12,500
Revolving demand promissory notes – Leonard Mazur	—	500,000
Amended and restated convertible promissory note – Leonard Mazur	3,333,333	—
May 10, 2017 future advance convertible promissory note – Leonard Mazur	1,500,000	—
June 23, 2017 future advance convertible promissory note – Leonard Mazur	410,000	—
Notes payable – related parties	$ 5,416,303	$ 672,970

On March 30, 2016, the Company assumed $772,970 of demand notes payable in the acquisition of LMB. The principal balance of the notes payable to our Chairman, Leonard Mazur, was $760,470 and the principal balance of the notes payable to our Chief Executive Officer, Myron Holubiak, was $12,500. Notes with a principal balance of $704,000 accrue interest at the prime rate plus 1.0% per annum and notes with a principal balance of $68,970 accrue interest at 12% per annum. In April 2016, $600,000 of the prime rate plus 1.0% demand notes payable and accrued interest of $1,985 was repaid to Leonard Mazur.

The Board of Directors authorized revolving demand promissory notes with Leonard Mazur in an aggregate principal amount of up to $2,500,000. On September 7, 2016, the Company issued a $500,000 demand promissory note. The Company issued $2,000,000 of additional demand promissory notes through the period ended May 10, 2017. As of May 10, 2017, the revolving demand promissory notes of $2,500,000 were converted into a convertible promissory note that matures on June 30, 2018. The principal balance of the note is convertible into shares of the Company's common stock, at the sole discretion of Mr. Mazur, at a conversion price equal to 75% of the price per share paid by investors in the Company's securities offering pursuant to an S-1 registration statement filed with the U.S. Securities and Exchange Commission. In connection with the modification of the note, the Company recorded a charge of $833,333 to additional paid-in capital and increased the carrying value of the notes to $3,333,333. The note is convertible to common stock with a fair value of $3,333,333 (see Note 9). These notes accrue interest at the prime rate plus 1%.

On May 10, 2017, the Company executed a $1,500,000 future advance convertible promissory note with Leonard Mazur that matures on December 31, 2017. The principal balance of the note is convertible into shares of the Company's common stock, at the sole discretion of Mr. Mazur, at a conversion price equal to 75% of the price per share paid by investors in the Company's securities offering pursuant to an S-1 registration statement filed with the U.S. Securities and Exchange Commission. Additionally, in the event the Company enters into a debt financing with a third party on terms better than those of the note while the note remains outstanding, Leonard Mazur may elect to amend the note to incorporate such terms. At June 30, 2017, $1,500,000 of the note was drawn by the Company. This note accrues interest at the prime rate plus 1%.

On June 23, 2017, the Company executed a $1,000,000 future advance convertible promissory note with Leonard Mazur that matures on December 31, 2017. The principal balance of the note is convertible into shares of the Company's common stock, at the sole discretion of Mr. Mazur, at a conversion price equal to 75% of the price per share paid by investors in the Company's securities offering pursuant to an S-1 registration statement filed with the U.S. Securities and Exchange Commission. Additionally, in the event the Company enters into a debt financing with a third party on terms better than those of the note while the note remains outstanding, Leonard Mazur may elect to amend the note to incorporate such terms. At June 30, 2017, $410,000 of the note was drawn by the Company. This note accrues interest at the prime rate plus 1%.

The Company evaluated all terms of the future advance convertible promissory notes, including the Change in Control provision, to identify any embedded features that required bifurcation and recording as derivative instruments. The Company determined that there were no such features requiring separate accounting.

The Company initially measured the contingent beneficial conversion feature upon issuance of the future advance convertible promissory notes based on the discounted conversion rate of 75% of the price per share sold at the Company's

securities offering pursuant to an S-1 registration statement filed with the U.S. Securities and Exchange, assuming no changes to the circumstances other than passage of time. Based on this analysis, no beneficial conversion feature was recorded at issuance. Any beneficial conversion feature would be recognized at the time the contingency is resolved (see Note 9).

Interest expense on notes payable – related parties was $33,700 and $66,779, respectively, for the three and nine months ended June 30, 2017.

5. DERIVATIVE WARRANT LIABILITY

Derivative financial instruments are recognized as a liability on the condensed consolidated balance sheet and measured at fair value. At June 30, 2017 and September 30, 2016, the Company had outstanding warrants to purchase 140,819 shares and 307,778 shares, respectively, of its common stock that are considered to be derivative instruments since the agreements contain "down round" provisions whereby the exercise price of the warrants is subject to adjustment in the event that the Company issues common stock for a lower price per share than the investors paid within a specified time period after the original issuance of the warrants (see Note 6).

During the nine months ended June 30, 2017, anti-dilution rights related to warrants to purchase 307,778 shares of common stock expired which resulted in a reclassification from derivative warrant liability to additional paid-in capital of $1,433,316.

On June 8, 2017, the Company granted anti-dilution rights to the investors and the placement agent for the 2016 Offering (see Note 6) in connection with a release agreement. The investors and placement agent hold 140,819 warrants to purchase common stock at $8.25 per share as of June 30, 2017. The exercise price of the warrants is subject to adjustment in the event that the price per share paid by investors in the Company's securities offering pursuant to an S-1 registration statement filed with the U.S. Securities and Exchange Commission is lower than the $8.25 exercise price of the warrants. In the event that the securities are priced at less than $8.25 per share, the warrant exercise price will be reduced to the lower price. On June 8, 2017, the Company reclassified the $641,385 fair value of the warrants to derivative warrant liability.

The Company performs valuations of the warrants using the Black-Scholes option pricing model which value was also compared to a Binomial Option Pricing Model for reasonableness. The Black-Scholes option pricing model requires input of assumptions including the risk-free interest rates, volatility, expected life and dividends. Selection of these inputs involves management's judgment and may impact net loss. Due to our limited operating history and limited number of sales of our common stock, we estimate our volatility based on a number of factors including the volatility of comparable publicly traded pharmaceutical companies. The volatility factor used in the Black-Scholes option pricing model has a significant effect on the resulting valuation of the derivative liabilities on our balance sheet. The volatility calculated at June 30, 2017 was 95%. We used a risk-free interest rate of 1.85%, an estimated life of 4.52 years, which is the remaining weighted average contractual life of the warrants subject to "down round" provisions, and no dividends to our common stock. The volatility calculated at September 30, 2016 was 73%. We used a risk-free interest rate of 1.14%, estimated lives of 4.10 to 4.57 years, which are the remaining contractual lives of the warrants subject to "down round" provisions, and no dividends to our common stock.

The table below presents the changes in the derivative warrant liability, which is measured at fair value on a recurring basis and classified as Level 3 in the fair value hierarchy:

	Nine Months Ended June 30, 2017	Nine Months Ended June 30, 2016
Derivative warrant liability, beginning of period	$ 1,681,973	$ 738,955
Fair value of warrants issued/reclassified	641,385	1,198,564
Total realized/unrealized losses (gains) included in net loss	(308,878)	1,659,738
Reclassification of liability to additional paid-in capital	(1,433,316)	(649,656)
Derivative warrant liability, end of period	$ 581,164	$ 2,947,601

6. COMMON STOCK, STOCK OPTIONS AND WARRANTS

Common Stock

On September 15, 2016, the stockholders approved an increase in the number of shares of authorized common stock from 90,000,000 shares to 200,000,000 shares. On June 9, 2017, the Company affected a 1-for-15 reverse stock split of its issued and outstanding shares of common stock, $0.001 par value. Under the terms of the reverse stock split, fractional shares issuable to stockholders were rounded up to the nearest whole share, resulting in a reverse split slightly less than 1-for-15 in the aggregate.

Private Offerings

On September 12, 2014, the Company sold 226,671 Units for a purchase price of $9.00 per Unit for gross proceeds of $2,040,040. Each Unit consists of one share of common stock and one five-year warrant (the "Investor Warrants") to purchase one share of common stock at an exercise price of $9.00 (the "Private Offering"). The Investor Warrants will be redeemable by the Company at a price of $0.015 per Investor Warrant at any time subject to the conditions that (i) the common stock has traded for twenty (20) consecutive trading days with a closing price of at least $22.50 per share with an average trading volume of 3,333 shares per day and (ii) the Company provides 20 trading days prior notice of the redemption and the closing price of the common stock is not less than $17.55 for more than any 3 days during such notice period and (iii) the underlying shares of common stock are registered.

The Company issued the Placement Agent and their designees five-year warrants (the "Placement Agent Unit Warrants") to purchase 45,334 Units at an exercise price of $9.00 per Unit. The Placement Agent Unit Warrants are exercisable on a cash or cashless basis with respect to purchase of the Units, and will be exercisable only for cash with respect to warrants received as part of the Units.

In addition, the Placement Agent was issued warrants to purchase 66,667 shares of common stock exercisable for cash at $9.00 per share for investment banking services provided in connection with the transaction (the "Placement Agent Share Warrants").

In connection with the Private Offering, the Company entered into a Registration Rights Agreement pursuant to which the Company filed a registration statement, registering for resale all shares of common stock (i) included in the Units; and (ii) issuable upon exercise of the Investor Warrants. The Registration Statement was declared effective on January 21, 2016.

During the year ended September 30, 2015, the Company sold an additional 189,136 Units for a purchase price of $8.10 per Unit and 13,333 Units for a purchase price of $9.00 per Unit for gross proceeds of $1,652,000. Each Unit consists of one share of common stock and one Investor Warrant (see description above).

During the year ended September 30, 2016, the Company sold an additional 290,000 Units for a purchase price of $8.10 per Unit and 17,778 Units for a purchase price of $9.00 per Unit for gross proceeds of $2,509,000. Each Unit consists of one share of common stock and one Investor Warrant (see description above). On May 12, 2016, the Company announced that it had completed the final phase of the Private Offering.

On March 22, 2016, the Company sold 333,333 shares of common stock at $9.00 per share to its Chairman of the Board, Leonard Mazur, for gross proceeds of $3,000,000. There were no expenses related to this placement.

In February 2017, the Company completed an offering (the "2016 Offering") and sold 128,017 units at $6.00 per unit for gross proceeds of $768,100. Each unit consisted of (i) one share of common stock and (ii) a five year warrant to purchase one share of common stock at an exercise price of $8.25 per share (the "2016 Offering Warrants"). The placement agent received a 10% cash commission on the gross proceeds, an expense allowance equal to 3% of the proceeds, and warrants to purchase 12,802 shares of common stock at an exercise price of $8.25 per share. The estimated fair value of the 128,017 warrants issued to the investors was $587,592 and the estimated fair value of the 12,802 warrants issued to the placement agent was $58,759. The placement agent commissions and expense allowance was $99,853. Other costs of the placement were $176,896.

During January 2017, the Company issued 29,729 shares of its common stock for investor relations services. The $298,774 fair value of the common stock was expensed during the nine months ended June 30, 2017.

On May 5, 2017, the Company issued 11,400 shares of common stock valued at $77,748 in connection with a settlement agreement and release with a consultant that had an agreement with Leonard-Meron Biosciences. The Company expensed the $77,748 as a settlement expense during the nine months ended June 30, 2017.

On June 7, 2017, the Company entered into a release agreement with the placement agent for the 2016 Offering. The placement agent consented to future financings and waived certain covenants contained in the 2016 Offering agreements. As consideration for the release, the Company issued 6,668 shares of common stock valued at $45,476 to the placement agent. The Company expensed the $45,576 as a settlement expense during the nine months ended June 30, 2017.

On June 8, 2017, the Company entered into release agreements (the "Investor Release Agreements") with the investors in the 2016 Offering where each investor released the Company from the restrictions included in the unit purchase agreements. In exchange, the Company agreed that (i) in the event that a financing is conducted at a price per share or price per unit lower than $6.00, then the Company will issue additional shares to each investor sufficient to effectively reprice the sale of the 2016 Offering units to the lower price; (ii) in the event that the financing is conducted at a price per share or price per unit less than the $8.25 exercise price of the warrants issued in the 2016 Offering then the exercise price of the warrants shall be reduced to the lower price; and (iii) the Company will give each investor no less than 6 hours of notice before the closing of any subsequent financing, through and including the Company's securities offering pursuant to an S-1 registration statement filed with the U.S. Securities and Exchange Commission, and each investor shall have a 6-hour option to purchase up to 20% of the securities sold in such offering. In connection with these agreements the Company reclassified the fair value of the 140,819 warrants issued in the 2016 Offering to derivative warrant liability on June 8, 2017 (see Notes 5 and 9).

Public Offering

On May 12, 2017, the Company filed a registration statement on Form S-1 with the U.S. Securities and Exchange Commission to register up to approximately $18 million of securities, the proceeds of which will be used towards the research and development of our products and product candidates, and the remainder for capital expenditures, working capital and other general corporate purposes. No assurance can be given that such offering will be consummated, or if consummated, will raise the maximum amount contemplated thereunder. The Company may not sell securities pursuant to the registration statement until it is declared effective.

Unit Purchase Options

On April 7, 2017, the Company issued a three year Unit Purchase Option Agreement to a consultant 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. The consultant provided the Company with business development and financing assistance for the three months ended June 30, 2017. The Company estimated the fair value of the unit purchase option agreement at $104,138 and expensed it during the nine months ended June 30, 2017.

On June 29, 2017, the Company issued a three year Unit Purchase Option Agreement to a consultant 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. The consultant will provide the Company with business development and financing assistance through December 31, 2017. The Company estimated the fair value of the unit purchase option agreement at $193,860 and recorded it as a prepaid expense at June 30, 2017.

Stock Options

On September 12, 2014, the Board of Directors adopted the 2014 Stock Incentive Plan (the "2014 Plan") and reserved 866,667 shares of common stock for issuance to employees, directors and consultants. On September 12, 2014, the stockholders approved the plan. Pursuant to the 2014 Plan, the Board of Directors (or committees and/or executive officers delegated by the Board of Directors) may grant stock options, stock appreciation rights, restricted stock, restricted stock units, other stock-based awards and cash-based awards. As of June 30, 2017, there were options to purchase an aggregate of 586,039 shares of common stock outstanding, options to purchase 4,829 were exercised, and 275,799 shares were available for future grants.

The fair value of each stock option award is estimated on the date of grant using the Black-Scholes option pricing model. Due to its limited operating history and limited number of sales of its Common Stock, the Company estimated its volatility in consideration of a number of factors including the volatility of comparable public companies. The Company uses historical data, as well as subsequent events occurring prior to the issuance of the consolidated financial statements, to estimate option exercises and employee terminations within the valuation model. The risk-free interest rate is based on the U.S. Treasury yield curve in effect at the time of grant commensurate with the expected term assumption. The expected term of stock options granted, all of which qualify as "plain vanilla," is based on the average of the contractual term (generally 10 years) and the vesting period. For non-employee options, the expected term is the contractual term.

A summary of option activity under the 2014 Plan as of June 30, 2017 and the changes during the nine months then ended is presented below:

Options	Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term	Aggregate Intrinsic Value
Outstanding at September 30, 2016	582,199	$ 8.11	8.59 years	$ 1,355,924
Granted	8,669	10.05		
Exercised	(4,829)	0.01		
Forfeited or expired	—	—		
Outstanding at June 30, 2017	586,039	$ 8.21	7.88 years	$ 415,971
Exercisable at June 30, 2017	462,019	$ 7.68	7.71 years	$ 415,971

Stock-based compensation expense for the nine months ended June 30, 2017 and 2016 was $808,356 and $517,677, respectively.

At June 30, 2017, unrecognized total compensation cost related to unvested awards of $631,756 is expected to be recognized over a weighted average period of 1.56 years.

Warrants

The Company has reserved 1,385,195 shares of common stock for the exercise of outstanding warrants. The following table summarizes the warrants outstanding at June 30, 2017:

	Exercise price	Number	
Investor Warrants	$ 9.00	226,671	September 12, 2019
Placement Agent Unit Warrants	9.00	45,334	September 12, 2019
Warrants underlying Placement Agent Unit Warrants	9.00	45,334	September 12, 2019
Placement Agent Share Warrants	9.00	66,667	September 12, 2019
Investor Warrants	9.00	143,025	March 19, 2020 – June 26, 2020
Investor Warrants	9.00	59,444	July 2, 2020 – September 14, 2020
Investor Warrants	9.00	38,889	November 5, 2020 – November 20, 2020
Investor Warrants	9.00	142,222	January 7, 2021 – March 21, 2021
Investor Warrants	9.00	126,667	April 15, 2021 – April 25, 2021
LMB Warrants	6.15	90,151	June 12, 2019 - March 2, 2021
LMB Warrants	9.90	8,155	September 30, 2019 - January 8, 2020
LMB Warrants	20.70	17,721	November 3, 2019 - March 6, 2020
LMB Warrants	7.50	73,883	August 18, 2020 – March 14, 2021
LMB Warrants	7.50	53,110	March 24, 2025 – April 29, 2025
Financial Advisor Warrants	3.00	66,667	August 15, 2021
2016 Offering Warrants	8.25	128,017(1)	November 23, 2021 - February 27, 2022
2016 Offering Placement Agent Warrants	8.25	12,802(1)	November 23, 2021 - February 27, 2022
Convertible Note Warrants	9.75	40,436	September 12, 2019
		1,385,195	

(1) Fair value of these warrants are included in the derivative warrant liability

During the nine months ended June 30, 2017, the Company sold 128,017 2016 Offering Units, at a price of $6.00 per Unit, consisting of (i) one share of common stock and (ii) a warrant to purchase one share of common stock. Each 2016 Offering Warrant has an exercise price of $8.25 and is exercisable for five years from the date of issuance. Additionally, warrants to purchase 12,802 shares of common stock were granted to the Placement Agent pursuant to the above pricing terms.

On June 7, 2017, the Company issued a warrant to purchase 40,436 shares of common stock at $9.75 per share in settlement of issues related to the July 31, 2014 conversion of a subordinated convertible promissory note. The Company charged the $119,402 estimated fair value of the warrant to settlement expenses during the nine months ended June 30, 2017.

On June 8, 2017, the Company entered into release agreements with the investors in the 2016 Offering where each investor released the Company from the restrictions included in the unit purchase agreements. In exchange, the Company agreed that (i) in the event that a financing is conducted at a price per share or price per unit lower than $6.00, then the Company will issue additional shares to each investor sufficient to effectively reprice the sale of the 2016 Offering units to the lower price; (ii) in the event that the financing is conducted at a price per share or price per unit less than the $8.25 exercise price of the warrants issued in the 2016 Offering then the exercise price of the warrants shall be reduced to the lower price; and (iii) the Company will give each investor no less than 6 hours of notice before the closing of any subsequent financing, through and including the Company's securities offering pursuant to an S-1 registration statement filed with the U.S. Securities and Exchange Commission, and each investor shall have a 6-hour option to purchase up to 20% of the securities sold in such offering. In connection with these agreements the Company reclassified the fair value of the 140,819 warrants issued in the 2016 Offering to derivative warrant liability on June 8, 2017 (see Note 5).

Effective June 16, 2017, the Company amended warrants associated with the Leonard-Meron Biosciences, Inc. 2015 private placement offering. The warrant amendments removed the exercise price reset provisions, adjusted the exercise price of the warrants to $7.50 per share and extended the term of the warrants by three years. The estimated fair value of the warrants on June 16, 2017 after the amendments was $250,733. As a result of the amendment, the Company recorded an incremental cost of $71,488 as a settlement expense during the nine months ended June 30, 2017.

At June 30, 2017, the weighted average remaining life of all of the outstanding warrants is 3.26 years, all warrants are exercisable, and the aggregate intrinsic value for the warrants outstanding was $230,391.

Common Stock Reserved

A summary of common stock reserved for future issuances is as follows:

	June 30, 2017	September 30, 2016
2014 Stock Incentive Plan options outstanding	586,039	582,185
2014 Stock Incentive Plan reserved for future grants	275,799	284,482
Warrants	1,385,195	1,203,940
Unit purchase options	201,334	—
Total	2,448,367	2,070,607

The Company has also reserved an undetermined number of shares in connection with (i) the outstanding convertible promissory notes (See Notes 4 and 9), (ii) the rights granted to the investors in the 2016 Offering (See Note 6 – Private Offerings and Note 9), and (iii) the planned public offering (See Note 6 – Public Offering and Note 9).

7. RELATED PARTY TRANSACTIONS

As of June 30, 2017 and September 30, 2016, the Company owed $27,637 to a company affiliated through common ownership for the expenses the related party paid on the Company's behalf and services performed by the related party.

Our Chairman of the Board, Leonard Mazur, is the cofounder and Vice Chairman of Akrimax Pharmaceuticals, LLC ("Akrimax"), a privately held pharmaceutical company specializing in producing cardiovascular and general pharmaceutical products (see Note 3).

Our Chairman of the Board, Leonard Mazur, and our Chief Executive Officer, Myron Holubiak, were co-founders and significant shareholders in LMB. In connection with the acquisition of LMB, our Chairman purchased an additional 333,333 shares of the Company.

The Company has outstanding debt due to Leonard Mazur and Myron Holubiak (see Note 4).

General and administrative expense for each of the nine months ended June 30, 2017 and 2016 includes $36,000 paid to a financial consultant who is a stockholder of the Company.

8. OPERATING LEASE

LMB leases office space from Akrimax (see Note 7) in Cranford, New Jersey at a monthly rental rate of $2,167 pursuant to an agreement which currently expires on October 31, 2017. Rent expense for the nine months ended June 30, 2017 was $19,500. Rent expense for the nine months ended June 30, 2016 was $4,333.

9. SUBSEQUENT EVENTS

On July 27, 2017, the Company was notified by NASDAQ that its application to list its common stock and warrants on the NASDAQ Exchange was approved.

From July 1, 2017 through August 2, 2017 the Company received advances of $300,000 against the June 23, 2017 future advance convertible promissory note. Advances against this note totaled $710,000 as of August 2, 2017.

On August 8, 2017, Leonard Mazur converted $4,710,000 (which have a carrying value of $5,543,333) of outstanding convertible promissory notes and accrued interest of $76,240 into 1,547,067 shares of common stock at a conversion price per share of $3.09.

As a result of this conversion during the period ending September 30, 2017, the Company will record a beneficial conversion feature expense of $762,078, which is a result of the value of the purchased shares of $6,381,651, (1,547,067 shares at the public offering price of $4.125), netted against the carrying value and accrued interest of the notes, $5,619,573. (See Note 4.)

On August 8, 2017, the Company closed an underwritten public offering of 1,648,484 shares of common stock and warrants to purchase 1,648,484 shares of common stock at an offering price of $4.125 per share and $0.01 per warrant. The warrants have a per share exercise price of $4.125, are exercisable immediately and will expire five years from the date of issuance. The gross proceeds to Citius from this offering were approximately $6,800,000, before deducting underwriting discounts and commissions and other estimated offering expenses. The Company granted the underwriters a 45-day option to purchase up to an additional 247,272 shares of common stock and warrants to purchase 247,272 shares of common stock to cover over-allotments, if any. On August 8, 2017, the underwriters partially exercised the over-allotment to purchase an additional 247,272 warrants.

In connection with the Investor Release Agreements (see Note 6 – Private Offerings) dated June 8, 2017, the Company will issue 58,183 shares of common stock to investors that participated in the 2016 Offering. The shares of common stock are being issued to effectively reprice the sale of Units in the 2016 Offering from $6.00 per Unit to $4.125 per Unit, the price per share of common stock in our recently completed underwritten public offering. In addition, the exercise price of the warrants included in the Units will be repriced from $8.25 per warrant to $4.125 per warrant.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

The following discussion and analysis of our financial condition and results of operations for the three and nine months ended June 30, 2017 should be read together with our unaudited consolidated financial statements and related notes included elsewhere in this report and in conjunction with the audited financial statements of Citius Pharmaceuticals, Inc. included in our Annual Report on Form 10-K for the year ended September 30, 2016. The following discussion contains "forward-looking statements" that reflect our future plans, estimates, beliefs and expected performance. Our actual results may differ materially from those currently anticipated and expressed in such forward-looking statements as a result of a number of factors. We caution that assumptions, expectations, projections, intentions or beliefs about future events may, and often do, vary from actual results and the differences can be material. Please see "Cautionary Note Regarding Forward-Looking Statements."

Historical Background

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

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

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

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

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

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

Patent and Technology License Agreement

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

RESULTS OF OPERATIONS

Three months ended June 30, 2017 compared with the three months ended June 30, 2016

	Three Months Ended June 30, 2017	Three Months Ended June 30, 2016
Revenues	$ —	$ —
Operating expenses:		
Research and development	190,648	381,119
General and administrative	1,797,749	1,464,551
Stock-based compensation	266,812	280,764
Total operating expenses	2,255,209	2,126,434
Operating loss	(2,255,209)	(2,126,434)
Interest income	—	782
Loss on revaluation of derivative warrant liability	(133,512)	(1,485,832)
Interest expense	(33,700)	(4,445)
Net loss	$(2,422,421)	$(3,615,929)

Revenues

We did not generate any revenues for the three months ended June 30, 2017 and 2016.

Research and Development Expenses

For the three months ended June 30, 2017, research and development expenses were $190,648 as compared to $381,119 during the three months ended June 30, 2016. The $190,471 decrease in 2017 was due to a decrease of $62,834 in costs incurred on the development of Mino-Lok™ and a decrease of $127,637 in costs incurred on the hydrocortisone-lidocaine product. We are actively seeking to raise additional capital in order to fund our research and development efforts.

General and Administrative Expenses

For the three months ended June 30, 2017, general and administrative expenses were $1,797,749 as compared to $1,464,551 during the three months ended June 30, 2016. The $333,198 increase was primarily due to the $314,114 in settlement costs and $104,138 in financial consulting expenses incurred as a result of a unit purchase option granted during the three months ended June 30, 2017, offset by cost savings.

Stock-based Compensation Expense

For the three months ended June 30, 2017, stock-based compensation expense was $266,812 as compared to $280,764 for the three months ended June 30, 2016. The $13,952 decrease in expense is primarily due to the completion of the vesting period for a significant portion of our outstanding options and limited option grants during the current year. At June 30, 2017, unrecognized total compensation cost related to unvested awards of $631,756 is expected to be recognized over a weighted average period of 1.56 years.

Other Income (Expense)

There was no interest income earned on our cash balances for the three months ended June 30, 2017 compared to $782 of interest income earned for the three months ended June 30, 2016.

Loss on revaluation of derivative warrant liability for the three months ended June 30, 2017 was $133,512 compared to $1,485,832 for the three months ended June 30, 2016. The fair value of the derivative warrant liability fluctuates with changes in our stock price, volatility, remaining lives of the warrants, and interest rates. The loss for the three months ended June 30, 2016 was primarily due to the increase in the fair value of our stock from $9.00 at March 31, 2016 to $13.35 at June 30, 2016. At June 30, 2017, the Company has 140,819 outstanding warrants that are considered to be derivative instruments since the agreements contain “down round” provisions whereby the exercise price of the warrants is subject to adjustment in the event that the Company issues common stock for a lower price per share than the investors paid within a specified time period after the original issuance of the warrants.

Interest expense on the notes payables acquired in the acquisition of LMB and recent borrowings from our Chairman was $33,700 for the three months ended June 30, 2017. Interest expense on the notes payable acquired in the acquisition of LMB was $4,445 for the three months ended June 30, 2016.

Net Loss

For the three months ended June 30, 2017, we incurred a net loss of $2,422,241 compared to a net loss for the three months ended June 30, 2016 of $3,615,929. The $1,193,688 decrease in the net loss was primarily due to the $333,198 increase in general and administrative expenses being offset by a $190,471 decrease in research and development expense and a $1,352,320 decrease in the loss on revaluation of the derivative warrant liability.

Nine months ended June 30, 2017 compared with the nine months ended June 30, 2016

	Nine Months Ended June 30, 2017	Nine Months Ended June 30, 2016
Revenues	$ —	$ —
Operating expenses:		
Research and development	2,461,722	1,009,975
General and administrative	4,313,703	2,515,069
Stock-based compensation	808,356	517,677
Total operating expenses	7,583,781	4,042,721
Operating loss	(7,583,781)	(4,042,721)
Interest income	—	800
Gain (loss) on revaluation of derivative warrant liability	308,878	(1,659,738)
Interest expense	(66,779)	(4,445)
Net loss	$(7,341,682)	$(5,706,104)

Revenues

We did not generate any revenues for the nine months ended June 30, 2017 and 2016.

Research and Development Expenses

For the nine months ended June 30, 2017, research and development expenses were $2,461,722 as compared to $1,009,975 during the nine months ended June 30, 2016. The $1,451,747 increase in 2017 was primarily due to the $2,086,443 in costs incurred on the development of Mino-Lok™ offset by a decrease of $634,696 in costs incurred in the development of our product for the treatment of hemorrhoids and costs related to Suprenza, including the $292,575 received from Alpex as reimbursement for regulatory filing fees. We are actively seeking to raise additional capital in order to fund our research and development efforts.

General and Administrative Expenses

For the nine months ended June 30, 2017, general and administrative expenses were $4,313,703 as compared to $2,515,069 during the nine months ended June 30, 2016. The $1,798,634 increase in 2017 was primarily due to the acquisition of LMB on March 30, 2016, which resulted in increased compensation costs, increased consulting fees incurred for financing activities and corporate development services, and increased investor relations fees. The nine months ended June 30, 2016 only includes three months of expenses for LMB as the acquisition was completed on March 30, 2016.

Stock-based Compensation Expense

For the nine months ended June 30, 2017, stock-based compensation expense was $808,356 as compared to $517,677 for the nine months ended June 30, 2016. The $290,679 increase in expense includes the expense for options assumed in the acquisition of LMB, as well as grants to new directors and new employees.

Other Income (Expense)

There was no interest income earned on our cash balances for the nine months ended June 30, 2017 and only $800 in interest income earned for the nine months ended June 30, 2016.

Gain (loss) on revaluation of derivative warrant liability for the nine months ended June 30, 2017 was $308,878 compared to $(1,659,738) for the nine months ended June 30, 2016. The fair value of the derivative warrant liability fluctuates with changes in our stock price, volatility, remaining lives of the warrants, and interest rates. The gain for the nine months ended June 30, 2017 was primarily due to a decrease in the fair value of our stock from $9.45 per share at September 30, 2016 to $6.28 per share at June 30, 2017. The loss for the nine months ended June 30, 2016 was primarily due to an increase in the fair value of our common stock from $8.10 at September 30, 2015 to $13.35 at June 30, 2016. At June 30, 2017, the Company has 140,819 outstanding warrants that are considered to be derivative instruments since the agreements contain “down round” provisions whereby the exercise price of the warrants is subject to adjustment in the event that the Company issues common stock for a lower price per share than the investors paid within a specified time period after the original issuance of the warrants.

Interest expense on the notes payables acquired in the acquisition of LMB and recent borrowings from our Chairman was $66,779 for the nine months ended June 30, 2017. Interest expense on the notes payable acquired in the acquisition of LMB was $4,445 for the nine months ended June 30, 2016.

Net Loss

For the nine months ended June 30, 2017, we incurred a net loss of $7,341,682 compared to a net loss for the nine months ended June 30, 2016 of $5,706,104. The $1,635,578 increase in the net loss was primarily due to the $1,451,747 increase in research and development expenses and the $1,798,634 increase in general and administrative expenses offset by the $1,968,616 increase in the gain (loss) on the revaluation of derivative warrant liability.

LIQUIDITY AND CAPITAL RESOURCES

Going Concern Uncertainty and Working Capital

Citius has incurred operating losses since inception and incurred a net loss of $7,341,682 for the nine months ended June 30, 2017. At June 30, 2017, Citius had an accumulated deficit of $24,677,929. Citius’ net cash used in operations during the nine months ended June 30, 2017 was $4,541,815.

As of June 30, 2017, Citius had a working capital deficit of $9,416,758. The working capital deficit was attributable to the operating losses incurred by the Company since inception offset by our capital raising activities. At June 30, 2017, Citius had cash and cash equivalents of $198,728 available to fund its operations. The Company’s primary sources of cash flow since inception have been from financing activities. During the nine months ended June 30, 2017, the Company received net proceeds of $556,152 from the issuance of equity and $3,910,000 from the issuance of notes payable to our Chairman, Leonard Mazur. Our primary uses of operating cash were for product development and commercialization activities, regulatory expenses, employee compensation, consulting fees, legal and accounting fees, insurance and travel expenses.

On September 7, 2016, the Company issued a $500,000 demand promissory note to our Chairman, Leonard Mazur. The Company issued $2,000,000 of additional demand promissory notes through the period ended May 10, 2017. As of May 10, 2017, the revolving demand promissory notes of $2,500,000 were converted into a convertible promissory note that matures on June 30, 2018. The principal balance of the note is convertible into shares of the Company’s common stock, at the sole discretion of Mr. Mazur, at a conversion price equal to 75% of the price per share paid by investors in the Company’s securities offering pursuant to an S-1 registration statement filed with the U.S. Securities and Exchange Commission.

On May 10, 2017, the Company executed a $1,500,000 future advance convertible promissory note with Leonard Mazur that matures on December 31, 2017. The principal balance of the note is convertible into shares of the Company’s common stock, at the sole discretion of Mr. Mazur, at a conversion price equal to 75% of the price per share paid by investors in the Company’s securities offering pursuant to an S-1 registration statement filed with the U.S. Securities and Exchange Commission. At June 30, 2017, $1,500,000 of the note was drawn by the Company.

On June 23, 2017, the Company executed a $1,000,000 future advance convertible promissory note with Leonard Mazur that matures on December 31, 2017. The principal balance of the note is convertible into shares of the Company’s common stock, at the sole discretion of Mr. Mazur, at a conversion price equal to 75% of the price per share paid by investors in the Company’s securities offering pursuant to an S-1 registration statement filed with the U.S. Securities and Exchange Commission. At June 30, 2017, $410,000 of the note was drawn by the Company. From July 1, 2017 through August 2, 2017 an additional $300,000 was drawn by the Company. Advances against this note totaled $710,000 as of August 2, 2017.

As of August 2, 2017, Leonard Mazur had advanced a total of $4,710,000 under the 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 per share of $3.09 as part of an underwritten public offering which closed on the same date.

In February 2017, the Company completed an offering (the "2016 Offering") and sold 128,017 units at $6.00 per unit for gross proceeds of $768,100. Each unit consisted of (i) one share of common stock and (ii) a five year warrant to purchase one share of common stock at an exercise price of $8.25 per share (the "2016 Offering Warrants"). The placement agent received a 10% cash commission on the gross proceeds, an expense allowance equal to 3% of the proceeds, and warrants to purchase 12,802 shares of common stock at an exercise price of $8.25 per share. The placement agent commissions and expense allowance was $99,853. Other costs of the placement were $176,896.

On August 8, 2017, the Company closed an underwritten public offering of 1,648,484 shares of common stock and warrants to purchase 1,646,484 shares of common stock at an offering price of $4.125 per share and $0.01 per warrant. The warrants have a per share exercise price of $4.125, are exercisable immediately and will expire five years from the date of issuance. The gross proceeds to Citius from this offering were approximately $6,800,000, before deducting underwriting discounts and commissions and other estimated offering expenses. The Company granted the underwriters a 45-day option to purchase up to an additional 247,272 shares of common stock and warrants to purchase 247,272 shares of common stock to cover over-allotments, if any. On August 8, 2017, the underwriters partially exercised the over-allotment to purchase an additional 247,272 warrants.

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

Inflation

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

Off Balance Sheet Arrangements

We do not have any off balance sheet arrangements.

Critical Accounting Policies and Estimates

The preparation of our financial statements and related disclosures in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, and the disclosure of contingent assets and liabilities as of the date of the financial statements and the amounts of revenues and expenses recorded during the reporting periods. We base our estimates on historical experience, where applicable and other assumptions that we believe are reasonable under the circumstances. Actual results may differ from our estimates under different assumptions or conditions.

Our critical accounting policies and use of estimates are discussed in, and should be read in conjunction with, the annual consolidated financial statements and notes included in the Company's Annual Report on Form 10-K for the year ended September 30, 2016 as filed with the SEC.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

Not applicable.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

We maintain disclosure controls and procedures designed to provide reasonable assurance that information required to be disclosed in reports filed under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), is recorded, processed, summarized and reported within the specified time periods and accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding disclosure.

Our Chief Executive Officer and Principal Financial Officer ("CEO"), evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) promulgated under the Exchange Act) as of June 30, 2017. In designing and evaluating disclosure controls and procedures, we recognize that any disclosure controls and procedures, no matter how well designed and operated, can only provide reasonable assurance of achieving the desired control objective. As of June 30, 2017, based on the evaluation of these disclosure controls and procedures, and in light of the material weaknesses found in our internal controls, the CEO concluded that our disclosure controls and procedures were not effective. In our assessment of the effectiveness of internal control over financial reporting as of June 30, 2017, we determined that control deficiencies existed that constituted material weaknesses, as described below:

1) lack of documented policies and procedures;

2) the financial reporting function is carried out by consultants; and

3) ineffective separation of duties due to limited staff.

In light of the conclusion that our internal controls over financial reporting were ineffective as of June 30, 2017, we have applied procedures and processes as necessary to ensure the reliability of our financial reporting in regards to this quarterly report on Form 10-Q. Accordingly, the Company believes, based on its knowledge, that: (i) this quarterly report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which they were made, not misleading with respect to the periods covered by this report; and (ii) the financial statements, and other financial information included in this quarterly report, fairly present in all material respects our financial condition, results of operations and cash flows as of and for the periods presented in this quarterly report.

Changes in Internal Control Over Financial Reporting

There were no changes in our internal control over financial reporting during the quarter ended June 30, 2017 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II - OTHER INFORMATION

Item 1. Legal Proceedings

None.

Item 1A. Risk Factors

Our business is subject to numerous risks. The following important factors, among others, could have a material adverse effect on our business, financial condition or results of operations.

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

Citius was formed as a limited liability company in 2007 and since its inception has incurred a net loss in each of its previous operating years. Our ability to become profitable depends upon our ability to generate revenues from sales of our product candidates. Citius has been focused on product development and has not generated any revenues to date. Citius has incurred losses in each period of our operations, and we expect to continue to incur losses for the foreseeable future. These losses are likely to continue to adversely affect our working capital, total assets and shareholders' equity (deficit). The process of developing our products requires significant clinical, development and laboratory testing and clinical trials. In addition, commercialization of our product candidates will require that we obtain necessary regulatory approvals and establish sales, marketing and manufacturing capabilities, either through internal hiring or through contractual relationships with others. We expect to incur substantial losses for the foreseeable future as a result of anticipated increases in our research and development costs, including costs associated with conducting preclinical testing and clinical trials, and regulatory compliance activities. Citius incurred net losses of $7,341,682 for the nine months ended June 30, 2017, $8,295,698 and $2,902,268 for the years ended September 30, 2016 and 2015, respectively, and a net loss of $737,727 for the nine months ended September 30, 2014. At June 30, 2017, Citius had stockholders' equity of $11,593,932 and an accumulated deficit of $24,677,929. Citius' net cash used for operating activities was $4,541,815 for the nine months ended June 30, 2017, $5,900,421 and $2,385,416 for the years ended September 30, 2016 and 2015, respectively, and $183,164 for the nine months ended September 30, 2014.

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

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

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

Our auditors have issued a "going concern" audit opinion.

Our independent registered accountants have indicated, in their report on our September 30, 2016 financial statements, that there is substantial doubt about our ability to continue as a going concern. A "going concern" opinion indicates that the financial statements have been prepared assuming we will continue as a going concern and do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets, or the amounts and classification of liabilities that may result if we do not continue as a going concern. Currently, we do not have sufficient capital to continue our operations after the next six months. You should not rely on our consolidated balance sheet as an indication of the amount of proceeds that would be available to satisfy claims of creditors, and potentially be available for distribution to shareholders, in the event of liquidation.

We need to secure additional financing.

We anticipate that we will incur operating losses for the foreseeable future. We have received gross proceeds of approximately $7.8 million from our private placement offerings through February 2017. Additionally, in connection with the acquisition of LMB our Executive Chairman, Leonard Mazur, made an equity investment of $3.0 million in March 2016. Mr. Mazur has also loaned the Company $4,710,000 pursuant to convertible promissory notes. On August 8, 2017, these notes and accrued interest of $76,240 were converted into 1,547,067 shares of common stock at a price of $3.09 per share as part of an underwritten public offering which closed on the same date.

The Company has also engaged Paulson Investment Company, LLC to secure debt financing. We may need to seek additional financing, including from affiliates, to continue our clinical programs and manufacturing for clinical programs.

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

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

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

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

Our strategy of using collaborative partners to assist us in the development of our therapeutic products is unproven. Our success will depend upon our ability to enter into additional collaboration agreements on favorable terms and to select an appropriate commercialization strategy for each potential therapeutic product we and our collaborators choose to pursue. If we are not successful in implementing our strategy to commercialize our potential therapeutic products, we may never achieve, maintain or increase profitability. Our ability to successfully commercialize any of our products or product candidates will depend, among other things, on our ability to:

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

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

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

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

We face significant risks in our product candidate development efforts.

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

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

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

Any failure to obtain regulatory approval of our product candidates would significantly limit our ability to generate revenues, and any failure to obtain such approval for all of the indications and labeling claims we deem desirable could reduce our potential revenues.

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

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

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

There is typically a high rate of attrition from the failure of product candidates proceeding through clinical trials. In addition, certain subjects in our clinical trials may respond positively to placebo treatment - these subjects are commonly known as "placebo responders" - making it more difficult to demonstrate efficacy of the test drug compared to placebo. This effect is likely to be observed in the treatment of hemorrhoids. If any of our product candidates fail to demonstrate sufficient safety and efficacy in any clinical trial, we will experience potentially significant delays in, or may decide to abandon development of that product candidate. If we abandon or are delayed in our development efforts related to any of our product candidates, we may not be able to generate any revenues, continue our operations and clinical studies, or become profitable. Our reputation in the industry and in the investment community would likely be significantly damaged. It may not be possible for us to raise funds in the public or private markets, and our stock price would likely decrease significantly.

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

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

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

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

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

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

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

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

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

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

Even if approved for marketing by applicable regulatory bodies, we will not be able to create a market for any of our products if we fail to establish marketing, sales and distribution capabilities, or fail to enter into arrangements with third parties.

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

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

Competition in the pharmaceutical and medical products industries is intense and is characterized by costly and extensive research efforts and rapid technological progress. We are aware of several pharmaceutical companies also actively engaged in the development of therapies for the same conditions we are targeting. Many of these companies have substantially greater research and development capabilities as well as substantially greater marketing, financial and human resources than we do. In addition, many of these companies have significantly greater experience than us in undertaking pre-clinical testing, human clinical trials and other regulatory approval procedures. Our competitors may develop technologies and products that are more effective than those we are currently marketing or researching and developing. Such developments could render our products, if approved, less competitive or possibly obsolete. We are also competing with respect to marketing capabilities and manufacturing efficiency, areas in which we have limited experience. Mergers, acquisitions, joint ventures and similar events may also significantly increase the competition. New developments, including the development of other drug technologies and methods of preventing the incidence of disease, occur in the pharmaceutical and medical technology industries at a rapid pace. These developments may render our products and product candidates obsolete or noncompetitive. Compared to us, many of our potential competitors have substantially greater:

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

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

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

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

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

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

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

Our Hydro-Lido product candidate for the treatment of hemorrhoids is a combination product consisting of two drugs, hydrocortisone and lidocaine, that have each been separately approved by the FDA for other indications and which are commercially available and marketed by other companies. Hydrocortisone creams are available from strengths ranging from 0.5% to 2.5% and lidocaine creams are also available in strengths up to 5%. From our market analysis and discussions with a limited number of physicians, we know that patients sometimes obtain two separate cream products and co-administer them as prescribed, giving them a combination treatment which could be very similar to what we intend to study and seek approval for. As a branded, FDA-approved product with safety and efficacy data, we intend to price our product substantially higher than the generically available individual creams. We will then have to convince third-party payers and pharmacy benefit managers of the advantages of our product and justify our premium pricing. We may encounter resistance from these entities and will then be dependent on patients' willingness to pay the premium and not seek alternatives. In addition, pharmacists often suggest lower cost prescription treatment alternatives to both physicians and patients. Our 505(b)(2) approval and the market exclusivity we may receive will not guarantee that such alternatives will not exist, that substitution will not occur, or that there will be immediate acceptance to our pricing by payer formularies.

Our Mino-Lok solution contains minocycline, disodium ethylenediaminetetraacetic acid (edetate), and ethyl alcohol, all of which have been separately approved by the FDA for other indications, or are used as excipients in other parenteral products.

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

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

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

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

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

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

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

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

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

- We might be unable to identify manufacturers for commercial supply on acceptable terms or at all because the number of potential manufacturers is limited and the FDA must approve any replacement contractor. This approval would generally require compliance inspections. In addition, a new manufacturer would have to be educated in, or develop substantially equivalent processes for, production of our products after receipt of FDA approval, if any;

- Our third-party manufacturers might be unable to formulate and manufacture our drugs in the volume and of the quality required to meet our clinical and commercial needs, if any;

- Our contract manufacturers might not perform as agreed or might not remain in the contract manufacturing business for the time required to supply our clinical trials or to successfully produce, store and distribute our products;

- Currently, our contract manufacturer is foreign, which increases the risk of shipping delays and adds the risk of import restrictions;

- Drug manufacturers are subject to ongoing periodic unannounced inspection by the FDA and corresponding state agencies to ensure strict compliance with cGMP and other government regulations and corresponding foreign standards. We do not have complete control over third-party manufacturers' compliance with these regulations and standards;

- If any third-party manufacturer makes improvements in the manufacturing process for our products, we might not own, or might have to share, the intellectual property rights to the innovation with our licensors;

- Operations of our third-party manufacturers or suppliers could be disrupted by conditions unrelated to our business or operations, including a bankruptcy of the manufacturer or supplier, and

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

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

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

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

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

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

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

We utilize the services of a clinical management team on part-time basis to assist us in managing our Phase 2 and Phase 3 trials. While we believe this will provide us with sufficient staffing for our current development efforts, we will need to hire or contract with additional qualified personnel with expertise in preclinical testing, clinical research and testing, government regulation, formulation and manufacturing and sales and marketing in connection with the continued development, regulatory approval and commercialization of our product candidates. We compete for qualified individuals with numerous pharmaceutical and biopharmaceutical companies, universities and other research institutions. Competition for these individuals is intense, and we cannot be certain that our search for such personnel will be successful. Attracting and retaining qualified personnel will be critical to our success.

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

We will need to increase the size of our organization, and we may experience difficulties in managing growth.

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

- manage our regulatory approval trials effectively;
- manage our internal development efforts effectively while complying with our contractual obligations to licensors, licensees, contractors, collaborators and other third parties;
- develop internal sales and marketing capabilities or establish collaborations with third parties with such capabilities;
- commercialize our product candidates;
- improve our operational, financial and management controls, reporting systems and procedures; and

- attract and motivate sufficient numbers of talented employees.

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

Risks Related to Our Regulatory and Legal Environment

We are subject to extensive and costly government regulation.

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

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

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

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

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

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

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

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

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

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

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

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

The use of any of our product candidates in clinical trials, and the sale of any approved products, may expose us to liability claims and financial losses resulting from the use or sale of our products. We have obtained limited product liability insurance coverage for our clinical trials of $2 million per occurrence and in the aggregate, subject to a deductible of $50,000 per occurrence. There can be no assurance that our existing insurance coverage will extend to our other products in the future. Any product liability insurance coverage may not be sufficient to satisfy all liabilities resulting from product liability claims. A successful claim may prevent us from obtaining adequate product liability insurance in the future on commercially desirable terms, if at all. Even if a claim is not successful, defending such a claim would be time consuming and expensive, may damage our reputation in the marketplace, and would likely divert management's attention.

Risks Related to our Intellectual Property

Our business depends on protecting our intellectual property.

If we do not obtain protection for our intellectual property rights, our competitors might be able to take advantage of our research and development efforts to develop competing drugs. Our success, competitive position and future revenues, if any, depend in part on our ability and the abilities of our licensors to obtain and maintain patent protection for our products, methods, processes and other technologies, to preserve our trade secrets, to prevent third parties from infringing on our proprietary rights and to operate without infringing the proprietary rights of third parties. We anticipate filing additional patent applications both in the U.S. and in other countries, as appropriate. However, the patent process is subject to numerous risks and uncertainties, and there can be no assurance that we will be successful in protecting our products by obtaining and defending patents. These risks and uncertainties include the following:

- Our patent rights might be challenged, invalidated, or circumvented, or otherwise might not provide any competitive advantage;

- Our competitors, many of which have substantially greater resources than we do and many of which might make significant investments in competing technologies, might seek, or might already have obtained, patents that will limit, interfere with, or eliminate our ability to make, use, and sell our potential products either in the U.S. or in international markets;

- As a matter of public policy regarding worldwide health concerns, there might be significant pressure on the U.S. government and other international governmental bodies to limit the scope of patent protection both inside and outside the U.S. for disease treatments that prove successful; and

- Countries other than the U.S. might have less restrictive patent laws than those upheld by U.S. courts, allowing foreign competitors the ability to exploit these laws to create, develop, and market competing products.

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

Because the time period from filing a patent application to the issuance, if ever, of the patent is often more than three years and because any regulatory approval and marketing for a drug often occurs several years after the related patent application is filed, the resulting market exclusivity afforded by any patent on our drug candidates and technologies will likely be substantially less than 20 years. In the United States, the European Union and some other jurisdictions, patent term extensions are available for certain delays in either patent office proceedings or marketing and regulatory approval processes. However, due to the specific requirements for obtaining these extensions, there is no assurance that our patents will be granted extensions even if we encounter significant delays in patent office proceedings or marketing and regulatory approval.

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

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

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

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

If we infringe the rights of third parties we might have to forgo selling our future products, pay damages, or defend against litigation.

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

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

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

Risks Related to Our Securities and Liquidity Risks

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

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

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

If we are an issuer of "penny stock", the protection provided by the federal securities laws relating to forward looking statements does not apply to us.

Although federal securities laws provide a safe harbor for forward-looking statements made by a public company that files reports under the federal securities laws, this safe harbor is not available to issuers of penny stocks. As a result, if our common stock is subject to the penny stock rules, we will not have the benefit of this safe harbor protection in the event of any legal action based upon a claim that the material provided by us contained a material misstatement of fact or was misleading in any material respect because of our failure to include any statements necessary to make the statements not misleading. Such an action could hurt our financial condition.

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

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

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

The Company must maintain effective internal controls to provide reliable financial reports and to be able to detect fraud. The Company has been assessing its internal controls to identify areas that need improvement. Our management concluded that our disclosure controls and procedures were, and continue to be, ineffective and as of September 30, 2016 identified a material weakness in our internal controls. While the Company is in the process of implementing changes to internal controls, it has not yet completed implementing these changes and there is no assurance that the changes will remediate the material weakness or that the controls will prevent or defect future material weakness. Failure to implement these changes to the Company's internal controls or any others that it identifies as necessary to maintain an effective system of internal controls could harm its operating results and cause shareholders to lose confidence in the Company's reported financial information. Any such loss of confidence would have a negative effect on the trading price of the Company's stock.

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

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

- actual or anticipated variations in the Company's operating results;
- announcements of developments by the Company or its competitors;
- the completion and/or results of the Company's clinical trials;
- regulatory actions regarding the Company's products
- announcements by the Company or its competitors of significant acquisitions, strategic partnerships, joint ventures or capital commitments;
- adoption of new accounting standards affecting the Company's industry;
- additions or departures of key personnel;
- introduction of new products by the Company or its competitors;
- sales of the Company's Common Stock or other securities in the open market; and
- other events or factors, many of which are beyond the Company's control.

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

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

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

You may experience dilution of your ownership interests because of the future issuance of additional shares of the Common Stock.

In the future, the Company may issue additional authorized but previously unissued equity securities, resulting in the dilution of the ownership interests of its present stockholders. The Company is currently authorized to issue an aggregate of 200,000,000 shares of Common Stock and 10,000,000 shares of preferred stock. As of August 8, 2017, there are 8,252,798 shares of Common Stock outstanding, 3,280,980 shares underlying warrants with a weighted average exercise price of $5.97 per share, and 586,039 shares underlying options with a weighted average exercise price of $8.21 per share. The Company may also issue additional shares of its Common Stock or other securities that are convertible into or exercisable for Common Stock in connection with hiring or retaining employees, future acquisitions, future sales of its securities for capital raising purposes, or for other business purposes. The future issuance of any such additional shares of Common Stock may create downward pressure on the trading price of the Common Stock.

The Common Stock is controlled by insiders.

As of August 8, 2017, the former managing members of Citius Pharmaceuticals, LLC beneficially own approximately 12.9% of our outstanding shares of Common Stock and the Company's current officers and directors beneficially own approximately 51.9% of our outstanding shares of Common Stock. Such concentrated control of the Company may adversely affect the price of the Common Stock. If you acquire Common Stock, you may have no effective voice in the management of the Company. Sales by insiders or affiliates of the Company, along with any other market transactions, could affect the market price of the Common Stock.

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

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

Our Certificate of Incorporation allows for the board of directors to create new series of preferred stock without further approval by stockholders, which could adversely affect the rights of the holders of the Common Stock.

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

There are a significant number of shares of Common Stock eligible for sale, which could depress the market price of such shares.

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

Risks Related to Ownership of our Securities

There is not an active liquid trading market for the Company's Common Stock.

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

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

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

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

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

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

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

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

Sales of a substantial number of shares of our common stock in the public market could occur at any time. These sales, or the perception in the market of such sales or that the holders of a large number of shares intend to sell shares, could reduce the market price of our shares of our common stock. As of August 8, 2017, we have 8,252,798 shares of common stock outstanding. This includes registered shares of common stock as well as 2,992,307 shares of our common stock which are available for resale under Rule 144 of the Securities Act of 1933, as amended, or the "Securities Act". On August 8, 2017, our executive officers and directors entered into lock-up agreements pursuant to which they agreed not to sell any of our shares for a period of 90 days from the effective date of our recent public offering. As representative of the underwriters, Aegis Capital Corp. may, in its sole discretion, allow early releases under the referenced lock-up restrictions.

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

If we fail to satisfy the continued listing requirements of the Nasdaq Capital Market, such as the corporate governance requirements or the minimum closing bid price requirement, Nasdaq may take steps to delist our common stock and warrants. Such a delisting would likely have a negative effect on the price of our common stock and warrants and would impair your ability to sell or purchase our common stock and warrants when you wish to do so. In the event of a delisting, we would take actions to restore our compliance with Nasdaq's listing requirements, but we can provide no assurance that any such action taken by us would allow our common stock to become listed again, stabilize the market price or improve the liquidity of our common stock, prevent our common stock from dropping below the Nasdaq minimum bid price requirement or prevent future non-compliance with Nasdaq's listing requirements.

Risks Related to Our Reverse Stock Split

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

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

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

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

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

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

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

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

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

During the nine months ended June 30, 2017, the Company sold 128,017 2016 Offering Units for a purchase price of $6.00 per unit for gross proceeds of $768,100. The Company registered the 128,017 shares issued and the shares underlying the warrants issued on a Form S-1 which was declared effective on April 11, 2017.

Item 3. Defaults Upon Senior Securities

None.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

None.

Item 6. Exhibits

3.1	Certificate of Amendment of the Amended and Restated Articles of Incorporation of Citius Pharmaceuticals, Inc. effective June 9, 2017 (incorporated by reference to the Company's Form 8-K dated June 7, 2017, as filed June 8, 2017).
10.1	Release Agreement by and between Citius Pharmaceuticals, Inc. and Garden State Securities, Inc. dated June 7, 2017 (incorporated by reference to the Company's Form 8-K dated June 7, 2017, as filed June 13, 2017).
10.2	Form of Release Agreement by and between Citius Pharmaceuticals, Inc. and each investor dated June 8, 2017 (incorporated by reference to the Company's Form 8-K dated June 7, 2017, as filed June 13, 2017).
10.3	Future Advance Convertible Promissory Note dated June 23, 2017 between Leonard Mazur and Citius Pharmaceuticals, Inc. (the form of Future Advance Convertible Promissory Note is incorporated by reference to Exhibit 10.1 to the Company's Form 10-Q for the fiscal quarter ended March 31, 2017).
31.1	Certification of the Principal Executive and Financial Officer pursuant to Exchange Act Rule 13a-14(a).*
32.1	Certification of the Principal Executive and Financial Officer pursuant to 18 U.S.C. 1350, as adopted pursuant to Section 906 of the Sarbanes Oxley Act of 2002.*
EX-101.INS	XBRL INSTANCE DOCUMENT
EX-101.SCH	XBRL TAXONOMY EXTENSION SCHEMA DOCUMENT
EX-101.CAL	XBRL TAXONOMY EXTENSION CALCULATION LINKBASE
EX-101.DEF	XBRL TAXONOMY EXTENSION DEFINITION LINKBASE
EX-101.LAB	XBRL TAXONOMY EXTENSION LABELS LINKBASE
EX-101.PRE	XBRL TAXONOMY EXTENSION PRESENTATION LINKBASE

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* Filed herewith.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

CITIUS PHARMACEUTICALS, INC.

Date: August 14, 2017

By: */s/ Myron Holubiak*
Myron Holubiak
Chief Executive Officer,
Principal Executive Officer and Principal Financial Officer

EXHIBIT 31.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER
PURSUANT TO SECTION 302 OF THE
SARBANES-OXLEY ACT OF 2002

I, Myron Holubiak, certify that:

1. I have reviewed this report on Form 10-Q of Citius Pharmaceuticals, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 14, 2017

By: */s/ Myron Holubiak*
Myron Holubiak
Chief Executive Officer,
Principal Executive Officer and Principal
Financial Officer

EXHIBIT 32.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER
PURSUANT TO 18 U.S.C. SECTION 1350
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of Citius Pharmaceuticals, Inc. (the "Company") on Form 10-Q for the period ended June 30, 2017 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Myron Holubiak, Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: August 14, 2017

By: */s/ Myron Holubiak*
Myron Holubiak
Chief Executive Officer,
Principal Executive Officer and Principal Financial Officer