UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the Fiscal Year Ended September 30, 2015

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

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)	(I.R.S. Employer Identification No.)

63 Great Road, Maynard, MA 01754
(Address of principal executive offices) (Zip Code)

(978) 938-0338
(Registrant's telephone number, including area code)

_____
(Former name and address, if changed since last report)

Securities registered pursuant to Section 12(g) of the Exchange Act:

Common Stock, par value $0.001 per share
(Title or Class)

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. ☐ Yes ☒ No

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act. ☒ Yes ☐ No

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

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

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendments to this Form 10-K. ☐

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

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☐	Smaller reporting company	☒

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

The aggregate market value of the voting and non-voting common equity held by non-affiliates* computed by reference to the price at which the common equity was last sold, or the average bid and asked price of such common equity, as of the last business day of the registrant's most recently completed second fiscal quarter (March 31, 2015) was $6,640,797.

* Affiliates for the purpose of this item refers to the issuer's officers and directors and/or any persons or firms (excluding those brokerage firms and/or clearing houses and/or depository companies holding issuer's securities as record holders only for their respective clienteles' beneficial interest) owning 10% or more of the issuer's Common Stock, both of record and beneficially.

APPLICABLE ONLY TO CORPORATE REGISTRANTS

Indicate the number of shares outstanding of each of the registrant's classes of common stock, as of the latest practicable date:

34,701,220 shares as of December 1, 2015, all of one class of common stock, $0.001 par value.

DOCUMENTS INCORPORATED BY REFERENCE

None.

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EXPLANATORY NOTE

In this annual report on Form 10-K, and unless the context otherwise requires the "Company," "we," "us" and "our" refer to Citius Pharmaceuticals, Inc. and its wholly owned subsidiary, Citius Pharmaceuticals, LLC, taken as a whole.

FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K 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, including the risks described under Item 1A - "Risk Factors," and Item 7 - "Management's Discussion and Analysis of Financial Condition and Results of Operations" 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.

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

ITEM 1. BUSINESS

Overview

The Company was formed in the state of Nevada on September 9, 2010 as Trail One, Inc. On September 12, 2014, we entered into a Share Exchange and Reorganization Agreement (the "Exchange Agreement"), among Trail One, Inc., Citius Pharmaceuticals, LLC, a Massachusetts limited liability company ("Citius"), and the beneficial holders of the membership interests of Citius (the "Citius Stockholders"). On September 12, 2014, Trail One, Inc. had no assets, no liabilities, and 5,000,000 shares of issued and outstanding common stock.

Pursuant to the Exchange Agreement, (i) Trail One, Inc. issued 21,625,219 shares of common stock to the Citius Stockholders, which represented approximately 72.0% of the outstanding shares of common stock following the closing of the Exchange Agreement (the "Reverse Acquisition") and the first closing of the Private Offering described below. The Trail One, Inc. existing shareholders before the Reverse Acquisition and the first closing of the Private Offering owned 5,000,000 shares of common stock or 16.7% of the outstanding shares of common stock following the closing of the Exchange Agreement.

In connection with the Exchange Agreement, on September 12, 2014, we sold 3,400,067 Units for a purchase price of $0.60 per Unit, each Unit consisting 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 $0.60, (the "September 2014 Private Offering"). As of September 12, 2014, we raised gross proceeds of $2,040,040. Between March 19, 2015 and September 30, 2015, we issued an aggregate of 2,837,037 Units for a purchase price of $0.54 per Unit and an aggregate of 200,000 Units for a purchase price of $0.60 per Unit. The exercise price of the Investor Warrants is subject to adjustment, for up to one year from the issuance date, in the event that we sell common stock at a price lower than the exercise price, subject to certain exceptions. The Investor Warrants are redeemable by us at a price of $0.001 per Investor Warrant at any time subject to the conditions that (i) our Common Stock has traded for twenty (20) consecutive trading days with a closing price of at least $1.50 per share with an average trading volume of 50,000 shares per day and (ii) we provide twenty (20) trading days prior notice of the redemption and the closing price of our Common Stock is not less than $1.17 for more than any three (3) days during such notice period and (iii) the underlying shares of Common Stock are registered for resale.

Prior to the Reverse Acquisition, our business plan was to manufacture TOCNC Tags, which were personalized/customized license plates for customers who want one of a kind luxury car jewelry to uniquely define them and to offer a sense of identification privacy at public events such as car shows, photo shoots, auto clubs, and other public venues. We are no longer pursuing this line of business.

On September 12, 2014, Citius became a wholly-owned subsidiary of the Company. The acquisition of Citius is treated as a "reverse merger" and the business of Citius, as described below, became our business. Citius is deemed to be the accounting acquirer. In connection with the Reverse Acquisition, we adopted the fiscal year end of Trail One, Inc. thereby changing our fiscal year end from December 31 to September 30. In addition on September 12, 2014, Trail One, Inc. changed its name to Citius Pharmaceuticals, Inc.

References to "we," "us," "our" and similar words refer to the Company and its wholly owned subsidiary Citius, taken as a whole. References to "Trail One" refer to the Company and its business prior to the Reverse Acquisition.

Summary of Citius Pharmaceuticals' Business

Citius Pharmaceuticals, LLC, founded on January 23, 2007 as a Massachusetts limited liability company is a specialty pharmaceutical company dedicated to the development and commercialization of therapeutic products for large and growing markets using innovative, patented or proprietary formulations and modified drug delivery technology. We seek new and expanded indications for previously approved pharmaceutical products as a means to achieving differentiated market positions or market exclusivity. Our goal is to build a successful pharmaceutical company through the development and commercialization of low-risk, innovative, efficacious and cost-effective products that address compelling market opportunities.

We seek to achieve our business objectives by utilizing the U.S. Food and Drug Administration's, or FDA's, 505(b)(2) pathway for our new drug approvals. We believe this pathway is faster, has lower risk and is less expensive than the FDA's traditional new drug approval pathway. Although this pathway is less risky and less expensive compared to developing newly discovered drugs, we believe that development, clinical trials and FDA filing fees for our hydrocortisone and lidocaine combination product will require $20 million of additional capital. Following the Company's year-end and the release of its financial statements, the Company's Chief Executive Officer and President, Leonard Mazur, anticipates meeting with investment banking firms and certain other investors to raise additional capital to fund the Company's research and development efforts; however, there can be no assurance that the Company will be able to obtain financing or anticipate the terms of such financing. In addition to focusing on new drug approvals, we focus on obtaining intellectual property protection with the objective of listing relevant patents in the FDA Orange Book in order to limit generic competition.

By using previously approved drugs with substantial safety and efficacy data already available, we seek to reduce the risks associated with pharmaceutical product development. We have already successfully employed this strategy to obtain FDA approval for Suprenza, our approved and marketed product for the treatment of obesity. We also plan to utilize this strategy to seek approval for other new drug product candidates for obesity. We also have a development candidate completing Phase 2 trials for the treatment of hemorrhoids. In addition, we are developing a topical cream product containing both hydrocortisone and lidocaine for the treatment of mild to moderate hemorrhoids. We have recently completed dosing 200 patients with the topical cream product in a Phase 2a study and are waiting for results from that study. If our Phase 2a study is positive, we will conduct a Phase 2b study followed by Phase 3 studies. We will conduct additional non-clinical and human safety studies to support our New Drug Application ("NDA"). If all of our studies are positive, we anticipate filing the NDA three to four years from the date of this Annual Report. Although both hydrocortisone and lidocaine are FDA approved drugs, we will not be permitted to market our product candidates in the United States until we receive approval from the FDA of our NDA. We believe the markets for obesity and hemorrhoid treatments are both large and underserved by innovative, efficacious and cost-effective new products. The U.S. Centers for Disease Control, or CDC, estimates that more than 35% of U.S. adult men and women, or approximately 78 million U.S. adults, were obese in 2009-2010. In addition, it is estimated that hemorrhoids affect nearly 5% of the U.S. population, with approximately 10 million persons annually reporting to be suffering from the symptoms of hemorrhoidal disease.

Since inception, we have focused on product development, have not generated any revenues and incurred losses in each period of our operations, and we expect to continue to incur losses for the foreseeable future. As of September 30, 2015, our accumulated deficit was $9,040,549 and our capital working deficit was $640,614. These losses are likely to continue to adversely affect our working capital, total assets and shareholders' deficit, and are attributable to the process of developing our products which 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 third parties. Due to our financial condition, our independent registered accountants have indicated, in their report for the year ended September 30, 2015, that there is substantial doubt about our ability to continue as a going concern. All the aforementioned factors may have a material, adverse effect on our ability to raise additional capital.

In November 2011, the Company entered into an agreement with Prenzamax LLC ("Prenzamax") pursuant to which the Company granted Prenzamax an exclusive, royalty-bearing, transferable license to use and sell Suprenza in the United States and to manufacture or have Suprenza manufactured by third parties for subsequent sale in the United States (the "Exclusive License Agreement"). Prenzamax is a specialty pharmaceutical company focused on providing innovative and advanced ethical prescription medications which have differential and therapeutically meaningful advantages to health care professionals and their patients. Prenzamax is an affiliate of Akrimax LLC ("Akrimax"), a privately-held pharmaceutical company which acquires and develops and markets advanced ethical prescription medications. Prenzamax was formed for the purpose of managing the license granted pursuant to the Exclusive License Agreement. Pursuant to the terms of the Exclusive License Agreement, Prenzamax purchases Suprenza from our manufacturer, Alpex Pharma S.A., and is responsible for arranging import and custom requirements. Once Suprenza is in the U.S., it is delivered to Prenzamax's third party logistics provider for warehousing, order processing and shipping to the end customers. Prenzamax is responsible for all costs related to manufacturing, warehousing and distribution. In addition, Prenzamax is also solely responsible for the sales and marketing costs associated with Suprenza. These costs include, but are not limited to, preparation of marketing materials such as brochures and electronic media as well as other advertising and promotional costs including providing samples of Suprenza to physicians and patients. A major cost component for Prenzamax is sales force salaries, training and travel expenses. Akrimax has agreed to act as a guarantor of Prenzamax's obligations owed to the Company pursuant to the Exclusive License Agreement. Specifically, the Exclusive License Agreement provides that Akrimax unconditionally guarantees the full and prompt performance of all obligations of Prenzamax pursuant to the terms and conditions of the Exclusive License Agreement, including the payment of all amounts that become due and payable by Prenzamax. In addition, Akrimax prepares estimates of time and costs with respect to selling Suprenza and allocates those costs to calculate the Product EBITDA. Product EBITDA is defined as Sales less the Cost of Goods sold, Marketing Expenses and regulatory expenses. All terms which are not defined herein are defined in the Exclusive License Agreement by and between Citius and Prenzamax dated November 15, 2011 which has been filed with the SEC.

Since the launch of Suprenza in 2012, Prenzamax has been unable to generate revenues sufficient to cover its costs and generate profits. Costs include, but are not limited to, the cost of goods from Alpex, FDA facility and product fees, the cost of marketing materials including samples provided to physicians and patients and product literature and the cost of its sales force including travel and out of pocket expenses. These costs are significantly higher than revenue derived from the sale of Suprenza and therefore, Prenzamax has thus far been unable to generate profits from such sales. Based upon the revenue to cost ratio, we do not believe that we will receive any Profit Share Payments from Prenzamax in the foreseeable future. We anticipate that we will receive Profit Share Payments from Prenzamax at such time as the revenues generated from the

sale of Suprenza exceed Prenzamax's costs associated with the sale of the product.

In addition, we have entered into an agreement with Alpex pursuant to which Alpex may use clinical data generated by the Company to file for regulatory approval in markets where we are not licensed to sell the product. If Alpex sells the product directly to such markets, we shall receive thirteen percent (13%) of the net sales as royalty; provided, however, if Alpex does not market the product in such markets and licenses the product to third parties for resale, we shall receive twenty five percent (25%) of the net sales as royalty. Pursuant to the Exclusive License Agreement with Prenzamax, we are required to pay Prenzamax thirty five percent (35%) of the royalty payments which we receive from Alpex. To date, we have not received any payments from Alpex pursuant to the agreement because Alpex has not filed for regulatory approval in any countries, and we do not anticipate that Alpex will file for such approval in the near future.

After we received approval and launched Suprenza in 2012, we planned to make improvements to our Suprenza formulation. In addition, we planned to use profits generated from the sale of Suprenza for the development and clinical testing program. However, sales of Suprenza have so far been minimal and we have been unable to obtain sufficient funding and therefore, currently, we suspended our plans for the next generation of Suprenza. Currently, we are only developing our hemorrhoid treatment product.

As a condition to obtaining approval for Suprenza, the FDA required us to conduct a post-marketing study on the pharmacokinectic, or PK, parameters of Suprenza ODT in subjects with renal impairment. Drug exposure increases can be expected in patients with renal impairment who are treated with phentermine. However, Suprenza ODT's pharmacokinetics has not been assessed in renal impaired patients. Since obesity can lead to renal failure, there exists a possibility that patients with mild or moderate renal failure may be prescribed Suprenza ODT. Therefore, it is important to assess the changes in the PK parameters of Suprenza ODT in patients with renal impairment. The primary endpoint of this study is the pharmacokinetic assessment of Suprenza ODT in renal impaired patients, and the results of this study would provide important new information to prescribing physicians regarding phentermine dosing and dose adjustments for these at-risk patients.

A clinical research organization has indicated that it will cost approximately $400,000 and 18 months to conduct the renal impairment study. Due to the limited current sales of Suprenza, we requested the FDA waive the renal PK study. In the FDA's letter dated August 28, 2015, the FDA notified us that our request to waive the study was denied because financial hardship was an inadequate reason to justify a waiver of the study. In addition, the FDA restated the FDA's concern that there is a signal of serious risk of increased drug exposure in patients with decreased renal function. If we fail to conduct the post-marketing renal PK study, the FDA may ask us to discontinue selling the product or impose other penalties which they deem suitable.

In general the FDA allows companies to continue selling their product while post-marketing studies are being conducted. Based upon limited sales and usage of our product, we intend to reapply for a waiver of the post-marketing study. However, there can be no assurance that the FDA will release us from such requirement. If our next request to waive the post-marketing studying is denied and we do not have sufficient funding to conduct the study, we will likely discontinue the sale of Suprenza. If we receive sufficient funding and determine to proceed with the renal impairment study, and the results of such study demonstrate safety concerns, we may have to add additional disclosures to our label or alternatively, discontinue the sale of the product.

The co-founder and vice Chairman of Akrimax is Leonard Mazur who is our President, Chief Executive Officer and Chief Operating Officer. Pursuant to the terms of the license agreement, Prenzamax will be solely responsible for the pricing of Suprenza and will have the option to participate in the future development program of Suprenza which may result in a conflict of interest. Although Mr. Mazur does not have any direct management role in Akrimax or Prenzamax, there can be no assurance that Prenzamax will conduct its business affairs in a manner which is beneficial to our company.

Our Strategy

Our goal is to build a successful pharmaceutical company through the development and commercialization of low-risk, innovative, efficacious and cost-effective products that address compelling market opportunities. We will seek to achieve this goal by:

- Identifying new drug product candidates that are typically prescribed by a relatively small number of specialist physicians and can therefore be successfully commercialized by a small, specialty sales force;
- Obtaining licenses for the most relevant and advanced technologies to provide our new product candidates with superior product characteristics and intellectual property protection;
- Outsourcing formulation development and manufacturing in order to reduce our required capital investment;
- Leveraging our in-house clinical and regulatory expertise to more rapidly advance the development of product candidates in our pipeline;
- Establishing strategic relationships with marketing partners to maximize sales potential for our products that require significant commercial support; and
- Managing our business in a financially disciplined and cost-conscious manner.

The FDA's 505(b)(2) New Drug Application Approval Pathway

The FDA's 505(b)(2) New Drug Application, or NDA, approval pathway can be utilized for a wide range of products, especially for those that represent a limited change from a previously approved drug. Further, there are compelling commercial benefits, such as the availability of three years of market exclusivity, to employing a 505(b)(2) regulatory strategy. Depending on the extent of the changes to the previously approved drug and the type of clinical data included in the NDA, the FDA may also grant pediatric exclusivity and orphan drug status. The 505(b)(2) approval pathway was designed by the FDA to encourage innovation while eliminating costly and time-consuming duplicative clinical studies.

The following are examples of changes to approved drugs which would be appropriate to submit as 505(b)(2) applications:

- Changes in dosage form, strength, route of administration, formulation, dosing regimen, or indication;
- A new combination product where the active ingredients have been previously approved;
- Changes to an active ingredient (e.g., different salt, ester complex, chelate, etc.);
- New Chemical Entity, or NCE, when studies have been conducted by other sponsors and published information is pertinent to the application (e.g., a pro-drug or active metabolite of an approved drug);
- Change from a prescription, or Rx, indication to an over-the-counter, or OTC, indication;
- Change to an OTC monograph drug (e.g., non-monograph indication, new dosage form); and
- Drugs with naturally derived or recombinant (i.e., biological) active ingredients where additional limited clinical data is necessary to show the ingredient is the same as the ingredient in the reference drug.

For some products, FDA's Reference Listed Drug, or RLD, can be relied upon for most of the safety and efficacy information; however, products that were approved with no or limited clinical trials and efficacy studies, and more importantly, those non FDA-approved prescription products that rely on the FDA's Drug Efficacy Study Implementation, or DESI, route to market are subject to various additional pre-clinical, clinical and safety studies.

Our Marketed Product and New Product Candidates

Product	Indication	Current Status	Patent Expiry; Patent Number
Suprenza ODT (phentermine orally disintegrating tablet)	Obesity	Marketed	July 23, 2018; 6,149,938
Hydrocortisone-Lidocaine Cream	Hemorrhoids	In Phase 2 study	TBD

We recently completed dosing patients in a double blind placebo controlled Phase 2 study where we tested six different formulations containing hydrocortisone and lidocaine in various strengths against placebo. There is no assurance that the results of this study will be positive. However, in the event that we obtain positive results, our next step will be to conduct a Phase 2b study to demonstrate efficacy contribution of the two active drugs. This study may require approximately 400 patients, could cost approximately $4.0 million and will require one year to complete. Assuming that the results of this study are positive, we would begin a Phase 3 efficacy study in approximately 600 to 800 patients. The Phase 3 study is the most time consuming study, and we anticipate that it will take approximately 18 months to complete and could cost approximately $8.0 million. Assuming that the Phase 3 study is positive, we intend to conduct several other supporting studies which could cost approximately $3 to $4 million. Since both hydrocortisone and lidocaine are FDA approved drugs, the FDA has permitted us to conduct some of the supporting studies concurrently with the Phase 3 study. In addition to the supporting studies conducted concurrently with the Phase 3 study, other supporting studies may require six months to complete after the completion of the Phase 3 study. If all data results are positive, we anticipate being able to file a New Drug Application in three to four years.

Licensing agreement with Prenzamax LLC

In November 2011, we granted an exclusive license for sales and marketing of Suprenza to Prenzamax LLC, a specialty pharmaceutical company focused on providing innovative and advanced ethical prescription medications which have differential and therapeutically meaningful advantages to health care professionals and their patients. Prenzamax is an affiliate of Akrimax and was formed for the specific purpose of managing the Citius and Suprenza agreement.

Akrimax, founded in 2008, is a privately-held pharmaceutical company, which acquires, develops and markets advanced ethical prescription medications. The management team at Akrimax has extensive industry experience in identifying and developing innovative therapies to help health care professionals improve the lives of their patients. Akrimax has experienced rapid growth in sales due to its attractive product line, highly experienced management team, dedicated sales force and innovative marketing techniques. Akrimax has launched several successful branded generic products which are marketed to physicians by a trained team of sales representatives. In order to bring the best treatments to patients, Akrimax continuously evaluates opportunities to partner with other organizations that strive to improve patient care. With a proven track record of brand growth and success at Akrimax, it seeks and evaluates opportunities to in-license and/or acquire products in a variety of therapeutic areas including:

- Late stage (phase III and pending approval) and/or approved products not yet launched
- Unpromoted or underpromoted marketed products
- Strategic co-promotion/cross promotion product
- Company acquisitions

Akrimax and Prenzamax are majority owned by common investors and are therefore considered affiliates. Both Prenzamax and Akrimax have jointly agreed to the terms of performance on the agreement. Any reference to Prenzamax in this discussion also refers to Akrimax and vice versa.

Terms of the license

In November 2011, Citius granted Prenzamax an exclusive, royalty-bearing, transferable license to use and sell Suprenza in the United States and to manufacture or have Suprenza manufactured by third parties for subsequent sale in the United States (the "License"). Prenzamax and its affiliates have the right to sublicense any of the rights granted in this agreement to contract manufacturers, distributors, co-promotion partners, contract sales organizations and other service providers assisting Prenzamax in the commercialization of Suprenza. If Prenzamax or its affiliates grants any such sublicense to a co-promotion partner, it will remain an active participant in the promotion and marketing of the products, and will ensure that the economic return to Citius under this Agreement is the same as if Prenzamax was promoting the product without such co-promotion partner.

All terms which are not defined herein are defined in the Exclusive License Agreement by and between Citius and Prenzamax dated November 15, 2011 which is on file with the SEC.

Pursuant to the terms of the license agreement, Prenzamax shall pay to Citius fifty percent (50%) of the Product EBITDA generated during each Fiscal Quarter during the Term (the "Profit Share Payments"). Each Profit Share Payment shall be accompanied by the Profit Share Statement. Profit Share Payments shall be subject to certain offsets, shall be made on a quarterly basis and shall be paid no later than 45 days following the end of each Fiscal Quarter.

"Product EBITDA" means Product Net Sales, less the following amounts incurred by Licensee or its Affiliates (in each case as calculated by Licensee and its Affiliates in accordance with GAAP, as consistently applied):

(i) Cost of Goods of such Product;

(ii) Selling Expenses;

(iii) Marketing Expenses;

(iv) fees paid to third party distributors, third party logistics providers and shippers (such as shipping to and from wholesalers) and other distribution costs, in each case to the extent related to Product and actually paid by Licensee or its Affiliates;

(v) the amount of FDA fees paid by Licensee as well as any other costs (including, but not limited to, governmental fees and attorney and consultant costs) incurred in connection with obtaining and maintaining any Regulatory Filings and Approvals;

(vi) Development Costs;

(vii) any costs incurred in connection with the prosecution, maintenance, defense or enforcement of any of the Licensed Intellectual Property;

(viii) that portion of any Alpex Royalty paid by Licensee, and any other royalty payments that may be paid by Licensee or its Affiliates in connection with the Product; and

(ix) any costs incurred in connection with the qualification of an alternate manufacturing facility (i.e., other than Alpex) for the Product (including, but not limited to, any fees charged by the Alternate Manufacturing Facility or Licensee's other third party vendors in connection with the qualification of an alternate manufacturing facility).

In addition, the License provides for Development Cost Reimbursement which Prenzamax shall pay to Citius in equal quarterly installments of $115,152 over the course of twelve Fiscal Quarters, starting with the first Fiscal Quarter after the Profitability Date. "Profitability Date" means the date on which four Profit Share Payments have been made to Citius for any four Fiscal Quarters (whether or not such Fiscal Quarters are consecutive). Each installment shall be paid no later than 45 days following the end of each such Fiscal Quarter.

Royalty Payments to Alpex.

Pursuant to the terms of the license agreement, Prenzamax purchases Suprenza from our manufacturer, Alpex S.A. and is responsible for arranging import and custom requirements. Once the product is in the U.S. it is delivered to Prenzamax's third party logistics provider for warehousing, order processing and shipping to the end customers. Prenzamax is responsible for all costs associated with manufacturing, warehousing and distribution. In addition, Prenzamax is also solely responsible for sales and marketing costs associated with Suprenza. These costs include, but are not limited to, preparation of marketing material such as brochures and electronic media as well as advertising and promotional costs including providing samples of products to physicians and patients. A major cost component for Prenzamax is sales force salaries, training and travel expenses. Prenzamax sales professionals call on cardiologists, endocrinologists, primary care physicians and bariatric or weight loss management physicians. None of the sales people are exclusive to any product or physician specialty but are cross trained to sell all of Akrimax's products. Akrimax prepares estimates of time and costs incurred in selling Suprenza and allocates those costs to calculate the Product EBITDA. Product EBITDA is defined as Sales less the Cost of Goods sold, Marketing Expenses and regulatory expenses.

The Company and Akrimax shall each pay fifty percent (50%) of the cost of goods per Suprenza tablet that Alpex or a third party manufactures. In the event tablets are manufactured by a third party, Alpex shall not be entitled to receive any payments for the cost of goods; provided, however, Alpex shall receive a royalty payment in the amount of eight percent (8%) of net sales. In addition, Prenzamax and the Company shall each be responsible for fifty percent (50%) of the royalty due to Alpex.

The Company has the right to market Suprenza in the Territory and Alpex has the right to market Suprenza outside the Territory (defined hereafter) and use clinical data generated by the Company to file for regulatory approvals in markets where the Company is not licensed to sell the Product. Territory means the United States (including all of its states, territories and possessions), Canada and Mexico. We have been granted an exclusive license by Alpex to the Alpex intellectual property defined in our agreement as Alpex patents and Alpex know-how as it applies to our product (the "Alpex IP").We pay royalties to Alpex for the use of the Alpex IP. Upon expiration of the patent and discontinued use of the Alpex IP, including when such Alpex IP comes into the public domain and becomes freely available to us and the public, we will stop paying royalties to Alpex. The Agreement by and between the Company and Alpex shall terminate upon the earlier of (i) July 23, 2018, the date upon which the patent expires and (ii) the discontinued use of the Alpex IP, including when such Alpex IP comes into the public domain.

In addition, we have entered into an agreement with Alpex pursuant to which Alpex may use clinical data generated by the Company to file for regulatory approval in markets where we are not licensed to sell the product. If Alpex sells the product directly to such markets, we shall receive from Alpex thirteen percent (13%) of the net sales as a royalty; provided, however, if Alpex does not market the product in such markets and instead licenses the product to third parties for resale, we shall receive twenty five percent (25%) of the net sales as a royalty.

In the event that Alpex licenses the product to third parties (the "Sublicensee"), we shall first receive our out of pocket cost related to the development, clinical studies, regulatory filings and incidental expenses related to obtaining the regulatory approvals for the Products. Out of pocket costs shall not include salaries and General and Administrative costs incidental to operating the Company. After such costs are recovered, all payments received by Alpex from the Sublicensee after Alpex receives payment for the completion of milestones shall be apportioned as follows: seventy-five percent (75%) of payments shall be paid to Alpex and twenty-five percent (25%) of payments shall be paid to the Company. A milestone is generally understood as a completion of a specific defined task towards the completion of a project or performance of a contract. For example, pursuant to our agreement with Alpex, we are required to pay Alpex for the completion of certain tasks including, but not limited to, the development of the analytical methods, formulations and filings of the NDA.

Pursuant to the Exclusive License Agreement with Prenzamax, we are required to pay Prenzamax thirty five percent (35%) of the royalty payments which we receive from Alpex. To date, we have not received any payments from Alpex pursuant to the agreement because Alpex has not filed for regulatory approval in any countries, and we do not anticipate that Alpex will file for such approval in the near future. Akrimax has the right to determine the sale price of Suprenza in its sole and absolute discretion. Neither the Company nor Alpex have any discretion with respect to the sale price of Suprenza.

Improvements and follow-on products

We intend to improve on the Suprenza formulation and conduct additional studies to develop a superior formulation to the one currently employed by Suprenza. In our agreement with Prenzamax, we have outlined a pathway to achieve this. Specifically, we will provide an opportunity to Prenzamax to participate in the costs and share in the profits of the new formulation. Following is a brief description of the process we expect to undertake.

If Citius, alone or with or through any of its affiliates or a third party, desires to develop, market or sell any improved form of product containing phentermine we will present the proposal to Prenzamax. Prenzamax will then have a period of thirty (30) days from receipt of the proposal to notify us as to whether it is interested in participating in the performance and funding of the development work in exchange for access to commercialization rights. This is what is commonly known as a right of first refusal ("ROFR"). If Prenzamax is not interested in participating, or if it fails to timely notify Citius of its interest, then we will be permitted to proceed with such development and commercialization with commercial launch to be no earlier than four (4) years after the date that the proposal is submitted and Prenzamax shall have no right to participate in the development or commercialization of any new product and Prenzamax will have no right of access to or use of any data or materials generated in connection with such development work except for the right to submit such data to the Regulatory Authorities.

If Prenzamax timely notifies us of its interest in participating in the development work then we will negotiate our respective roles in such development work, including our respective commitment to provide funding for the performance of the work and our respective rights to commercialize any product. Unless otherwise agreed to by the Parties in writing we will each bear fifty percent (50%) of the development costs for the product and the product will be licensed on an exclusive basis to Prenzamax on the same terms and conditions (including sharing of EBITA on a 50-50 basis) as are set forth in this Licensing Agreement.

In the event that Prenzamax is not interested in the participation or we are unable to reach agreement on the terms of such participation, then we alone will be permitted to launch a follow-on product on or after the fourth (4^{th}) anniversary of the date of the proposal and Prenzamax shall have the right, to be exercised by written notice to Citius within three (3) months prior to such fourth (4^{th}) anniversary date, to terminate this Agreement, and to receive from Citius a payment equal to two (2) times the Product EBITDA for the most recent period of twelve (12) full calendar months ending prior to such fourth anniversary date.

We have been unable to obtain sufficient funding to conduct additional development activities on Suprenza. Because of our limited resources we have decided to focus on the development of the hemorrhoid product first. If we are unable to obtain additional funding in the near future we may not initiate any additional development activity on Suprenza.

Prevalence of Obesity

Obesity is a serious chronic disease condition that afflicts millions of people worldwide and often requires long-term or invasive treatment to promote and sustain weight loss. In the U.S., nationally representative survey data show that the prevalence of obesity has steadily increased over the past 30 years. In 1980, approximately 15% of the adult population in the U.S. was obese, defined as having a Body Mass Index, or BMI, greater than 30, based on data from the National Health and Nutrition Examination Survey, or NHANES. In the most recent NHANES, conducted for the period 2009 to 2010, over 78 million U.S. adult men and women, or over 35% of all U.S. adults, were classified as obese. In a separate study, the obesity prevalence trends from the NHANES data collected between the 1970s and 2004 were analyzed, and according to a report published in July 2008, it was estimated that by 2030, over 50% of the U.S. adult population will be obese.

The growing prevalence of obesity has increasingly been recognized as a significant public health problem. Comorbidities, which are life threatening conditions, associated with obesity which include heart disease, diabetes, cancer, breathing problems, arthritis and reproductive complications. According to the U.S. Department of Health and Human Services, or HHS, obese individuals have a 50% to 100% increased risk of premature death from all causes, as compared to individuals with healthy weights, and an estimated 300,000 deaths per year in the U.S. may be associated with obesity-related comorbidities. We believe there is a growing recognition within the medical community that obesity significantly exacerbates many other comorbidities and that obesity and its comorbidities cause significant added cost to the health care system. We further believe that more effective treatment of obesity may become an important cornerstone in managing its comorbidities.

Treatments for Obesity

Treatments for obesity consist of behavioral modification, pharmaceutical therapies and surgical interventions. Behavior modifications to diet and exercise are the preferred initial treatment in obesity according to the National Institutes of Health, or NIH; however, obese patients frequently drop out of behavioral modification programs, which typically results in weight regain. If pharmaceutical therapies are recommended, such recommendations are generally made after behavioral modification alone has failed. Bariatric surgery, including gastric bypass and gastric banding procedures, is employed in more extreme cases, typically for obese individuals with a BMI over 40. Surgery can be associated with significant side effects, potential complications including mortality, and substantial costs and recovery time.

Several pharmaceutical products have been approved for treating obesity in the U.S. Approved obesity drugs are generally prescribed for short-term use, with only a select few having been approved for longer-term maintenance therapy. Several older drugs, indicated for short-term administration, include phentermine, phendimetrazine, benzphetamine and diethylpropion. Of all the drugs used to treat obesity, phentermine is the most widely used. It was approved by the FDA in 1959 based on published clinical studies, not the rigorous double blinded clinical trials that are customary in modern day approvals. Despite a lack of clinical data, limited safety information included in the label, and a short-term therapy limitation, the use of phentermine has increased significantly in the past several years. This suggests that physicians are relying on the extensive safety and efficacy experience they have when prescribing the drug.

Our first product, Suprenza, is based on the generic molecule phentermine hydrochloride, a commonly used therapeutic drug for weight loss programs. Phentermine was first introduced in the United States to counter the widespread use of amphetamines which were commonly prescribed for weight loss, especially post pregnancy. Phentermine was found to be far less addictive than amphetamines, safe and equally efficacious and therefore was readily accepted as a standard treatment for obesity. It is currently approved in tablet (37.5 mg) and capsule (15 and 30 mg) dosage forms as a short-term adjunct (6-8 weeks) in a weight loss regimen. Phentermine is prescribed as an adjunct in weight reduction based on exercise, behavioral modification and caloric restriction in the management of exogenous obesity. In several cases, its good safety record and demonstrated effectiveness has led to longer use (10-12 weeks) in physician-directed weight loss programs. Although not approved for the general pediatric population, phentermine is also being used in adolescents. We conducted limited clinical testing of our formulation of Suprenza comparing it to the presently marketed generic formulations and we have demonstrated that Suprenza can be taken with or without water and with or without food. We believe these attributes, which are not offered by the generic formulations are important distinguishing factors making Suprenza an attractive choice.

Currently approved anti-obesity drugs include Xenical (orlistat), marketed by Roche, the over-the-counter version, Alli, marketed by GlaxoSmithKline, phentermine, in several dosage forms and strengths which are available from several generic manufacturers, Qsymia (a combination of topiramate and phentermine HCL) marketed by VIVUS, Inc. and BELVIQ (lorcaserin HCL) marketed by Eisai Inc. Xenical works by inhibiting lipase, thus preventing digestion and absorption of dietary fat in the gastrointestinal tract. MeridiaÒ (sibutramine) was previously marketed by Abbott Laboratories; however, in October 2010, Abbott Laboratories withdrew Meridia in the U.S. at the FDA's request. The FDA requested the withdrawal because they believed Meridia's risks were not justified compared with the modest weight loss that patients achieved on the drug. There are several drugs in development for obesity including an investigational drug candidate, Victoza, in Phase 3 clinical trials being developed by Novo Nordisk A/S and several other investigational drug candidates in Phase 2 clinical trials. Amylin Pharmaceuticals, Inc. announced that they have discontinued clinical activities in an ongoing Phase 2 study examining the safety and effectiveness of the investigational combination therapy pramlintide/metreleptin for the treatment of obesity.

Orexigen Therapeutics, Inc. submitted an NDA to the FDA for their investigational obesity drug candidate, Contrave (naltrexone sustained release/bupropion sustained release), which was approved by the FDA in early September 2014. In June 2012, the FDA approved Arena Pharmaceuticals Inc.'s drug, BELVIQ, for chronic weight management in adults who are obese or are overweight with at least one weight related comorbidity condition. BELVIQ may, in the future, be marketed outside of the United States. In July 2012, VIVUS, Inc.'s weight loss drug Qsymia was approved by the FDA, as an adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in adult patients with an initial BMI of 30 or greater (obese), or 27 or greater (overweight) in the presence of at least one weight-related comorbidity, such as hypertension, type 2 diabetes mellitus or high cholesterol. Qsymia incorporates low doses of active ingredients from two previously approved drugs, phentermine and topiramate. Due to certain adverse events observed during the clinical trials, the FDA has imposed marketing restrictions on Qsymia.

Many of these drugs are, or if approved, will be marketed by pharmaceutical companies with substantially greater resources than us.

There are also surgical approaches to treat severe obesity that are becoming increasingly accepted and could become competing alternatives. Two of the most well established surgical procedures are gastric bypass surgery and adjustable gastric banding, or lap bands. In February 2011, the FDA approved the use of a lap band in patients with a BMI of 30 (reduced from 35) with co-morbidities. The lowering of the BMI requirement is likely to make more obese patients eligible for lap band surgery. A lap band is indicated for use in adult patients who have failed more conservative weight reduction alternatives, such as supervised diet, exercise and behavior modification programs. Patients who elect to have this surgery must make the commitment to accept significant changes in their eating habits for the rest of their lives. The potential impact on Suprenza and/or other weight loss pharmacotherapy is unknown. In addition, other potential approaches that utilize various implantable devices or surgical tools are in development. Some of these approaches are in late stage development and may be approved for marketing. If approved, the companies that market these drugs may have substantially greater resources than we have.

Background on Phentermine

Phentermine is approved by the FDA as an appetite suppressant to help reduce weight in obese patients when used short-term (a few weeks) and combined with exercise, diet, and behavioral modification. Based on its extensive clinical usage and relatively low cost, phentermine is considered by many clinicians in the field as the first line drug therapy for obesity. It is typically prescribed for individuals who are at increased medical risk because of their weight, and it works by helping to release certain chemicals in the brain that control appetite. It was approved by the FDA based on the published medical literature available prior to 1962, not on the basis of rigorous clinical safety and efficacy trials that are now generally required. Nevertheless, the safety and efficacy of phentermine has been confirmed in at least nine clinical trials with 2026 adult patients. In addition, its safety and efficacy in children has also been established, reported initially with a 91-patient trial in 1965 and confirmed in an 84-patient trial by another investigator in 1966. In 2004, FDA's Agency for Healthcare Research and Quality, or AHRQ, published an Evidence Report titled "Pharmacological and Surgical Treatment of Obesity." The AHRQ Study consisted of a pooled analysis of the above mentioned clinical trials and it determined that subjects treated with phentermine lost an average of 3.6 additional kilograms of weight compared to placebo (95% CI, 0.6 to 6.0). In assessing the effect on maintenance of weight loss, the authors reported that patients treated with phentermine maintained a "fairly large" weight loss compared to placebo (2.43 kg) after discontinuation of the drug. The authors also concluded that phentermine use, in addition to lifestyle interventions, resulted in a statistically significant, but modest, increase in weight loss. In this review, no side-effect or adverse-event data were reported. For all these reasons, we identified phentermine as the preferred anorectic drug to develop for our new orally disintegrating tablets and for additional formulations to follow.

Phentermine – Market Opportunity

Phentermine is predominantly prescribed by bariatric physicians, meaning physicians whose practice is centered on the causes, prevention, and treatment of obesity. The American Society of Bariatric Physicians, or ASBP, includes approximately 1,600 health care professionals as members, the majority of whom are family medicine, internal medicine or obstetrics and gynecology practitioners. According to IMS, a pharmaceutical industry pricing data collection company, for the twelve month period commencing September 1, 2013 and ending on August 31, 2014 there were 221.8 million tablets and capsules of phentermine of all strengths dispensed in the U.S. This compares to the 235.1 million total dosages dispensed during the twelve months ended August 31, 2015. Phentermine remains a popular choice of physicians, and we believe that a branded phentermine product with important competitive features is a product ideally suited for commercialization by a small specialty sales force.

Suprenza Brand Phentermine – Orally Disintegrating Tablets for Obesity

Suprenza, our first FDA-approved product, is an orally disintegrating tablet, or ODT, formulation of phentermine with several unique, patient-friendly features. Through clinical trials, we have demonstrated that Suprenza can be taken with or without water, with or without food and can be orally disintegrated or swallowed and still produce the same level of drug in the blood and therefore produce efficacy. These features make our Suprenza formulation patient friendly. We believe Suprenza has significant market potential due to these special features and due to the fact that phentermine is the most frequently prescribed drug for the treatment of obesity. We received FDA approval for two dosage strengths of Suprenza (15 and 30 mg) on June 13, 2011, and a third strength (37.5 mg) on March 27, 2012. In addition, U.S. Patent #6,149,938 for Suprenza's ODT formulation is listed in the FDA Orange Book, and one additional U.S. patent for our formulation is pending. There is no generic equivalent for Suprenza and, as a result, drug substitution is limited. We granted a license for the U.S. commercial sales of Suprenza to Prenzamax LLC in November 2011 and Prenzamax launched the 15 and 30 mg tablets nationally in April 2012 and launched the 37.5mg tablets in early 2013. Suprenza ODT was formulated and is manufactured for us by Alpex Pharma SA of Mezzovico, Switzerland.

Suprenza ODT Post-Marketing Studies

In connection with our NDA, we committed to conduct the following two post-marketing studies of Suprenza ODT:

Renal Pharmacokinetics Study

The FDA required that we study the pharmacokinetic, or PK, parameters of Suprenza ODT in subjects with renal impairement. Drug exposure increases can be expected in patients with renal impairment who are treated with phentermine. However, Suprenza ODT's pharmacokinetics has not been assessed in renal impaired patients. Since obesity can lead to renal failure, there exists a possibility that patients with mild or moderate renal failure may be prescribed Suprenza ODT. Therefore, it is important to assess the changes in the PK parameters of Suprenza ODT in patients with renal impairment. The primary endpoint of this study is the pharmacokinetic assessment of Suprenza ODT in renal impaired patients and results of this study will provide important new information to prescribing physicians regarding phentermine dosing and dose adjustments for these at-risk patients. We believe that this is the first such study of phentermine in renal compromised patients and may provide us with label claims and marketing advantages over competing phentermine products.

A clinical research organization has indicated that it will cost approximately $400,000 and 18 months to conduct the renal impairment study. Due to the limited current sales of Suprenza, we requested the FDA waive the renal PK study requirement. In the FDA's letter dated August 28, 2015, the FDA notified us that our request to waive the study was denied because financial hardship was an inadequate reason to justify a waiver of the study. In addition, the FDA restated the FDA's concern that there is a signal of serious risk of increased drug exposure in patients with decreased renal function. If we fail to conduct the post-marketing renal PK study, the FDA may ask us to discontinue selling the product or impose other penalties which they deem suitable.

In general the FDA allows companies to continue selling their product while post-marketing studies are being conducted. Based upon limited sales and usage of our product, we intend to reapply for a waiver of the post-marketing study. However, there can be no assurance that the FDA will release us from such requirement. If our next request to waive the post-marketing studying is denied and we do not have sufficient funding to conduct the study, we will likely discontinue the sale of Suprenza. If we receive sufficient funding and determine to proceed with the renal impairment study, and the results of such study demonstrate safety concerns, we may have to add additional disclosures to our label or alternatively, discontinue the sale of the product.

Drug Utilization Study

Phentermine is classified by the Drug Enforcement Administration, or DEA, as a Category IV controlled substance, the lowest category for addiction and abuse, as a result of its properties as a mild stimulant. Based on this classification, the FDA expressed concern regarding phentermine abuse and addiction. As part of our New Drug Approval, we committed to conducting a study of the annual use of Suprenza ODT for three years after product launch. However, upon further internal analysis, the FDA concluded that such a study is not necessary and informed us that we need not conduct this study.

Treatments for Hemorrhoids

Our next product is intended for the treatment of grade I and grade II hemorrhoids. We believe that there are no FDA-approved drug products for the treatment of grade I and grade II hemorrhoids. There are several OTC medications used to treat hemorrhoids including Preparation H cream, hydrocortisone creams in various strengths up to 1%, and Anusol suppositories and medicated wipes and pads. In addition, several companies manufacture and market higher, prescription strengths of hydrocortisone creams, gels, ointments and suppositories, lidocaine creams and gels, and combination creams containing hydrocortisone and lidocaine. AlavenÒ Pharmaceuticals LLC, now part of Meda Pharmaceuticals, Inc. manufactures and sells a combination product containing hydrocortisone and pramoxine which patients and physicians are utilizing for the treatment of hemorrhoids. This product has also not been approved by the FDA for the indication and claims contained in the product label.

To our knowledge, there are currently no FDA-approved drug products for the treatment of hemorrhoids. Some physicians are known to prescribe topical steroids, such as Anusol-HC, for the treatment of hemorrhoids. In addition, there are various strengths of topical combination prescription products containing hydrocortisone along with lidocaine or pramoxine, each a topical anesthetic, that are prescribed by physicians for the treatment of hemorrhoids. However, none of these single-agent or combination prescription products have been clinically evaluated for safety and efficacy and approved by the FDA for the treatment of hemorrhoids. Further, many hemorrhoid patients use OTC products as their first line therapy. OTC products, such as Preparation H, contain any one of several active ingredients including glycerin, phenylephrine, pramoxine, white petrolatum, shark liver oil and/or witch hazel, for symptomatic relief. No data are available regarding the clinical efficacy of these OTC symptomatic treatments for hemorrhoids.

There has been very limited research conducted on treatment of hemorrhoids and therefore there is very limited historical clinical trial protocols or outcomes information available to us to design our programs. The clinical end points in our studies will be subjective responses from patients as they perceive improvements or lack thereof in their symptoms. Such outcome trials have high variability and are also subject to site-to-site variability, making them more risky.

Development of Hemorrhoids Drugs

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

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

Grade I Hemorrhoids not prolapsed but bleeding.

Grade II Hemorrhoids prolapse and reduce spontaneously with or without bleeding.

Grade III Prolapsed hemorrhoids that require reduction manually.

Grade IV Prolapsed and cannot be reduced including both internal and external hemorrhoids that are confluent from skin tag to inner anal canal.

Topical Combination Prescription Hemorrhoid Products – Recent U.S. Prescription Data and Market Opportunity

The current market for topical DESI formulations of hydrocortisone and lidocaine is highly fragmented. Several topical combination prescription products for the treatment of hemorrhoids are available containing hydrocortisone in strengths ranging from 0.5% to 3.0%, combined with lidocaine in strengths ranging from 1.0% to 3.0%. The various topical formulations include creams, ointments, gels, lotions, enemas, pads, and suppositories. The most commonly prescribed topical combination gel, AnaMantleÒ, is sold as a branded generic product and contains 2.5% hydrocortisone and 3.0% lidocaine. According to IMS, over 25 million units of topical combination prescription products for hemorrhoids were sold in the U.S. during the twelve-month period ended June 2012 comprising an estimated $80 million annual market in the United States.

We believe that the development of an FDA-approved, topical combination prescription product for the treatment of grade I and II hemorrhoids represents an attractive, low-risk product opportunity with meaningful upside potential.

Hydrocortisone-Lidocaine Topical Combination Prescription Cream for Hemorrhoids

As discussed above, we believe there are no FDA-approved prescription therapies for grade I and II hemorrhoids. Although there are numerous prescription and OTC products commonly used to treat hemorrhoids, none possess proven safety and efficacy data generated from rigorously conducted clinical trials. We believe that a novel topical formulation of hydrocortisone and lidocaine designed to provide anti-inflammatory and anesthetic relief and which has an FDA-approved label specifically claiming the treatment of grade I and II hemorrhoids will become an important treatment option for physicians who want to provide their patients with a therapy that has demonstrated safety and efficacy in treating this uncomfortable and often recurring disease.

Development Activities to Date

- Drug Manufacturing – We have completed manufacturing of 7 different strengths of single active and combination drug products in sufficient quantities for us to complete Phase 2 clinical studies. The investigational drug was manufactured under current Good Manufacturing Practice by IG Laboratories, Inc. and has been undergoing long-term stability studies. The drug product meets all our specifications and is stable.

- Investigational New Drug application, or IND, Submission to FDA – In September 2012, we submitted our IND to the FDA to initiate Phase 2 dose ranging study. We have proposed conducting this study in approximately 140 subjects. We have not received any negative communication on this filing and we are prepared to initiate the study.

- Initiation of Phase 2 studies – We recently completed dosing of patients for Phase 2 study of our formulation.

Market Exclusivity

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

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

Manufacturing

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

Alpex Supply Agreement

In June of 2008, we entered into a development and supply agreement with Alpex Pharma SA ("Alpex"), of Mezzovico, Switzerland. Under the agreement, Alpex developed the formulations of Suprenza and is manufacturing and supplying the product to our marketing partner, Prenzamax LLC. In November 2011, the agreement was amended such that we now have the right to have Alpex transfer the technology to a third party for manufacture and supply of the product. Also, if Alpex fails to supply the product, we may use an alternate manufacturer for our supply of such products until Alpex is able to resume production.

The Alpex facility has been inspected by several regulatory agencies including the FDA for compliance with cGMP. Currently, Alpex is the primary manufacturer for Suprenza and has supplied sufficient quantities to meet the demand for our products to date.

IGI Laboratories Supply Agreement

IGI Laboratories, Inc. of Buena, New Jersey ("IGI"), a developer and manufacturer of prescription topical drugs for the development of hydrocortisone and lidocaine cream formulations, has expertise in developing topical products in a wide range of dosage forms, including topical solutions, creams, ointments and gels.

We received a quote from IGI to formulate various prototypes of our product for us to conduct Phase 2 studies. We accepted the terms and conditions defined in the quotation and IGI manufactured and developed prototypes of our product for Phase 2 studies. We have not entered into any other agreements with IGI. For our future needs, we may continue our relationship with IGI or we may seek a different manufacturer.

Sources and Availability of Raw Materials and Clinical Supplies

In general, our suppliers purchase raw materials and supplies on the open market. Substantially all such materials are obtainable from a number of sources so that the loss of any one source of supply would not have a material adverse effect on us. We have entered into a supply agreement with Alpex pursuant to which Alpex supplies us with the active pharmaceutical ingredient, or API, for phentermine hydrochloride. Alpex currently has one source of supply for API, Siegfried (USA), Inc., a U.S. based manufacturer ("Siegfried"). There are several other sources of phentermine

hydrochloride API, and if Alpex is unable to obtain the API from Siegfried, it will have to qualify another source. Qualification of alternate source is costly and a time consuming process. Alpex generally maintains enough API on hand to meet our projected forecast for several months and we do not expect supply disruptions.

Compliance with Environmental Regulations

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

Sales and Marketing

We are primarily focused on identifying medical needs and proposing product solutions that we believe offer superior benefits and additional safety and clinical information. Once we identify such needs and product concepts through market research, we sub-contract the drug formulation development work to companies specializing in drug development. We manage the regulatory process through product approval. As of now, we do not market our products ourselves. We have identified several specialty pharmaceutical companies with large sales forces, experienced sales and marketing management teams, significantly larger resources than ours, and non-competing product portfolios that we believe would make excellent sales and marketing partners for us and our existing and expected products. We intend to license our products to such companies for sales and marketing.

In November 2011, we entered into an exclusive license agreement with Prenzamax LLC ("Prenzamax"), pursuant to which we granted to Prenzamax a license for sales of Suprenza in the U.S. Prenzamax's performance of this agreement is guaranteed by Akrimax LLC ("Akrimax"), a specialty pharmaceuticals sales and marketing company. Akrimax has several branded and branded-generic products that are being sold to cardiologists, endocrinologists and general practitioners. Suprenza is sold by the Akrimax sales force which consists of approximately 40 sales and marketing professionals. The exclusive license agreement provides that all of the sales and marketing expenses will be incurred and borne by Prenzamax. Both we and Prenzamax will equally share the expenses related to FDA establishment fees, product fees and post-marketing studies and the resulting earnings will be shared equally by us and Prenzamax. The co-founder and Vice Chairman of Akrimax is Leonard Mazur, our Chief Executive Officer, President and Chief Operating Officer. See "Related Party Transactions".

Our agreement with Prenzamax also provides that we will offer them the opportunity to share costs of new product development. If Prenzamax offers to share in our development costs, we will negotiate the terms on which such investment from Prenzamax will be accepted by us. We have not made any decision regarding the terms we would offer Prenzamax in our future development program for Suprenza. There is no assurance that Prenzamax will participate in the cost of our development program. Also, we do not have any limitations or conditions on our second product candidate, hydrocortisone/lidocaine and we are not required to offer this product to either Prenzamax or any other third party for sales and marketing. We have not decided whether we will market our future products or elect to license their sales and marketing. We have very limited resources and management capabilities in managing pharmaceutical sales, and we cannot offer any assurance that our decision will necessarily result in the best possible financial return for our products.

Patents and Proprietary Rights

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

Our success depends in large part on our ability to protect our proprietary technologies, compounds and information, and to operate without infringing the proprietary rights of third parties. We rely on a combination of patent, trade secret, copyright, and trademark laws, as well as confidentiality, licensing and other agreements, to establish and protect our proprietary rights. There is no assurance that any of our patent applications will be granted, or that any of the patents will be enforceable or will cover a drug or other commercially significant product or method.

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 patent protection, we rely on trade secrets, proprietary know-how, and continuing technological advances to develop and maintain our competitive position. To maintain the confidentiality of our trade secrets and proprietary information, all of our employees are required to enter into and adhere to an employee confidentiality and invention assignment agreement, laboratory notebook policy, and invention disclosure procedures as a condition of employment. Additionally, our employee confidentiality and invention assignment agreements require that our employees not bring to us, or use without proper authorization, any third-party proprietary technology. We also require our consultants and collaborators that have access to proprietary property and information to execute confidentiality and invention rights agreements in our favor before beginning their relationship with us. While such arrangements are intended to enable us to better control the use and disclosure of our proprietary information and provide for our ownership of proprietary technology developed on our behalf, they may not provide us with meaningful protection for such property and technology in the event of unauthorized use or disclosure.

Suprenza Intellectual Property

Suprenza is based on the know-how, technology and intellectual property, including patents, owned by Alpex Pharma S.A. All of the intellectual property used for Suprenza is owned by Alpex and licensed to us pursuant to a licensing agreement. We do not generate any data or encounter discoveries that could be patented and have not filed and do not expect to file any patents with respect to Suprenza which will be owned by the Company. We are dependent on the ability and competence of Alpex and other third parties for the continued development of Suprenza. Suprenza is covered by the following issued and pending patents. We have listed the issued patent, U.S. #6,149,938, titled "Process for the preparation of a granulate suitable to the preparation of rapidly disintegrable mouth-soluble tablets and compositions obtained thereby" in the FDA's publication called "Approved Drug Products with Therapeutic Equivalence Evaluations" otherwise known as the "Orange Book". We also have a pending patent titled "Solid Dosage formulations containing weight-loss drugs" which, if granted, will be listed in the Orange Book. There is no assurance that additional patents will be granted, or if granted, that they will be enforceable.

Competition

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

Government Regulation

Our activities are subject to the laws and regulations of multiple governmental authorities in the United States as well as in other countries in which our products may be tested or marketed. In the United States, prescription drug products are subject to extensive pre- and post-market regulation by the FDA, including regulations that govern the testing, manufacturing, safety, efficacy, labeling, storage, record keeping, advertising and promotion under the Federal Food, Drug, and Cosmetic Act, or FFDCA, and by comparable agencies and laws in foreign countries. We are also subject to other federal, state and local environmental and safety laws and regulations, including regulation of the use and care of laboratory animals. Failure to comply with applicable FDA or other requirements may result in civil or criminal penalties, recall or seizure of products, partial or total suspension of production or withdrawal of the product from the market.

Product Approval Process

The process required by the FDA before our drug candidates may be marketed in the United States generally involves the following:

Preclinical Testing

Preclinical tests include laboratory studies to evaluate toxicity in animals. The results of preclinical tests, together with manufacturing information and analytical data, are submitted as part of an Investigational New Drug application, or IND, to the FDA. Clinical testing also must satisfy extensive Good Clinical Practice, or GCP, regulations.

Clinical Trials

Clinical trials are typically conducted in the following sequential phases, which may overlap:

- Phase 1 Clinical Trials. Studies are initially conducted in a limited number of healthy volunteers to test for safety, dose tolerance, absorption, metabolism, distribution and excretion.

- Phase 2 Clinical Trials. Studies are conducted in a limited patient population to identify possible adverse effects and safety risks, to determine the efficacy of the product for specific targeted indications and to determine dose tolerance and optimal dosage. We may have to conduct multiple Phase 2 clinical trials prior to beginning larger and more expensive Phase 3 clinical trials.

- Phase 3 Clinical Trials. These are commonly referred to as pivotal studies. When Phase 2 evaluations demonstrate that a dose range of the product is effective and has an acceptable safety profile, Phase 3 clinical trials are undertaken in large patient populations to further evaluate dosage, to provide statistically significant evidence of clinical efficacy and to confirm safety in an expanded and diverse patient population at multiple, geographically dispersed clinical trial sites.

- Phase 4 Clinical Trials. In some cases, the FDA may condition approval of an NDA for a drug candidate on the sponsor's agreement to conduct additional clinical trials to continue to monitor the drug's safety after NDA approval. In addition, a sponsor may decide to conduct additional clinical trials after the FDA has approved an NDA to test efficacy in additional conditions and seek approval for new indications. Post-approval trials are typically referred to as Phase 4 clinical trials.

In addition some of our product candidates are combination prescription drugs. To test these products we will need to comply with the FDA's regulation that we show contribution of each active drug in the formulation and that the combination provides superior efficacy compared to individual drugs taken alone. This means that our clinical trials for our product candidates will need to evaluate the combination as compared to each component separately and to placebo.

New Drug Application

The results of product development, preclinical studies, manufacturing process and clinical trials are submitted to the FDA as part of an NDA. The cost of preparing and submitting an NDA is substantial. The Prescription Drug User Fee Act, requires the payment of user fees with the submission of NDAs, including 505(b)(2) NDAs. These application fees are substantial ($1,841,500 in the FDA's Fiscal Year 2012) and will likely increase in future years. Manufacturers and sponsors of approved drugs are subject to annual product and establishment fees of $520,100 per manufacturing establishment and $98,970 per product.

Upon completion of its review of the NDA, FDA issues an approval letter. If the FDA is not satisfied with the information provided in the application it issues a Complete Response Letter, or CRL. A complete response letter outlines the deficiencies in the submission and may require additional testing or information in order for the FDA to reconsider the application. If and when those deficiencies have been addressed to the FDA's satisfaction in a resubmission of the NDA, the FDA will issue an approval letter. The FDA has committed to reviewing such resubmissions in 2 or 6 months depending on the type of information included.

An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications. As a condition of NDA approval, the FDA may require post-approval testing and surveillance to monitor the drug's safety or efficacy and may impose other conditions, including labeling restrictions which can materially affect the potential market and profitability of the drug. Once granted, product approvals may be withdrawn if compliance with regulatory standards is not maintained or problems are identified following initial marketing.

Section 505(b)(2) New Drug Applications

As an alternate path to FDA approval for modifications to products previously approved by the FDA, an applicant may file an NDA under Section 505(b)(2) of the FFDCA. Section 505(b)(2) was enacted as part of the Hatch-Waxman Act. This statutory provision permits the filing of an NDA where at least some of the information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference. The Hatch-Waxman Act permits the applicant to rely upon the FDA's findings of safety and effectiveness for previously approved products. The FDA may then approve the new product candidate for all or some of the label indications for which the referenced product has been approved, as well as for any new indication for which the Section 505(b)(2) applicant has its own data.

Applications filed pursuant to Section 505(b)(2) are assessed by the FDA on a case by case basis. The application process commences upon a company submitting a Pre IND letter to the FDA outlining its program, objectives and the course of action to be taken. The FDA responds by scheduling a meeting and requesting an expanded briefing package which further summarizes our proposal. After receiving the package, the FDA schedules a meeting to discuss steps necessary to file the New Drug Application. This process takes up to six months and costs between $100,000 and $500,000. Although each product is unique and is assessed on a case by case basis, the following steps are typically required to achieve FDA approval:

1. Phase 1 – Full pre-clincial or toxicology studies are generally not required if the drug is already approved. However, depending on the proposed modification, the FDA may require 3 month to 12 month studies which can cost between $500,000 and $2 million.

2. Phase 2 – These studies are usually necessary in small patient populations to test the hypothesis and obtain sufficient information to design Phase 3 studies. These studies can cost between $2 million to $6 million and require approximately 12 months to complete.

3. Phase 3 – Efficacy or Phase 3 studies are costly and time consuming. Even though a drug has been previously approved and determined to be efficacious, there is always a possibility that the proposed drug modification may not demonstrate efficacy. Phrase 3 studies can cost between $10 million to $30 million and require approximately 18 months to complete.

The FDA requires companies to perform additional studies or measurements to support the change from the approved product. We submitted our initial NDA for Suprenza under Section 505(b)(2), based on bioequivalence studies which we conducted and safety information that has been collected for the approved drug product that is incorporated in this product candidate. To the extent that a Section 505(b)(2) application relies on the FDA's finding of safety and effectiveness of a previously-approved drug, the applicant is required to certify to the FDA concerning any patents listed for the approved product in the Orange Book. Specifically, the applicant must certify when the application is submitted that: (1) there is no patent information listed; (2) the listed patent has expired; (3) the listed patent has not expired, but will expire on a particular date and approval is sought after patent expiration; or (4) the listed patent is invalid or will not be infringed by the manufacture, use or sale of the product. A certification that the new product will not infringe the already approved product's Orange Book listed patents or that such patents are invalid is called a paragraph IV certification. If the applicant has provided a paragraph IV certification to the FDA, the applicant must also send notice of the paragraph IV certification to the patent holder and the original NDA holder. In the event that the patent holder or NDA holder files a patent infringement lawsuit against the applicant within 45 days of its receipt of our paragraph IV notification, such lawsuit would automatically prevent the FDA from approving the applicant's Section 505(b)(2) NDA until the earliest of 30 months, expiration of the patent, settlement of the lawsuit or a decision in the infringement case that is favorable to the applicant. Any such patent infringement lawsuits could be costly, take a substantial amount of time to resolve and divert management resources.

Product approvals based on new clinical investigation are granted three years of Hatch-Waxman marketing exclusivity. Under this form of exclusivity, the FDA is precluded from approving a competing generic drug application or, in some cases, a competing 505(b)(2) application. However the FDA can accept and commence review of such applications during the three year exclusivity period and grant the approval concurrent with the expiration of the exclusivity period. Further, if another company obtains approval for either product candidate for the same indication we are studying before we do, our approval could be blocked until the other company's Hatch-Waxman marketing exclusivity expires.

Pediatric Information

Under the Pediatric Research Equity Act of 2003, or PREA, NDAs or supplements to NDAs must contain data to assess the safety and effectiveness of the drug for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the drug is safe and effective. The FDA may grant deferrals for submission of data or full or partial waivers. The Best Pharmaceuticals For Children Act, or BPCA, provides sponsors with an additional six (6) month period of market exclusivity on all forms of the drug containing the active ingredient, if the sponsor submits results of pediatric studies specifically requested by the FDA under BPCA. In order to receive the BPCA exclusivity, the drug must have other existing patent or exclusivity protection in effect.

Post-Approval Requirements

Once an NDA is approved, a product will be subject to certain post-approval requirements. We and our contract manufacturers are required to comply with applicable FDA manufacturing requirements contained in the FDA's cGMP regulations. cGMP regulations require, among other things, quality control, and quality assurance.

Risk Evaluation and Mitigation Strategy Programs

The FDA can require a drug-specific Risk Evaluation and Mitigation Strategy, or REMS to ensure the benefits of the drug outweighs the risks. In determining whether a REMS is necessary, the FDA considers the size of the population likely to use the drug, the seriousness of the disease or condition to be treated, the expected benefit of the drug, the duration of treatment, the seriousness of known or potential adverse events and whether the drug is a new molecular entity. If the FDA determines a REMS is necessary, a sponsor must submit a proposed REMS as part of its application, or if the request is made post-approval, not later than 120 days after the FDA notifies the drug sponsor. A REMS may be required to include various elements, such as a medication guide or patient package insert, a communication plan to educate health care providers of the drug's risks, limitations on how a drug may be prescribed or dispensed or other measures that the FDA deems necessary to assure the safe use of the drug. REMS programs must be evaluated on an ongoing basis and the FDA may require changes needed to address ongoing safety issues or corrective actions to address any noncompliance.

Additional Government Regulations

In addition to FDA restrictions on marketing of pharmaceutical products, several other types of state and federal laws have been applied to restrict certain marketing practices in the pharmaceutical industry in recent years. These laws include antikickback statutes and false claims statutes. The federal healthcare program anti-kickback statute prohibits, among other things, knowingly and willfully offering, paying, soliciting or receiving remuneration to induce or in return for purchasing, leasing, ordering or arranging for the purchase, lease or order of any healthcare item or service reimbursable under Medicare, Medicaid or other federally financed healthcare programs. This statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers and formulary managers on the other. Violations of the anti-kickback statute are punishable by imprisonment, criminal fines, civil monetary penalties and exclusion from participation in federal healthcare programs. Although there are a number of statutory exemptions and regulatory safe harbors protecting certain common activities from prosecution or other regulatory sanctions, the exemptions and safe harbors are drawn narrowly, and practices that involve remuneration intended to induce prescribing, purchases or recommendations may be subject to scrutiny if they do not qualify for an exemption or safe harbor.

We operate our business in the United States and do not conduct studies in other countries. In addition, we do not sell our product, directly or indirectly, in other countries. As such, we are not subject to foreign regulations.

Drug Enforcement Administration Regulation

The Drug Enforcement Administration, or DEA, regulates drugs that are controlled substances. Controlled substances are those drugs that appear on one of the five schedules promulgated and administered by the DEA under the Controlled Substances Act, or CSA. The CSA governs, among other things, the inventory, distribution, recordkeeping, handling, security and disposal of controlled substances. If our drug candidates are scheduled by the DEA as controlled substances, we will be subject to periodic and ongoing inspections by the DEA and similar state drug enforcement authorities to assess our ongoing compliance with DEA's regulations. Any failure to comply with these regulations could lead to a variety of sanctions, including the revocation, or a denial of renewal of any DEA registration, injunctions, or civil or criminal penalties.

Other U.S. Regulatory Requirements

In addition to the FDA regulations, 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 and individual U.S. Attorney offices within the Department of Justice, and state and local governments also have jurisdiction over us and our activities. For example, sales, marketing, and scientific/educational grant programs must comply with the anti-fraud and abuse provisions of the Social Security Act, the False Claims Act, the privacy provision of the Health Insurance Portability and Accountability Act, and similar state laws, each as amended. Pricing and rebate programs must comply with the Medicaid rebate requirements of the Omnibus Budget Reconciliation Act of 1990 and the Veterans Health Care Act of 1992, each as amended. If products are made available to authorized users of the Federal Supply Schedule of the General Services Administration, additional laws and requirements apply. All of these activities are also potentially subject to federal and state consumer protection, unfair competition, and other laws. Moreover, we are now, and in the future may become subject to, additional federal, state, and local laws, regulations, and policies relating to safe working conditions, laboratory practices, the experimental use of animals, and/or the use, storage, handling, transportation, and disposal of human tissue, waste, and hazardous substances, including radioactive and toxic materials and infectious disease agents used in conjunction with our research work.

Employees

As of the date of this Annual Report, we have one (1) employee in a senior management position and we employ one (1) part-time consultant for business development purposes. We also have two (2) part-time consultants in accounting and finance. None of our employees are covered by a collective bargaining agreement. We consider our relationship with our employee and consultants to be good. We believe that our future success will depend in part on our continued ability to attract, hire and retain qualified personnel.

Other Information

While the Company was not previously subject to the filing requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934 (the "Exchange Act"), it filed certain reports with the Securities and Exchange Commission ("SEC") on a voluntarily 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. You may read and copy these reports and other information at the SEC's Public Reference Room at 100 F Street N.E., Washington, D.C. 20549. Please call the SEC at 1-800-SEC-0330 or e-mail the SEC at publicinfo@sec.gov for more information on the operation of the public reference room. Our SEC filings are also available at the SEC's website at http://www.sec.gov. Our internet address is http://www.citiuspharma.com.

Item 1A. Risk Factors

Risks related to our Business and our Industry

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

Citius was formed as a limited liability company in 2007 and has only a limited operating history. 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' 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 $2,902,268 for the year ended September 30, 2015, $737,727 for the nine months ended September 30, 2014 and $1,288,003 for the year ended December 31, 2013, respectively. At September 30, 2015, Citius had a stockholders' deficit of $635,213 and an accumulated deficit of $9,040,549. Citius' net cash used for operating activities was $2,385,416 for the year ended September 30, 2015, $183,164 for the nine months ended September 30, 2014 and $1,095,266 for the year ended December 31, 2013, respectively.

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

- developing and testing product candidates;
- receiving regulatory approvals;
- commercializing our products;
- manufacturing of 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 we will ever have another product 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, 2015 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 for the next twelve 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 may need to secure additional financing.

We anticipate that we will incur operating losses for the foreseeable future. We have received gross proceeds of approximately $3.6 million to date from our Private Placements, which we expect to continue. If we fail to raise additional funds, our development programs will be materially curtailed. In such event, we expect that we will only be able to conduct a very limited clinical evaluation of our hydrocortisone/lidocaine program. Since this study will involve only a small number of patients, we may not get meaningful and productive data or we may get misleading results.

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, product candidates or products.

We are an early-stage 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. Because of our limited resources, we have decided to focus on the development of our hemorrhoid product prior to developing the next generation of Suprenza products. If we are unable to obtain additional funding and/or manage our spending, we may not be able to initiate any additional development activity on Suprenza. If we experience unanticipated delays or problems, our development costs could substantially increase and our business, financial condition and results of operations will be adversely affected.

We face significant risks in our product candidate development efforts.

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

We have received FDA approval for our first product, Suprenza. However, 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 obesity and 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.

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 2014 we received a letter from the FDA notifying us that we were in breach of post-marketing regulations with respect to the promotion and advertisement of Suprenza. The FDA demanded that we immediately cease violating the Federal Food, Drug and Cosmetics Act, and we, along with our marketing partner Prenzamax, took actions necessary to remedy the violation.

The FDA notified us that in light of the actions which were taken to remedy the violation, we are no longer in violation of the Federal Food, Drug and Cosmetics Act and the matter has been closed. The FDA's determination was based upon representations we made and supporting documents which we provided to the FDA assuring the FDA that we have taken corrective action. We believe that we have presented all of the information and that our corrective actions are appropriate and adequate. In the event the FDA discovers repeat or new violations, we could face stiffer penalties in the future including the FDA's issuance of a cease and desist order, impounding of our products, and civil or criminal penalties.

We cannot be certain that we, or our marketing partner Prenzamax, will, in the future, be able to comply with post-marketing regulations or other FDA regulatory requirements. If we, Prenzamax or our future partners are not able to comply with such requirements, the FDA may issue a warning letter which may require us to stop our clinical trials and/or the sale of our drug, require us to recall our drug from distribution or result in withdrawing approval of the NDA for such drug. Any of the foregoing actions by the FDA may adversely affect our business, financial condition and results of operation.

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:

- timing of market introduction of competitive drugs;
- 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.

Our agreement with Prenzamax may result in a conflict of interest.

In November 2011, we entered into an exclusive license agreement with Prenzamax LLC, pursuant to which we granted Prenzamax a license for sales of Suprenza in the U.S. Prenzamax's performance of this agreement is guaranteed by Akrimax LLC. The co-founder and vice Chairman of Akrimax is Leonard Mazur who is our President, Chief Executive Officer and Chief Operating Officer. In connection with the license agreement, Prenzamax will be solely responsible for the pricing of Suprenza and will have the option to participate in the future development program of Suprenza. There may be a conflict of interest in what may be beneficial to the Company and to Prenzamax. There can be no assurance that Prenzamax will choose the option that best suits the Company.

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, other than Suprenza which is already approved, 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 product;
- 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 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. 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.

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. We expect the same resistance with regard to our phentermine product where several cheaper generics are already commercially available and physicians have extensive experience in prescribing these 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 depend upon Alpex Pharma, S.A. ("Alpex") to supply us withthe active pharmaceutical ingredient, or API, for phentermine hydrochloride which makes us vulnerable to the extent we rely upon Alpex for API.

In general, our suppliers purchase raw materials and supplies on the open market. Substantially all such materials are obtainable from a number of sources so that the loss of any one source of supply would not have a material adverse effect on us. We have entered into a supply agreement with Alpex pursuant to which Alpex supplies us with the active pharmaceutical ingredient, or API, for phentermine hydrochloride. Alpex currently has one source of supply for API, Siegfried (USA), Inc., a U.S. based manufacturer ("Siegfried"). If Alpex can no longer obtain API from Siegfried or if Siegfried refuses to continue to supply to Alpex on commercially reasonable terms or at all, Alpex will have to qualify another supplier. Qualification of alternate sources is costly and a time consuming process. If Alpex cannot find a replacement supplier, our margins and our profitability may be adversely affected. Although management believes there are several other potential sources of API, there can be no assurance that Alpex can obtain API from such suppliers upon favorable terms, or at all.

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.

As of the date of this annual report, we have one (1) employee and one (1) part-time consultant for business development purposes. We also have two (2) part-time consultants in accounting and finance. In addition, we utilize the services of a clinical management ream on part time basis to assist us in managing our current on-going phase 2 trial. 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 and our ability to obtain or retain listing of the shares of Company Common Stock on any stock exchange or quotation platform other than OTC Markets or the OTCQB where the Company's shares are currently quoted (assuming we elect to seek and are successful in obtaining such listing) 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.

In connection with our NDA, we committed to conducting two post-marketing studies of Suprenza ODT. The FDA required us to conduct a drug utilization study because phentermine is classified by the Drug Enforcement Administration, or DEA, as a Category IV controlled substance, and the FDA expressed concern regarding the potential for phentermine abuse and addiction. We prepared and submitted protocols for this study to the FDA however, upon further internal analysis, the FDA concluded that such a study is not necessary and informed us that we need not conduct this study.

In addition, the FDA required that we study the pharmacokinetic, or PK, parameters of Suprenza ODT in subjects with renal impairment. Drug exposure increases can be expected in patients with renal impairment who are treated with phentermine. However, Suprenza ODT's pharmacokinetics has not been assessed in renal impaired patients. Since obesity can lead to renal failure, there exists a possibility that patients with mild or moderate renal failure may be prescribed Suprenza ODT. Therefore, it is important to assess the changes in the PK parameters of Suprenza ODT in patients with renal impairment. The primary endpoint of this study is the pharmacokinetic assessment of Suprenza ODT in renal impaired patients, and the results of this study will provide important new information to prescribing physicians regarding phentermine dosing and dose adjustments for these at-risk patients.

A clinical research organization has indicated that it will cost approximately $400,000 and take 18 months to conduct the renal impairment study. Due to the limited current sales of Suprenza, we requested the FDA waive the renal PK study requirement. however, our request was denied. In the FDA's letter dated August 28, 2015, the FDA notified us that our request to waive the study was denied because financial hardship was an inadequate reason to justify a waiver of the study. In addition, the FDA restated the FDA's concern that there is a signal of serious risk of increased drug exposure in patients with decreased renal function. If we fail to conduct the post-marketing renal PK study, the FDA may ask us to discontinue selling the product or impose other penalties which they deem suitable.

In general, the FDA allows companies to continue selling their product while post-marketing studies are being conducted. Based upon limited sales and usage of our product, we intend to reapply for a waiver of the post-marketing study. However, there can be no assurance that the FDA will release us from such requirement. If our next request to waive the post-marketing studying is denied and we do not have sufficient funding to conduct the study, we will likely discontinue the sale of Suprenza. If we receive sufficient funding and determine to proceed with the renal impairment study, and the results of such study demonstrate safety concerns, we may have to add additional disclosures to our label or alternatively, discontinue the sale of the product. Adding additional disclosures to our label will delay the timeline for when our product reaches the market. A delay in our product reaching the market or the discontinuance of the sale of Suprenza will result in a material adverse effect to our business, financial condition and results of operation.

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

We have received FDA approval for the sale of our first product, Suprenza. We cannot assure you that we will receive the approvals necessary to commercialize for sale any additional product candidates, or any additional product candidate we acquire or develop in the future. We will need FDA approval to commercialize our additional product candidates in the U.S. In order to obtain FDA approval of any additional 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 additional 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 any additional product candidates. Failure to obtain FDA approval of our additional product candidates will severely undermine our business by leaving us without additional saleable products, and therefore without any potential additional 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 additional 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 additional potential drugs.

If one of our additional 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.

We have an agreement with Alpex Pharma S.A. ("Alpex") to supply our Suprenza tablets. The Alpex manufacturing sites have been inspected by the U.S. FDA and corresponding EU authorities. If Alpex is unable to maintain ongoing FDA or local or foreign regulatory compliance, or manufacture Suprenza tablets in sufficient quantities to meet projected demand, the approval, the commercial launch, and future sales of Suprenza will be adversely effected, which in turn could have a detrimental impact on our financial results.

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 Suprenza tablets could face generic competition before the patent protecting them expires on July 23, 2018.

On May 17, 2013, we received notification from Zydus that Zydus had submitted Abbreviated New Drug Application No. 204663 to the FDA seeking approval to engage in the commercial manufacture, use or sale of generic versions of the 15 mg and 30 mg dosages of our SuprenzaÒ tablets. The notification informed us that Zydus was seeking to manufacture and sell its generic product prior to the expiration of U.S. Patent No. 6,149,938 (the "938 patent") which is listed in the Orange Book and covers SuprenzaÒ, and that the Zydus ANDA contained a certification that its proposed generic product does not infringe the '938 patent ("Paragraph IV Certification"). On June 19, 2013, we received a separate notification from Zydus that it was also pursuing approval for the 37.5 mg dosage of SuprenzaÒ under the same-numbered ANDA, with a separate Paragraph IV Certification. In response, within 45 days of receiving the first notification from Zydus, we and our partners (Alpex Pharma, S.A. and Prenzamax, LLC), filed suit against Zydus and its parent Cadila Healthcare Limited (d/b/a Zydus Cadila) in Federal District Court in Delaware and New Jersey for infringement of the '938 patent pursuant, pursuant to the Hatch-Waxman statutory regime. We promptly notified the FDA of the initiation of this lawsuit and, pursuant to the statute, Zydus's ANDA for a generic version of SuprenzaÒ cannot be approved by the FDA for 30 months from our receipt of Zydus' Paragraph IV notice letters while this lawsuit proceeds.

Several months after initiation of the suit, we initiated discussions with Zydus to seek a resolution to this dispute. We diligently negotiated a settlement agreement and dismissal of the pending lawsuit to the mutual satisfaction of all parties. As a result of this mutual agreement, the district court officially terminated the suit on November 21, 2014. The terms of the settlement agreement remain confidential per mutual agreement of the parties. The resolution of this matter has been deemed a success by Akrimax and its partners Citius, Prenzamax, and Alpex.

On November 24, 2015, a petition for inter partes review (the "Petition") was filed by Mr. J. Kyle Bass and Mr. Erich Spengenberg with the Patent Trial and Appeal Board (the "PTAB") of the U.S. Patent and Trademark Office ("USPTO"), challenging claims of U.S. Patent No. 8,440,170 (the "170 Patent"), titled "Orally Disintegrating Tablets with Speckled Appearance," which patent is owned by Alpex Pharma and is licensed by the Company. The inter partes review procedure allows a party to challenge the patentability of a patent before the PTAB. A patentability trial will commence if the PTAB decides to institute the inter partes review proceedings after considering the Petition and Alpex's preliminary response to the Petition. Pursuant to our agreement with Alpex, it is Alpex' primary responsibility to defend the patents. Alpex is reviewing its options and will inform us of its decision accordingly. If Alpex elects to not defend this patent, then we have the right to do so. The 170 patent relates to the appearance of the Suprenza tablets and we believe that loss of this patent will not have any material impact on Suprenza sales. Since we have already settled with Zydus on the main patent and we fully expect to have competition to our Suprenza, we are unlikely to defend this patent.

Aside from risks in outcome, there are a number of aspects of any intellectual property litigation that may have an impact on the Company, including:

- high litigation costs;
- distractions and other business interruptions due to litigation-related responsibilities such as discovery, depositions, court appearances, trial, etc.;
- media coverage and other marketing-oriented influences relating to the progress of the litigation; and
- general uncertainty pending district court outcome and exhaustion of all appeals.

Our business depends on protecting our intellectual property.

If we and our strategic manufacturing partner, Alpex, do not obtain protection for our respective 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. To date, we exclusively license one patent from Alpex. We also have the exclusive right to one pending patent from Alpex. 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.

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, supplies, 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 Common Stock, Liquidity Risks and Reverse Acquisition

Our securities will be deemed to be "Penny Stock" and subject to specific rules governing their sale.

The SEC has adopted Rule 15g-9 which establishes the definition of a "penny stock," for the purposes relevant to Company, as any equity security that has a market price of less than $5.00 per share, subject to certain exceptions. For any transaction involving a penny stock, unless exempt, the rules require that a broker or dealer approve a person's account for transactions in penny stocks, and the broker or dealer receive from the investor a written agreement to the transaction, setting forth the identity and quantity of the penny stock to be purchased.

In order to approve a person's account for transactions in penny stocks, the broker or dealer must obtain financial information and investment experience objectives of the person, and make a reasonable determination that the transactions in penny stocks are suitable for that person and the person has sufficient knowledge and experience in financial matters to be capable of evaluating the risks of transactions in penny stocks.

The broker or dealer must also deliver, prior to any transaction in a penny stock, a disclosure schedule prescribed by the SEC relating to the penny stock market, which, in highlight form sets forth the basis on which the broker or dealer made the suitability determination, and that the broker or dealer received a signed, written agreement from the investor prior to the transaction.

Generally, brokers may be less willing to execute transactions in securities subject to the "penny stock" rules. This may make it more difficult for shareholders to dispose of the Company's Common Stock if and when such shares are eligible for sale and may cause a decline in the market value of its stock.

Disclosure also has to be made about the risks of investing in penny stocks in both public offerings and in secondary trading and about the commissions payable to both the broker-dealer and the registered representative, current quotations for the securities and the rights and remedies available to an investor in cases of fraud in penny stock transactions. Finally, monthly statements have to be sent disclosing recent price information for the penny stock held in the account and information on the limited market in penny stocks.

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 ("SEC") on a voluntary basis. On October 22, 2015, the Company registered its Common Stock under the Exchange Act and the filing of the reports with the SEC became mandatory. The quotation of the Company's common stock on the OTCQB 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. In addition, the Company will incur substantial expenses in connection with the preparation of its Registration Statement and related documents with respect to the registration of resale of the Common Stock sold in our Private Placements.

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. It is in the process of implementing changes to internal controls, but has not yet completed implementing these changes. 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 the Common Stock may become volatile, which could lead to losses by shareholders and costly securities litigation.

The trading price of the Common Stock 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.

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 90,000,000 shares of Common Stock and 10,000,000 shares of preferred stock. As of December 1, 2015, there are 34,701,220 shares of Common Stock outstanding, 7,020,438 shares underlying the Investor Warrants issued in the Private Placements, 680,013 shares issuable upon the exercise of the Placement Agent Unit Warrants, 680,013 shares issuable upon the exercise of the warrants underlying the Placement Agent Unit Warrants, 1,000,000 shares underlying the Placement Agent Share Warrants issued in connection with investment banking services, 3,300,000 shares underlying the options granted to our President and CEO, Leonard Mazur, 800,000 shares underlying options granted to directors, and 600,000 shares underlying options granted to consultants. 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. There can be no assurance that the Company will not be required to issue additional shares, warrants or other convertible securities in the future in conjunction with any capital raising efforts, including at a price (or exercise prices) below the price at which shares of the Common Stock are currently quoted on the OTCQB, which is one of OTC Markets' three marketplaces for trading over-the-counter stocks.

The Common Stock is controlled by insiders.

As of December 1, 2015, the former managing members of Citius Pharmaceuticals, LLC beneficially own approximately 46% of our outstanding shares of Common Stock and the Company's current officer and directors beneficially own approximately 7% 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.

If and when our Registration Statement No. 333-206903 becomes effective, there will be a significant number of shares of Common Stock eligible for sale, which could depress the market price of such shares.

Following the effective date of our Registration Statement No. 333-206903, 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.

We have broad discretion on how we use the proceeds we received in our Private Placements.

Our management has broad discretion on how to use and spend any proceeds we receive from our Private Placements and may use the proceeds in ways that differ from the proposed uses discussed in this filing. Our stockholders may not agree with our decision on how to use such proceeds. If we fail to spend the proceeds effectively, our business and financial condition could be harmed and we may need to seek additional financing sooner than expected.

Risks Related to Our Common Stock

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

The Company files reports under the Exchange Act and its common stock is eligible for quotation on the OTCQB. However, there is no regular active trading market in the Company's common stock, and we cannot give any assurance that an active trading market will develop. In October 2015, the Company's Common Stock traded on only four days for an aggregate volume of 5,900 shares. 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.

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 elects to seek and are successful in obtaining such listing) could be adversely affected.

As 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, 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.

ITEM 1B. UNRESOLVED STAFF COMMENTS

Not Applicable

ITEM 2. PROPERTIES

We maintain our offices at 63 Great Road, Maynard, MA 01754. We do not intend to expand our operations for the foreseeable future and do not intend to lease additional space. Our arrangement is on month-to-month basis and we are not being charged for the use of the space.

ITEM 3. LEGAL PROCEEDINGS

From time to time, we may become involved in various lawsuits and legal proceedings, which arise, in the ordinary course of business. Litigation is subject to inherent uncertainties and an adverse result in these or other matters may arise from time to time that may harm our business.

On May 17, 2013, we received notification from Zydus Pharmaceuticals (USA) Inc. ("Zydus") that Zydus had submitted Abbreviated New Drug Application No. 204663 to the FDA seeking approval to engage in the commercial manufacture, use or sale of generic versions of the 15 mg and 30 mg dosages of our SuprenzaÒ tablets. The notification informed us that Zydus was seeking to manufacture and sell its generic product prior to the expiration of U.S. Patent No. 6,149,938 (the "'938 patent") which is listed in the Orange Book and covers SuprenzaÒ, and that the Zydus ANDA contained a certification that its proposed generic product does not infringe the '938 patent ("Paragraph IV Certification"). On June 19, 2013, we received a separate notification from Zydus that it was also pursuing approval for the 37.5 mg dosage of SuprenzaÒ under the same-numbered ANDA, with a separate Paragraph IV Certification.

In response, within 45 days of receiving the first notification from Zydus, we and our partners (Alpex Pharma, S.A. and Prenzamax, LLC), filed suit against Zydus and its parent Cadila Healthcare Limited (d/b/a Zydus Cadila) in Federal District Court in Delaware and New Jersey for infringement of the '938 patent pursuant, pursuant to the Hatch-Waxman statutory regime.

Several months after initiation of the suit, the Company initiated discussions with Zydus to seek a resolution to this dispute. We diligently negotiated a settlement agreement and dismissal of the pending lawsuit to the mutual satisfaction of all parties. As a result of this mutual agreement, the district court officially terminated the suit on November 21, 2014. The terms of the settlement agreement remain confidential per mutual agreement of the parties. The resolution of this matter has been deemed a success by Akrimax and its partners Citius, Prenzamax, and Alpex.

On November 24, 2015, a petition for inter partes review (the "Petition") was filed by Mr. J. Kyle Bass and Mr. Erich Spengenberg with the Patent Trial and Appeal Board (the "PTAB") of the U.S. Patent and Trademark Office ("USPTO"), challenging claims of U.S. Patent No. 8,440,170 (the "170 Patent"), titled "Orally Disintegrating Tablets with Speckled Appearance," which patent is owned by Alpex Pharma and is licensed by the Company. The inter partes review procedure allows a party to challenge the patentability of a patent before the PTAB. A patentability trial will commence if the PTAB decides to institute the inter partes review proceedings after considering the Petition and Alpex's preliminary response to the Petition. Pursuant to our agreement with Alpex, it is Alpex' primary responsibility to defend the patents. Alpex is reviewing its options and will inform us of its decision accordingly. If Alpex elects to not defend this patent, then we have the right to do so. The 170 patent relates to the appearance of the Suprenza tablets and we believe that loss of this patent will not have any material impact on Suprenza sales. Since we have already settled with Zydus on the main patent and we fully expect to have competition to our Suprenza, we are unlikely to defend this patent.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

PART II

ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

Market Information

Our common stock was not traded during the nine months ended September 30, 2014 and the year ended December 31, 2013. We were quoted under the ticker symbol TRLO.QB through October 9, 2014. On October 10, 2014, our ticker symbol changed to CTXR.QB.

Our common stock traded on a limited basis during the year ended September 30, 2015. The following table sets forth the range of the high and low bid quotations of our common stock for the last four fiscal quarters, as reported by the OTCQB:

	High	Low
Quarter ended December 31, 2014	$ 10.01	$ 0.0002
Quarter ended March 31, 2015	$ 2.00	$ 0.80
Quarter ended June 30, 2015	$ 1.80	$ 1.00
Quarter ended September 30, 2015	$ 1.75	$ 1.70

On December 1, 2015, the closing bid price of our common stock as reported by the OTCQB was $1.20 per share.

Holders of Common Stock

We are authorized to issue 90,000,000 shares of common stock, $0.001 par value per share. As of December 1, 2015, we have 34,701,220 shares of common stock issued and outstanding and there are approximately 81 shareholders of record of the Company's common stock.

Each share of common stock shall have one (1) vote per share for all purposes. The holders of a majority of the shares entitled to vote, present in person or represented by proxy shall constitute a quorum at all meetings of our shareholders. Our common stock does not provide preemptive, subscription or conversion rights and there are no redemption or sinking fund provisions or rights. Our common stock holders are not entitled to cumulative voting for election of the board of directors.

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

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

Dividends

We have never paid dividends on our Common Stock. We intend to follow a policy of retaining earnings, if any, to finance the growth of our business and do not anticipate paying any cash dividends in the foreseeable future. The declaration and payment of future dividends on the Common Stock will be at sole discretion of the Board of Directors and will depend on the our profitability and financial condition, capital requirements, statutory and contractual restrictions, future prospects and other factors deemed relevant.

Securities Authorized for Issuance under Equity Compensation Plans

On September 12, 2014, we adopted the 2014 Stock Incentive Plan (the "2014 Plan"). Under the 2014 Plan we are authorized to issue up to 13,000,000 shares of our common stock to employees, directors, consultants and advisors in exchange for consideration in the form of services (See Item 11 – "Executive Compensation"). As of September 30, 2015, we have issued 3,900,000 options pursuant to the 2014 Plan.

Recent Sales of Unregistered Securities

Between July 12, 2010 and March 25, 2013, Citius issued convertible promissory notes in the aggregate principal amount of $1,685,000, including $850,000 to Dr. Geoffrey Clark, Citius's former Chief Medical Officer, and $835,000 to Dr. Reinier Beeuwkes, Citius's former Chief Executive Officer. The convertible notes accrued interest at 3% per year, were payable on demand commencing 10 years after issuance, and were convertible into common stock following a reorganization or conversion into a corporation, at a conversion price equal to the greater of the fair market value or $0.25 ($0.60 if the common stock trade is traded on a national securities exchange). The outstanding convertible notes and accrued interest were converted into 3,061,355 Citius Membership Interests on July 31, 2014.

In April 2013, Citius issued a subordinated convertible promissory note in the principal amount of $350,000 to Lifestyle Healthcare LLC. The note accrued interest at 10% per year and was payable on demand any time after April 2014. The note and accrued interest was converted into 606,531 Citius Membership Interests on July 31, 2014.

On November 19, 2013, Citius issued two promissory notes, each in the principal amount of $300,000, to Dr. Geoffrey Clark and Dr. Reinier Beeuwkes, respectively. Each note bears interest at the rate of 5% per year. The principal amount of each note, together with accrued interest with respect to the amount of principal due, was payable in December 2014.

In May 2014, Citius sold 200,000 Membership Interests to Leonard Mazur for a purchase price of $50,000.

On September 12, 2014, in connection with the Reverse Acquisition, each Citius Membership Interest was exchanged for one share of our Common Stock.

On September 12, 2014, we sold 3,400,067 Units for a purchase price of $0.60 per Unit, each Unit consisting 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 $0.60, (the "Private Offering"). As of September 12, 2014, we raised gross proceeds of $2,040,040. The exercise price of the Investor Warrants is subject to adjustment, for up to one year, in the event that we sell common stock at a price lower than the exercise price, subject to certain exceptions. The Investor Warrants are redeemable by us at a price of $0.001 per Investor Warrant at any time subject to the conditions that (i) our Common Stock has traded for twenty (20) consecutive trading days with a closing price of at least $1.50 per share with an average trading volume of 50,000 shares per day and (ii) we provide 20 trading days prior notice of the redemption and the closing price of our Common Stock is not less than $1.17 for more than any 3 days during such notice period and (iii) the underlying shares of Common Stock are registered.

On September 12, 2014, the Company issued its President and CEO options to purchase 3,300,000 shares of common stock at $.45 per share pursuant to the 2014 Plan.

On December 31, 2014, note holders requested conversion of $600,000 in Promissory Notes and accrued interest of $33,333 into 1,055,554 shares of common stock at a conversion price of $0.60 per share.

Between March 19, 2015 and September 30, 2015, we sold an aggregate of 2,837,037 Units at $0.54 per Unit and an aggregate of 200,000 Units at a price of $0.60 per Unit.

Between October 1, 2015 and November 20, 2015, we sold an additional 416,667 Units for a purchase price of $0.54 per Unit and 166,667 Units for a purchase price of $0.60 per Unit.

The transactions described above were exempt from registration under Section 4(a)(2) of the Securities Act.

Issuer Purchases of Equity Securities

We did not make any purchases of our common stock during the three months ended September 30, 2015, which is the fourth quarter of our fiscal year.

ITEM 6. SELECTED FINANCIAL DATA

Not required.

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion and analysis of our financial condition and results of operations should be read together with our financial statements and related notes included elsewhere in this annual report on Form 10-K. Management's discussion and analysis contains forward-looking statements, such as statements of our plans, objectives, expectations and intentions. Any statements that are not statements of historical fact are forward-looking statements. When used, the words "believe," "plan," "intend," "anticipate," "target," "estimate," "expect" and the like, and/or future tense or conditional constructions ("will," "may," "could," "should," etc.), or similar expressions, identify certain of these forward-looking statements. These forward-looking statements are subject to risks and uncertainties including those under "Risk Factors" in Item 1A in this Form 10-K that could cause actual results or events to differ materially from those expressed or implied by the forward-looking statements. Our actual results and the timing of events could differ materially from those anticipated in these forward-looking statements as a result of several factors. The Company does not undertake any obligation to update forward-looking statements to reflect events or circumstances occurring after the filing date of this report.

Historical Background

Citius Pharmaceuticals, Inc. ("Citius" or the "Company") is a pharmaceutical company focused on developing innovative formulations aimed at improving the delivery and compliance of approved drugs. On September 12, 2014, we acquired Citius Pharmaceuticals, LLC as a wholly-owned subsidiary.

Citius Pharmaceuticals, LLC was founded in Massachusetts in January 2007. Activities since Citius Pharmaceuticals, LLC's inception through September 30, 2015, 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.

Through September 30, 2015, 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 first commercial product Suprenza. The Company has not yet realized any revenues from its planned principal operations.

Accounting principles generally accepted in the United States require that a company whose security holders retain the majority voting interest in the combined business be treated as the acquirer for financial statement reporting purposes. The acquisition was accounted for as a "Reverse Acquisition" whereby Citius Pharmaceuticals, LLC was deemed to be the accounting acquirer. The historical financial statements of Citius Pharmaceuticals, LLC are presented as our historical financial statements. The historical fiscal year end of Citius Pharmaceuticals, LLC was December 31. In connection with the Reverse Acquisition, we adopted the fiscal year end of Citius Pharmaceuticals, Inc. thereby changing our fiscal year end from December 31 to September 30. As a result, the fiscal year ended September 30, 2014 consists of only nine months. The following analysis of our results of operations reflects the accounting treatment required as a result of the Reverse Acquisition.

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). A milestone is generally understood in the industry as a completion of a specific defined task towards the completion of a project or performance of a contract. Pursuant to our agreement with Alpex, we are required to pay Alpex for the completion of certain tasks including, but not limited to, the development of the analytical methods, formulations and filings of the NDA, which we have done. 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 have been earned or received by the Company through September 30, 2015.

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 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 through September 30, 2015.

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.

Results of Operations for Year Ended September 30, 2015 compared to Nine Months Ended September 30, 2014

	Year Ended September 30, 2015	Nine Months Ended September 30, 2014
Revenues	$ -	$ -
Operating expenses:		
Research and development	1,797,045	574
General and administrative	946,613	183,044
Stock-based compensation – general and administrative	486,271	470,185
Total operating expenses	3,229,929	653,803
Operating loss	(3,229,929)	(653,803)
Interest income	3,066	555
Gain on revaluation of derivative warrant liability	332,095	8,588
Interest expense	(7,500)	(93,067)
Net loss	$(2,902,268)	$ (737,727)

Revenues

We did not generate any revenues for the year ended September 30, 2015 and the nine months ended September 30, 2014. Beginning in May 2012, our strategic sales and marketing partner, Prenzamax, generated revenues from the sale of Suprenza, our first commercial product. Under the partnering agreement, we were not entitled to any revenues during the year ended September 30, 2015 and the nine months ended September 30, 2014. It is unlikely that we will ever receive any material revenues from Suprenza.

Research and Development Expenses

For the year ended September 30, 2015, research and development expenses were $1,797,045 as compared to $574 during the nine months ended September 30, 2014. The $1,796,471 increase in 2015 was primarily due to costs incurred in the development of our product for the treatment of hemorrhoids in the current year and our limited working capital in the prior period. We are actively seeking additional capital in order to fund our research and development efforts.

General and Administrative Expenses

For the year ended September 30, 2015, general and administrative expenses were $946,613, as compared to $183,044 for the nine months ended September 30, 2014. The increase of $763,569 was attributable to additional compensation costs for our new Chief Executive Officer, plus additional financial and consulting expenses, higher insurance costs and increases in professional fees due to being a public company. Expense increases in the year ended September 30, 2015 were also attributable to our ability to fund our efforts as a result of the working capital raised in our private placements. Expenses were limited in 2014 as we focused our efforts solely on raising new capital to fund operations.

Stock-based Compensation Expense

For the year ended September 30, 2015, stock-based compensation expense was $486,271 compared to $470,185 for the nine months ended September 30, 2014. The $16,086 increase in 2015 was primarily due to options granted to two consultants during the year ended September 30, 2015. A majority of the stock-based compensation expense for the year ended September 30, 2015 and all of the stock-based compensation expense for the nine month period ended September 30, 2014 relates to options granted to our Chief Executive Officer in September 2014 in connection with his employment agreement to purchase 3,300,000 shares of the Company's common stock.

Other Income (Expense)

Interest income earned was $3,066 for the year ended September 30, 2015 compared to $555 for the nine months ended September 30, 2014. The interest income was earned on the proceeds of our private offerings that were invested in money market accounts.

Gain on revaluation of derivative warrant liability for the year ended September 30, 2015 was $332,095 compared to a gain of $8,588 for the nine months ended September 30, 2014 was $8,588. The $332,095 gain for the year ended September 30, 2015 was primarily due to the decrease in our stock price used to calculate the fair value of the derivative liability from $0.60 at September 30, 2014 to $0.54 at September 30, 2015. The $8,588 gain for the nine months ended September 30, 2014 was due to the change in the fair value of the derivative warrant liability that we recognized in connection with the first closing of the Private Offering on September 12, 2014.

For the year ended September 30, 2015, interest expense decreased by $85,567 in comparison to the nine months ended September 30, 2014. On July 31, 2014, $2,035,000 of convertible promissory notes and accrued interest of $196,058 were converted to equity, and on December 31, 2014, $600,000 of promissory notes and accrued interest of $33,333 were converted to equity. Since December 31, 2014 the Company has had no outstanding interest bearing debt.

Net Loss

For the year ended September 30, 2015, we incurred a net loss of $2,902,268 compared to a net loss of $737,727 for the nine months ended September 30, 2014. The $2,164,541 increase in the net loss was primarily due to our $1,796,471 increase in research and development expenses.

Results of Operations for Nine Months Ended September 30, 2014 compared to Year Ended December 31, 2013

	Nine Months Ended September 30, 2014	Year Ended December 31, 2013
Revenues	$ -	$ -
Operating expenses:		
Research and development	574	492,136
General and administrative	183,044	690,396
Stock-based compensation	470,185	-
Total operating expenses	653,803	1,182,532
Operating loss	(653,803)	(1,182,532)
Interest income	555	-
Gain on revaluation of derivative warrant liability	8,588	-
Interest expense	(93,067)	(105,471)
Net loss	$ (737,727)	$(1,288,003)

Revenues

We did not generate any revenues for the nine months ended September 30, 2014 and the year ended December 31, 2013. Beginning in May 2012, our strategic sales and marketing partner, Prenzamax, generated revenues from the sale of Suprenza, our first commercial product. Under the partnering agreement, we were not entitled to any revenues during the nine months ended September 30, 2014 and the year ended December 31, 2013.

Research and Development Expenses

For the nine months ended September 30, 2014, research and development expenses were $574 as compared to $492,136 during the year ended December 31, 2013. The $491,562 decrease in 2014 was primarily due to our limited working capital. During the nine months ended September 30, 2014, we were actively seeking to raise additional capital in order to fund our research and development efforts.

General and Administrative Expenses

For the nine months ended September 30, 2014, general and administrative expenses decreased by $507,352, or approximately 73%, compared to general and administrative expenses for the year ended December 31, 2013. Expense decreases were primarily attributable to our limited working capital as we focused our efforts solely on raising new capital to fund operations.

General and administrative staffing expenses decreased by $338,656 during the nine months ended September 30, 2014 compared to the year ended December 31, 2013 due to the resignation of certain employees. In addition, professional fees decreased by $176,686 primarily due to higher financing costs incurred for legal services, financial consulting and accounting fees during the year ended December 31, 2013.

Stock-based Compensation Expense

For the nine months ended September 30, 2014, stock-based compensation expense was $470,185 as compared to no expense for the year ended December 31, 2013. The $470,185 expense was due to the stock options to purchase 3,300,000 shares of the Company's common stock granted to our Chief Executive Officer in connection with his employment agreement.

Other Income (Expense)

Interest income earned on the net proceeds of our September 12, 2014 Private Offering was $555 for the nine months ended September 30, 2014. There was no interest income for the year ended December 31, 2013.

Gain on revaluation of derivative warrant liability for the nine months ended September 30, 2014 was $8,588. The gain was due to the change in the fair value of the derivative warrant liability that we recognized in connection with the first closing of the Private Offering on September 12, 2014.

For the nine months ended September 30, 2014, interest expense decreased by $12,404 in comparison to the year ended December 31, 2013. On July 31, 2014, $2,035,000 of convertible promissory notes and accrued interest of $196,058 were converted to equity. The Company borrowed $1,175,000 during the year ended December 31, 2013. In addition, we incurred $42,000 in debt issuance costs in April 2013 that were amortized to interest expense over the twelve month term of the note. Amortization expense was $14,000 and $28,000 for the nine months ended September 30, 2014 and the year ended December 31, 2013, respectively.

Net Loss

For the nine months ended September 30, 2014, we incurred a net loss of $737,727 compared to a net loss for the year ended December 31, 2013 of $1,288,003. The decrease in the net loss was primarily due to our decreased activities resulting from our inability to fund our operations.

LIQUIDITY AND CAPITAL RESOURCES

Going Concern Uncertainty and Working Capital

Citius has incurred operating losses of $2,902,268, $737,727 and $1,288,003 for the year ended September 30, 2015, the nine months ended September 30, 2014, and the year ended December 31, 2013, respectively. At September 30, 2015, Citius had a stockholders' deficit of $635,213 and an accumulated deficit of $9,040,549. Citius' net cash used in operations during the year ended September 30, 2015, the nine months ended September 30, 2014, and the year ended December 31, 2013 was $2,385,416, $183,164 and $1,095,266, respectively.

As of September 30, 2015, Citius had a working capital deficit of $640,614. The working capital deficit was attributable to the operating losses incurred by the Company since inception offset by our capital raising activities. At September 30, 2015, Citius had cash and cash equivalents of $676,137 available to fund its operations. The Company's primary sources of cash flow since inception have been from financing activities. During the year ended September 30, 2015 and the nine months ended September 30, 2014, the Company received net proceeds of $1,509,493 and $1,680,834, respectively from the issuance of equity. During the year ended December 31, 2013, the Company received proceeds of $1,175,000 from the issuance of debt. Our primary uses of operating cash were for product development and commercialization activities, regulatory expenses, employee compensation, consulting fees, legal and accounting fees, and insurance and travel expenses.

On July 31, 2014, the note holders demanded conversion of the outstanding $1,685,000 in Convertible Notes, the $350,000 Subordinated Note and the accrued interest of $196,058 into 3,667,886 membership interests of Citius. Citius and the two note holders agreed to convert the Convertible Notes and accrued interest at the 2014 Private Offering price of $0.60 per share of common stock while the Subordinated Note issued in the 2013 private placement converted at $0.65 per share. All the Citius membership interests were exchanged on a one for one basis for shares of common stock in the Reverse Acquisition.

On September 12, 2014, the Company sold 3,400,067 units ("Units") for a purchase price of $0.60 per Unit for gross proceeds of $2,040,040 and net proceeds of $1,630,834. 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 $0.60, (the "Private Offering"). The exercise price of the Investor Warrants is subject to adjustment, for up to one year, if the Company issues common stock at a price lower than the exercise price, subject to certain exceptions. The Investor Warrants will be redeemable by the Company at a price of $0.001 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 $1.50 per share with an average trading volume of 50,000 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 $1.17 for more than any 3 days during such notice period and (iii) the underlying shares of common stock are registered.

On December 31, 2014, the note holders requested conversion of $600,000 in Promissory Notes and accrued interest of $33,333 into 1,055,554 shares of common stock at a conversion price of $0.60 per share.

Between March 19, 2015 and September 14, 2015, the Company sold an additional 2,837,037 Units for a purchase price of $0.54 per Unit and 200,000 Units for a purchase price of $0.60 per Unit for gross proceeds of $1,652,000.

We expect that we will have sufficient capital to continue our operations for the next six months however, based upon our cash availability and expenses, we will not have sufficient capital to fund our operations for the next twelve 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

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

Principles of Consolidation

As a result of the Reverse Acquisition, the accompanying consolidated financial statements include the operations of Citius Pharmaceuticals, LLC (the accounting acquirer) and its parent, Citius Pharmaceuticals, Inc. (formerly Trail One) since the Reverse Acquisition. All significant inter-company balances and transactions have been eliminated in consolidation.

Research and Development

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

Patents and Trademarks

Certain costs of outside legal counsel related to obtaining our patents and trademarks are capitalized. Patent costs are amortized over the legal life of the patents, generally twenty years, starting at the patent issuance date. The costs of unsuccessful and abandoned applications are expensed when abandoned. The cost of maintaining existing patents are expensed as incurred.

Derivative Warrant Liability

The FASB ASC 815-40: *Derivatives and Hedging-Contracts in Entity's Own Equity* requires freestanding contracts that are settled in a company's own stock, including common stock warrants, to be designated as an equity instrument, asset or a liability. Under the provisions of ASC 815-40, a contract designated as an asset or a liability must be carried at fair value on a company's balance sheet, with any changes in fair value recorded in the company's results of operations. A contract designated as an equity instrument must be included within equity, and no fair value adjustments are required from period to period. The 3,400,067 Investor Warrants, the 680,013 warrants underlying the placement agent's Unit warrants and the 1,000,000 warrants issued for investment banking services in the Private Offering on September 12, 2014 were separately accounted for as liabilities at issuance. In addition, the 3,037,037 Investor Warrants issued between March 19, 2015 and September 14, 2015 were accounted for as liabilities at issuance. The warrants are classified as liabilities because the exercise price of the warrants is subject to adjustment in the event that the Company issues common stock for less than $0.60 per share within one-year of the issuance of the warrants. The 2015 private placements did not result in an adjustment of the exercise price.

The Company performs valuations of the warrants issued in the Private Offering using a probability weighted Black-Scholes Pricing Model which value was compared to a Binomial Option Pricing Model for reasonableness. The model uses market-sourced inputs such as underlying stock prices, risk-free interest rates, volatility, expected life and dividend rates and has also considered the likelihood of "down-round" financings. Selection of these inputs involves management's judgment and may impact net income. Due to our limited operating history and limited number of sales of our Common Stock, we estimate our volatility based on a number of factors including the volatility of comparable publicly traded pharmaceutical companies. The volatility factor used in the Black-Scholes Pricing Model has a significant effect on the resulting valuation of the derivative liabilities on our balance sheet. The volatility calculated at September 30, 2015 was 57%. We used a risk-free interest rate of 1.37% and estimated lives of 4.47 to 4.96 years, which are the remaining contractual lives of the warrants. The volatility calculated at September 30, 2014 was 54%. We used a risk-free interest rate of 1.78% and an estimated life of 4.95 years, which is the remaining contractual life of the warrants.

On September 12, 2015, anti-dilution rights related to warrants to purchase 5,080,080 shares of common stock expired which resulted in a reclassification from derivative warrant liability to additional paid-in capital of $1,148,328.

Income Taxes

Citius Pharmaceuticals, LLC was treated as a partnership for federal and state income taxes prior to the Reverse Acquisition. A partnership's income or loss is allocated directly to the Members for income tax purposes. Accordingly, there is no provision for federal and state income taxes in the accompanying financial statements for the year ended December 31, 2013.

We follow accounting guidance regarding the recognition, measurement, presentation and disclosure of uncertain tax positions in the financial statements. Tax positions taken or expected to be taken in the course of preparing our tax returns, including the position that Citius Pharmaceuticals, LLC qualified as a pass-through entity, are required to be evaluated to determine whether the tax positions are "more-likely-than-not" of being sustained by the applicable tax authorities. Tax positions not deemed to meet a more-likely-than-not threshold would be recorded in the financial statements. There are no uncertain tax positions, however the Company is still in the process of filing their 2013, 2014 and 2015 tax returns.

Any interest or penalties are charged to expense. None have been recognized in these financial statements. Generally, we are subject to federal and state tax examinations by tax authorities for all years subsequent to December 31, 2011.

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

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Not required.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

CITIUS PHARMACEUTICALS, INC.
CONSOLIDATED FINANCIAL STATEMENTS

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders of Citius Pharmaceuticals, Inc.

We have audited the accompanying consolidated balance sheets of Citius Pharmaceuticals, Inc. as of September 30, 2015 and 2014, and the related consolidated statements of operations, changes in stockholders' deficit and cash flows for the year ended September 30, 2015, the nine month period ended September 30, 2014, and the year ended December 31, 2013. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the financial statements are free of material misstatement. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of Citius Pharmaceuticals, Inc. as of September 30, 2015 and 2014, and the results of its operations and its cash flows for the year ended September 30, 2015, the nine month period ended September 30, 2014, and the year ended December 31, 2013, in conformity with U.S. generally accepted accounting principles.

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 2 to the consolidated financial statements, the Company has suffered recurring losses from operations, has negative cash flows from operations, and has a significant accumulated deficit. These conditions raise substantial doubt about the Company's ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 2. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

/s/ Wolf & Company, P.C.

Boston, Massachusetts
December 14, 2015

CITIUS PHARMACEUTICALS, INC.
CONSOLIDATED BALANCE SHEETS
SEPTEMBER 30, 2015 AND 2014

	2015	2014
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 676,137	$ 1,552,060
Prepaid expenses	60,000	—
Total Current Assets	736,137	1,552,060
Other Assets:		
Trademarks	5,401	5,401
Total Other Assets	5,401	5,401
Total Assets	$ 741,538	$ 1,557,461
LIABILITIES AND STOCKHOLDERS' DEFICIT		
Current Liabilities:		
Accounts payable	$ 559,150	$ 106,169
Accrued expenses	8,260	60,317
Accrued interest	—	25,833
Promissory notes	—	600,000
Derivative warrant liability	738,955	1,450,943
Due to related party	70,386	56,134
Total Current Liabilities	1,376,751	2,299,396
Commitments and Contingencies		
Stockholders' Deficit:		
Preferred stock - $0.001 par value; 10,000,000 shares authorized; no shares issued and outstanding	—	—
Common stock - $0.001 par value; 90,000,000 shares authorized; 34,117,886 and 30,025,295 shares issued and outstanding at September 30, 2015 and 2014, respectively	34,118	30,025
Additional paid-in capital	8,371,218	5,366,321
Accumulated deficit	(9,040,549)	(6,138,281)
Total Stockholders' Deficit	(635,213)	(741,935)
Total Liabilities and Stockholders' Deficit	$ 741,538	$ 1,557,461

See accompanying report of independent registered public accounting firm and notes to the consolidated financial statements.

CITIUS PHARMACEUTICALS, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS

	Year Ended September 30, 2015	Nine Months Ended September 30, 2014	Year Ended December 31, 2013
Revenues	$ —	$ —	$ —
Operating Expenses:			
Research and development	1,797,045	574	492,136
General and administrative	946,613	183,044	690,396
Stock-based compensation – general and administrative	486,271	470,185	—
Total Operating Expenses	3,229,929	653,803	1,182,532
Operating Loss	(3,229,929)	(653,803)	(1,182,532)
Other Income (Expense), Net:			
Interest income	3,066	555	—
Gain on revaluation of derivative warrant liability	332,095	8,588	—
Interest expense	(7,500)	(93,067)	(105,471)
Total Other Income (Expense), Net	327,661	(83,924)	(105,471)
Loss before Income Taxes	(2,902,268)	(737,727)	(1,288,003)
Income tax benefit	—	—	—
Net Loss	$ (2,902,268)	$ (737,727)	$ (1,288,003)
Net Loss Per Share - Basic and Diluted	$ (0.09)	$ (0.04)	$ (0.07)
Weighted Average Common Shares Outstanding			
Basic and diluted	31,835,440	19,322,206	17,757,333

See accompanying report of independent registered public accounting firm and notes to the consolidated financial statements.

CITIUS PHARMACEUTICALS, INC.
CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' DEFICIT
FOR THE YEAR ENDED SEPTEMBER 30, 2015, THE NINE MONTHS ENDED SEPTEMBER 30, 2014, AND THE YEAR ENDED DECEMBER 31, 2013

	Preferred Stock	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Equity (Deficit)
		Shares	Amount			
Balance, January 1, 2013	$ —	17,757,342	$ 17,757	$ 2,481,043	$ (4,112,551)	$ (1,613,751)
Net loss	—	—	—	—	(1,288,003)	(1,288,003)
Balance, December 31, 2013	—	17,757,342	17,757	2,481,043	(5,400,554)	(2,901,754
Issuance of common stock	—	200,000	200	49,800	—	50,000
Conversion of subordinated convertible promissory note and accrued interest	—	606,531	607	393,638	—	394,245
Conversion of convertible promissory notes and accrued interest	—	3,061,355	3,061	1,833,752	—	1,836,813
Issuance of common stock in private placement, net of costs	—	3,400,067	3,400	142,903	—	146,303
Issuance of common stock in reverse acquisition	—	5,000,000	5,000	(5,000)	—	—
Stock-based compensation	—	—	—	470,185	—	470,185
Net loss	—	—	—	—	(737,727)	(737,727)
Balance, September 30, 2014	—	30,025,295	30,025	5,366,321	(6,138,281)	(741,935)
Conversion of promissory notes and accrued interest	—	1,055,554	1,056	632,277	—	633,333
Issuance of common stock in private placement, net of costs	—	3,037,037	3,037	738,021	—	741,058
Reclassification of derivative warrant liability to additional paid-in capital	—	—	—	1,148,328	—	1,148,328
Stock-based compensation	—	—	—	486,271	—	486,271
Net loss	—	—	—	—	(2,902,268)	(2,902,268)
Balance, September 30, 2015	—	34,117,886	$ 34,118	$ 8,371,218	$ (9,040,549)	$ (635,213)

See accompanying report of independent registered public accounting firm and notes to the consolidated financial statements.

CITIUS PHARMACEUTICALS, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS

	Year Ended September 30, 2015	Nine Months Ended September 30, 2014	Year Ended December 31, 2013
Cash Flows From Operating Activities:			
Net loss	$(2,902,268)	$ (737,727)	$(1,288,003)
Adjustments to reconcile net loss to net cash used in operating activities:			
Amortization of debt issuance costs	—	14,000	28,000
Stock-based compensation	486,271	470,185	—
Gain on revaluation of derivative warrant liability	(332,095)	(8,588)	—
Changes in operating assets and liabilities:			
Prepaid expenses	(60,000)	9,174	(9,174)
Accounts payable	452,981	(66,320)	75,097
Accrued expenses	(52,057)	56,764	3,033
Accrued interest	7,500	79,067	77,472
Due to related party	14,252	281	18,309
Net Cash Used In Operating Activities	(2,385,416)	(183,164)	(1,095,266)
Cash Flows From Financing Activities:			
Proceeds from convertible promissory notes	—	—	225,000
Proceeds from promissory notes	—	—	600,000
Proceeds from subordinated convertible promissory note	—	—	350,000
Proceeds from issuance of common stock	—	50,000	—
Net proceeds from private placement	1,509,493	1,630,834	—
Deferred offering costs	—	—	(25,000)
Debt issuance costs	—	—	(42,000)
Net Cash Provided by Financing Activities	1,509,493	1,680,834	1,108,000
Increase (Decrease) in Cash and Cash Equivalents	(875,923)	1,497,670	12,734
Cash and Cash Equivalents - Beginning of Period	1,552,060	54,390	41,656
Cash and Cash Equivalents - End of Period	$ 676,137	$ 1,552,060	$ 54,390
Supplemental Disclosures of Cash Flow Information and Non-cash Transactions:			
Interest paid	$ —	$ —	$ —
Income taxes paid	$ —	$ —	$ —
Fair value of warrants recorded as derivative warrant liability	$ 768,435	$ 1,459,531	$ —
Reclassification of derivative warrant liability to additional paid-in capital	$ 1,148,328	$ —	$ —
Conversion of promissory notes and accrued interest into common stock	$ 633,333	$ —	$ —
Conversion of convertible promissory notes and accrued interest into common stock	$ —	$ 1,836,813	$ —
Conversion of subordinated convertible promissory note and accrued interest into common stock	$ —	$ 394,245	$ —

See accompanying report of independent registered public accounting firm and notes to the consolidated financial statements.

1. NATURE OF OPERATIONS AND BASIS OF PRESENTATION

Business

Citius Pharmaceuticals, Inc. ("Citius" or the "Company") is a pharmaceutical company headquartered in Maynard, Massachusetts focusing on developing innovative formulations aimed at improving the delivery and compliance of approved drugs. 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 (the "Exchange 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 (see "Reverse Acquisition" below).

The Company currently has one approved and marketed product, Suprenza (phentermine hydrochloride), which it has out licensed for promotion in the United States, Canada and Mexico. 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 Acquisition

On September 12, 2014, Citius completed a reverse acquisition transaction with Citius Pharmaceuticals, LLC, which became a wholly-owned subsidiary of Citius. As part of the reverse acquisition, the former members of Citius Pharmaceuticals, LLC received 21,625,219 shares of the Company's common stock in exchange for their interest in Citius Pharmaceuticals, LLC and, immediately after the transaction, owned 72% of the outstanding common stock. Immediately prior to the transaction, Citius had 5,000,000 shares of common stock outstanding. In connection with the Exchange Agreement, the Company completed the first closing of a Private Offering (see Note 7). Following the acquisition, Citius Pharmaceuticals, LLC began operating as a wholly-owned subsidiary of Citius Pharmaceuticals, Inc.

Accounting principles generally accepted in the United States generally require that a company whose security holders retain the majority voting interest in the combined business be treated as the acquirer for financial reporting purposes. The acquisition was accounted for as a reverse acquisition whereby Citius Pharmaceuticals, LLC was deemed to be the accounting acquirer. Accordingly, the historical consolidated financial statements are those of Citius Pharmaceuticals, LLC as the accounting acquirer. The post-merger combination of Citius Pharmaceuticals, Inc. and Citius Pharmaceuticals, LLC is referred to throughout these notes to consolidated financial statements as the "Company." As the accounting acquirer, Citius Pharmaceuticals, LLC did not acquire any tangible assets from Citius and did not assume any liabilities of Citius. This transaction is not considered a business combination because Citius, the non-operating public corporation, did not meet the definition of a business. Instead, this transaction is considered to be a capital transaction of Citius Pharmaceuticals, LLC and is equivalent to the issuance of shares by Citius Pharmaceuticals, LLC for the net assets of Citius accompanied by a recapitalization.

In connection with the reverse acquisition, Citius Pharmaceuticals, LLC adopted the fiscal year end of Citius, thereby changing our fiscal year end from December 31 to September 30.

Basis of Presentation

As a result of the reverse acquisition, the accompanying consolidated financial statements include the operations of Citius Pharmaceuticals, LLC (the accounting acquirer). The accompanying consolidated financial statements also include the operations of Citius Pharmaceuticals, Inc. (formerly Trail One, Inc.) since the date of the reverse acquisition. All significant inter-company balances and transactions have been eliminated in consolidation.

All share and per share amounts presented in these consolidated financial statements reflect the one-for-one exchange ratio of Citius Pharmaceuticals, LLC member interests to common shares in the reverse acquisition.

See report of independent registered public accounting firm.

2. GOING CONCERN UNCERTAINTY AND MANAGEMENT'S PLAN

The accompanying 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 $2,385,416, $183,164, and $1,095,266 for the year ended September 30, 2015, the nine months ended September 30, 2014 and the year ended December 31, 2013, respectively. At September 30, 2015, the Company had a working capital deficit of $640,614 and a stockholders' deficit of $635,213. The Company has no revenue and has relied on proceeds from equity transactions and debt to finance its operations. At September 30, 2015, 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. There is no assurance, however, that 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 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). A milestone is generally understood as a completion of a specific defined task towards the completion of a project or performance of a contract. For example, pursuant to the Company's agreement with Alpex, the Company is required to pay Alpex for the completion of certain tasks including, but not limited to, the development of the analytical methods, formulations and filings of the NDA. 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 have been earned or received by the Company through September 30, 2015.

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 8) 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 through September 30, 2015.

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.

See report of independent registered public accounting firm.

4. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

A summary of the significant accounting policies followed by the Company in the preparation of the consolidated financial statements is as follows:

Use of Estimates

The process of preparing financial statements in conformity with accounting principles generally accepted in the United States of America ("GAAP") requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of assets and liabilities at the date of financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates and changes in estimates may occur.

Cash and Cash Equivalents

The Company considers all highly liquid instruments with maturities of less than three months at the time of purchase to be cash equivalents. From time to time, the Company may have cash balances in financial institutions in excess of insurance limits. The Company has never experienced any losses related to these balances.

Research and Development

Research and development costs, including upfront fees and milestones paid to collaborators who are performing research and development activities under contractual agreement with the Company, are expensed as incurred. The Company defers and capitalizes its nonrefundable advance payments that are for research and development activities until the related goods are delivered or the related services are performed. When the Company is reimbursed by a collaboration partner for work the Company performs, it records the costs incurred as research and development expenses and the related reimbursement as a reduction to research and development expenses in its consolidated statement of operations. Research and development expenses primarily consist of clinical and non-clinical studies, materials and supplies, third-party costs for contracted services, and payments related to external collaborations and other research and development related costs.

Patents and Trademarks

Certain costs of outside legal counsel related to obtaining trademarks for the Company are capitalized. Patent costs are amortized over the legal life of the patents, generally twenty years, starting at the patent issuance date. The costs of unsuccessful and abandoned applications are expensed when abandoned. The cost of maintaining existing patents are expensed as incurred.

Revenue Recognition

The Company recognizes revenue using the four basic criteria that must be met before revenue can be recognized: (1) persuasive evidence of an arrangement exists, (2) delivery has occurred, (3) the selling price is fixed and determinable, and (4) collectability is reasonably assured. Provisions for discounts, rebates, estimated returns and allowances, and other adjustments are provided in the period that the revenue is recorded.

The Company's license and collaboration agreements with certain partners also provide for contingent payments to us based solely upon the performance of the respective partner. For such contingent amounts we expect to recognize the payments as revenue when earned under the applicable contract, which is generally upon completion of performance by the respective partner, provided that collection is reasonably assured.

The Company's license and collaboration agreements with its partners also provide for payments to us upon the achievement of specified sales volumes of approved drugs. We consider these payments to be similar to royalty payments and we will recognize such sales-based payments upon achievement of such sales volumes, provided that collection is reasonably assured.

Stock-Based Compensation

The Company recognizes compensation costs resulting from the issuance of stock-based awards to employees and directors as an expense in the consolidated statement of operations over the requisite service period based on the fair value for each stock award on the grant date. The fair value of each option grant is estimated as of the date of grant using the Black-Scholes option pricing model. The fair value is amortized as compensation cost on a straight-line basis over the requisite service period of the awards, which is generally the vesting period. Due to its limited operating history, limited number of sales of its Common Stock and limited history of its shares being publicly traded, the Company estimates its volatility in consideration of a number of factors including the volatility of comparable public companies.

See report of independent registered public accounting firm.

Derivative Instruments

The Company generally does not use derivative instruments to hedge exposures to cash-flow or market risks; however, certain warrants to purchase common stock that do not meet the requirements for classification as equity are classified as liabilities. In such instances, net-cash settlement is assumed for financial reporting purposes, even when the terms of the underlying contracts do not provide for a net-cash settlement. Such financial instruments are initially recorded at fair value with subsequent changes in fair value charged (credited) to operations in each reporting period. If these instruments subsequently meet the requirements for classification as equity, the Company reclassifies the fair value to equity.

Income Taxes

Citius Pharmaceuticals, LLC was treated as a partnership for federal and state income taxes prior to the Reverse Acquisition. A partnership's income or loss is allocated directly to the Members for income tax purposes. Accordingly, there is no provision for federal and state income taxes in the accompanying consolidated financial statements for the year ended December 31, 2013.

The Company follows accounting guidance regarding the recognition, measurement, presentation and disclosure of uncertain tax positions in the consolidated financial statements. Tax positions taken or expected to be taken in the course of preparing our tax returns, including the position that Citius Pharmaceuticals, LLC qualified as a pass-through entity, are required to be evaluated to determine whether the tax positions are "more-likely-than-not" of being sustained by the applicable tax authorities. Tax positions not deemed to meet a more-likely-than-not threshold would be recorded in the consolidated financial statements. There are no uncertain tax positions, however the Company is still in the process of filing their 2013, 2014 and 2015 tax returns.

Any interest or penalties are charged to expense. None have been recognized in these consolidated financial statements. Generally, we are subject to federal and state tax examinations by tax authorities for all years subsequent to December 31, 2011.

After the Reverse Acquisition, we recognize deferred tax assets and liabilities based on differences between the financial reporting and tax basis of assets and liabilities, and operating loss and tax credit carry forwards. Deferred tax assets and liabilities are measured using the enacted tax rates and laws that are expected to be in effect when the differences are expected to reverse. We provide a valuation allowance, if necessary, for deferred tax assets for which we do not consider realization of such assets to be "more-likely-than-not". The deferred tax benefit or expense for the period represents the change in the deferred tax asset or liability from the beginning to the end of the period.

Basic and Diluted Loss per 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.

Fair Value of Financial Instruments

The financial statements include various estimated fair value information. Financial instruments are initially recorded at historical cost. If subsequent circumstances indicate that a decline in the fair value of a financial asset is other than temporary, the financial asset is written down to its fair value.

Unless otherwise indicated, the fair values of financial instruments approximate their carrying amounts. By their nature, all financial instruments involve risk, including credit risk for non-performance by counterparties. The fair values of cash and cash equivalents, accounts payable, accrued interest, accrued expenses, notes payable and due to related party approximate their recorded amounts because of their relatively short settlement terms.

See report of independent registered public accounting firm.

The Company groups its financial assets and financial liabilities generally measured at fair value in three levels, based on the markets in which the assets and liabilities are traded and the reliability of the assumptions used to determine fair value.

Level 1: Valuation is based on quoted prices in active markets for identical assets or liabilities. Level 1 assets and liabilities generally include debt and equity securities that are traded in an active exchange market. Valuations are obtained from readily available pricing sources for market transactions involving identical assets or liabilities.

Level 2: Valuation is based on observable inputs other than Level 1 prices, such as quoted prices for similar assets or liabilities; quoted prices in markets that are not active; or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities. For example, Level 2 assets and liabilities may include debt securities with quoted prices that are traded less frequently than exchange-traded instruments.

Level 3: Valuation is based on unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities. Level 3 assets and liabilities include financial instruments whose value is determined using pricing models, discounted cash flow methodologies, or similar techniques, as well as instruments for which the determination of fair value requires significant management judgment or estimation. This category generally includes certain private equity investments and long-term derivative contracts.

The Company's financial liabilities measured at fair value on September 30, 2015 and 2014 consists solely of the derivative warrant liability which is classified as Level 3 in fair value hierarchy (see Note 6). The Company uses a valuation method, the Black-Scholes option pricing model, and the requisite assumptions in estimating the fair value for the warrants considered to be derivative instruments. The Company has no financial assets measured at fair value.

The Company may also be required, from time to time, to measure certain other financial assets at fair value on a nonrecurring basis. These adjustments to fair value usually result from application of lower-of-cost-or-market accounting or write-downs of individual assets. There were no such adjustments in the year ended September 30, 2015, the nine month period ended September 30, 2014, and the year ended December 31, 2013.

Segment Reporting

The Company currently operates as a single segment.

Concentrations of Credit Risk

The Company has no significant off-balance-sheet concentration of credit risk such as foreign exchange contracts, option contracts or other hedging arrangements.

Recently Adopted Accounting Standards – Development Stage Entities

In June 2014, the Financial Accounting Standards Board (the "FASB") issued Accounting Standards Update ("ASU") 2014-10, "Development Stage Entities", Topic 915. The objective of the ASU is to improve financial reporting by reducing the cost and complexity associated with the incremental reporting requirements for development stage entities. The ASU removes Topic 915, Development Stage Entities in its entirety from FASB Accounting Standards Codification ("ASC"). The ASU removes all incremental financial reporting requirements from U.S. GAAP for development stage entities, including the inception-to-date information and certain other disclosures. It also eliminates the guidance in ASC 810 on how to assess whether a development stage entity has sufficient equity at risk in the evaluation of whether the development stage entity is a variable interest entity. Additionally, the ASU clarifies that all entities, including entities that have not begun operations, should provide the risk and uncertainty disclosures required in ASC 275. The Company has elected to early adopt as permitted by ASU 2014-10 and therefore has omitted the incremental development stage reporting requirements.

Recently Issued Accounting Standards

In August 2015, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2015-15, "Interest – Imputation of Interest (Subtopic 835-30) - Presentation and Subsequent Measurement of Debt Issuance Costs Associated with Line-of-Credit Arrangements (Amendments to SEC Paragraphs Pursuant to Staff Announcement at June 18, 2015 EITF Meeting)". Given the absence of authoritative guidance within ASU 2015-03 for debt issuance costs related to line-of-credit arrangements, the SEC staff stated that they would not object to an entity deferring and presenting debt issuance costs as an asset and subsequently amortizing the deferred debt issuance costs ratably over the term of the line-of-credit arrangement, regardless of whether there are any outstanding borrowings on the line-of-credit arrangement.

In August 2015, the FASB also issued ASU No. 2015-14, "Revenue from Contracts with Customers (Topic 606) Deferral of the Effective Date. Deferred the effective date of ASU 2014-09 by one year. Originally scheduled to be effective for fiscal years beginning after December 15, 2016, ASU 2015-14 is effective for the year ended September 30, 2019.

In August 2014, the FASB issued ASU No. 2014-15, "Presentation of Financial Statements—Going Concern (Subtopic 205-40); Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern" which applies should a company be facing probable liquidation within one year of the issuance of the financial statements, but is not actually in liquidation at the time of issuance. The applicable accounting basis for presentation remains as a going concern, but if liquidation within one year is probable, then certain disclosures must be included in the financial statement presentation.

ASU 2014-15 is effective for annual and interim periods beginning after December 15, 2016, with early adoption permitted. We are currently in the process of evaluating the impact of adoption of this ASU on the consolidated financial statements.

See report of independent registered public accounting firm.

5. NOTES PAYABLE

Convertible Promissory Notes

Between July 12, 2010 and November 30, 2012, the Company issued several convertible promissory notes (collectively the "Convertible Notes") to two existing investors in aggregate total principal amount of $1,460,000. The Convertible Notes accrue interest at 3.00% per annum and are payable on demand only after their respective 10-year maturities. Between January 1, 2013 and March 25, 2013, the Company issued additional Convertible Notes to existing investors in aggregate total principal amount of $225,000. The additional Convertible Notes accrue interest at 5.00% per annum and are payable on demand only after their respective 10-year maturities. The unpaid principal and accrued interest are only convertible into common stock following a reorganization or conversion into a corporation at the option of the holder. The unpaid principal and accrued interest will convert into common stock at the greater of the fair value of the common stock on the date of the conversion or $0.25 ($0.69 if the Company's common stock is admitted to trade on a national exchange prior to the date of conversion).

On July 31, 2014, in anticipation of the completion of the reverse acquisition and the Private Offering, the note holders demanded conversion of the outstanding $1,685,000 Convertible Notes and accrued interest of $151,813 into 3,061,355 shares of common stock at a conversion price of $0.60 per share.

Promissory Notes

In November 2013, the Company issued two promissory notes (the "Promissory Notes") to two existing investors in aggregate total principal amount of $600,000. The Promissory Notes accrue interest at 5.00% per annum and are due at the earliest of (1) December 19, 2014, (2) the occurrence of an event of default as defined in the Promissory Notes, (3) an initial installment of $100,000 principal amount, to each investor, upon the receipt by the Company of a minimum $6,500,000 in aggregate proceeds under any financing transaction, (4) a second installment of $100,000 principal amount, to each investor, upon the receipt by the Company of a minimum $8,500,000 in aggregate proceeds under any financing transaction, and (5) a third installment of $100,000 principal amount, to each investor, upon the receipt by the Company of a minimum $10,000,000 in aggregate proceeds under any financing transaction. At September 30, 2014, the Promissory Notes had an outstanding aggregate principal balance of $600,000.

On December 31, 2014, the note holders requested conversion of the outstanding $600,000 Promissory Notes and accrued interest of $33,333 into 1,055,554 shares of common stock at a conversion price of $0.60 per share.

Subordinated Convertible Promissory Note

In 2013, the Company entered into an investment banking agreement to raise up to $6 million of 10% subordinated convertible promissory notes. The agreement contemplated a reverse acquisition with a public company and an automatic conversion of the notes into units of common stock and warrants, as defined therein. In April 2013, the Company issued a $350,000 subordinated convertible promissory note (the "Subordinated Note"). The Subordinated Note accrued interest at 10% per annum and was payable on demand any time after April 2014. If the Company has not repaid the Subordinated Note at the closing of a reverse acquisition, the unpaid principal and accrued interest will automatically convert into common stock by dividing the amount due by a price per unit of $0.65. Also, upon automatic conversion, the purchaser of the Subordinated Note will receive a warrant to purchase the same number of shares in to which the Subordinated Note converts.

On July 31, 2014, in anticipation of the completion of the reverse acquisition and the Private Offering, the note holder demanded conversion of the outstanding $350,000 Subordinated Note and accrued interest of $44,245 into 606,531 shares of common stock at a conversion price of $0.65 per share.

Interest Expense

During 2013, the Company incurred $42,000 of debt issuance costs related to the Subordinated Note which was amortized over the term of the underlying debt. Amortization of debt issuance costs recorded as interest expense for the nine months ended September 30, 2014 and the year ended December 31, 2013 amounted to $14,000 and $28,000, respectively.

Interest expense on the notes for the year ended September 30, 2015, the nine months ended September 30, 2014 and the year ended December 31, 2013, including non-cash interest related to debt issuance costs, was $7,500, $93,067, and $105,471, respectively.

See report of independent registered public accounting firm.

6. DERIVATIVE WARRANT LIABILITY

Derivative financial instruments are recognized as a liability on the consolidated balance sheet and measured at fair value. At September 30, 2015 and 2014, the Company had outstanding warrants to purchase 3,037,037 and 5,080,080 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 less than $0.60 per share within one-year of the issuance of the warrants (see Note 7).

The Company performs valuations of the warrants using a probability weighted Black-Scholes option pricing model which value was also compared to a Binomial Option Pricing Model for reasonableness. This model requires input of assumptions including the risk-free interest rates, volatility, expected life and dividend rates, and has also considered the likelihood of "down-round" financings. Selection of these inputs involves management's judgment and may impact net income. 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 September 30, 2015 was 57% and we used a risk-free interest rate of 1.37%, estimated lives of 4.47 to 4.96 years, which are the remaining contractual lives of the warrants subject to "down-round" provisions, and no dividends to our common stock. The volatility calculated at September 30, 2014 was 54% and we used a risk-free interest rate of 1.78%, an estimated life of 4.95 years, which is the remaining contractual life of the warrants and no dividends to our common stock.

On September 12, 2015, anti-dilution rights related to warrants to purchase 5,080,080 shares of common stock expired which resulted in a reclassification from derivative warrant liability to additional paid-in capital of $1,148,328.

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 fair value hierarchy (see Note 4):

	Year Ended September 30, 2015	Nine Months Ended September 30, 2014
Derivative warrant liability, beginning of period	$ 1,450,943	$ —
Fair value of warrants issued	768,435	1,459,531
Total realized/unrealized gains included in net loss [1]	(332,095)	(8,588)
Reclassification of liability to additional paid-in capital	(1,148,328)	—
Derivative warrant liability, end of period	$ 738,955	$ 1,450,943

(1) Included in gain or loss on revaluation of derivative warrant liability in the Consolidated Statement of Operations.

7. COMMON STOCK, STOCK OPTIONS AND WARRANTS

Common Stock

In May 2014, the Company issued 200,000 shares of common stock for $50,000, or $0.25 per share.

On September 12, 2014, in connection with the Reverse Acquisition, 5,000,000 shares of common stock were recorded in the financial statements of Citius Pharmaceuticals, LLC, the accounting acquirer (See Note 1 – Reverse Acquisition).

See report of independent registered public accounting firm.

Private Offerings

In 2014, the Company entered into an investment banking agreement to raise up to $5.1 million and issue up to 8,500,000 Units described below. The agreement contemplated a Reverse Acquisition with a public company. As of December 31, 2013, the Company capitalized as deferred offering costs a $25,000 retainer for legal costs associated with this offering. The $25,000 retainer was charged to additional paid-in capital on completion of the first closing of the offering.

On September 12, 2014, the Company sold 3,400,067 Units for a purchase price of $0.60 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 $0.60, (the "Private Offering"). The exercise price of the Investor Warrants is subject to adjustment, for up to one year, if the Company issues common stock at a price lower than the exercise price, subject to certain exceptions. The 2015 private placement described below did not result in an adjustment of the exercise price of the Investor Warrants. The Investor Warrants will be redeemable by the Company at a price of $0.001 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 $1.50 per share with an average trading volume of 50,000 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 $1.17 for more than any 3 days during such notice period and (iii) the underlying shares of common stock are registered.

The Placement Agent was paid a commission of ten percent (10%) and a non-accountable expense allowance of three percent (3%) of the funds raised in the Private Offering. As a result of the foregoing arrangement, the Placement Agent was paid commissions and expenses of $265,206. In addition, the Company issued to the Placement Agent and their designees five-year warrants (the "Placement Agent Unit Warrants") to purchase 680,013 Units at an exercise price of $0.60 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. The exercise price of the warrants underlying the Placement Agent Unit Warrants is subject to adjustment, for up to one year, if the Company issues common stock at a price lower than the exercise price, subject to certain exceptions.

In addition, the Placement Agent was issued warrants to purchase 1,000,000 shares of common stock exercisable for cash at $0.60 per share for investment banking services provided in connection with the transaction (the "Placement Agent Share Warrants"). Other cash expenses related to the private placement totaled $169,000. The Placement Agent may, while the Placement Agent Unit Warrants are outstanding, appoint one person to the Board of Directors, and designate one person who may attend meetings of the Board of Directors as an observer. On November 2, 2015, the Placement Agent waived its right to appoint a person to the Board of Directors.

In connection with the Private Offering, the Company entered into a Registration Rights Agreement pursuant to which the Company is required to file a registration statement (the "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 Company has agreed to use its reasonable efforts to cause the Registration Statement to be filed no later than 60 days after the completion of the Private Offering (the "Filing Deadline"), and to have the Registration Statement declared effective within 180 days of the Filing Deadline. Any holders of the shares of common stock removed from the Registration Statement as a result of a Section 415 comment from the SEC shall be included in a subsequent registration statement the Company will file no later than six months after the prior registration statement (or such other period as permitted by SEC rules). The Company filed the Registration Statement on September 11, 2015, however, it was not declared effective as of September 30, 2015.

Between March 19, 2015 and September 14, 2015, the Company sold an additional 2,837,037 Units for a purchase price of $0.54 per Unit and 200,000 Units for a purchase price of $0.60 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). There was no placement agent for the 2015 private placements and other cash expenses related to the placements were $142,507. In connection with these placements, the Company credited $741,058 to stockholders' equity (deficit) and $768,435 to derivative warrant liability.

Stock Options

On September 12, 2014, the Board of Directors adopted the 2014 Stock Incentive Plan (the "2014 Plan") and reserved 13,000,000 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 September 30, 2015, there were options to purchase an aggregate of 3,900,000 shares of common stock outstanding under the 2014 Plan and 9,100,000 shares 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.

The following assumptions were used in determining the fair value of stock option grants:

	Year Ended September 30, 2015	Nine Months Ended September 30, 2014
Risk-free interest rate	1.37 – 1.52%	1.83%
Expected dividend yield	0%	0%
Expected term	2.5 – 6 years	5 – 6 years
Forfeiture rate	0	0
Expected volatility	53 – 58%	54%

A summary of option activity under the 2014 Plan is presented below:

Options	Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term	Aggregate Intrinsic Value
Outstanding at January 1, 2014	—	$ —		
Granted	3,300,000	0.45		
Exercised	—	—		
Forfeited or expired	—	—		
Outstanding at September 30, 2014	3,300,000	0.45	9.96 years	$ 495,000
Granted	600,000	0.60		
Exercised	—	—		
Forfeited or expired	—	—		
Outstanding at September 30, 2015	3,900,000	$ 0.47	8.94 years	$ 297,000
Exercisable at September 30, 2015	2,090,000	$ 0.47	8.81 years	$ 162,000

On September 12, 2014, the Board of Directors granted stock options to purchase 3,300,000 shares of common stock at an exercise price of $0.45 per share. The weighted average grant-date fair value of the options granted was estimated at $0.34 per share. These options vest over three years and have a term of 10 years.

On April 1, 2015, the Board of Directors granted stock options to purchase 100,000 shares of common stock at an exercise price of $0.60 per share. The weighted average grant-date fair value of the options granted was estimated at $0.16 per share. These options vested immediately and have a term of 5 years. On June 1, 2015, the Board of Directors granted stock options to purchase 500,000 shares of common stock at an exercise price of $0.60 per share. The weighted average grant-date fair value of the options granted was estimated at $0.27 per share. These options vest over three years and have a term of 10 years.

Stock-based compensation expense for the year ended September 30, 2015 and the nine months ended September 30, 2014 was $486,271 and $470,185, respectively.

At September 30, 2015, unrecognized total compensation cost related to unvested awards of $325,316 is expected to be recognized over a weighted average period of 1.62 years.

See report of independent registered public accounting firm.

Warrants

The Company has reserved 8,797,130 shares of common stock for the exercise of outstanding warrants. The following table summarizes the warrants outstanding at September 30, 2015:

	Exercise price	Number	Expiration Date
Investor Warrants	$ 0.60	3,400,067	September 12, 2019
Placement Agent Unit Warrants	0.60	680,013	September 12, 2019
Warrants underlying Placement Agent Unit Warrants	0.60	680,013	September 12, 2019
Placement Agent Share Warrants	0.60	1,000,000	September 12, 2019
Investor Warrants	0.60	500,000(1)	March 19, 2020
Investor Warrants	0.60	583,334(1)	April 22, 2020
Investor Warrants	0.60	258,333(1)	April 30, 2020
Investor Warrants	0.60	333,334(1)	June 10, 2020
Investor Warrants	0.60	100,000(1)	June 22, 2020
Investor Warrants	0.60	370,370(1)	June 26, 2020
Investor Warrants	0.60	208,333(1)	July 2, 2020
Investor Warrants	0.60	100,000(1)	July 7, 2020
Investor Warrants	0.60	333,333(1)	July 15, 2020
Investor Warrants	0.60	250,000(1)	September 14, 2020
		8,797,130	

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

At September 30, 2015, the weighted average remaining life of the warrants is 4.23 years, all warrants are exercisable, and there is no aggregate intrinsic value for the warrants outstanding.

8. RELATED PARTY TRANSACTIONS

The Company's headquarters is located in the office space of a company affiliated through common ownership. The Company has not recorded any revenue or expense related to the use of the office space as management has determined the usage to be immaterial and the affiliate has not charged for the usage.

As of September 30, 2015 and 2014, the Company owed $70,386 and $56,134, respectively, 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 Chief Executive Officer 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).

9. EMPLOYMENT AND CONSULTING AGREEMENTS

Employment Agreements

In December 2012 and January 2013, the Company entered into employment agreements with two employees. As of December 31, 2013, the employment agreements had expired.

The Company entered into a three year employment agreement with its new Chief Executive Officer effective September 12, 2014. Upon expiration, the agreement automatically renews for successive periods of one-year. The agreement requires the Company to pay base compensation plus incentives over the employment term plus severance benefits upon the occurrence of certain events as described in the agreement. Under the agreement, the Chief Executive Officer was granted options to purchase 3,300,000 shares of common stock (see Note 7 – *Stock Options*).

Consulting Agreements

Effective September 1, 2014, the Company entered into three consulting agreements. Two of the agreements are for financial consulting services including accounting, preparation of financial statements and filings with the SEC. The third agreement is for financing activities, product development strategies and corporate development. The agreements may be terminated by the Company or the consultant with 90 days written notice.

Consulting expense under the agreements for the year ended September 30, 2015 and the nine months ended September 30, 2014 was $348,000 and $29,000, respectively. Consulting expense for the year ended September 30, 2015 and the nine months ended September 30, 2014 includes $48,000 and $4,000, respectively, paid to a financial consultant who is a stockholder of the Company. In addition, one financial consulting services agreement provides for the grant of options to purchase 500,000 shares of common stock contingent upon approval by the Board of Directors. The options were granted on June 1, 2015.

10. COMMITMENTS AND CONTINGENCIES

Legal Proceedings

On May 17, 2013, the Company received notification from Zydus Pharmaceuticals (USA) Inc. ("Zydus") that Zydus had submitted Abbreviated New Drug Application No. 204663 to the FDA seeking approval to engage in the commercial manufacture, use or sale of generic versions of the 15 mg and 30 mg dosages of our SuprenzaÒ tablets. The notification informed the Company that Zydus was seeking to manufacture and sell its generic product prior to the expiration of U.S. Patent No. 6,149,938 (the "938 patent") which is listed in the Orange Book and covers SuprenzaÒ, and that the Zydus ANDA contained a certification that its proposed generic product does not infringe the '938 patent ("Paragraph IV Certification"). On June 19, 2013, the Company received a separate notification from Zydus that it was also pursuing approval for the 37.5 mg dosage of SuprenzaÒ under the same-numbered ANDA, with a separate Paragraph IV Certification.

In response, within 45 days of receiving the first notification from Zydus, the Company and our partners (Alpex Pharma, S.A. and Prenzamax, LLC), filed suit against Zydus and its parent Cadila Healthcare Limited (d/b/a Zydus Cadila) in Federal District Court in Delaware and New Jersey for infringement of the 938 patent pursuant, pursuant to the Hatch-Waxman statutory regime.

Several months after initiation of the suit, the Company initiated discussions with Zydus to seek a resolution to this dispute. We diligently negotiated a settlement agreement and dismissal of the pending lawsuit to the mutual satisfaction of all parties. As a result of this mutual agreement, the district court officially terminated the suit on November 21, 2014. The terms of the settlement agreement remain confidential per mutual agreement of the parties. The resolution of this matter has been deemed a success by Akrimax and its partners Citius, Prenzamax, and Alpex.

On November 24, 2015, a petition for inter partes review (the "Petition") was filed by Mr. J. Kyle Bass and Mr. Erich Spengenberg with the Patent Trial and Appeal Board (the "PTAB") of the U.S. Patent and Trademark Office ("USPTO"), challenging claims of U.S. Patent No. 8.440.170 (the "170 Patent"), titled "Orally Disintegrating Tablets with Speckled Appearance," which patent is owned by Alpex Pharma and is licensed by the Company. The inter partes review procedure allows a party to challenge the patentability of a patent before the PTAB. A patentability trial will commence if the PTAB decides to institute the inter partes review proceedings after considering the Petition and Alpex's preliminary response to the Petition. Pursuant to our agreement with Alpex, it is Alpex's primary responsibility to defend the patents. Alpex is reviewing its options and will inform us of its decision accordingly. If Alpex elects to not defend this patent, then we have the right to do so. The 170 patent relates to the appearance of the Suprenza tablets and we believe that loss of this patent will not have any impact on the Suprenza sales. Since we have already settled with Zydus on the main patent and we fully expect to have competition to our Suprenza, we are unlikely to defend this patent.

11. INCOME TAXES

There was no provision for federal or state income taxes for the year ended September 30, 2015 and the nine months ended September 30, 2014 due to the Company's operating losses and a full valuation reserve on deferred tax assets. In addition, Citius Pharmaceuticals, LLC (the accounting acquirer) was treated as a partnership for federal and state income taxes from inception until the Reverse Acquisition was completed. A partnership's income or loss is allocated directly to the partners for income tax purposes. Accordingly, there was no provision for federal and state income taxes for the year ended December 31, 2013.

The income tax benefit differs from the amount of income tax determined by applying the U.S. federal income tax rate to pretax income due to the following:

	Year Ended September 30, 2015	Nine Months Ended September 30, 2014
Computed "expected" tax benefit	(35.0)%	(35.0)%
Increase (decrease) in income taxes resulting from:		
State taxes, net of federal benefit	(5.2)%	(5.2)%

Permanent differences	(4.6)%	—%
Tax reporting differences due to the reverse acquisition	—%	11.3%
Increase in the valuation reserve	44.8%	28.9%
	0.0%	0.0%

See report of independent registered public accounting firm.

Deferred income taxes reflect the net tax effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. Significant components of the Company's deferred tax assets and liabilities are as follows:

	September 30, 2015	September 30, 2014
Deferred tax assets:		
Net operating loss carryforward	$ 1,131,000	$ 27,000
Stock-based compensation	384,000	189,000
Valuation allowance	(1,515,000)	(216,000)
Deferred tax assets	$ —	$ —

The Company has recorded a valuation allowance against deferred tax assets as the utilization of the net operating loss carryforward and other deferred tax assets is uncertain. There were no deferred tax assets or liabilities carried forward from Trail One, Inc. (the legal acquirer in the Reverse Acquisition) as the Company did not acquire any assets or liabilities in the Reverse Acquisition. Accordingly, during the nine months ended September 30, 2014, the valuation allowance increased by $216,000. During the year ended September 30, 2015, the valuation allowance increased by $1,299,000. The increase in the valuation allowance during the year ended September 30, 2015 and the nine months ended September 30, 2014 was due to the Company's net operating loss. At September 30, 2015, the Company has a net operating loss carryforward of approximately $2,814,000 which begins expiring in 2034.

During the year ended September 30, 2015 and the nine months ended September 30, 2014, the Company did not recognize any interest and penalties. As of September 30, 2015, the Company had no uncertain tax positions, however the Company is still in the process of filing their 2013, 2014 and 2015 tax returns. Tax years subsequent to 2011 are subject to examination by federal and state authorities.

12. SUBSEQUENT EVENTS

On October 1 and October 8, 2015, the Company appointed two new directors. Each director received an option to purchase 400,000 shares of the Company's common stock at an exercise price of $0.54 per share in consideration for their services as members of the Company's board of directors. The options were issued pursuant to the Company's 2014 Stock Incentive Plan.

Between October 1, 2015 and November 20, 2015, the Company sold an additional 416,667 Units for a purchase price of $0.54 per Unit and 166,667 Units for a purchase price of $0.60 per Unit for gross proceeds of $325,000. Each Unit consists of one share of common stock and one Investor Warrant (see Note 7 – Private Offerings).

On November 24, 2015, a petition for inter partes review (the "Petition") was filed by Mr. J. Kyle Bass and Mr. Erich Spengenberg with the Patent Trial and Appeal Board (the "PTAB") of the U.S. Patent and Trademark Office ("USPTO"), challenging claims of U.S. Patent No. 8.440.170 (the "170 Patent"), titled "Orally Disintegrating Tablets with Speckled Appearance," which patent is owned by Alpex Pharma and is licensed by the Company. The inter partes review procedure allows a party to challenge the patentability of a patent before the PTAB. A patentability trial will commence if the PTAB decides to institute the inter partes review proceedings after considering the Petition and Alpex's preliminary response to the Petition. Pursuant to our agreement with Alpex, it is Alpex's primary responsibility to defend the patents. Alpex is reviewing its options and will inform us of its decision accordingly. If Alpex elects to not defend this patent, then we have the right to do so. The 170 patent relates to the appearance of the Suprenza tablets and we believe that loss of this patent will not have any impact on the Suprenza sales. Since we have already settled with Zydus on the main patent and we fully expect to have competition to our Suprenza, we are unlikely to defend this patent.

See report of independent registered public accounting firm.

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

None.

ITEM 9A. CONTROLS AND PROCEDURES

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 September 30, 2015, the end of our fiscal year. 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 September 30, 2015, 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 light of the conclusion that our internal controls over financial reporting were ineffective as of September 30, 2015, we have applied procedures and processes as necessary to ensure the reliability of our financial reporting in regards to this annual report. Accordingly, the Company believes, based on its knowledge, that: (i) this annual 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 period covered by this report; and (ii) the financial statements, and other financial information included in this annual 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 annual report.

Management's Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining effective internal control over financial reporting as defined in Rule 13a-15(f) under the Exchange Act. Because of its inherent limitations, internal control over financial reporting is not intended to provide absolute assurance that a misstatement of our financial statements would be prevented or detected. Under the supervision of our CEO, the Company conducted an evaluation of the effectiveness of our internal control over financial reporting as of September 30, 2015 using the criteria established in Internal Control—*Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission ("COSO") (2013 Framework).

A material weakness is a deficiency, or combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis. In our assessment of the effectiveness of internal control over financial reporting as of September 30, 2015, we determined that control deficiencies existed that constituted material weaknesses, as described below:

1) the Company does not have an independent board of directors or an audit committee;
2) lack of documented policies and procedures;
3) the financial reporting function is carried out by consultants; and
4) ineffective separation of duties due to limited staff.

Subject to our ability to obtain additional financing and hire additional employees, the Company expects to be able to design and implement effective internal controls in the future that address these material weaknesses. In October 2015, the Company appointed two new independent directors.

Accordingly, we concluded that these material weaknesses resulted in a reasonable possibility that a material misstatement of the annual or interim financial statements will not be prevented or detected on a timely basis by the Company's internal controls.

As a result of the material weaknesses described above, our CEO concluded that the Company did not maintain effective internal control over financial reporting as of September 30, 2015 based on criteria established in Internal Control —*Integrated Framework* issued by COSO (2013 Framework).

Changes in Internal Controls

There were no changes in our internal controls over financial reporting during the fourth quarter of fiscal 2015 that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Limitations on the Effectiveness of Controls

Our CEO does not expect that our disclosure controls or our internal control over financial reporting will prevent or detect all errors and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system's objectives will be met. The design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Further, because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud, if any, within the Company have been detected. These inherent limitations include the realities that judgments in decision-making can be faulty and that breakdowns can occur because of simple error or mistake. Controls can also be circumvented by the individual acts of some persons, by collusion of two or more people, or by management override of the controls. The design of any system of controls is based in part on certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions. Projections of any evaluation of controls effectiveness to future periods are subject to risks. Over time, controls may become inadequate because of changes in conditions or deterioration in the degree of compliance with policies or procedures.

ITEM 9B. OTHER INFORMATION.

None.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

Below are the names and certain information regarding the Company's executive officers and directors.

Name	Age	Position(s)
Leonard Mazur	69	Chief Executive Officer, President, Chief Operating Officer, and Director
Myron Holubiak	68	Director
Suren Dutia	73	Director

On September 12, 2014, Leonard Mazur was appointed as Chief Executive Officer, President, Chief Operating Officer and sole director of the Company. On October 1, 2015, Myron Holubiak was appointed as a member of our Board of Directors and on October 8, 2015, Suren Dutia was appointed as a member of our Board of Directors. The Board will seek to appoint one additional director and the Company expects that its Board of Directors will consist of four members.

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. Akrimax was founded in September 2008 and has successfully launched prescription drugs while acquiring drugs from major pharmaceutical companies. From January 2005 to May 2012, Mr. Mazur also co-founded and served as the Chief Operating Officer of Triax Pharmaceuticals LLC ("Triax"), a specialty pharmaceutical company producing prescription dermatological drugs. Prior to joining Triax, he was the founder and, from 1995 to 2005, Chief Executive Officer of Genesis Pharmaceutical, Inc. ("Genesis"), a dermatological products company that marketed its products through dermatologists' offices as well as co-promoting products for major pharmaceutical companies. In 2003, Mr. Mazur successfully sold Genesis to Pierre Fabre, a leading pharmaceutical company.

Mr. Mazur has extensive sales, marketing and business development experience from his tenures at Medicis Pharmaceutical Corporation, as executive vice president, ICN Pharmaceuticals, Inc. as Vice President, Sales & Marketing, Knoll Pharma (a division of BASF), and Cooper Laboratories, Inc.

Mr. Mazur is a member of the Board of Trustees of Manor College and is a recipient of the Ellis Island Medal of Honor. Mr. Mazur received both his BA and MBA from Temple University and has served in the U.S. Marine Corps Reserves. We believe that Mr. Mazur's entrepreneurial experience and marketing knowledge qualifies him to serve on our Board of Directors.

Myron Holubiak has extensive experience in managing and advising large and emerging pharmaceutical and life sciences companies. Mr. Holubiak was the President of Roche Laboratories, Inc. ("Roche"), a major research-based pharmaceutical company, from December 1998 to August 2001. Prior to that, he held sales and marketing positions at Roche during his 19-year tenure. Since September, 2002, Mr. Holubiak has served on the board of directors and is currently the Chairman of the board of BioScrip, Inc. ("BioScrip") (Nasdaq: BIOS), a leading national provider of infusion and home care management solutions. BioScrip partners with physicians, hospital systems, facilities-based providers, healthcare payors and pharmaceutical manufacturers to provide patients access to post-acute care services. Since July 2010, Mr. Holubiak has served as a member of the board of directors of Assembly Biosciences, Inc. ("Assembly") (Nasdaq: ASMB) and its predecessor Ventrus Biosciences, Inc. ("Ventrus"). Assembly is a biopharmaceutical company developing innovative treatments for hepatitis B virus infection (HBV) and C. difficile-associated diarrhea (CDAD), and Ventrus developed treatment for hemorrhoids, however, phase 3 clinical trials of their compound (which was a new molecular entity and not previously approved HC/Lido) failed to demonstrate efficacy. After Ventrus' merger with Assembly, this program was discontinued.

Mr. Holubiak is the founder, Chief Executive Officer and a director of Leonard-Meron Biosciences, Inc. ("LMB"), a private, late-stage specialty pharmaceutical company focused on the development and commercialization of critical care products with a concentration on anti-infectives. The Company is developing Mino-Lok™, an antibiotic lock solution used to treat patients with catheter-related bloodstream infections, or CRBSIs. In addition, Mr. Holubiak is also a trustee of the Academy of Managed Care Pharmacy Foundation. Mr. Holubiak received a B.S. in Molecular Biology and Biophysics from the University of Pittsburg. Although Mr. Holubiak serves as an officer and director of other pharmaceutical companies, including BioScrip, Assembly and LMB, none of these companies compete with us. Although LMB will also utilize 505(b)(2) pathway for approvals, their product focus is on treating patients catheter-related bloodstream infections which is different from our focus. Accordingly, we do not believe that Mr. Holubiak's role with other pharmaceutical companies will result in any conflicts of interest, and that Mr. Holubiak's industry knowledge and experience managing both large and small firms qualifies him to serve on our Board of Directors.

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

Conflicts of Interest

In November 2011, we entered into an exclusive license agreement with Prenzamax LLC, pursuant to which we granted Prenzamax a license for sales of Suprenza in the U.S. Prenzamax's performance of this agreement is guaranteed by Akrimax LLC.

The co-founder and vice Chairman of Akrimax is Leonard Mazur who is our President, Chief Executive Officer and Chief Operating Officer. Pursuant to the terms of the exclusive license agreement, Prenzamax will be solely responsible for the pricing of Suprenza and will have the option to participate in the future development program of Suprenza which may result in a conflict of interest. Although Mr. Mazur does not have any direct management role in Akrimax or Prenzamax, there can be no assurance that Prenzamax will conduct its business affairs in a manner which is beneficial to our company.

Board Leadership Structure and Role in Risk Oversight

Our Board of Directors is primarily responsible for overseeing our risk management processes on behalf of the Company. The Board of Directors receives and reviews periodic reports from management, auditors, legal counsel, and others, as considered appropriate regarding our Company's assessment of risks. The Board of Directors focuses on the most significant risks facing our Company and our Company's general risk management strategy, and also ensures that risks undertaken by our Company are consistent with the board's appetite for risk. While the board oversees our Company's risk management, management is responsible for day-to-day risk management processes. We believe this division of responsibilities is the most effective approach for addressing the risks facing our Company and that our board leadership structure supports this approach.

Involvement in Certain Legal Proceedings

To our knowledge, our directors and executive officers have not been involved in any of the following events during the past ten years:

1. any bankruptcy petition filed by or against such person or any business of which such person was a general partner or executive officer either at the time of the bankruptcy or within two years prior to that time;
2. any conviction in a criminal proceeding or being subject to a pending criminal proceeding (excluding traffic violations and other minor offenses);
3. being subject to any order, judgment, or decree, not subsequently reversed, suspended or vacated, of any court of competent jurisdiction, permanently or temporarily enjoining him from or otherwise limiting his involvement in any type of business, securities or banking activities or to be associated with any person practicing in banking or securities activities;
4. being found by a court of competent jurisdiction in a civil action, the SEC or the Commodity Futures Trading Commission to have violated a Federal or state securities or commodities law, and the judgment has not been reversed, suspended, or vacated;
5. being subject of, or a party to, any Federal or state judicial or administrative order, judgment decree, or finding, not subsequently reversed, suspended or vacated, relating to an alleged violation of any Federal or state securities or commodities law or regulation, any law or regulation respecting financial institutions or insurance companies, or any law or regulation prohibiting mail or wire fraud or fraud in connection with any business entity; or
6. being subject of or party to any sanction or order, not subsequently reversed, suspended, or vacated, of any self-regulatory organization, any registered entity or any equivalent exchange, association, entity or organization that has disciplinary authority over its members or persons associated with a member.

Board of Directors and Corporate Governance

The Company expects that its Board of Directors will consist of four members. The Company's directors are elected at the annual meeting of shareholders to hold office until the annual meeting of shareholders for the ensuing year or until their successors have been duly elected and qualified.

Officers are elected annually by the Board of Directors and serve at the discretion of the Board.

Board Committees

The Board may appoint an audit committee, nominating committee and/or compensation committee, to adopt charters relative to each such committee and to formulate and adopt a code of ethics.

Board Independence

After review of all relevant transactions or relationships between each director and nominee for director, or any of his or her family members, and the Company, its senior management and its Independent Registered Public Accounting Firm, the Board of Directors has determined that all of the Company's directors and the Company's nominees for director are independent within the meaning of the applicable NASDAQ listing standards, except Mr. Mazur, the Chief Executive Officer, Chief Operating Officer, President and director of the Company. Although the Company is not currently NASDAQ-listed we believe it is in the Company's interests to comply with these standards both as a matter of good governance and to facilitate any future listing.

Section 16(a) Beneficial Ownership Reporting Compliance

Section 16(a) of the Exchange Act, requires the Company's directors and named executive officers, and persons who beneficially own more than ten percent of our common stock, to file initial reports of ownership and reports of changes in ownership of our common stock and our other equity securities with the SEC. As a practical matter, the Company assists its directors and officers by monitoring transactions and completing and filing Section 16 reports on their behalf. Based solely on a review of the copies of such forms in our possession and on written representations from reporting persons, we believe that during the year ended September 30, 2015 all of our named executive officers and directors filed the required reports on a timely basis under Section 16(a) of the Exchange Act.

ITEM 11. EXECUTIVE COMPENSATION

The following table sets forth information regarding compensation paid to our executive officers for the year ended September 30, 2015, the nine months ended September 30, 2014 and the year ended December 31, 2013. Trail One, Inc. did not pay any compensation to its Chief Executive Officer for its fiscal years ended September 30, 2014 and 2013.

Name & Position	Fiscal Year	Salary ($)	Bonus ($)	Option Awards ($)	All Other Compensation ($)	Total ($)
Leonard Mazur (1)	2015	250,000	0	420,710(3)	0	670,710
Chief Executive Officer	2014	20,833	0	470,185(3)	0	491,018
	2013	0	0	0	0	0
Reinier Beeuwkes (2)	2015	0	0	0	0	0
Chief Executive Officer	2014	0	0	0	0	0
	2013	0	0	0	0	0
Geoffrey E. Clark (2)	2015	0	0	0	0	0
Chief Medical Officer	2014	0	0	0	0	0
	2013	0	0	0	0	0

(1) Appointed as executive officer on September 12, 2014

(2) Resigned as executive officer and director on September 12, 2014

(3) On September 12, 2014, Leonard Mazur was granted options to purchase 3,300,000 shares of Common Stock at an exercise price of $0.45 per share that vest 1,300,000 shares on the grant date; 500,000 shares on September 12, 2015; 500,000 shares on March 12, 2016; 500,000 shares on September 12, 2016; and 500,000 shares on September 12, 2017. The dollar amount set forth in the table represents the dollar amount recognized for financial statement reporting purposes with respect to the fiscal year in accordance with FASB ASC Topic 718.

Outstanding Equity Awards at Fiscal Year-End

OUTSTANDING EQUITY AWARDS AT FISCAL YEAR-END

	OPTION AWARDS					STOCK AWARDS			
Name (a)	Number of Securities Underlying Unexercised Options (#) Exercisable (b)	Number of Securities Underlying Unexercised Options (#) Unexercisable (c)	Equity Incentive Plan Awards: Number of Securities Underlying Unexercised Unearned Options (#) (d)	Option Exercise Price ($) (e)	Option Expiration Date (f)	Number of Shares or Units of Stock That Have Not Vested (#) (g)	Market Value of Shares or Units of Stock That Have Not Vested ($) (h)	Equity Incentive Plan Awards: Number of Unearned Shares, Units or Other Rights That Have Not Vested (#) (i)	Equity Incentive Plan Awards: Market or Payout Value of Unearned Shares, Units or Other Rights That Have Not Vested (#) (j)
Leonard Mazur	1,800,000	–	1,500,000(1)	$ 0.45	9/12/24	–	–	–	–

(1) On September 12, 2014, Leonard Mazur was granted options to purchase 3,300,000 shares of Common Stock at an exercise price of $0.45 per share that vest 1,300,000 shares on the grant date; 500,000 shares on September 12, 2015; 500,000 shares on March 12, 2016; 500,000 shares on September 12, 2016; and 500,000 shares on September 12, 2017.

Employment Agreement with Leonard Mazur

Mr. Leonard Mazur, our Chief Executive Officer, and the Company entered into an employment agreement on September 12, 2014. Below are the material terms of his employment agreement:

- a term of three years beginning on September 12, 2014 and upon expiration, the agreement shall automatically renew for successive periods of one-year;
- an initial base salary of $250,000 per year;
- a $120,000 cash bonus if the Company is successful in raising $2,000,000 in equity financing during the term;
- a stock option grant dated September 12, 2014 to purchase 3,300,000 shares of common stock under the Company's 2014 Stock Incentive Plan at $0.45 per share vesting over a three-year term; and
- participation in any regular Company benefits, such as medical insurance plans, life insurance plans, disability income plans, retirement plans, vacation and other paid time off plans, in addition to reimbursement for ordinary and necessary business expenses.

The employment agreement provides that if Mr. Mazur is terminated by the Company without cause, or that if Mr. Mazur resigns for "Good Reason" (as defined in the agreement), the Company would continue to pay Mr. Mazur's salary and health insurance for a period of six months from the date of termination, and fully vest any options that would have vested at the next immediate vesting event following termination. In the event that Mr. Mazur was terminated as a result of a "Change of Control" (as defined in the agreement), he would be entitled to receive his salary and health insurance for a period of twelve months and any options would become fully vested. In the event that Mr. Mazur's employment was terminated for any other reason, there would be no continuation of salary or health insurance.

Director Compensation

No director of the Company received any compensation for services as a director during the year ended September 30, 2015 and the nine month period ended September 30, 2014.

On October 1 and October 8, 2015, the Company appointed Myron Holubiak and Suren Dutia, respectively to the Company's board of directors. Mr. Holubiak and Mr. Dutia each received an option to purchase 400,000 shares of the Company's common stock at an exercise price of $0.54 per share in consideration for their services as members of the Company's board of directors. The options were issued pursuant to the Company's 2014 Stock Incentive Plan.

Equity Compensation Plan Information

The following table provides information about the securities authorized for issuance under the Company's equity compensation plan as of September 30, 2015:

Plan category	Number of securities to be issued upon exercise of outstanding options, warrants and rights	Weighted average exercise price of outstanding options, warrants and rights	Number of securities remaining available for future issuance
	(a)	(b)	(c)
Equity compensation plans approved by security holders (1) Stock options	3,900,000	$ 0.47	9,100,000
Equity compensation plans not approved by security holders	-		-
Total	3,900,000	$ 0.47	9,100,000

(1) On September 12, 2014, the Board approved the Citius Pharmaceuticals, Inc. 2014 Stock Incentive Plan pursuant to which the Company may grant stock options, stock appreciation rights, restricted stock, restricted stock units, other stock-based awards and cash-based awards covering an aggregate of 13,000,000 shares of its Common Stock. On September 12, 2014, the Company received a written consent in lieu of a meeting from the holders of a majority of the Common Stock of the Company ratifying the Citius Pharmaceuticals, Inc. 2014 Stock Incentive Plan.

Adoption of Citius Pharmaceuticals, Inc. 2014 Stock Incentive Plan

On September 12, 2014, the Board approved the Citius Pharmaceuticals, Inc. 2014 Stock Incentive Plan (the "2014 Plan"). The purpose of the 2014 Plan is to promote the interests of the Company and its stockholders by providing (i) officers and employees, (ii) advisors, and (iii) non-employee directors with appropriate incentives and rewards.

The 2014 Plan provides for the granting of stock options, stock appreciation rights, restricted stock, restricted stock units, other stock-based awards and cash-based awards. The 2014 Plan also provides for the granting of performance stock awards so that the Board may use performance criteria in establishing specific targets to be attained as a condition to the grant or vesting of awards under the 2014 Plan.

The 2014 Plan provides for the grant of stock awards to employees, directors and consultants of the Company and its affiliates covering an aggregate of 13,000,000 shares of common stock, subject to adjustments in the event of certain changes to the Company's capitalization.

The common stock subject to the 2014 Plan may be unissued shares or reacquired shares, including shares purchased on the open market. If a stock award granted under the 2014 Plan is forfeited, expires or is canceled or settled without issuance of common stock it shall not count against the maximum number of shares that may be issued under the 2014 Plan.

The Board has broad discretion in making grants under the 2014 Plan and may make grants subject to such terms and conditions as determined by the Board or a duly appointed committee thereof. Grants under the 2014 Plan will be subject to the terms and conditions set forth in the document making the award, including, without limitation any applicable purchase price and provisions pursuant to which the grant may be forfeited.

The Board may terminate or amend the 2014 Plan at any time, except for certain actions that may not be taken without stockholder approval. The 2014 Plan is scheduled to terminate on September 12, 2024.

Risk Management

The Company does not believe risks arising from its compensation policies and practices for its employees are reasonably likely to have a material adverse effect on the Company.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The following table sets forth information known to us with respect to the beneficial ownership of Citius Pharmaceuticals, Inc. common stock as of December 1, 2015, unless otherwise noted, by:

- each stockholder known to own beneficially more than 5% of our common stock;
- each of our directors and executive officers; and
- all of our current directors and executive officers as a group.

Beneficial ownership is determined in accordance with the rules of the SEC and generally includes voting or dispositive power with respect to securities. Shares relating to options or warrants currently exercisable, or exercisable within 60 days of December 1, 2015, are deemed outstanding for computing the percentage of the person holding such securities but are not deemed outstanding for computing the percentage of any other person. Percentage of ownership is based on 34,701,220 shares of common stock outstanding on December 1, 2015. Except as indicated by footnote and subject to the community property laws where applicable, the persons or entities named in the tables have sole voting and investment power with respect to all shares shown as beneficially owned by them. Except as otherwise noted in the tables below, the address of each person or entity listed in the table is c/o Citius Pharmaceuticals, Inc. 63 Great Road, Maynard, MA 01754.

Name of Beneficial Owner	Number of Shares of Common Stock Beneficially Owned	Percentage of Shares of Common Stock Beneficially Owned
Geoffrey E. Clark (1)	7,960,283	22.94%
Reinier Beeuwkes (1)	8,013,959	23.09%
Lifestyle Healthcare LLC (2)	4,406,648	12.11%
Citius Special Purpose Fund (3)	4,907,410	13.21%
Nickolay Kukekov (4)	5,878,405	15.86%
Neeta Wadekar	2,500,000	7.20%
Leonard Mazur (5)	2,257,143	6.18%
Myron Holubiak (6)	70,000	0.20%
Suren Dutia (7)	70,000	0.20%
All executive officers and directors as a group	2,337,143	6.54%

(1) Executive officer and director resigned upon completion of the Reverse Acquisition on September 12, 2014.
(2) Includes 1,700,067 shares relating to warrants that are immediately exercisable.
(3) Includes 2,453,705 shares relating to warrants that are immediately exercisable.
(4) Includes the 540,422 shares beneficially owned by Chromium 24, LLC which is an affiliate of Nickolay Kukekov and Theodore Kalem, the 4,406,648 shares beneficially owned by Lifestyle Healthcare LLC, the 300,000 shares relating to immediately exercisable Placement Agent Share Warrants held by Mr. Kukekov, and 360,000 shares relating to immediately exercisable Placement Agent Unit Warrants held by Mr. Kukekov. Mr. Kukekov holds no equity interest in Lifestyle Healthcare LLC and he disclaims beneficial ownership to the securities of the entity.
(5) Executive officer and director. Includes 1,800,000 shares relating to options that are exercisable within 60 days of December 1, 2015.
(6) Director. Includes 40,000 shares relating to options that are exercisable within 60 days of December 1, 2015.
(7) Director. Includes 40,000 shares relating to options that are exercisable within 60 days of December 1, 2015.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

Citius's headquarters are located in the office space of Ischemix, LLC ("Ischemix"), a company majority-owned by Dr. Geoffrey Clark and Dr. Reinier Beeuwkes. Although Dr. Clark and Dr. Beeuwkes resigned as officers and directors of the Company effective as of September 12, 2014, the Company has an oral agreement with Ischemix to continue to maintain its headquarters in the office spare of Ischemix. The Company is not required to pay for use of the space.

As of September 30, 2015, the Company owes $70,386 to Ischemix LLC for expenses paid on the Company's behalf and services performed by Ischemix. Ischemix is owned by Reinier Beeuwkes and Geoffrey Clark who were both officers and directors, as well as principal stockholders of the Company. Reinier Beeuwkes and Geoffrey Clark have resigned as both officers and directors effective September 12, 2014.

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

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

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

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

Effective as of September 1, 2014, the Company entered into a consulting agreement (the "Consulting Agreement") with Neeta Wadekar, a stockholder of the Company. Pursuant to the terms of the Consulting Agreement, Mrs. Wadekar shall receive $4,000 per month and shall: (i) maintain and manage the Company's accounts including, but not limited to, accounts payable and accounts receivable, (ii) prepare bank reconciliations, (iii) assist with the preparation of quarterly and annual financial statements to be filed with the Securities and Exchange Commission (the "SEC") and (iv) assist with the preparation of filings required by the SEC including, but not limited to, registration statements, current reports and proxy statement. Consulting expenses pursuant to the Consulting Agreement for the nine months ended June 30, 2015 were $36,000.

Review, Approval or Ratification of Transactions with Related Parties

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

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

ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

Fees and Services

Audit Fees. The aggregate audit fees billed for professional services rendered by the independent registered public accounting firm, Wolf & Company, P.C. for the audit of our financial statements as of and for the year ended September 30, 2015, the nine months ended September 30, 2014, and the year ended December 31, 2013, our filings with the Securities and Exchange Commission and other audit fees were $61,500, $44,000 and $53,000, respectively.

Audit Related Fees. The aggregate audit related fees billed for professional services by the independent registered public accounting firm for the year ended September 30, 2015, the nine months ended September 30, 2014, and the year ended December 31, 2013 were $3,500, $9,000 and $0 and, respectively.

Tax Fees. The aggregate tax fees billed for professional services by the independent registered public accounting firm for the year ended September 30, 2015, the nine months ended September 30, 2014, and the year ended December 31, 2013 were $0, $0 and $0, respectively. Tax fees are for the preparation of federal and state income tax returns.

All Other Fees. No other fees were billed by or paid to the independent registered public accounting firm during the year ended September 30, 2015, the nine months ended September 30, 2014 or the year ended December 31, 2013.

Other than the services discussed above, Wolf & Company, P.C. has not rendered any non-audit related services.

At this time, we do not have a stand-alone Audit Committee. Until an independent director who also qualifies as an audit committee financial expert is elected to the Board of Directors, the full Board of Directors is serving the function of the Audit Committee.

For the year ended September 30, 2015, the full Board of Directors, functioning as the Audit Committee, approved the audit or non-audit services before the accounting firm was engaged to perform any such services. Management must obtain the specific prior approval of the Board of Directors for each engagement of the independent registered public accounting firm to perform any audit-related or other non-audit services. The Board of Directors does not delegate its responsibility to approve services performed by the independent registered public accounting firm to any member of management.

PART IV

ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES

All references to registrant's Forms 8-K, 10-K and 10-Q include reference to File No. 333-170781

2.1	Share Exchange and Reorganization Agreement, dated as of September 12, 2014 among the Company, Citius Pharmaceuticals, LLC, and the beneficial holders of the membership interests of Citius identified in the Agreement(1)
3.1	Amended and Restated Articles of Incorporation of the Company(1)
3.2	Bylaws of the Company (Incorporated by reference to Exhibit 3.2 to Registration Statement on Form S-1 as filed November 23, 2010)
10.1	Form of Subscription Agreement(1)
10.2	Form of Registration Rights Agreement(1)
10.3	Form of Investor Warrant(1)
10.4	Employment Agreement by and between the Company and Leonard Mazar dated September 12, 2014(2)
10.5	Amended and Coordination Agreement dated November 15, 2011 by and between Prenzamax LLC, Akrimax Pharmaceuticals, LLC ("Akrimax"), Citius Pharmaceuticals LLC and Alpex Pharma S.A. (3)
10.6	Collaboration and License Agreement dated June 12, 2008 by and between Citius Pharmaceuticals, LLC and Alpex Pharma S.A. (3)
10.7	Consultant Services Agreement dated September 1, 2014 by and between Neeta Wadekar and the Company (3)
10.8	Exclusive License Agreement dated November 15, 2011 by and between Prenzamax, LLC and Citius Pharmaceuticals (3)
10.9	Product Development and Pilot Lot Manufacturing Proposal Version 01 by and between the Company and IGI, Inc. dated July 21, 2010 (3)
10.10	Supply Agreement dated November 15, 2011 by and between Prenzamax, LLC and Alpex Pharma S.A. (3)
10.11	Technical and Quality Agreement dated November 15, 2011 by and among Citius Pharmaceuticals LLC, Alpex Pharma S.A. and Akrimax Pharmaceuticals, LLC. (3)
16	Letter from M&K CPAs, PLLC(1)
21	Subsidiaries*
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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(1) Incorporated by Reference to the Current Report on form 8-K filed by the Company on September 18, 2014.

(2) Incorporated by Reference to the Company's Annual Report on Form 10-K filed by the Company on December 29, 2014.

(3) Incorporated by Reference to the Company's Registration Statement on Form S-1 (Reg. No. 333-206903).

* 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: December 14, 2015

By: */s/ Leonard Mazur*
Leonard Mazur
Chief Executive Officer
(Principal Executive Officer, Principal Financial Officer and
Principal Accounting Officer)

In accordance with the Exchange Act, this Report has been signed below by the following persons on behalf of the Registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ Leonard Mazur Leonard Mazur	Chief Executive Officer and Director	December 14, 2015
/s/ Myron Holubiak Myron Holubiak	Director	December 14, 2015
/s/ Suren Dutia Suren Dutia	Director	December 14, 2015

EXHIBIT 21

Listing of Subsidiaries

Name of Subsidiary	Jurisdiction of Incorporation
Citius Pharmaceuticals, LLC	Massachusetts

EXHIBIT 31.1

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

I, Leonard Mazur, certify that:

1. I have reviewed this report on Form 10-K 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.

December 14, 2015

By */s/ Leonard Mazur*
Leonard Mazur
Chief Executive Officer
(Principal Executive Officer, Principal Financial
Officer and Principal Accounting 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 Annual Report of Citius Pharmaceuticals, Inc. (the "Company") on Form 10-K for the year ended September 30, 2015 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Leonard Mazur, 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: December 14, 2015

By: */s/ Leonard Mazur*
Leonard Mazur
Chief Executive Officer
(Principal Executive Officer, Principal Financial
Officer and Principal Accounting Officer)