ELITE PHARMACEUTICALS INC /NV/
Form 10-Q
February 09, 2018

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-Q

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

FOR THE QUARTERLY PERIOD ENDED DECEMBER 31, 2017

OR

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

FOR THE TRANSITION PERIOD FROM _____ TO _____

COMMISSION FILE NUMBER: 001-15697

ELITE PHARMACEUTICALS, INC.
(Exact Name of Registrant as Specified in Its Charter)

NEVADA	**22-3542636**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

165 LUDLOW AVENUE
NORTHVALE, NEW JERSEY **07647**
(Address of principal executive offices) (Zip Code)

(201) 750-2646
(Registrant's telephone number, including area code)

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

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

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

Large accelerated filer ¨	Accelerated filer	x
Non-accelerated filer ¨	Smaller reporting company	¨
	Emerging growth company	¨

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ¨

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

Indicate the number of shares outstanding of each of the issuer's classes of common stock, as of the latest practicable date: 791,516,926 shares of common stock were issued and outstanding as of February 2, 2018.

PART 1 – FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

ELITE PHARMACEUTICALS, INC. AND SUBSIDIARY

CONDENSED CONSOLIDATED BALANCE SHEETS

	December 31, 2017 (Unaudited)	March 31, 2017 (Audited)
ASSETS		
Current assets:		
Cash	$7,244,388	$10,594,693
Accounts receivable, net of allowance for doubtful accounts of $-0-, respectively	1,161,240	934,059
Inventory	5,298,943	6,415,966
Prepaid expenses and other current assets	1,059,396	468,002
Total current assets	14,763,967	18,412,720
Property and equipment, net of accumulated depreciation of $8,122,878 and $7,426,752, respectively	9,132,998	9,039,404
Intangible assets, net of accumulated amortization of $-0-, respectively	7,704,609	6,419,091
Other assets:		
Restricted cash - debt service for NJEDA bonds	390,654	389,081
Security deposits	81,932	50,846
Total other assets	472,586	439,927
Total assets	$32,074,160	$34,311,142
LIABILITIES, MEZZANINE EQUITY AND SHAREHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$1,444,178	$1,049,815
Accrued expenses	1,785,603	794,628
Deferred revenue, current portion	1,013,333	1,013,333
Bonds payable, current portion, net of bond issuance costs	75,822	70,822
Loans payable, current portion	424,160	416,148
Total current liabilities	4,743,096	3,344,746

Long-term liabilities:		
Deferred revenue, net of current portion	1,505,557	2,265,557
Bonds payable, net of current portion and bond issuance costs	1,504,589	1,583,956
Senior secured promissory note - related party	1,200,000	-
Loans payable, net current portion	636,701	577,612
Derivative financial instruments - warrants	2,550,254	843,464
Other long-term liabilities	39,587	31,770
Total long-term liabilities	7,436,688	5,302,359
Total liabilities	12,179,784	8,647,105
Mezzanine equity		
Series J convertible preferred stock; par value $0.01; 50 shares authorized, 24.0344 issued and outstanding as of December 31, 2017; 0 shares authorized, 0 issued and outstanding as of March 31, 2017	13,903,957	-
Shareholders' equity:		
Common stock; par value $0.001; 995,000,000 shares authorized; 788,801,827 shares issued and 788,701,827 outstanding as of December 31, 2017; 928,031,448 shares issued and 927,931,448 outstanding as of March 31, 2017	788,804	928,034
Additional paid-in capital	145,205,780	163,896,410
Treasury stock; 100,000 shares as of December 31, 2017 and March 31, 2017; at cost	(306,841)	(306,841)
Accumulated deficit	(139,697,324)	(138,853,566)
Total shareholders' equity	5,990,419	25,664,037
Total liabilities, mezzanine equity and shareholders' equity	$32,074,160	$34,311,142

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

ELITE PHARMACEUTICALS, INC. AND SUBSIDIARY

CONSOLIDATED STATEMENTS OF OPERATIONS

(UNAUDITED)

	For the Three Months Ended December 31,		For the Nine Months Ended December 31,	
	2017	2016	2017	2016
Manufacturing fees	$ 2,083,826	$ 1,885,765	$ 4,160,949	$ 6,470,697
Licensing fees	451,628	444,884	1,700,856	1,816,796
Total revenue	2,535,454	2,330,649	5,861,805	8,287,493
Cost of revenue	1,419,829	1,726,751	3,049,830	5,755,997
Gross profit	1,115,625	603,898	2,811,975	2,531,496
Operating expenses:				
Research and development	2,514,435	1,526,183	6,944,182	4,312,337
General and administrative	614,994	694,321	2,068,028	2,060,380
Non-cash compensation through issuance of stock options	37,961	84,785	208,719	258,954
Depreciation and amortization	7,196	21,032	21,149	64,408
Total operating expenses	3,174,586	2,326,321	9,242,078	6,696,079
Loss from operations	(2,058,961)	(1,722,423)	(6,430,103)	(4,164,583)
Other income (expense):				
Interest expense and amortization of debt issuance costs	(92,458)	(55,563)	(245,730)	(181,883)
Change in fair value of derivative instruments	605,448	1,571,471	4,767,884	9,468,320
Interest income	4,461	3,151	12,862	9,407
Other income (expense), net	517,451	1,519,059	4,535,016	9,295,844
Income (loss) from operations before income tax provision	(1,541,510)	(203,364)	(1,895,087)	5,131,261
Benefit from sale of state net operating loss credits	1,051,329	1,870,114	1,051,329	1,870,114
Net income (loss)	(490,181)	1,666,750	(843,758)	7,001,375
Change in carrying value of convertible preferred share mezzanine equity	-	-	-	20,714,286

Net income (loss) attributable to common shareholders'	$ (490,181)	$ 1,666,750	$ (843,758)	$ 27,715,661
Basic income (loss) per share attributable to common shareholders'	$ (0.00)	$ 0.00	$ (0.00)	$ 0.03
Diluted income (loss) per share attributable to common shareholders'	$ (0.00)	$ 0.00	$ (0.01)	$ (0.00)
Basic weighted average common shares outstanding	788,442,363	904,763,177	796,647,284	811,794,206
Diluted weighted average common shares outstanding	795,122,364	910,505,291	803,327,285	817,536,320

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

ELITE PHARMACEUTICALS, INC. AND SUBSIDIARY

CONSOLIDATED STATEMENTS OF SHAREHOLDERS' EQUITY

(UNAUDITED)

	Common Stock		Additional	Treasury Stock		Accumulated	Total Shareholders'
	Shares	Amount	Paid-In Capital	Shares	Amount	Deficit	Equity
Balance at March 31, 2017	928,031,448	$928,034	$163,896,410	100,000	$(306,841)	$(138,853,566)	$25,664,037
Net loss						(843,758)	(843,758)
Issuance of common shares pursuant to the exercise of cash warrants	2,910,532	2,910	178,998				181,908
Common shares issued as initial commitment shares pursuant to the Lincoln Park purchase agreement	5,540,551	5,541	914,191				919,732
Common shares issued as additional commitment shares pursuant to the Lincoln Park purchase agreement	167,336	167	22,755				22,922
Common shares sold pursuant to the Lincoln Park	10,169,281	10,169	1,197,931				1,208,100

purchase agreement							
Costs associated with raising capital			(992,610)				(992,610)
Non-cash compensation through the issuance of employee stock options			208,719				208,719
Retirement of common shares pursuant to the issuance of Series J convertible preferred shares	(158,017,321)	(158,017)	(20,220,614)				(20,378,631)
Balance at December 31, 2017	788,801,827	$788,804	$145,205,780	100,000	$(306,841)	$(139,697,324)	$5,990,419

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

ELITE PHARMACEUTICALS, INC. AND SUBSIDIARY

CONSOLIDATED STATEMENTS OF CASH FLOWS

(UNAUDITED)

	For the Nine Months Ended December 31,	
	2017	2016
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net (loss) income	$ (843,758)	$ 7,001,375
Adjustments to reconcile net (loss) income to net cash used in operating activities:		
Depreciation and amortization	706,759	504,932
Change in fair value of derivative financial instruments - warrants	(4,767,884)	(9,468,320)
Non-cash compensation accrued	925,000	1,232,950
Non-cash compensation from the issuance of common stock and options	208,719	272,705
Non-cash rent expense and lease accretion	7,820	(18,250)
Change in operating assets and liabilities:		
Accounts receivable	(227,181)	985,619
Inventory	1,117,023	(2,735,085)
Prepaid expenses and other current assets	(622,480)	(388,915)
Accounts payable, accrued expenses and other current liabilities	460,338	(434,885)
Deferred revenue and customer deposits	(760,000)	(759,997)
Net cash used in operating activities	(3,795,644)	(3,807,871)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of property and equipment	(291,115)	(804,762)
Intellectual property costs	(85,518)	(7,292)
Restricted cash	(1,573)	-
Net cash used in investing activities	(378,206)	(812,054)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from the issuance of stock	1,208,100	5,770,163
Proceeds from cash warrant and options exercises	181,908	1,856,480
Proceeds and repayments of line of credit, related party - net	-	(718,309)
Payment of bond principal	(85,000)	(209,366)
Other loan payments	(431,507)	(290,189)
Costs associated with raising capital	(49,956)	(17,671)
Net cash provided by financing activities	823,545	6,391,108
Net change in cash	(3,350,305)	1,771,183
Cash, beginning of period	10,594,693	11,512,179

Cash, end of period	$ 7,244,388	$ 13,283,362
Supplemental disclosure of cash and non-cash transactions:		
Cash paid for interest	$ 67,573	$ 142,351
Financing of equipment purchases and insurance renewal	$ 498,604	$ 308,834
Issuance of Senior Secured Promissory Note pursuant ANDA asset acquisition	$ 1,200,000	$ -
Commitment shares issued to Lincoln Park Capital	$ 942,654	$ 69,425
Change in carrying value of convertible preferred mezzanine equity	$ -	$ 20,714,286
Conversion of Series I convertible preferred shares into common shares	$ -	$ 23,571,429
Retirement of common shares pursuant to the issuance of Series J convertible preferred shares	$ 20,378,631	$ -

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

NOTE 1. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Overview

Elite Pharmaceuticals, Inc. (the "Company" or "Elite") was incorporated on October 1, 1997 under the laws of the State of Delaware, and its wholly-owned subsidiary Elite Laboratories, Inc. ("Elite Labs") which was incorporated on August 23, 1990 under the laws of the State of Delaware. On January 5, 2012, Elite Pharmaceuticals was reincorporated under the laws of the State of Nevada. Elite Labs engages primarily in researching, developing and licensing proprietary orally administered, controlled-release drug delivery systems and products with abuse deterrent capabilities and the manufacture of generic, oral dose pharmaceuticals. The Company is equipped to manufacture controlled-release products on a contract basis for third parties and itself, if and when the products are approved. These products include drugs that cover therapeutic areas for pain, allergy, bariatric and infection. Research and development activities are done so with an objective of developing products that will secure marketing approvals from the United States Food and Drug Administration ("FDA"), and thereafter, commercially exploiting such products.

Principles of Consolidation

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with generally accepted accounting principles in the United States ("GAAP") and in conformity with the instructions on Form 10-Q and Rule 8-03 of Regulation S-X and the related rules and regulations of the Securities and Exchange Commission ("SEC"). The unaudited condensed consolidated financial statements include the accounts of the Company and its wholly-owned subsidiary, Elite Laboratories, Inc. All significant intercompany accounts and transactions have been eliminated in consolidation. The unaudited condensed consolidated financial statements reflect all adjustments, consisting of normal recurring accruals, which are, in the opinion of management, necessary for a fair presentation of such statements. The results of operations for the three and nine months ended December 31, 2017 are not necessarily indicative of the results that may be expected for the entire year.

Going Concern

In connection with the preparation of the financial statements as of and for the nine month period ended December 31, 2017, the Company conducted an evaluation as to whether there were conditions and events, considered in the aggregate, which raised substantial doubt as to the entity's ability to continue as a going concern within one year after the date of the issuance, or the date the financial statements were available for issuance, noting that there did not appear to be evidence of substantial doubt of the entity's ability to continue as a going concern.

Segment Information

Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") Topic 280, *Segment Reporting*, establishes standards for reporting information about operating segments. Operating segments are defined as components of an enterprise about which separate financial information is available that is evaluated regularly by the chief operating decision maker, or decision-making group, in deciding how to allocate resources and in assessing performance. The Company's chief operating decision maker is the Chief Executive Officer, who reviews the financial performance and the results of operations of the segments prepared in accordance with GAAP when making decisions about allocating resources and assessing performance of the Company.

The Company has determined that its reportable segments are products whose marketing approvals were secured via an Abbreviated New Drug Applications ("ANDA") and products whose marketing approvals were secured via a New Drug Application ("NDA"). ANDA products are referred to as generic pharmaceuticals and NDA products are referred to as branded pharmaceuticals.

There are currently no intersegment revenues. Asset information by operating segment is not presented below since the chief operating decision maker does not review this information by segment. The reporting segments follow the same accounting policies used in the preparation of the Company's condensed unaudited consolidated financial statements.

Revenue Recognition

The Company enters into licensing, manufacturing and development agreements, which may include multiple revenue generating activities, including, without limitation, milestones, licensing fees, product sales and services. These multiple elements are assessed in accordance with ASC 605-25, *Revenue Recognition – Multiple-Element Arrangements* in order to determine whether particular components of the arrangement represent separate units of accounting.

An arrangement component is considered to be a separate unit of accounting if the deliverable relating to the component has value to the customer on a standalone basis, and if the arrangement includes a general right of return relative to the delivered item, delivery or performance of the undelivered item is considered probable and substantially in control of the Company.

The Company recognizes payments received pursuant to a multiple revenue agreement as revenue, only if the related delivered item(s) have stand-alone value, with the arrangement being accordingly accounted for as a separate unit of accounting. If such delivered item(s) are considered to either not have stand-alone value, the arrangement is accounted for as a single unit of accounting, and the payments received are recognized as revenue over the estimated period of when performance obligations relating to the item(s) will be performed.

Whenever the Company determines that an arrangement should be accounted for as a single unit of accounting, it determines the period over which the performance obligations will be performed, and revenue will be recognized. If it cannot reasonably estimate the timing and the level of effort to complete its performance obligations under a multiple-element arrangement, revenues are then recognized on a straight-line basis over the period encompassing the expected completion of such obligations, with such period being reassessed at each subsequent reporting period.

Arrangement consideration is allocated at the inception of the arrangement to all deliverables on the basis of their relative selling price (the relative selling price method). When applying the relative selling price method, the selling price of each deliverable is determined using vendor-specific objective evidence of selling price, if such exists; otherwise, third-party evidence of selling price. If neither vendor-specific objective evidence nor third-party evidence of selling price exists for a deliverable, the Company uses its best estimate of the selling price for that deliverable when applying the relative selling price method. In deciding whether we can determine vendor-specific objective evidence or third-party evidence of selling price, the Company does not ignore information that is reasonably available without undue cost and effort.

When determining the selling price for significant deliverables under a multiple-element revenue arrangement, the Company considers any or all of the following, without limitation, depending on information available or information that could be reasonably available without undue cost and effort: vendor-specific objective evidence, third party evidence or best estimate of selling price. More specifically, factors considered can include, without limitation and as appropriate: size of market for a specific product; number of suppliers and other competitive market factors; forecast market shares and gross profits; barriers/time frames to market entry/launch; intellectual property rights and protections; exclusive or non-exclusive arrangements; costs of similar/identical deliverables from third parties; contractual terms, including, without limitation, length of contract, renewal rights, commercial terms, and profit allocations; and other commercial, financial, tangible and intangible factors that may be relevant in the valuation of a specific deliverable.

Milestone payments are accounted for in accordance with ASC 605-28, *Revenue Recognition – Milestone Method* for any deliverables or units of accounting under which the Company must achieve a defined performance obligation which is contingent upon future events or circumstances that are uncertain as of the inception of the arrangement providing for such future milestone payment. Determination of the substantiveness of a milestone is a matter of subjective assessment performed at the inception of the arrangement, and with consideration earned from the achievement of a milestone meeting all of the following:

- It must be either commensurate with the Company's performance in achieving the milestone or the enhancement of the value of the delivered item(s) as a result of a specific outcome resulting from the Company's performance to achieve the milestone; and,
- It relates solely to past performance; and,
- It is reasonable relative to all of the deliverables and payment terms (including other potential milestone consideration) within the arrangement.

Collaborative Arrangements

Contracts are considered to be collaborative arrangements when they satisfy the following criteria defined in ASC 808, *Collaborative Arrangements*:

- The parties to the contract must actively participate in the joint operating activity; and,
- The joint operating activity must expose the parties to the possibility of significant risk and rewards, based on whether or not the activity is successful.

The Company entered into a sales and distribution licensing agreement with Epic Pharma LLC, dated June 4, 2015 (the "2015 Epic License Agreement"), which has been determined to satisfy the criteria for consideration as a collaborative agreement, and is accounted for accordingly, in accordance with GAAP.

The Company entered into a Master Development and License Agreement with SunGen Pharma LLC dated August 24, 2016 (the "SunGen Agreement"), which has been determined to satisfy the criteria for consideration as a collaborative agreement, and is accounted for accordingly, in accordance with GAAP.

Cash

The Company considers all highly liquid investments with an original maturity of three months or less to be cash equivalents. Cash and cash equivalents consist of cash on deposit with banks and money market instruments. The Company places its cash and cash equivalents with high-quality, U.S. financial institutions and, to date has not experienced losses on any of its balances.

Restricted Cash

As of December 31, 2017, and March 31, 2017, the Company had $390,654 and $389,081, respectively, of restricted cash, related to debt service reserve in regard to the New Jersey Economic Development Authority ("NJEDA") bonds (see Note 6).

Accounts Receivable

Accounts receivable are comprised of balances due from customers, net of estimated allowances for uncollectible accounts. In determining collectability, historical trends are evaluated, and specific customer issues are reviewed on a periodic basis to arrive at appropriate allowances.

Inventory

Inventory is recorded at the lower of cost or market on a first-in first-out basis.

Long-Lived Assets

The Company periodically evaluates the fair value of long-lived assets, which include property and equipment and intangibles, whenever events or changes in circumstances indicate that its carrying amounts may not be recoverable.

Property and equipment are stated at cost. Depreciation is provided on the straight-line method based on the estimated useful lives of the respective assets which range from three to forty years. Major repairs or improvements are capitalized. Minor replacements and maintenance and repairs which do not improve or extend asset lives are expensed currently.

Upon retirement or other disposition of assets, the cost and related accumulated depreciation are removed from the accounts and the resulting gain or loss, if any, is recognized in income.

Intangible Assets

The Company capitalizes certain costs to acquire intangible assets; if such assets are determined to have a finite useful life they are amortized on a straight-line basis over the estimated useful life. Costs to acquire indefinite lived intangible assets, such as costs related to ANDAs are capitalized accordingly.

The Company tests its intangible assets for impairment at least annually (as of March 31st) and whenever events or circumstances change that indicate impairment may have occurred. A significant amount of judgment is involved in determining if an indicator of impairment has occurred. Such indicators may include, among others and without limitation: a significant decline in the Company’s expected future cash flows; a sustained, significant decline in the Company’s stock price and market capitalization; a significant adverse change in legal factors or in the business climate of the Company’s segments; unanticipated competition; and slower growth rates.

As of December 31, 2017, the Company did not identify any indicators of impairment.

Research and Development

Research and development expenditures are charged to expense as incurred.

Contingencies

Occasionally, the Company may be involved in claims and legal proceedings arising from the ordinary course of its business. The Company records a provision for a liability when it believes that it is both probable that a liability has been incurred, and the amount can be reasonably estimated. If these estimates and assumptions change or prove to be incorrect, it could have a material impact on the Company's condensed consolidated financial statements. Contingencies are inherently unpredictable and the assessments of the value can involve a series of complex judgments about future events and can rely heavily on estimates and assumptions.

Income Taxes

Income taxes are accounted for under the asset and liability method. Deferred income tax assets and liabilities are determined based on differences between financial reporting and tax bases of assets and liabilities, and net operating loss and other tax credit carry-forwards. These items are measured using the enacted tax rates and laws that will be in effect when the differences are expected to reverse. The Company records a valuation allowance to reduce the deferred income tax assets to the amount that is more likely than not to be realized.

Warrants and Preferred Shares

The accounting treatment of warrants and preferred share series issued is determined pursuant to the guidance provided by ASC 470, *Debt*, ASC 480, *Distinguishing Liabilities from Equity*, and ASC 815, *Derivatives and Hedging*, as applicable. Each feature of a freestanding financial instruments including, without limitation, any rights relating to subsequent dilutive issuances, dividend issuances, equity sales, rights offerings, forced conversions, optional redemptions, automatic monthly conversions, dividends and exercise are assessed with determinations made regarding the proper classification in the Company's financial statements.

Stock-Based Compensation

The Company accounts for stock-based compensation in accordance with ASC Topic 718, *Compensation-Stock Compensation*. Under the fair value recognition provisions of this topic, stock-based compensation cost is measured at the grant date based on the fair value of the award and is recognized as an expense on a straight-line basis over the requisite service period, based on the terms of the awards. The cost of the stock-based payments to nonemployees that are fully vested and non-forfeitable as at the grant date is measured and recognized at that date, unless there is a

contractual term for services in which case such compensation would be amortized over the contractual term.

In accordance with the Company's Director compensation policy and certain employment contracts, director's fees and a portion of employee's salaries are to be paid via the issuance of shares of the Company's common stock, in lieu of cash, with the valuation of such share being calculated on a quarterly basis and equal to the average closing price of the Company's common stock.

Earnings (Loss) Per Share Applicable to Common Shareholders'

The Company follows ASC 260, *Earnings Per Share*, which requires presentation of basic and diluted earnings (loss) per share ("EPS") on the face of the income statement for all entities with complex capital structures and requires a reconciliation of the numerator and denominator of the basic EPS computation to the numerator and denominator of the diluted EPS computation. In the accompanying financial statements, basic earnings (loss) per share is computed by dividing net income (loss) by the weighted average number of shares of common stock outstanding during the period. Diluted EPS excluded all dilutive potential shares if their effect was anti-dilutive.

The following is the computation of earnings (loss) per share applicable to common shareholders for the periods indicated:

	For the Three Months Ended December 31,		For the Nine Months Ended December 31,	
	2017	2016	2017	2016
Numerator				
Net income (loss) attributable to common shareholders - basic	$(490,181)	$1,666,750	$(843,758)	$27,715,661
Effect of dilutive instrument on net income (loss)	(605,448)	(1,571,471)	(4,767,884)	(30,182,606)
Net income (loss) attributable to common shareholders - diluted	$(1,095,629)	$95,279	$(5,611,642)	$(2,466,945)
Denominator				
Weighted average shares of common stock outstanding - basic	788,442,363	904,763,177	796,647,284	811,794,206
Dilutive effect of stock options, warrants and convertible securities	6,680,001	5,742,114	6,680,001	5,742,114
Weighted average shares of common stock outstanding - diluted	795,122,364	910,505,291	803,327,285	817,536,320
Net income (loss) per share				
Basic	$(0.00)	$0.00	$(0.00)	$0.03

Diluted	$(0.00)	$0.00	$(0.01)	$(0.00)

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Fair Value of Financial Instruments

ASC Topic 820, *Fair Value Measurements and Disclosures* ("ASC Topic 820") provides a framework for measuring fair value in accordance with generally accepted accounting principles.

ASC Topic 820 defines fair value as the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. ASC Topic 820 establishes a fair value hierarchy that distinguishes between (1) market participant assumptions developed based on market data obtained from independent sources (observable inputs) and (2) an entity's own assumptions about market participant assumptions developed based on the best information available in the circumstances (unobservable inputs).

The fair value hierarchy consists of three broad levels, which gives the highest priority to unadjusted quoted prices in active markets for identical assets or liabilities (Level 1) and the lowest priority to unobservable inputs (Level 3). The three levels of the fair value hierarchy under ASC Topic 820 are described as follows:

- Level 1 – Unadjusted quoted prices in active markets for identical assets or liabilities that are accessible at the measurement date.
- Level 2 – Inputs other than quoted prices included within Level 1 that are observable for the asset or liability, either directly or indirectly. Level 2 inputs include quoted prices for similar assets or liabilities in active markets; quoted prices for identical or similar assets or liabilities in markets that are not active; inputs other than quoted prices that are observable for the asset or liability; and inputs that are derived principally from or corroborated by observable market data by correlation or other means.
- Level 3 – Inputs that are unobservable for the asset or liability.

Measured on a Recurring Basis

The following table presents information about our liabilities measured at fair value on a recurring basis, aggregated by the level in the fair value hierarchy within which those measurements fell:

		Fair Value Measurement Using		
	Amount at Fair Value	Level 1	Level 2	Level 3

December 31, 2017				
Liabilities				
Derivative financial instruments - warrants	$ 2,550,254	$-	$ -	$2,550,254
March 31, 2017				
Liabilities				
Derivative financial instruments - warrants	$ 843,464	$-	$ -	$843,464

See Note 12 for specific inputs used in determining fair value.

The carrying amounts of the Company’s financial assets and liabilities, such as cash, accounts receivable, prepaid expenses and other current assets, accounts payable and accrued expenses, approximate their fair values because of the short maturity of these instruments.

Non-Financial Assets that are Measured at Fair Value on a Non-Recurring Basis

Non-financial assets such as intangible assets, and property and equipment are measured at fair value only when an impairment loss is recognized. The Company did not record an impairment charge related to these assets in the periods presented.

Treasury Stock

The Company records treasury stock at the cost to acquire it and includes treasury stock as a component of shareholders' equity.

Recently Adopted Accounting Pronouncements

In January 2017, the Financial Accounting Standards Board ("FASB") issued Accounting Standard Update ("ASU") 2017-01, *Business Combinations: Clarifying the Definition of a Business*, which amends the current definition of a business. Under ASU 2017-01, to be considered a business, an acquisition would have to include an input and a substantive process that together significantly contributes to the ability to create outputs. ASU 2017-01 further states that when substantially all of the fair value of gross assets acquired is concentrated in a single asset (or a group of similar assets), the assets acquired would not represent a business. The new guidance also narrows the definition of the term "outputs" to be consistent with how it is described in Topic 606, *Revenue from Contracts with Customers*. The changes to the definition of a business will likely result in more acquisitions being accounted for as asset acquisitions. The guidance is effective for the annual period beginning after December 15, 2017, with early adoption permitted. The Company has elected to early adopt ASU 2017-01 and to apply it to any transaction, which occurred prior to the issuance date that has not been reported in financial statements that have been issued or made available for issuance.

Recently Issued Accounting Pronouncements

In May 2014, the FASB issued ASU 2014-09, *Revenue from Contracts with Customers (Topic 606)*. The core principle of ASU 2014-09 is that an entity should recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods and services. This standard is effective for fiscal years and interim reporting periods beginning after December 15, 2016. In August 2015, the FASB issued ASU 2015-14, Revenue *from Contracts with Customers (Topic 606): Deferral of the Effective Date.* The amendments in this update deferred the effective date for implementation of ASU 2014-09 by one year and is now effective for annual reporting periods beginning after December 15, 2017. Early application is permitted only as of annual reporting periods beginning after December 15, 2016 including interim reporting periods within that period. Topic 606 is effective for the Company in the first quarter of Fiscal 2019. The Company is currently evaluating the new revenue recognition guidance. The Company has completed its initial impact assessment and has commenced an in-depth evaluation of the adoption impact, which involves review of selected revenue arrangements. Based on the Company's preliminary review, the Company believes that the timing and measurement of revenue for its customers will be similar to the Company's current revenue recognition. However, this view is preliminary and could change based on further analysis associated with the conversion and implementation phases of our ASU 2014-09 project.

From March 2016 through September 2017, the FASB issued ASU 2016-08, *Revenue from Contracts with Customers (Topic 606): Principal versus Agent Considerations (Reporting Revenue Gross versus Net),* ASU 2016-10, *Revenue from Contracts with Customers (Topic 606): Identifying Performance Obligations and Licensing,* ASU 2016-11, *Revenue Recognition (Topic 605) and Derivatives and Hedging (Topic 815): Rescission of SEC Guidance Because of Accounting Standards Updates 2014-09 and 2014-16 Pursuant to Staff Announcements at the March 3, 2016 EITF Meeting,* ASU No. 2016-12, *Revenue from Contracts with Customers (Topic 606):Narrow-Scope Improvements and Practical Expedients*, ASU No. 2016-20, *Technical Corrections and Improvements to Topic 606, Revenue from Contracts with Customers* and ASU No. 2017-13, *Revenue Recognition (Topic 605), Revenue from Contracts with Customers (Topic 606), Leases (Topic 840), and Leases (Topic 842): Amendments to SEC Paragraphs Pursuant to the Staff Announcement at the July 20, 2017 EITF Meeting and Rescission of Prior SEC Staff Announcements and Observer Comments.* These amendments are intended to improve and clarify the implementation guidance of Topic 606. The effective date and transition requirements for the amendments are the same as the effective date and transition requirements of ASU No. 2014-09 and ASU No. 2015-14.

In February 2016, the FASB issued ASU No. 2016-02, *Leases (Topic 842)*, which is effective for public entities for annual reporting periods beginning after December 15, 2018. Under ASU 2016-02, lessees will be required to recognize the following for all leases (with the exception of short-term leases) at the commencement date: 1) a lease liability, which is a lessee's obligation to make lease payments arising from a lease, measured on a discounted basis, and 2) a right-of-use asset, which is an asset that represents the lessee's right to use, or control the use of, a specified asset for the lease term. The Company is currently evaluating the effects of ASU 2016-02 on its unaudited condensed financial statements.

In August 2016, the FASB issued ASU 2016-15, *Statement of Cash Flows (Topic 230) Classification of Certain Cash Receipts and Cash Payments*. ASU 2016-15 eliminates the diversity in practice related to the classification of certain cash receipts and payments for debt prepayment or extinguishment costs, the maturing of a zero-coupon bond, the settlement of contingent liabilities arising from a business combination, proceeds from insurance settlements, distributions from certain equity method investees and beneficial interests obtained in a financial asset securitization. ASU 2016-15 designates the appropriate cash flow classification, including requirements to allocate certain components of these cash receipts and payments among operating, investing and financing activities. The guidance is effective for the Company beginning after December 15, 2017, although early adoption is permitted. The Company is currently evaluating the effects of ASU 2016-15 on its unaudited condensed consolidated financial statements.

In November 2016, the FASB issued ASU No. 2016-18, *Statement of Cash Flows (Topic 230) Restricted Cash a consensus of the FASB Emerging Issues Task Force*. ASU 2016-18 requires restricted cash and cash equivalents to be included with cash and cash equivalents on the statement cash flows. The new standard is expected to be effective for fiscal years, and interim periods within those years, beginning after December 15, 2017, with early adoption permitted. The Company is currently evaluating the effects of ASU 2016-18 on its unaudited condensed consolidated financial statements.

In July 2017, the FASB issued ASU 2017-11, *Earnings Per Share (Topic 260), Distinguishing Liabilities from Equity (Topic 480) and Derivatives and Hedging (Topic 815): I. Accounting for Certain Financial Instruments with Down Round Features; II. Replacement of the Indefinite Deferral for Mandatorily Redeemable Financial Instruments of Certain Nonpublic Entities and Certain Mandatorily Redeemable Noncontrolling Interests with a Scope Exception*. Part I of this update addresses the complexity of accounting for certain financial instruments with down round features. Down round features are features of certain equity-linked instruments (or embedded features) that result in the strike price being reduced on the basis of the pricing of future equity offerings. Current accounting guidance creates cost and complexity for entities that issue financial instruments (such as warrants and convertible instruments) with down round features that require fair value measurement of the entire instrument or conversion option. Part II of this update addresses the difficulty of navigating *Topic 480, Distinguishing Liabilities from Equity*, because of the existence of extensive pending content in the FASB Accounting Standards Codification. This pending content is the result of the indefinite deferral of accounting requirements about mandatorily redeemable financial instruments of certain nonpublic entities and certain mandatorily redeemable noncontrolling interests. The amendments in Part II of this update do not have an accounting effect. This ASU is effective for fiscal years, and interim periods within those years, beginning after December 15, 2018. The Company is currently assessing the potential impact of adopting ASU 2017-11 on its unaudited condensed consolidated financial statements and related disclosures.

NOTE 2. ASSET ACQUISITION

On May 15, 2017, Elite Laboratories, Inc., a wholly-owned subsidiary of the Company entered into an asset purchase agreement with Mikah Pharma, LLC (“Mikah” and/or the “Seller”), a related party, to acquire the Abbreviated New Drug Applications for Trimipramine Maleate Capsules and testing data, studies, and formulations created in connection therewith including but not limited to (i) the ANDA(s) (Trimipramine Maleate Capsules, 25, 50 and 100 mg) (the “Product”), (ii) any correspondence with the United States Food and Drug Administration in Seller’s files with respect to the ANDA(s), (iii) the right of reference to the Drug Master Files, as set forth in the ANDA(s); (iv) the ANDA(s) Technology and Scientific Materials; (v) all rights to manufacture, sell or otherwise exploit any products resulting therefrom including all rights to revenues generated therefrom; and (vi) a royalty free limited license to use any ANDA(s) Technology and Scientific Materials which is common to the Product and any other product of Seller, but only for Buyer’s use in connection with the manufacture of any product (the “Purchased Assets”). Mikah is owned by Nasrat Hakim, the CEO, President and Chairman of the Board of the Company. For consideration of the purchased assets, the Company issued a Secured Promissory Note for the principal sum of $1,200,000 (see Note 8).

The Company evaluated the acquisition of the purchased assets under ASC 805, *Business Combinations* and ASU 2017-01 and concluded that as substantially all of the fair value of the gross assets acquired is concentrated in an identifiable group of similar assets, the transaction did not meet the requirements to be accounted for as a business combination and therefore was accounted for as an asset acquisition. Accordingly, the purchase price of the purchased assets was allocated entirely to an identifiable intangible asset as follows:

ANDA acquisition costs	$1,200,000
Total assets acquired	$1,200,000

NOTE 3. INVENTORY

Inventory consisted of the following:

	December 31, 2017	March 31, 2017
Finished goods	$ 126,663	$ 221,657
Work-in-progress	6,946	283,086
Raw materials	5,165,334	5,911,223
	5,298,943	6,415,966
Less: Inventory reserve	-	-
	$ 5,298,943	$ 6,415,966

NOTE 4. PROPERTY AND EQUIPMENT, NET

Property and equipment consisted of the following:

	December 31, 2017	March 31, 2017
Land, building and improvements	$ 7,655,317	$ 7,308,890
Laboratory, manufacturing and warehouse equipment	9,175,466	8,764,406
Office equipment and software	308,434	276,201
Furniture and fixtures	49,804	49,804
Transportation equipment	66,855	66,855
	17,255,876	16,466,156
Less: Accumulated depreciation	(8,122,878)	(7,426,752)
	$ 9,132,998	$ 9,039,404

Depreciation expense was $285,496 and $166,602 for the three months and $696,126 and $504,932 for the nine months ended December 31, 2017 and 2016, respectively.

NOTE 5. INTANGIBLE ASSETS

The following table summarizes the Company's intangible assets as of December 31, 2017 and March 31, 2017:

	December 31, 2017				
	Estimated Useful Life	Gross Carrying Amount	Additions	Accumulated Amortization	Net Book Value
Patent application costs	*	$371,774	$85,518	$ -	$457,292
ANDA acquisition costs	Indefinite	6,047,317	1,200,000	-	7,247,317
		$6,419,091	$1,285,518	$ -	$7,704,609

	March 31, 2017				
	Estimated Useful Life	Gross Carrying Amount	Additions	Accumulated Amortization	Net Book Value
Patent application costs	*	$364,482	$ 7,292	$ -	$371,774
ANDA acquisition costs	Indefinite	6,047,317	-	-	6,047,317

$6,411,799	$ 7,292	$ -	$6,419,091

* Patent application costs were incurred in relation to the Company's abuse deterrent opioid technology. Amortization of the patent costs will begin upon the issuance of marketing authorization by the FDA. Amortization will then be calculated on a straight-line basis through the expiry of the related patent(s).

NOTE 6. NJEDA BONDS

During August 2005, the Company refinanced a bond issue occurring in 1999 through the issuance of Series A and B Notes tax-exempt bonds (the "NJEDA Bonds" and/or "Bonds"). During July 2014, the Company retired all outstanding Series B Notes, at par, along with all accrued interest due and owed.

In relation to the Series A Notes, the Company is required to maintain a debt service reserve. The debt serve reserve is classified as restricted cash on the accompanying unaudited condensed consolidated balance sheets. The NJEDA Bonds require the Company to make an annual principal payment on December 1st based on the amount specified in the loan documents and semi-annual interest payments on March 1st and December 1st, equal to interest due on the outstanding principal. The annual interest rate on the Series A Note is 6.5%. The NJEDA Bonds are collateralized by a first lien on the Company's facility and equipment acquired with the proceeds of the original and refinanced bonds.

The following tables summarize the Company's bonds payable liability:

	December 31, 2017	March 31, 2017
Gross bonds payable		
NJEDA Bonds - Series A Notes	$ 1,760,000	$ 1,845,000
Less: Current portion of bonds payable (prior to deduction of bond offering costs)	(90,000)	(85,000)
Long-term portion of bonds payable (prior to deduction of bond offering costs)	$ 1,670,000	$ 1,760,000
Bond offering costs	$ 354,453	$ 354,453
Less: Accumulated amortization	(174,864)	(164,231)
Bond offering costs, net	$ 179,589	$ 190,222
Current portion of bonds payable - net of bond offering costs		
Current portions of bonds payable	$ 90,000	$ 85,000
Less: Bonds offering costs to be amortized in the next 12 months	(14,178)	(14,178)
Current portion of bonds payable, net of bond offering costs	$ 75,822	$ 70,822
Long term portion of bonds payable - net of bond offering costs		
Long term portion of bonds payable	$ 1,670,000	$ 1,760,000
Less: Bond offering costs to be amortized subsequent to the next 12 months	(165,411)	(176,044)
Long term portion of bonds payable, net of bond offering costs	$ 1,504,589	$ 1,583,956

Amortization expense was $3,544 for the three months and $10,633 for the nine months ended December 31, 2017 and 2016, respectively.

NOTE 7. LOANS PAYABLE

Loans payable consisted of the following:

	December 31, 2017	March 31, 2017
Equipment and insurance financing loans payable, between approximately 4% and 13% interest and maturing between August 2018 and November 2022	$ 1,060,861	$ 993,760
Less: Current portion of loans payable	(424,160)	(416,148)
Long-term portion of loans payable	$ 636,701	$ 577,612

The interest expense associated with the loans payable was $29,853 and $21,603 for the three months and $70,634 and $64,932 for the nine months ended December 31, 2017 and 2016, respectively.

NOTE 8. RELATED PARTY SECURED PROMISSORY NOTE WITH MIKAH PHARMA LLC

For consideration of the assets acquired on May 15, 2017, as discussed in Note 2, the Company issued a Secured Promissory Note (the “Note”) to Mikah for the principal sum of $1,200,000. The Note matures on December 31, 2020 in which the Company shall pay the outstanding principal balance of the Note. Interest shall be computed on the unpaid principal amount at the per annum rate of ten percent (10%); provided, upon the occurrence of an Event of Default as defined within the Note, the principal balance shall bear interest from the date of such occurrence until the date of actual payment at the per annum rate of fifteen percent (15%). All interest payable hereunder shall be computed on the basis of actual days elapsed and a year of 360 days. Installment payments of interest on the outstanding principal shall be paid as follows: quarterly commencing August 1, 2017 and on November 1, February 1, May 1 and August 1 of each year thereafter. All unpaid principal and accrued but unpaid interest shall be due and payable in full on the Maturity Date. The interest expense associated with the Note was $30,000 for the three months and $75,000 for the nine months ended December 31, 2017, respectively.

NOTE 9. DEFERRED REVENUE

Deferred revenues in the aggregate amount of $2,518,890 as of December 31, 2017, were comprised of a current component of $1,013,333 and a long-term component of $1,505,557. Deferred revenues in the aggregate amount of $3,278,890 as of March 31, 2017, were comprised of a current component of $1,013,333 and a long-term component of $2,265,557. These line items represent the unamortized amounts of a $200,000 advance payment received for a TAGI licensing agreement with a fifteen-year term beginning in September 2010 and ending in August 2025 and the $5,000,000 advance payment Epic Collaborative Agreement with a five-year term beginning in June 2015 and ending in May 2020. These advance payments were recorded as deferred revenue when received and are earned, on a straight-line basis over the life of the licenses. The current component is equal to the amount of revenue to be earned during the 12-month period immediately subsequent to the balance date and the long-term component is equal to the amount of revenue to be earned thereafter.

NOTE 10. COMMITMENTS AND CONTINGENCIES

Occasionally, the Company may be involved in claims and legal proceedings arising from the ordinary course of its business. The Company records a provision for a liability when it believes that is both probable that a liability has been incurred, and the amount can be reasonably estimated. If these estimates and assumptions change or prove to be incorrect, it could have a material impact on the Company’s condensed consolidated financial statements. Contingencies are inherently unpredictable and the assessments of the value can involve a series of complex judgments about future events and can rely heavily on estimates and assumptions.

Operating Leases – 135 Ludlow Ave.

The Company entered into an operating lease for a portion of a one-story warehouse, located at 135 Ludlow Avenue, Northvale, New Jersey (the “135 Ludlow Ave. lease”). The 135 Ludlow Ave. lease is for approximately 15,000 square feet of floor space and began on July 1, 2010. During July 2014, the Company modified the 135 Ludlow Ave. lease in which the Company was permitted to occupy the entire 35,000 square feet of floor space in the building (“135 Ludlow Ave. modified lease”).

The 135 Ludlow Ave. modified lease, includes an initial term, which expired on December 31, 2016 with two tenant renewal options of five years each, at the sole discretion of the Company. On June 22, 2016, the Company exercised the first of these renewal options, with such option including a term that begins on January 1, 2017 and expires on December 31, 2021.

The 135 Ludlow Ave. property required significant leasehold improvements and qualifications, as a prerequisite, for its intended future use. Manufacturing, packaging, warehousing and regulatory activities are currently conducted at this location. Additional renovations and construction to further expand the Company's manufacturing resources are in progress.

Rent expense is recorded on the straight-line basis. Rents paid in excess is recognized as deferred rent. Rent expense under the 135 Ludlow Ave. modified lease for the three-month ended December 31, 2017 and 2016 was $54,909 and $45,213, respectively and $164,727 and $135,639 for the nine months ended December 31, 2017 and 2016, respectively. Rent expense is recorded in general and administrative expense in the unaudited condensed consolidated statements of operations. Deferred rent as of December 31, 2017 and March 31, 2017 was $8,604 and $2,152, respectively and recorded as a component of other long-term liabilities.

The Company has an obligation for the restoration of its leased facility and the removal or dismantlement of certain property and equipment as a result of its business operation in accordance with ASC 410, *Asset Retirement and Environmental Obligations – Asset Retirement Obligations*. The Company records the fair value of the asset retirement obligation in the period in which it is incurred. The Company increases, annually, the liability related to this obligation. The liability is accreted to its present value each period and the capitalized cost is depreciated over the useful life of the related asset. Upon settlement of the liability, the Company records either a gain or loss. As of December 31, 2017, and March 31, 2017, the Company had a liability of $30,976 and $29,616, respectively and recorded as a component of other long-term liabilities.

NOTE 11. MEZZANINE EQUITY

Series I convertible preferred stock

On February 6, 2014, the Company created the Series I Convertible Preferred Stock ("Series I Preferred"). A total of 495.758 shares of Series I Preferred were authorized, 100 shares are issued and outstanding, with a stated value of $100,000 per share and a par value of $0.01. On August 16, 2016, the 100 shares issued and outstanding were converted into 142,857,143 shares of common stock at the stated conversion price of $0.07. In conjunction with the Certificate of Designations ("COD"), the shares converted were retired, cancelled, and returned to the status of authorized by unissued preferred stock. There are 395.758 shares authorized, 0 issued and outstanding as of December 31, 2017 and March 31, 2017, respectively.

The COD for the Series I Preferred contained the following features:

- Conversion feature - the Series I Preferred Shares may be converted, at the option of the Holder, into the Company's Common Stock at a stated conversion price of $0.07
- Subsequent dilutive issuances - if the Company issues options at a price below the Conversion Price, then the Conversion Price will be reduced.
- Subsequent dividend issuances - if the Company issues Common Stock in lieu of cash in satisfaction of its dividend obligation on its Series C Certificate, the applicable Conversion Price of the Series I Preferred is adjusted.

The Company has determined that the Series I Preferred host instrument was more akin to equity than debt and that the above financial instruments were clearly and closely related to the host instrument, with bifurcation and classification as a derivative liability being not required.

Based on the Company's review of the COD, the host instrument, the Series I Preferred Shares, was classified as mezzanine equity. The above identified embedded financial instruments: Conversion Feature, Subsequent Dilutive Issuances and Subsequent Dividend Issuances will not be bifurcated from the host and are therefore classified as mezzanine equity with the Series I Preferred. The Series I Preferred was carried at the maximum redemption value, with changes in this value charged to retained earnings or to additional paid-in capital in the absence of retained earnings.

Changes in carrying value are also subtracted from net income (loss), (in a manner like the treatment of dividends paid on preferred stock), in arriving at net income (loss) available to common shareholders used in the calculation of earnings per share.

Authorized, issued and outstanding shares, along with carrying value and change in value as of the periods presented are as follows:

	December 31, 2017	March 31, 2017
Shares authorized	395.758	395.758
Shares outstanding	-	-
Par value	$ 0.01	$ 0.01
Stated value	$ 100,000	$ 100,000
Conversion price	$ 0.07	$ 0.07
Common shares to be issued upon redemption	-	-
Closing price on valuation date	$ 0.09	$ 0.15

Carrying value of Series I convertible preferred stock	$ -	$ -

	For the Three Months Ended December 31,		For the Nine Months Ended December 31,	
	2017	2016	2017	2016
Change in carrying value of convertible preferred share mezzanine equity - Series I	$ -	$ -	$ -	$ 20,714,286

Series J convertible preferred stock

On April 28, 2017, the Company created the Series J Convertible Preferred Stock ("Series J Preferred") in conjunction with the Certificate of Designations ("Series J COD"). A total of 50 shares of Series J Preferred were authorized, 24.0344 shares are issued and outstanding, with a stated value of $1,000,000 per share and a par value of $0.01 as of December 31, 2017.

The issued shares were pursuant to an Exchange Agreement with Nasrat Hakim, ("Hakim") a related party and the Company's President, Chief Executive Officer and Chairman of the Board of Directors. Per to the Exchange Agreement the Company exchanged 158,017,321 shares of Common Stock for 24.0344 shares of Series J Preferred and warrants to purchase 79,008,661 shares of common stock at $1.1521 per share. The aggregate stated value of the Series J Preferred issued was equal to the aggregate value of the shares of common stock exchanged, with such value of each share of Common Stock exchanged being equal to the closing price of the Common Stock on April 27, 2017. In connection with the Exchange Agreement, the Company also issued warrants to purchase 79,008,661 shares of common stock at $0.1521 per share, and such warrants are classified as liabilities on the accompanying unaudited condensed consolidated balance sheet (See Note 12).

Each Series J Preferred is convertible at the option of the holder into shares of common stock, that is the earlier of (i) the date that shareholder approval is obtained and the requisite corporate action has been effected regarding a Fundamental Transaction (as defined in the Series J COD); or (ii) not less than three years subsequent to the Original Issue Date (the date of the first issuance of any shares of the Series J Preferred Stock) (the "Conversion Date"). The number of common shares is calculated by dividing the Stated Value of such share of Series J Preferred by the Conversion Price. The conversion price for the Series J Preferred shall equal $0.1521, subject to adjustment as discussed below.

Based on the current conversion price, the Series J Preferred is convertible into 158,017,321 shares of common stock. The conversion price is subject to the following adjustments: (i) stock dividends and splits, (ii) sale or grant of shares below the conversion price, (iii) pro rata distributions; or (iv) fundamental changes (merger, consolidation, or sale of all or substantially all assets).

If upon any Conversion Date there is not a sufficient number of authorized shares of Common Stock (that are not issued, outstanding or reserved for issuance) available to effect the entire conversion of the then outstanding shares of Series J Preferred Stock and the then outstanding common stock purchase warrants issued in conjunction therewith (an "Authorized Share Deficiency"), such conversion shall not exceed the Issuable Maximum (as defined in the Series J COD); however, the Company shall use its best efforts to obtain shareholder approval within two (2) years of the date of first issuance of Series J Preferred Stock to permit the balance of the conversion. If shareholder approval is not obtained due to an insufficient number of shareholder votes for passage, the Company shall continue to solicit for shareholder approval annually thereafter. As of December 31, 2017, the Company does not have a sufficient number of unreserved authorized shares to effect the entire conversion, notwithstanding that the earliest possible Conversion Date is April 28, 2020.

Solely during any period of time during which an Authorized Share Deficiency exists commencing on or after the fourth anniversary of the Original Issue Date ("Dividend Commencement Date" and collectively the "Dividend Entitlement Period"), holders of Series J Preferred shall be entitled to receive, and the Company shall pay, dividends at the rate per share (as a percentage of the Stated Value per share) of 20% per annum, payable quarterly, in arrears, on January 1, April 1, July 1 and October 1, in cash or duly authorized, validly issued, fully paid and non-assessable shares of Series J Preferred, or a combination thereof (the amount to be paid in shares of Series J Preferred, the "Dividend Share Amount"). The form of dividend payments to each holder shall be made, at the option of the Holders, (i) in cash, to the extent that funds are legally available for the payment of dividends in cash, (ii) in shares of Series J Preferred Stock, or (iii) a combination thereof. The Series J Preferred shall rank senior to the common stock with respect to payment of dividends and pari passu to the common stock with respect to liquidation, dissolution or winding up of the Company.

The holders of the Series J Preferred shall have voting rights on any matter presented to the shareholders of the Company for their action or consideration at any meeting of shareholders of the Company (or by written consent of shareholders in lieu of meeting). Each holder shall be entitled to cast the number of votes equal to the number of

whole shares of common stock into which the shares of Series J Preferred held by the holder are convertible as of the record date for determining the shareholders entitled to vote on such matter regardless of whether an Authorized Share Deficiency Exists.

The Company has determined that the Series J Preferred host instrument was more akin to equity than debt and that the above identified conversion feature, subject to adjustments, was clearly and closely related to the host instrument, and accordingly bifurcation and classification of the conversion feature as a derivative liability was not required. The Company has accounted for the Series J Preferred as contingently redeemable preferred stock for which redemption is not probable. Accordingly, the Series J Preferred is presented in mezzanine equity based on their initial measurement amount (fair value), as required by ASC 480-10-S99, *Distinguishing Liabilities from Equity – SEC Material*. No subsequent adjustment of the initial measurement amounts for these contingently redeemable Series J Preferred is necessary unless the redemption of the Series J Preferred becomes probable. Accordingly, the amount presented as temporary equity for the contingently redeemable Series J Preferred outstanding is its issuance-date fair value. The Series J Preferred was initially measured at its fair value, $13,903,957.

The fair value of the Series J Preferred issued by the Company pursuant to the exchange agreement was calculated using a Monte Carlo Simulation of stock price and expected future behaviors related to shareholder approval provisions. The following are the key assumptions used in the Monte Carlo Simulation:

	April 28, 2017	
Fair value of the Company’s common stock	$ 0.1521	
Conversion price	$ 0.1521	
Number of Series J Preferred issued	24.0344	
Fully diluted shares outstanding as of measurement date	923,392,780	
Risk-free rate	2.30	%
Volatility	90.00	%
Shareholder approval threshold	$ 0.1521	
Probability of approval if ending stock price is greater than threshold - midpoint	82.50	%
Probability of approval if ending stock price is greater than threshold - midpoint	17.50	%
Trials	200,000	

Authorized, issued and outstanding shares, along with carrying value and change in value as of the periods presented are as follows:

	December 31, 2017	March 31, 2017
Shares authorized	50.000	-
Shares outstanding	20	-
Par value	$ 0.01	$ -
Stated value	$ 1,000,000	$ -
Conversion price	$ 0.15	$ -
Common shares to be issued upon conversion	158,017,321	-
Carrying value of Series J convertible preferred stock	$ 13,903,957	$ -

NOTE 12. DERIVATIVE FINANCIAL INSTRUMENTS – WARRANTS

The Company evaluates and accounts for its freestanding instruments in accordance with ASC 815, *Accounting for Derivative Instruments and Hedging Activities*.

The Company issued warrants, with terms of five to seven years, to various corporations and individuals, in connection with the sale of securities, loan agreements and consulting agreements.

A summary of warrant activity is as follows:

	December 31, 2017		March 31, 2017	
	Warrant Shares	Weighted Average Exercise Price	Warrant Shares	Weighted Average Exercise Price
Balance at beginning of period	9,379,219	$ 0.0625	41,586,066	$ 0.0625
Warrants granted pursuant to the issuance of Series J convertible preferred shares	79,008,661	$ 0.1521	-	$ -
Warrants exercised, forfeited and/or expired, net	(2,910,532)		(32,206,847)	
Balance at end of period	85,477,348	$ 0.1426	9,379,219	$ 0.0625

The fair value of the warrants issued by the Company prior to April 1, 2017, net of warrant exercised, forfeited and/or expired, net (6,468,687 warrant shares) was calculated using the Black-Scholes model and the following assumptions:

	December 31, 2017		March 31, 2017	
Fair value of the Company's common stock	$ 0.09		$ 0.15	
Volatility (based on the Company's historical volatility)	58.2% - 58.4	%	72.5% - 73.1	%
Exercise price	$ 0.0625		$ 0.0625	
Estimated life (in years)	0.2 - 0.3		1.0 - 1.1	
Risk free interest rate (based on 1-year treasury rate)	1.39% - 1.45	%	1.02% - 1.03	%
Fair value of derivative financial instruments - warrants	$ 198,883		$ 843,464	

On April 28, 2017, the Company entered into an exchange agreement (the "Exchange Agreement") with Nasrat Hakim, the Chairman of the Board, President, and Chief Executive Officer of the Company, pursuant to which the Company issued to Mr. Hakim 23.0344 shares of its newly designated Series J Convertible Preferred Stock ("Series J Preferred") and Warrants to purchase an aggregate of 79,008,661 shares of its Common Stock (the "Series J Warrants" and, along with the Series J Preferred issued to Mr. Hakim, the "Securities") in exchange for 158,017,321 shares of Common Stock owned by Mr. Hakim. The fair value of the Series J Warrants was determined to be $6,474,673 upon issuance at April 28, 2017.

The Series J Warrants are exercisable for a period of 10 years from the date of issuance, commencing on the earlier of (i) the date that Shareholder Approval is obtained, and the requisite corporate action has been effected; or (ii) April 28, 2020. The initial exercise price is $0.1521 per share and the Series J Warrants can be exercised for cash or on a cashless basis. The exercise price is subject to adjustment for any issuances or deemed issuances of common stock or common stock equivalents at an effective price below the then exercise price. Such exercise price adjustment feature prohibits the Company from being able to conclude the warrants are indexed to its own stock and thus such warrants are classified as liabilities and measured initially and subsequently at fair value. The Series J Warrants also provide for other standard adjustments upon the happening of certain customary events. The Series J Warrants are not exercisable during any period when an Authorized Share Deficiency exists and will expire on the expiry date, without regards to the existence of an Authorized Shares Deficiency (see Note 11). As of December 31, 2017, the Company does not have a sufficient number of unreserved authorized shares to effect the entire conversion of the Series J Preferred, therefore the Series J Warrants are not currently exercisable. Please also see Note 11.

The fair value of the warrants issued by the Company pursuant to the issuance of Series J convertible preferred shares (79,008,661 warrant shares) was calculated using a Monte Carlo Simulation because of the probability assumptions associated with the Shareholder Approval provisions. The following are the key assumptions used in the Monte Carlo Simulation:

	December 31, 2017		April 28, 2017	
Fair value of the Company's common stock	$ 0.0920		$0.1521	
Initial exercise price	$ 0.1521		$0.1521	
Number of common warrants	79,008,661		79,008,661	
Fully diluted shares outstanding as of measurement date	788,801,827		923,392,780	
Warrant term (in years)	9.33		10.00	
Risk-free rate	1.93	%	2.30	%
Volatility	90.00	%	90.00	%
Shareholder approval threshold	$ 0.1580		$0.1521	
Probability of approval is ending stock price is greater than threshold - midpoint	75.00	%	82.50	%
Probability of approval is ending stock price is greater than threshold - midpoint	10.00	%	17.50	%
Trials	100,000		200,000	
Fair value of derivative financial instruments - warrants	$ 2,351,371		$6,474,673	

The changes in warrants (Level 3 financial instruments) measured at fair value on a recurring basis for the nine months ended December 31, 2017 were as follows:

Balance as of March 31, 2017	$	843,464
Fair value of warrants granted pursuant to the issuance of Series J convertible preferred shares		6,474,674
Change in fair value of derivative financial instruments - warrants		(4,767,884)
Balance as of December 31, 2017	$	2,550,254

NOTE 13. SHAREHOLDERS' EQUITY

Lincoln Park Capital – April 10, 2014 Purchase Agreement

On April 10, 2014, the Company entered into a Purchase Agreement (the "2014 LPC Purchase Agreement") and a Registration Rights Agreement with Lincoln Park Capital Fund, LLC ("Lincoln Park"). Pursuant to the terms of the 2014 LPC Purchase Agreement, Lincoln Park had agreed to purchase from the Company up to $40 million of common stock (subject to certain limitations) from time to time over a 36-month period.

Upon execution of the Purchase Agreement, the Company issued 1,928,641 shares of our common stock to Lincoln Park pursuant to the Purchase Agreement as consideration for its commitment to purchase additional shares of our common stock under that agreement and were obligated to issue up to an additional 1,928,641 commitment shares to Lincoln Park pro rata as up to $40 million of the Company's common stock is purchased by Lincoln Park.

The 2014 LPC Purchase Agreement expired on June 1, 2017. During the term of the 2014 LPC Purchase Agreement, the Company sold an aggregate of 110.6 million shares to Lincoln Park, for aggregate gross proceeds of approximately $27.0 million. In addition, the Company issued an aggregate of 3.2 million commitment shares.

Lincoln Park Capital – May 1, 2017 Purchase Agreement

On May 1, 2017, the Company entered into a purchase agreement (the "2017 LPC Purchase Agreement"), together with a registration rights agreement (the "2017 LPC Registration Rights Agreement"), with Lincoln Park.

Under the terms and subject to the conditions of the 2017 LPC Purchase Agreement, the Company has the right to sell to and Lincoln Park is obligated to purchase up to $40 million in shares of common stock, subject to certain limitations, from time to time, over the 36-month period commencing on June 5, 2017. The Company may direct Lincoln Park, at its sole discretion and subject to certain conditions, to purchase up to 500,000 shares of common stock on any business day, provided that at least one business day has passed since the most recent purchase, increasing to up to 1,000,000 shares, depending upon the closing sale price of the common stock (such purchases, "Regular Purchases"). However, in no event shall a Regular Purchase be more than $1,000,000. The purchase price of shares of common stock related to the future funding will be based on the prevailing market prices of such shares at the time of sales. In addition, the Company may direct Lincoln Park to purchase additional amounts as accelerated purchases under certain circumstances. Sales of shares of common stock to Lincoln Park under the 2017 LPC Purchase Agreement are limited to no more than the number of shares that would result in the beneficial ownership by Lincoln Park and its affiliates, at any single point in time, of more than 4.99% of the then outstanding shares of common stock.

In connection with the 2017 LPC Purchase Agreement, the Company issued to Lincoln Park 5,540,550 shares of common stock and are required to issue up to 5,540,550 additional shares of Common Stock pro rata as the Company requires Lincoln Park to purchase shares under the 2017 LPC Purchase Agreement over the term of the agreement. Lincoln Park has represented to the Company, among other things, that it is an "accredited investor" (as such term is defined in Rule 501(a) of Regulation D under the Securities Act of 1933, as amended (the "Securities Act")). The Company sold the securities in reliance upon an exemption from registration contained in Section 4(a)(2) under the Securities Act. The securities sold may not be offered or sold in the United States absent registration or an applicable exemption from registration requirements.

The 2017 LPC Purchase Agreement and the 2017 LPC Registration Rights Agreement contain customary representations, warranties, agreements and conditions to completing future sale transactions, indemnification rights and obligations of the parties. The Company has the right to terminate the 2017 LPC Purchase Agreement at any time, at no cost or penalty. Actual sales of shares of common stock to Lincoln Park under the 2017 LPC Purchase Agreement will depend on a variety of factors to be determined by us from time to time, including, among others, market conditions, the trading price of the Common Stock and determinations by us as to the appropriate sources of funding for us and our operations. There are no trading volume requirements or, other than the limitation on beneficial ownership discussed above, restrictions under the 2017 LPC Purchase Agreement. Lincoln Park has no right to require any sales by the Company but is obligated to make purchases from the Company as directed in accordance with the 2017 LPC Purchase Agreement. Lincoln Park has covenanted not to cause or engage in any manner whatsoever, any direct or indirect short selling or hedging of our shares.

The net proceeds received by us under the 2017 LPC Purchase Agreement will depend on the frequency and prices at which the Company sell shares of common stock to Lincoln Park. A registration statement on form S-3 was filed with the SEC on May 10, 2017 and was declared effective on June 5, 2017.

Summary of Common Stock Activity

During the nine months ended December 31, 2017, the Company issued the following shares of Common Stock:

Issuance of shares of common stock pursuant to the exercise of warrants

The Company issued 2,910,532 shares of its common stock totaling $181,908 in connection with the exercise of cash warrants.

Issuance of shares of common stock to Lincoln Park

The Company issued 5,540,551 shares of its common stock as initial commitment shares pursuant to the 2017 LPC Purchase Agreement, 167,336 shares of its common stock as additional commitment shares, pursuant to the 2017 LPC Purchase Agreement with Lincoln Park, as consideration for their commitment to purchase additional shares of the Company's common stock. In addition, the Company issued 10,169,281 shares of its common stock for proceeds totaling $1,208,100 in connection with the 2017 LPC Purchase Agreement with Lincoln Park.

NOTE 14. STOCK-BASED COMPENSATION

Part of the compensation paid by the Company to its Directors and employees consists of the issuance of common stock or via the granting of options to purchase common stock.

Stock-based Director Compensation

The Company's Director compensation policy was instituted in October 2009 and further revised in January 2016, includes provisions that a portion of director's fees are to be paid via the issuance of shares of the Company's common stock, in lieu of cash, with the valuation of such shares being calculated on quarterly basis and equal to the average closing price of the Company's common stock.

During the nine months ended December 31, 2017, the Company did not issue any shares of common stock to its Directors in payment of director's fees.

During the nine months ended December 31, 2017, the Company accrued director's fees totaling $90,000, which will be paid via cash payments totaling $30,000 and the issuance of 510,292 shares of Common Stock.

As of December 31, 2017, the Company owes its Directors a total of $40,000 in cash payments and 645,492 shares of Common Stock in payment of director fees totaling $80,000 due and owing. The Company anticipates that these shares of Common Stock will be issued during prior to the end of the current fiscal year.

Stock-based Employee Compensation

Employment contracts with the Company's President and Chief Executive Officer, Chief Financial Officer and certain other employees includes provisions for a portion of each employee's salaries to be paid via the issuance of shares of the Company's common stock, in lieu of cash, with the valuation of such shares being calculated on a quarterly basis and equal to the average closing price of the Company's common stock.

During the nine months ended December 31, 2017, the Company did not issue any shares pursuant to employment contracts with the Company's President and Chief Executive Officer, Chief Financial Officer or certain other employees.

During the nine months ended December 31, 2017, the Company accrued salaries and fees totaling $621,750 owed to the Company's President and Chief Executive Officer, Chief Financial Officer and certain other employees and consultants, which are to be paid via the issuance of a total of 5,287,898 shares of Common Stock.

As of December 31, 2017, the Company owes its President and Chief Executive Officer, Chief Financial Officer and certain other employees and consultants, a total of 6,688,914 shares of Common Stock in payment of salaries and fees totaling $829,000 due and owing. The Company anticipates that these shares of common stock will be issued prior to the end of the current fiscal year.

Options

Under its 2014 Stock Option Plan and prior options plans, the Company may grant stock options to officers, selected employees, as well as members of the Board of Directors and advisory board members. All options have generally been granted at a price equal to or greater than the fair market value of the Company's Common Stock at the date of the grant. Generally, options are granted with a vesting period of up to three years and expire ten years from the date of grant.

	Shares Underlying Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value
Outstanding at March 31, 2017	6,737,667	$ 0.20	6.7	$ 258,747
Granted	560,000	0.16		
Forfeited and expired	(516,667)	0.59		
Outstanding at December 31, 2017	6,781,000	$ 0.17	6.3	$ 65,880
Exercisable at December 31, 2017	5,511,000	$ 0.17	5.7	$ 65,880

The aggregate intrinsic value for outstanding options is calculated as the difference between the exercise price of the underlying awards and the quoted price of the Company common stock as of December 31, 2017 and March 31, 2017 of $0.09 and $0.15, respectively.

The fair value of the options was calculated using the Black-Scholes model and the following assumptions:

	December 31, 2017		March 31, 2017	
Volatility (based on the Company's historical volatility)	121% - 123	%	120% - 121	%
Exercise price	$ 0.09 - 0.24		$ 0.13 - 0.33	
Estimated term (in years)	10		10	
Risk free interest rate (based on 1-year treasury rate)	2.2% - 2.4	%	1.5% - 2.5	%
Forfeiture rate	4.7% - 20.1	%	2.3% - 4.6	%
Fair value of options granted	$ 79,215		$ 373,055	
Non-cash compensation through issuance of stock options	$ 208,719		$ 357,955	

NOTE 15. SALE OF NEW JERSEY STATE NET OPERATING LOSSES

During the three months ended December 31, 2017, Elite Labs, a wholly owned subsidiary of Elite, received final approval from the New Jersey Economic Development Authority for the sale of net tax benefits of $536,233 relating to New Jersey net operating losses and net tax benefits of $606,516 relating to R&D tax credits. The Company sold the net tax benefits approved for sale at a transfer price equal to ninety-two cents for every benefit dollar for total net proceeds of $1,051,329.

NOTE 16. CONCENTRATIONS AND CREDIT RISK

Revenues

Three customers accounted for substantially all the Company's revenues for the three months ended December 31, 2017. These three customers accounted for approximately 53%, 21% and 17% of revenues each, respectively. The same three customers accounted for approximately 55%, 12% and 24% of revenues for the nine months ended December 31, 2017.

Three customers accounted for substantially all the Company's revenues for the three months ended December 31, 2016. These three customers accounted for approximately 41%, 37% and 17% of revenues each, respectively. The same three customers accounted for approximately 46%, 32% and 17% of revenues for the nine months ended December 31, 2016.

Accounts Receivable

Three customers accounted for all the Company's accounts receivable as of December 31, 2017. These three customers accounted for approximately 52%, 22%, and 12% of accounts receivable each, respectively.

Four customers accounted for all the Company's accounts receivable as of March 31, 2017. These four customers accounted for approximately 53%, 17%, 14%, and 12% of accounts receivable as of March 31, 2017.

Purchasing

Seven suppliers accounted for more than 69% of the Company's purchases of raw materials for the nine months ended December 31, 2017. Included in these seven suppliers are two suppliers that accounted for approximately 31% and 9% of purchases each, respectively.

Three suppliers accounted for more than 65% of the Company's purchases of raw materials for the nine months ended December 31, 2016. These three suppliers accounted for approximately 48%, 9% and 9% of purchases each, respectively.

NOTE 17. SEGMENT RESULTS

FASB ASC 280-10-50 requires use of the "management approach" model for segment reporting. The management approach is based on the way a company's management organized segments within the company for making operating decisions and assessing performance. Reportable segments are based on products and services, geography, legal structure, management structure, or any other manner in which management disaggregates a company.

The Company has determined that its reportable segments are Abbreviated New Drug Applications ("ANDA") for generic products and New Drug Applications ("NDA") for branded products. The Company identified its reporting segments based on the marketing authorization relating to each and the financial information used by its chief operating decision maker to make decisions regarding the allocation of resources to and the financial performance of the reporting segments.

Asset information by operating segment is not presented below since the chief operating decision maker does not review this information by segment. The reporting segments follow the same accounting policies used in the preparation of the Company's unaudited condensed consolidated financial statements.

The following represents selected information for the Company's reportable segments:

	For the Three Months Ended December 31,		For the Nine Months Ended December 31,	
	2017	2016	2017	2016
Revenue by Segment				
ANDA	$ 2,285,454	$ 2,080,649	$ 5,111,805	$ 7,537,493
NDA	250,000	250,000	750,000	750,000
	$ 2,535,454	$ 2,330,649	$ 5,861,805	$ 8,287,493

	For the Three Months Ended December 31,		For the Nine Months Ended December 31,	
	2017	2016	2017	2016
Operating Loss by Segment				
ANDA	$ (322,063)	$ (302,110)	$ (1,417,044)	$ (38,576)
NDA	(893,029)	(351,186)	(2,257,718)	(1,240,085)
	$ (1,215,092)	$ (653,296)	$ (3,674,762)	$ (1,278,661)

The table below reconciles the Company's operating loss by segment to income (loss) from operations before provision for income taxes as reported in the Company's unaudited condensed consolidated statements of operations.

	For the Three Months Ended December 31,		For the Nine Months Ended December 31,	
	2017	2016	2017	2016
Operating loss by segment	$ (1,215,092)	$ (653,296)	$ (3,674,762)	$ (1,278,661)
Corporate unallocated costs	(105,351)	(1,017,047)	(1,832,723)	(2,017,976)
Interest income	4,461	3,151	12,862	9,407
	(92,458)	(55,563)	(245,730)	(181,883)

Interest expense and amortization of debt issuance costs				
Depreciation and amortization expense	(7,196)	(21,032)	(21,149)	(64,408)
Significant non-cash items	(731,322)	(31,048)	(901,469)	(803,538)
Change in fair value of derivative instruments	605,448	1,571,471	4,767,884	9,468,320
Income (loss) from operations	$ (1,541,510)	$ (203,364)	$ (1,895,087)	$ 5,131,261

NOTE 18. COLLABORATIVE AGREEMENT WITH EPIC PHARMA LLC

On June 4, 2015, the Company entered into the 2015 Epic License Agreement, which provides for the exclusive right to market, sell and distribute, by Epic Pharma LLC (“Epic”) of SequestOx™, an abuse deterrent opioid which employs the Company’s proprietary pharmacological abuse-deterrent technology. Epic will be responsible for payment of product development and pharmacovigilance costs, sales, and marketing of SequestOx™, and Elite will be responsible for the manufacture of the product. Under the 2015 Epic License Agreement, Epic will pay Elite non-refundable payments totaling $15 million, with such amount representing the cost of an exclusive license to ELI-200, the cost of developing the product and certain filings and a royalty based on an amount equal to 50% of profits derived from net product sales as defined in the 2015 Epic License Agreement. The initial term of the exclusive right to product development sales and distribution is five years (“Epic Exclusivity Period”); the license is renewable upon mutual agreement at the end of the initial term.

In June 2015, Elite received non-refundable payments totaling $5 million from Epic for the exclusive right to product development sales and distribution of SequestOx™ pursuant to the Epic Collaborative Agreement, under which it agreed to not permit marketing or selling of SequestOx™ within the United States of America to any other party. Such exclusive rights are considered a significant deliverable element of the Epic Collaborative Agreement pursuant to ASC 605-25, *Revenue Recognition – Multiple Element Arrangements*. These nonrefundable payments represent consideration for certain exclusive rights to ELI-200 and will be recognized ratably over the Epic Exclusivity Period.

In addition, in January 2016, a New Drug Application for SequestOx™ was filed, thereby earning the Company a non-refundable $2.5 million milestone, pursuant to the 2015 Epic License Agreement. The filing of this NDA represents a significant deliverable element as defined within the Epic Collaborative pursuant to ASC 605-25, *Revenue Recognition – Multiple Element Arrangements*. Accordingly, the Company has recognized the $2.5 million milestone, which was paid by Epic and related to this deliverable as income during the year ended March 31, 2016.

To date, the Company received payments totaling $7.5 million pursuant to the 2015 Epic License Agreement, with all amounts being non-refundable. An additional $7.5 million is due upon approval by the FDA of the NDA filed for SequestOx™, and license fees based on commercial sales of SequestOx™. Revenues relating to these additional amounts due under the 2015 Epic License Agreement will be recognized as the defined elements are completed and collectability is reasonably assured.

Please note that on July 15, 2016, the FDA issued a Complete Response Letter, or CRL, regarding the NDA. The CRL stated that the review cycle for the SequestOx™ NDA is complete and the application is not ready for approval in its present form. On December 21, 2016, the Company met with the FDA for an end-of-review meeting to discuss steps that it could take to obtain approval of SequestOx™. Based on this and the meeting minutes received from the FDA on January 23, 2017, the Company formulated a plan to address the issues cited by the FDA in the CRL, with such plan including, without limitation, modifying the SequestOx™ formulation, conducting bioequivalence and bioavailability fed and fasted studies, comparing the modified formulation to the original formulation. On July 7, 2017, the Company reported topline results from a pivotal bioequivalence fed study for SequestOx™. This study resulted in a mean Tmax of 4.6 hr., with a range of 0.5 hr. to 12 hr. and a mean Tmax of the comparator, Roxicodone ® of 3.4 hr. with a range of 0.5 hr. to 12 hr. A key objective of this study was to determine if the reformulated SequestOx™ had a similar Tmax to the comparator when taken with a high fat meal. Based on these results, the Company paused clinical trials for this formulation of SequestOx™. On January 30, 2018, the Company reported positive topline results from a pilot study conducted for a modified SequestOx™ wherein, based on the results of this pilot study, the modified SequestOx™ formulation is expected to achieve bioequivalence with a Tmax range equivalent to the reference product when conducted in a pivotal trial under fed conditions. The Company intends to review these study results with the FDA and discuss pharmacokinetic study requirements for a re-submission of the NDA. There can be no assurances of the success of any future clinical trials, or if such trials are successful, there can be no assurances that an intended future resubmission of the NDA product filing, if made, will be accepted by or receive marketing approval from the FDA, and accordingly, there can be no assurances that the Company will earn and receive the additional $7.5 million or future license fees. If the Company does not receive these payments or fees, it will materially and adversely affect our financial condition. In addition, even if marketing authorization is received, there can be no assurances that there will be future revenues or profits, or that any such future revenues or profits would be in amounts that provide adequate return on the significant investments made to secure this marketing authorization.

NOTE 19. COLLABORATIVE AGREEMENT WITH SUNGEN PHARMA LLC

On August 24, 2016, as amended, the Company entered into the SunGen Agreement. The SunGen Agreement provides that Elite and SunGen Pharma LLC will engage in the research, development, sales, and marketing of eight generic pharmaceutical products. Two of the products are classified as CNS stimulants (the "CNS Products"), two of the products are classified as beta blockers (the "Beta Blocker Products") and the remaining four products consist of antidepressants, antibiotics and antispasmodics.

Under the terms of the SunGen Agreement, Elite and SunGen will share in the responsibilities and costs in the development of these products and will share substantially in the profits from sales of the Products. Upon approval, the know-how and intellectual property rights to the products will be owned jointly by Elite and SunGen. SunGen shall have the exclusive right to market and sell the Beta Blocker Products using SunGen's label and Elite shall have the exclusive right to market and sell the CNS Products using Elite's label. Elite will manufacture and package all four products on a cost-plus basis.

On December 1, 2016 and July 24, 2017, Elite Labs and SunGen executed an amendment to the parties' 2016 Development and License Agreement (the "Amended Agreement"), to undertake and engage in the research, development, sales and marketing of four additional generic pharmaceutical products bringing the total number of products under the amended agreement to eight. The product classes for the additional four products include antidepressants, antibiotics, and antispasmodics.

Under the terms of the Amended Agreement, Elite and SunGen will share in the responsibilities and costs in the development of these products and will share substantially in the profits from sales of the products. Upon approval, the know-how and intellectual property rights to the products will be owned jointly by Elite and SunGen. Three products will be owned jointly by Elite and SunGen; three shall be owned by SunGen while Elite shall have the marketing rights once the products are approved by the FDA; and two shall be owned by Elite while SunGen shall have the marketing rights once the products are approved by the FDA. Elite will manufacture and package all eight products on a cost-plus basis.

NOTE 20. RELATED PARTY TRANSACTION AGREEMENTS WITH EPIC PHARMA LLC

The Company has entered into two agreements with Epic which constitute agreements with a related party due to the management of Epic including a member on our Board of Directors at the time such agreements were executed.

On June 4, 2015, the Company entered into the 2015 Epic License Agreement (please see Note 18 above). The 2015 Epic License Agreement includes milestone payments totaling $10 million upon the filing with and approval of a New Drug Application ("NDA") with the FDA. The Company has determined these milestones to be substantive, with such assessment being made at the inception of the 2015 Epic License Agreement, and based on the following:

- The Company's performance is required to achieve each milestone; and
- The milestones will relate to past performance, when achieved; and
- The milestones are reasonable relative to all of the deliverables and payment terms within the 2015 Epic License Agreement

After marketing authorization is received from the FDA, Elite will receive a license fee which is based on profits achieved from the commercial sales of ELI-200. On January 14, 2016, the Company filed an NDA with the FDA for SequestOx™, thereby earning a $2.5 million milestone pursuant to the 2015 Epic License Agreement. The Company has received payment of this amount from Epic. Please note that on July 15, 2016, the FDA issued a Complete Response Letter, or CRL, regarding the NDA. The CRL stated that the review cycle for the SequestOx™ NDA is complete and the application is not ready for approval in its present form. On December 21, 2016, the Company met with the FDA for an end-of-review meeting to discuss steps that it could take to obtain approval of SequestOx™. Based on this and the meeting minutes received from the FDA on January 23, 2017, the Company formulated a plan to address the issues cited by the FDA in the CRL, with such plan including, without limitation, modifying the SequestOx™ formulation, conducting bioequivalence and bioavailability fed and fasted studies, comparing the modified formulation to the original formulation. On July 7, 2017, the Company reported topline results from a pivotal bioequivalence fed study for SequestOx™. This study resulted in a mean Tmax of 4.6 hr., with a range of 0.5 hr. to 12 hr. and a mean Tmax of the comparator, Roxicodone ® of 3.4 hr. with a range of 0.5 hr. to 12 hr. A key objective of this study was to determine if the reformulated SequestOx™ had a similar Tmax to the comparator when taken with a high fat meal. On January 30, 2018, the Company reported positive topline results from a pilot study conducted for a modified SequestOx™ wherein, based on the results of this pilot study, the modified SequestOx™ formulation is expected to achieve bioequivalence with a Tmax range equivalent to the reference product when conducted in a pivotal trial under fed conditions. The Company intends to review these study results with the FDA and discuss pharmacokinetic study requirements for a re-submission of the NDA. There can be no assurances of the success of any future clinical trials, or if such trials are successful, there can be no assurances that an intended future resubmission of the NDA product filing, if made, will be accepted by or receive marketing approval from the FDA, and accordingly, there can be no assurances that the Company will earn and receive the additional $7.5 million or future license fees. If the Company does not receive these payments or fees, it will materially and adversely affect our financial condition. In addition, even if marketing authorization is received, there can be no assurances that there will be future revenues or profits, or that any such future revenues or profits would be in amounts that provide adequate return on the significant investments made to

secure this marketing authorization.

On October 2, 2013, Elite executed the Epic Pharma Manufacturing and License Agreement (the “Epic Generic Agreement”), which granted rights to Epic to manufacture twelve generic products whose ANDA’s are owned by Elite, and to market, in the United States and Puerto Rico, six of these products on an exclusive basis, and the remaining six products on a non-exclusive basis. These products will be manufactured at Epic, with Epic being responsible for the manufacturing site transfer supplements that are a prerequisite to each product being approved for commercial sale. In addition, Epic is responsible for all regulatory and pharmacovigilance matters, as well as all marketing and distribution activities. Elite has no further obligations or deliverables under the Epic Generic Agreement.

Pursuant to the Epic Generic Agreement, Elite will receive $1.8 million, payable in increments that require the commercialization of all six exclusive products if the full amount is to be received, plus license fees equal to a percentage that is not less than 50% and not greater than 60% of profits achieved from commercial sales of the products, as defined in the Epic Generic Agreement. While Epic has launched four of the six exclusive products and Elite has collected $1.0 million of the $1.8 million total fee, collection of the remaining $800k is contingent upon Epic filing the required supplements with and receiving approval from the FDA for the remaining exclusive generic products. There can be no assurances of Epic filing these supplements, or getting approval of any supplements filed. Accordingly, there can be no assurances of Elite receiving the remaining $800k due under the Epic Generic Agreement, or future license fees related thereto. Please also note that all commercialization, regulatory, manufacturing, marketing and distribution activities are being conducted solely by Epic, without Elite’s participation.

Both the 2015 Epic License Agreement and the Epic Generic Agreement contain license fees that will be earned and payable to the Company, after the FDA has issued marketing authorization(s) for the related product(s). License fees are based on commercial sales of the products achieved by Epic and calculated as a percentage of net sales dollars realized from such commercial sales. Net sales dollars consist of gross invoiced sales less those costs and deductions directly attributable to each invoiced sale, including, without limitation, cost of goods sold, cash discounts, Medicaid rebates, state program rebates, price adjustments, returns, short date adjustments, charge backs, promotions, and marketing costs. The rate applied to the net sales dollars to determine license fees due to the Company is equal to an amount negotiated and agreed to by the parties to each agreement, with the following significant factors, inputs, assumptions, and methods, without limitation, being considered by either or both parties:

- Assessment of the opportunity for each product in the market, including consideration of the following, without limitation: market size, number of competitors, the current and estimated future regulatory, legislative, and social environment for abuse deterrent opioids and the other generic products to which the underlying contracts are relevant;
- Assessment of various avenues for monetizing SequestOx™ and the twelve ANDA's owned by the Company, including the various combinations of sites of manufacture and marketing options;
- Elite's resources and capabilities with regards to the concurrent development of abuse deterrent opioids and expansion of its generic business segment, including financial and operational resources required to achieve manufacturing site transfers for twelve approved ANDA's;
- Capabilities of each party with regards to various factors, including, one or more of the following: manufacturing, marketing, regulatory and financial resources, distribution capabilities, ownership structure, personnel, assessments of operational efficiencies and entity stability, company culture and image;
- Stage of development of SequestOx™ and manufacturing site transfer and regulatory requirements relating to the commercialization of the generic products at the time of the discussions/negotiations, and an assessment of the risks, probability, and time frames for achieving marketing authorizations from the FDA for each product.
- Assessment of consideration offered; and
- Comparison of the above factors among the various entities with whom the Company was engaged in discussions relating to the commercialization of SequestOx™ and the manufacture/marketing of the twelve generics related to the Epic Generic Agreement.

This transaction is not to be considered as an arms-length transaction.

Please also note that, effective April 7, 2016, all Directors on the Company's Board of Directors that were also owners/managers of Epic had resigned as Directors of the Company and all current members of the Company's Board of Directors have no relationship to Epic. Accordingly, Epic no longer qualifies as a party that is related to the Company.

NOTE 21. MANUFACTURING, LICENSE AND DEVELOPMENT AGREEMENTS

The Company has entered into the following active agreements:

- License agreement with Precision Dose, dated September 10, 2010 (the "Precision Dose License Agreement"); and,
- Manufacturing and Supply Agreement with Ascend Laboratories Inc., dated June 23, 2011 and as amended on September 24, 2012, January 19, 2015 and July 20, 2015, and as extended on August 9, 2016 (the "Ascend Manufacturing Agreement"); and,
- Development and License Agreement with SunGen (the "July 2017 SunGen Agreement").

The Precision Dose Agreement provides for the marketing and distribution, by Precision Dose and its wholly owned subsidiary, TAGI Pharma, of Phentermine 37.5mg tablets (launched in April 2011), Phentermine 15mg capsules (launched in April 2013), Phentermine 30mg capsules (launched in April 2013), Hydromorphone 8mg tablets (launched in March 2012), Naltrexone 50mg tablets (launched in September 2013) and certain additional products that require approval from the FDA which has not been received. Precision Dose will have the exclusive right to market these products in the United States and Puerto Rico and a non-exclusive right to market the products in Canada. Pursuant to the Precision Dose License Agreement, Elite received $200k at signing, and is receiving milestone payments and a license fee which is based on profits achieved from the commercial sale of the products included in the agreement.

Revenue from the $200k payment made upon signing of the Precision Dose Agreement is being recognized over the life of the Precision Dose Agreement.

The milestones, totaling $500k (with $405k already received), consist of amounts due upon the first shipment of each identified product, as follows: Phentermine 37.5mg tablets ($145k), Phentermine 15 & 30mg capsules ($45k), Hydromorphone 8mg ($125k), Naltrexone 50mg ($95k) and the balance of $95k due in relation to the first shipment of generic products which still require marketing authorizations from the FDA, and to which there can be no assurances of such marketing authorizations being granted and accordingly there can be no assurances that the Company will earn and receive these milestone amounts. These milestones have been determined to be substantive, with such determination being made by the Company after assessments based on the following:

- The Company's performance is required to achieve each milestone; and
- The milestones will relate to past performance, when achieved; and
- The milestones are reasonable relative to all of the deliverables and payment terms within the Precision Dose License Agreement.

The license fees provided for in the Precision Dose Agreement are calculated as a percentage of net sales dollars realized from commercial sales of the related products. Net sales dollars consist of gross invoiced sales less those costs and deductions directly attributable to each invoiced sale, including, without limitation, cost of goods sold, cash discounts, Medicaid rebates, state program rebates, price adjustments, returns, short date adjustments, charge backs, promotions, and marketing costs. The rate applied to the net sales dollars to determine license fees due to the Company is equal to an amount negotiated and agreed to by the parties to the Precision Dose License Agreement, with the following significant factors, inputs, assumptions, and methods, without limitation, being considered by either or both parties:

- Assessment of the opportunity for each generic product in the market, including consideration of the following, without limitation: market size, number of competitors, the current and estimated future regulatory, legislative, and social environment for each generic product, and the maturity of the market;
- Assessment of various avenues for monetizing the generic products, including the various combinations of sites of manufacture and marketing options;
- Capabilities of each party with regards to various factors, including, one or more of the following: manufacturing resources, marketing resources, financial resources, distribution capabilities, ownership structure, personnel, assessment of operational efficiencies and stability, company culture and image;
- Stage of development of each generic product, all of which did not have FDA approval at the time of the discussions/negotiations and an assessment of the risks, probability, and time frame for achieving marketing authorizations from the FDA for the products;
- Assessment of consideration offered by Precision and other entities with whom discussions were conducted; and,
- Comparison of the above factors among the various entities with whom the Company was engaged in discussions relating to the commercialization of the generic products.

The Ascend Manufacturing Agreement provides for the manufacturing by Elite of Methadone 10mg for supply to Ascend Laboratories LLC ("Ascend"). Ascend is the owner of the approved ANDA for Methadone 10mg, and the Northvale Facility is an approved manufacturing site for this ANDA. There are no license fees or milestones relating to this agreement. All revenues earned are recognized as manufacturing revenues on the date of shipment of the product, when title for the goods is transferred, and for which the price is agreed to and it has been determined that collectability is reasonably assured. The initial shipment of Methadone 10mg pursuant to the Ascend Manufacturing Agreement occurred in January 2012 and expires on December 31, 2017. The Company is evaluating extension of this agreement and there have not been any formal negotiations of such with Ascend to date.

The new Development and License Agreement with SunGen is to collaborate, develop and commercialize generic pharmaceutical products based upon a unique drug delivery platform used for extended release products. The Company and SunGen intend to begin with the development of five generic extended release products and to develop

additional such products subsequently. More than a dozen products utilize this type of technology. This new co-development agreement will build upon the success of the first development agreement between the Company and SunGen and signed in 2016.

Under the terms of the July 2017 SunGen Agreement, the Company and SunGen will share the responsibilities and costs of the development and marketing of the products. Upon FDA approval, the products will be owned jointly by Elite and SunGen. Elite will manufacture and package all products on a cost-plus basis.

NOTE 22. RELATED PARTY AGREEMENTS WITH MIKAH PHARMA LLC

Pursuant to the asset acquisition as discussed in Note 2 , on May 17, 2017, Elite Labs, executed an assignment agreement with Mikah, pursuant to which the Company acquired all rights, interests, and obligations under a supply and distribution agreement (the “Distribution Agreement”) with Dr. Reddy’s Laboratories, Inc. (“Dr. Reddy’s”) originally entered into by Mikah on May 7, 2017 and relating to the supply, sale and distribution of generic Trimipramine Maleate Capsules 25mg, 50mg and 100mg (“Trimipramine”).

On May 22, 2017, the Company executed an assignment agreement with Mikah, pursuant to which the Company acquired all rights, interests and obligations under a manufacturing and supply agreement with Epic Pharma LLC (“Epic”) originally entered into by Mikah on June 30, 2015 and relating to the manufacture and supply of Trimipramine (the “Manufacturing Agreement”).

Mikah is owned by Nasrat Hakim, the Chief Executive Officer, President and Chairman of the Board of the Company.

Under the Manufacturing Agreement, Epic will manufacture Trimipramine under license from the Company pursuant to the FDA approved and currently marketed ANDA that was acquired in conjunction with the Company's entry into these agreements (see Note 2).

Under the Distribution Agreement, the Company will supply Trimipramine on an exclusive basis to Dr. Reddy's and Dr. Reddy's will be responsible for all marketing and distribution of Trimipramine in the United States, its territories, possessions and commonwealth. The Trimipramine will be manufactured by Epic and transferred to Dr. Reddy's at cost, without markup.

Dr. Reddy's will pay to the Company a share of the profits, calculated without any deduction for cost of sales and marketing, derived from the sale of Trimipramine. The Company's share of these profits is in excess of 50%

NOTE 23. SUBSEQUENT EVENTS

The Company has evaluated subsequent events from the balance sheet date through February 2, 2018, the date the accompanying financial statements were issued. The following are material subsequent events.

Common Stock sold pursuant to the Lincoln Park Purchase Agreement

Subsequent to December 31, 2017 and up to February 2, 2017 (the latest practicable date), a total of 2,677,495 shares of Common Stock were sold and 37,604 additional commitment shares were issued, pursuant to the Lincoln Park Purchase Agreement. Proceeds received from such transactions totaled $271,475.

FDA Approval of Phendimetrazine Tartrate Tablets USP

On January 2, 2018, the Company announced that it received approval of its abbreviated new drug application ("ANDA") from the U.S. Food and Drug Administration ("FDA") for Phendimetrazine Tartrate Tablets USP, 35mg. This

product approval is from an ANDA that the Company filed approximately six years ago. Subsequent to this filing, the Company obtained a second, approved ANDA for this product and the Company has been selling this product for more than five years. The Company is considering strategic options, including divestiture, for this newly approved ANDA.

ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

THREE AND NINE MONTHS ENDED DECEMBER 31, 2017 (UNAUDITED)

COMPARED TO THE

THREE AND NINE MONTHS ENDED DECEMBER 31, 2016 (UNAUDITED)

The following discussion of our financial condition and results of operations for the three and nine months ended December 31, 2017 and 2016 should be read in conjunction with our unaudited condensed consolidated financial statements and the notes to those statements that are included elsewhere in this report. Our discussion includes forward-looking statements based upon current expectations that involve risks and uncertainties, such as our plans, objectives, expectations and intentions. Actual results and the timing of events could differ materially from those anticipated in these forward-looking statements as a result of a number of factors, including those set forth under Item 1A. Risk Factors appearing in our Annual Report on Form 10-K for the year ended March 31, 2017, as filed on June 14, 2017 with the SEC. We use words such as "anticipate," "estimate," "plan," "project," "continuing," "ongoing," "expect," "believe," "intend," "may," "will," "should," "could," and similar expressions to identify forward-looking statements.

Unless expressly indicated or the context requires otherwise, the terms "Elite", the "Company", "we", "us", and "our" refer to Elite Pharmaceuticals, Inc. and subsidiary.

Background

We are a specialty pharmaceutical company principally engaged in the development and manufacture of oral, controlled-release products, using proprietary know-how and technology, particularly as it relates to abuse resistant products.

We occupy manufacturing, warehouse, laboratory and office space at 165 Ludlow Avenue and 135 Ludlow Avenue in Northvale, NJ (the "Northvale Facility"). The Northvale Facility operates under Current Good Manufacturing Practice ("cGMP") and is a United States Drug Enforcement Agency ("DEA") registered facility for research, development and manufacturing.

Strategy

We focus our efforts on the following areas: (i) development of our pain management products; (ii) manufacturing of a line of generic pharmaceutical products with approved Abbreviated New Drug Application's ("ANDAs"); (iii) development of additional generic pharmaceutical products; (iv) development of the other products in our pipeline including the products with our partners; (v) commercial exploitation of our products either by license and the collection of royalties, or through the manufacture of our formulations; and (vi) development of new products and the expansion of our licensing agreements with other pharmaceutical companies, including co-development projects, joint ventures and other collaborations.

Our focus is on the development of various types of drug products, including branded drug products which require new drug applications ("NDAs") under Section 505(b)(1) or 505(b)(2) of the Drug Price Competition and Patent Term Restoration Act of 1984 (the "Drug Price Competition Act") as well as generic drug products which require ANDAs.

We believe that our business strategy enables us to reduce its risk by having a diverse product portfolio that includes both branded and generic products in various therapeutic categories and to build collaborations and establish licensing agreements with companies with greater resources thereby allowing us to share costs of development and improve cash-flow.

Commercial Products

We own, license or contract manufacture the following products currently being sold commercially:

Product	Branded Product Equivalent	Therapeutic Category	Launch Date
Phentermine HCl 37.5mg tablets ("Phentermine 37.5mg")	Adipex-P®	Bariatric	April 2011
Lodrane D ® Immediate Release capsules ("Lodrane D")	n/a	OTC Allergy	September 2011
Methadone HCl 10mg tablets ("Methadone 10mg")	Dolophine®	Pain	January 2012
Hydromorphone HCl 8mg tablets ("Hydromorphone 8mg")	Dilaudid®	Pain	March 2012
Phendimetrazine Tartrate 35mg tablets ("Phendimetrazine 35mg")	Bontril®	Bariatric	November 2012
Phentermine HCl 15mg and 30mg capsules ("Phentermine 15mg" and "Phentermine 30mg")	Adipex-P®	Bariatric	April 2013
Naltrexone HCl 50mg tablets ("Naltrexone 50mg")	Revia®	Pain	September 2013
	n/a	Cardiovascular	

Isradipine 2.5mg and 5mg capsules (“Isradipine 2.5mg” and “Isradipine 5mg”)			January 2015
Hydroxyzine HCl 10mg, 25mg and 50mg tablets (“Hydroxyzine 10mg” and “Hydroxyzine 25mg” and “Hydroxyzine 50mg”)	Atarax®, Vistaril®	Antihistamine	April 2015
Oxycodone HCl Immediate Release 5mg, 10mg, 15mg, 20mg and 30mg tablets (“OXY IR 5mg”, “Oxy IR 10mg”, “Oxy IR 15mg”, “OXY IR 20mg” and “Oxy IR 30mg”)	Roxicodone®	Pain	March 2016
Trimipramine Maleate Immediate Release 25mg, 50mg and 100mg capsules (“Trimipramine 25mg”, “Trimipramine 50mg”, “Trimipramine 100mg”)	Surmontil®	Antidepressant	May 2017

Note: Phentermine 15mg and Phentermine 30mg are collectively and individually referred to as "Phentermine Capsules". Isradipine 2.5mg and Isradipine 5mg are collectively and individually referred to as "Isradipine Capsules". Hydroxyzine 10mg, Hydroxyzine 25mg and Hydroxyzine 50mg are collectively and individually referred to as "Hydroxyzine". Oxy IR 5mg, Oxy IR 10mg, Oxy IR 15mg Oxy IR 20mg and Oxy IR 30mg are collectively and individually referred to as "Oxy IR". Trimipramine 25mg, Trimipramine 50mg, and Trimipramine 100mg are collectively and individually referred to as "Trimipramine".

Phentermine 37.5mg

The approved ANDA for Phentermine 37.5mg was acquired pursuant to an asset purchase agreement with Epic Pharma LLC ("Epic") dated September 10, 2010 (the "Phentermine Purchase Agreement").

Sales and marketing rights for Phentermine 37.5mg are included in the licensing agreement between the Company and Precision Dose Inc. ("Precision Dose") dated September 10, 2010 (the "Precision Dose License Agreement"). Please see the section below titled "Precision Dose License Agreement" for further details of this agreement.

The first shipment of Phentermine 37.5mg was made to Precision Dose's wholly owned subsidiary, TAGI Pharmaceuticals Inc. ("TAGI"), pursuant to the Precision Dose License Agreement, with such initial shipment triggering a milestone payment under this agreement. Phentermine 37.5mg is currently being manufactured by Elite and distributed by TAGI under the Precision Dose License Agreement.

Lodrane D®

On September 27, 2011, the Company, along with ECR Pharmaceuticals ("ECR"), launched Lodrane D®, an immediate release formulation of brompheniramine maleate and pseudoephedrine HCl, an effective, low-sedating antihistamine combined with a decongestant.

Lodrane D® is marketed under the Over-the-Counter Monograph (the "OTC Monograph") and accordingly, under the Code of Federal Regulations can be lawfully marketed in the US without prior approval of the United States Food and Drug Administration ("FDA"). Within the past few years, the FDA has revised its enforcement policies, significantly limiting the circumstances under which these unapproved products may be marketed. If the FDA determines that a company is distributing an unapproved product that requires approval, the FDA may take enforcement action in a variety of ways, including, without limitation, product seizures and seeking a judicial injunction against distribution.

ECR products have since been divested so that Lodrane D® is promoted and distributed in the United States of America (“U.S.”) now by Valeant Pharmaceuticals International Inc. Lodrane D® is available over-the-counter but also has physician promotion. Lodrane D® is one of the only adult brompheniramine containing products available to the consumer at this time.

There have been several mergers relating to ECR and successor entities and transfer of brand name ownership since this product was originally launched. Lodrane D® is accordingly currently promoted and distributed in the U.S. by Valeant Pharmaceuticals International Inc. (“Valeant”). Lodrane D® is available over-the-counter but also has physician promotion. Lodrane D® is the one of the only adult brompheniramine containing products available to the consumer at this time.

Elite is manufacturing the product for Valeant and will receive manufacturing revenues for this product.

Methadone 10mg

Methadone 10mg is contract manufactured by Elite for Ascend Laboratories, LLC ("Ascend"), the owner of the approved ANDA.

On January 17, 2012, Elite commenced shipping Methadone 10mg tablets to Ascend pursuant to a commercial manufacturing and supply agreement dated June 23, 2011, as amended on September 24, 2012 and January 19, 2015, July 20, 2015 and as extended on August 9, 2016 between Elite and Ascend (the "Methadone Manufacturing and Supply Agreement"). Under the terms of the Methadone Manufacturing and Supply Agreement, Elite performs manufacturing and packaging of Methadone 10mg for Ascend.

Hydromorphone 8mg

The approved ANDA for Hydromorphone 8mg was acquired pursuant to an asset purchase agreement with Mikah Pharma LLC ("Mikah Pharma") dated May 18, 2010 (the "Hydromorphone Purchase Agreement"). Transfer of the manufacturing process of Hydromorphone 8mg to the Northvale Facility, a prerequisite of the Company's commercial launch of the product, was approved by the FDA on January 23, 2012.

Sales and marketing rights for Hydromorphone 8mg are included in the Precision Dose License Agreement. Please see the section below titled "Precision Dose License Agreement" for further details of this agreement.

The first shipment of Hydromorphone 8mg was made to TAGI, pursuant to the Precision Dose License Agreement, in March 2012, with such initial shipment triggering a milestone payment under this agreement. Hydromorphone 8mg is currently being manufactured by Elite and distributed by TAGI under the Precision Dose License Agreement.

Phendimetrazine Tartrate 35mg

The ANDA for Phendimetrazine 35mg was acquired by Elite as part of the asset purchase agreement between the Company and Mikah Pharma, dated August 1, 2013 (the "Mikah ANDA Purchase"). Please see "Thirteen Abbreviated New Drug Applications" below for more information on this agreement. The Northvale Facility was already an approved manufacturing site for this product as of the date of the Mikah ANDA Purchase. Prior to the acquisition of this ANDA, Elite had been manufacturing this product on a contract basis pursuant to a manufacturing and supply agreement with Mikah Pharma, dated June 1, 2011.

Phendimetrazine 35mg is currently a commercial product being manufactured by Elite and distributed by Epic Pharma LLC ("Epic") on a non-exclusive basis, and by Elite.

On January 2, 2018, the Company announced that an ANDA filed approximately six years ago for Phendimetrazine 35mg was approved by the FDA, resulting in the Company owning two approved ANDA's for this product. The Company is considering strategic options, including divestiture, for this newly approved ANDA.

Phentermine 15mg and Phentermine 30mg

Phentermine 15mg capsules and Phentermine 30mg capsules were developed by the Company, with Elite receiving approval of the related ANDA in September 2012.

Sales and marketing rights for Phentermine 15mg and Phentermine 30mg are included in the Precision Dose License Agreement. Please see the section below titled "Precision Dose License Agreement" for further details of this agreement.

The first shipments of Phentermine 15mg and Phentermine 30mg were made to TAGI, pursuant to the Precision Dose License Agreement, in April 2013, with such initial shipments triggering a milestone payment under this agreement. Phentermine 15mg and Phentermine 30mg are currently being manufactured by Elite and distributed by TAGI under the Precision Dose License Agreement.

Naltrexone 50mg

The approved ANDA for Naltrexone 50mg was acquired by the Company pursuant to an asset purchase agreement between the Company and Mikah Pharma dated August 27, 2010 (the "Naltrexone Acquisition Agreement") for aggregate consideration of $200,000.

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Sales and marketing rights for Naltrexone 50mg are included in the Precision Dose License Agreement. Please see the section below titled “Precision Dose License Agreement” for further details of this agreement.

The first shipment of Naltrexone 50mg was made to TAGI, pursuant to the Precision Dose License Agreement, in September 2013, with such initial shipment triggering a milestone payment under this agreement. Naltrexone 50mg is currently being manufactured by Elite and distributed by TAGI under the Precision Dose License Agreement.

Isradipine 2.5mg and Isradipine 5mg

The approved ANDAs for Isradipine 2.5mg and Isradipine 5mg were acquired by Elite as part of the Mikah ANDA Purchase.

Sales and marketing rights for Isradipine 2.5mg and Isradipine 5mg are included in the Epic Manufacturing and License Agreement. Please see the section below titled “Manufacturing and License Agreement with Epic Pharma LLC” for further details of this agreement.

The first shipment of Isradipine 2.5mg and Isradipine 5mg were made to Epic, pursuant to the Epic Manufacturing and License Agreement, in January 2015. Isradipine 2.5mg and Isradipine 5mg are currently being manufactured by Elite and distributed by Epic under the Epic Manufacturing and License Agreement.

Hydroxyzine 10mg, Hydroxyzine 25mg and Hydroxyzine 50mg

The approved ANDAs for Hydroxyzine 10mg, Hydroxyzine 25mg and Hydroxyzine 50mg were acquired by Elite as part of the Mikah ANDA Purchase.

Sales and marketing rights for Hydroxyzine 10mg, Hydroxyzine 25mg and Hydroxyzine 50mg are included in the Epic Manufacturing and License Agreement.

The first shipment of Hydroxyzine 10mg, Hydroxyzine 25mg and Hydroxyzine 50mg were made by Epic, pursuant to the Epic Manufacturing and License Agreement, in April 2015. Hydroxyzine 10mg, Hydroxyzine 25mg and Hydroxyzine 50mg are currently being manufactured and distributed by Epic under the Epic Manufacturing and License Agreement.

Oxycodone 5mg, Oxycodone 10mg, Oxycodone 15mg, Oxycodone 20mg and Oxycodone 30mg ("Oxy IR")

We received notification from Epic in October 2015 of the approval by the FDA of Epic's ANDA for Oxy IR. This product was an Identified IR Product in the Epic Strategic Alliance Agreement Dated March 18, 2009 (the "Epic Strategic Alliance"). Oxy IR was developed at the Northvale Facility pursuant to the Epic Strategic Alliance, in which we are entitled to a Product Fee of 15% of Profits as defined in the Epic Strategic Alliance. The first commercial sale of Oxy IR occurred in March 2016, and sales by Epic of this product are ongoing.

Trimipramine 25mg, Trimipramine 50mg, and Trimipramine 100mg

Through Elite Labs, Elite acquired an approved and currently marketed ANDA for Trimipramine Maleate Capsules ("Trimipramine") 25, 50 and 100 mg, from Mikah Pharma. Through agreements assigned to Elite in the acquisition, Dr. Reddy's Laboratories, Inc. will market and sell the Trimipramine products and Epic Pharma will manufacture the products. The Epic Pharma agreement insures the uninterrupted supply of generic Trimipramine. Trimipramine is a generic version of Surmontil®, a tricyclic antidepressant. Surmontil® and generic Trimipramine have total US sales of approximately $2 million in 2016 according to IMS Health Data ("IMS"). The ANDA purchased by Elite is currently the only marketed generic Trimipramine product.

Filed products under FDA review

SequestOx™ - Immediate Release Oxycodone with sequestered Naltrexone

SequestOx™ is our lead abuse-deterrent candidate for the management of moderate to severe pain where the use of an opioid analgesic is appropriate. SequestOx™ is an immediate-release Oxycodone Hydrochloride containing sequestered Naltrexone which incorporates 5mg, 10mg, 15mg, 20mg and 30mg doses of oxycodone into capsules.

In January 2016, the Company submitted a 505(b)(2) New Drug Application for SequestOx™, after receiving a waiver of the $2.3 million filing fee from the FDA. In March 2016, the Company received notification of the FDA's acceptance of this filing and that such filing has been granted priority review by the FDA with a target action under the Prescription Drug User Fee Act ("PDUFA") of July 14, 2016.

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On July 15, 2016, the FDA issued a Complete Response Letter, or CRL, regarding the NDA. The CRL stated that the review cycle for the SequestOx™ NDA is complete and the application is not ready for approval in its present form.

On December 21, 2016, the Company met with the FDA for an end-of-review meeting to discuss steps that it could take to obtain approval of SequestOx™. Based on this and the meeting minutes received from the FDA on January 23, 2017, the Company formulated a plan to address the issues cited by the FDA in the CRL, with such plan including, without limitation, modifying the SequestOx™ formulation, conducting bioequivalence and bioavailability fed and fasted studies, comparing the modified formulation to the original formulation.

On July 7, 2017, the Company reported topline results from a pivotal bioequivalence fed study for or SequestOx™. The mean Tmax (the amount of time that a drug is present at the maximum concentration in serum) of SequestOx™ was 4.6 hr. with a range of 0.5 hr. to 12 hr. and the mean Tmax of the comparator, Roxicodone®, was 3.4 hr. with a range of 0.5 hr. to 12 hr. A key objective for the study was to determine if the reformulated SequestOx™ had a similar Tmax to the comparator when taken with a high fat meal. Based on these results, the Company paused clinical trials for this formulation of SequestOx™. On January 30, 2018, the Company reported positive topline results from a pilot study conducted for a modified SequestOx™ wherein, based on the results of this pilot study, the modified SequestOx™ formulation is expected to achieve bioequivalence with a Tmax range equivalent to the reference product when conducted in a pivotal trial under fed conditions. The Company intends to review these study results with the FDA and discuss pharmacokinetic study requirements for a re-submission of the NDA. The Company will continue to pursue extended release products with its proprietary abuse deterrent technology.

There can be no assurances of the success of any future clinical trials, or if such trials are successful, there can be no assurances that an intended future resubmission of the NDA product filing, if made, will be accepted by or receive marketing approval from the FDA, and accordingly, there can be no assurances that the Company will earn and receive the additional $7.5 million or future license fees. If the Company does not receive these payments or fees, it will materially and adversely affect our financial condition. In addition, even if marketing authorization is received, there can be no assurances that there will be future revenues or profits, or that any such future revenues or profits would be in amounts that provide adequate return on the significant investments made to secure this marketing authorization.

Oxycodone hydrochloride and acetaminophen USP CII (generic version of Percocet®)

On August 9, 2016, the Company filed an ANDA with the FDA for a generic version of Percocet® (oxycodone hydrochloride and acetaminophen, USP CII) 5mg, 7.5mg and 10mg tablets with 325mg of acetaminophen. Percocet® is a combination medication and is used to help relieve moderate to severe pain. On September 7, 2017, the Company received a CRL from the FDA for the ANDA filed for this product. The Company has responded to the CRL and submitted the required amendment which the Company believes addresses the deficiencies identified in the CRL. As

of the date of filing of this Quarterly Report on Form 10-Q, the Company has received no further communication from the FDA in relation to this product.

Hydrocodone bitartrate and acetaminophen tablets USP CII (generic version of Norco®)

On December 12, 2016, the Company filed an ANDA with the FDA for a generic version of Norco® (hydrocodone bitartrate and acetaminophen tablets USP CII) 2.5mg/325mg, 5mg/325mg, 7.5mg/325mg and 10mg/325mg tablets. Norco® is a combination medication and is used to help relieve moderate to moderately severe pain. The combination products of hydrocodone and acetaminophen have total annual US sales of approximately $700 million, according to IMS Health Data. The Company received a CRL from the FDA in October 2017 regarding this ANDA filing with actions required to resolve the deficiencies being in process. The Company intends to submit a response to the FDA addressing the deficiencies noted in the CRL and expects such response to be submitted prior to year end.

Oxycodone Hydrochloride Extended Release (generic version of OxyContin ®)

On September 20, 2017, the Company filed an ANDA with the FDA for a generic version of OxyContin ® (extended release Oxycodone Hydrochloride) tablets. OxyContin ® is approved for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate. OxyContin ® is formulated such that the tablets provide physical abuse deterrent properties. IMS reported approximately $2.3 billion in revenue for OxyContin ® and its equivalents in 2016. The FDA has requested additional information related to this filing and the Company expects to submit a response to the FDA’s request later this year.

Undisclosed generic for management of pain

In 2017, the Company filed an ANDA with the FDA for a generic version of an undisclosed generic to a reference product approved for the management of pain. IMS reported approximately $40 million in revenue for this undisclosed product and its equivalents in 2016. The Company has not received a response from the FDA regarding this ANDA filing.

There can be no assurances that any of these products will receive marketing authorization and achieve commercialization within this time period, or at all. In addition, even if marketing authorization is received, there can be no assurances that there will be future revenues of profits, or that any such future revenues or profits would be in amounts that provide adequate return on the significant investments made to secure these marketing authorizations.

Approved Products Not Yet Commercialized

We currently own seven different approved ANDAs, all of which were acquired as part of the Mikah ANDA Purchase. Each approved ANDA requires manufacturing site transfers as a prerequisite to commencement of commercial manufacturing and distribution. The products relating to each approved ANDA are included in the Epic Manufacturing and License Agreement, with Elite granting ANDA specific, exclusive or non-exclusive market rights (depending on the ANDA) to Epic. Commercial manufacturing of these products is expected to be transferred to either Epic or the Northvale Facility, with the required supplements to be filed with FDA in the manner and time frame that is economically beneficial to us.

Asset Acquisition Agreements

Generic Phentermine Capsules

On September 10, 2010, together with our wholly owned subsidiary, Elite Laboratories, Inc., executed a purchase agreement (the “Phentermine Purchase Agreement”) with Epic for the purpose of acquiring from Epic, an ANDA for a generic phentermine product (the “Phentermine ANDA”), with such being filed with the FDA at the time the Phentermine Purchase Agreement was executed. On February 4, 2011, the FDA approved the Phentermine ANDA. The acquisition of the Phentermine ANDA closed on March 31, 2011 and Elite paid the full acquisition price of $450,000 from the purchase agreement with Epic Pharma.

This product is being marketed and distributed by Precision Dose and its wholly owned subsidiary, TAGI, pursuant to the Precision Dose License Agreement, a description of which is set forth below.

Generic Hydromorphone HCl Product

On May 18, 2010, we executed an asset purchase agreement with Mikah Pharma (the "Hydromorphone Purchase Agreement"). Pursuant to the Hydromorphone Purchase Agreement, the Company acquired from Mikah Pharma an approved ANDA for Hydromorphone 8 mg for aggregate consideration of $225,000, comprised of an initial payment of $150,000, which was made on May 18, 2010. A second payment of $75,000 was due to be paid to Mikah Pharma on June 15, 2010, with the Company having the option to make this payment in cash or by issuing to Mikah Pharma 937,500 shares of our common stock. We elected and did issue 937,500 shares of Common Stock during the quarter ended December 31, 2010, in full payment of the $75,000 due to Mikah Pharma pursuant to the Hydromorphone Purchase Agreement dated May 18, 2010.

This product is currently being marketed and distributed by Precision Dose and its wholly owned subsidiary, TAGI, pursuant to the Precision Dose License Agreement, a description of which is set forth below.

Generic Naltrexone Product

On August 27, 2010, we executed an asset purchase with Mikah Pharma (the "Naltrexone Acquisition Agreement"). Pursuant to the Naltrexone Acquisition Agreement, Elite acquired from Mikah Pharma the ANDA number 75-274 (Naltrexone Hydrochloride Tablets USP, 50 mg), and all amendments thereto, that have to date been filed with the FDA seeking authorization and approval to manufacture, package, ship and sell the products described in this ANDA within the United States and its territories (including Puerto Rico) for aggregate consideration of $200,000. In lieu of cash, Mikah Pharma agreed to accept product development services to be performed by us.

This product is being marketed and distributed by Precision Dose and its wholly owned subsidiary, TAGI, pursuant to the Precision Dose License Agreement, a description of which is set forth below.

Thirteen Abbreviated New Drug Applications

On August 1, 2013, Elite executed the Mikah ANDA Purchase with Mikah Pharma and acquired a total of thirteen ANDAs, consisting of twelve ANDAs approved by the FDA and one ANDA under active review with the FDA, and

all amendments thereto (the "Mikah Thirteen ANDA Acquisition") for aggregate consideration of $10,000,000, payable pursuant to a secured convertible note due in August 2016.

Each of the products referenced in the twelve approved ANDAs require manufacturing site approval with the FDA. We believe that the site transfers qualify for Changes Being Effected in 30 Days ("CBE 30") review, with one exception, which would allow for the product manufacturing transfer on an expedited basis. However, we can give no assurances that all will qualify for CBE 30 review, or on the timing of these transfers of manufacturing site, or on the approval by the FDA of the transfers of manufacturing site.

As of the date of filing of this Quarterly Report on Form 10-Q, the following products included in the Mikah Purchase Agreement have successfully achieved manufacturing site transfers:

- Phendimetrazine 35mg
- Isradipine 2.5mg and Isradipine 5mg
- Hydroxyzine 10mg, Hydroxyzine 25mg and Hydroxyzine 50mg

We have executed the Epic Pharma Manufacturing and License Agreement, relating to the manufacturing, marketing and sale of these twelve ANDAs. Please see below for further details on the Epic Pharma Manufacturing and License Agreement.

Trimipramine

In May 2017, through Elite Labs, we acquired from Mikah Pharma an FDA approved ANDA for Trimipramine for aggregate consideration of $1,200,000. In conjunction with this acquisition, we also acquired from Mikah Pharma all rights, interests, and obligations under a supply and distribution agreement with Dr. Reddy's Laboratories, Inc. relating to the supply, sale and distribution of generic Trimipramine, and under a manufacturing and supply agreement with Epic Pharma relating to the manufacture and supply of Trimipramine.

Please see Note 22: Related Party Agreements with Mikah Pharma LLC to the Financial Statements above.

Licensing, Manufacturing and Development Agreements

Sales and Distribution Licensing Agreement with Epic Pharma LLC for SequestOx™

On June 4, 2015, we executed an exclusive License Agreement (the "2015 SequestOx™ License Agreement") with Epic, to market and sell in the U.S., SequestOx™, an immediate release oxycodone with sequestered naltrexone capsule, owned by us. Epic will have the exclusive right to market ELI-200 and its various dosage forms as listed in Schedule A of the Agreement. Epic is responsible for all regulatory and pharmacovigilance matters related to the products. Pursuant to the 2015 SequestOx™ License Agreement, Epic will pay us non-refundable payments totaling $15 million, with such amount representing the cost of an exclusive license to SequestOx™, the cost of developing the product, the filing of a NDA with the FDA and the receipt of the approval letter for the NDA from the FDA. As of the date of filing of this annual report on Form 10-K, the Company has received $7.5 million of the $15 million in non-refundable payments due pursuant to the 2015 SequestOx™ License Agreement, with such amount consisting of $5 million being due and owing on the execution date of the 2015 SequestOx™ License Agreement, and $2.5 million being earned as of January 14, 2016, the date of Elite's filing of an NDA with the FDA for the relevant product. Both of these non-refundable fees (i.e., the $5 million fee and the $2.5 million fee), have been paid by Epic.

The remaining $7.5 million in non-refundable payments due pursuant to the 2015 SequestOx™ License Agreement is due on the FDA's approval of SequestOx™ for commercial sale in the United States of America (please see the paragraph below for further details). In addition, we will receive a license fee computed as a percentage (50%) of net sales of the products as defined in the 2015 SequestOx™ License Agreement and is entitled to multi-million-dollar minimum annual license fees we will manufacture the product for sale by Epic on a cost-plus basis and both parties agree to execute a separate Manufacturing and Supply Agreement. The license fee is payable quarterly for the term of the 2015 SequestOx™ License Agreement. The term of the 2015 SequestOx™ License Agreement is five years and may be extended for an additional five years upon mutual agreement of the parties. Elite can terminate the 2015 SequestOx™ License Agreement on 90 days' written notice in the event that Epic does not pay us certain minimum annual license fees over the initial five-year term of the 2015 SequestOx™ License Agreement. Either party may terminate this 2015 SequestOx™ License Agreement upon a material breach and failure to cure that breach by the other party within a specified period. Please note that there was a change in management of Epic that occurred in May 2016, concurrent with a change in ownership of Epic. The new management of Epic has advised us of their desire to renegotiate the 2015 SequestOx™ License Agreement. Prior to conclusion of these renegotiations, in July 2016, the Company received a Complete Response Letter from the FDA stating that the FDA's review of the Company's NDA was complete and the application was not ready for approval in its present form. Subsequently, the Company has met with the FDA to discuss steps it could take to obtain approval of SequestOx™, conducted a pivotal bioequivalence fed study on a modified formulation, with results reported in July 2017, that did not indicate the required characteristics of a comparator, and a pilot study on a further modified formulation, with results reported in January 2018, that indicated the expectation of bioequivalence with the comparator when conducted in a pivotal trial under fed conditions. The Company intends to review the latest study results with the FDA and discuss pharmacokinetic study requirements for a re-submission of the NDA for SequestOx™. Negotiations with Epic have not been concluded due to the status of the application with the FDA, and the Company believes that the conclusion of such negotiations will be significantly influenced by the future status and potential approval of a re-submission with the FDA of the NDA for SequestOx™. While the 2015 SequestOx™ License Agreement is still in effect, achievement of the commercial terms and conditions strongly correlates to the status of the related product NDA. As a prudent business practice, we continue to cooperate and communicate with Epic, as well as maintaining other options relating to the license and/or distribution of SequestOx™. We believe that if agreement is reached with Epic on revised terms and conditions and amendment is made to the 2015 SequestOx™ License Agreement, such amendment may materially differ from the current 2015 SequestOx™ License Agreement.

On July 15, 2016, the FDA issued a Complete Response Letter, or CRL, regarding the NDA. The CRL stated that the review cycle for the SequestOx™ NDA is complete and the application is not ready for approval in its present form.

On December 21, 2016, the Company met with the FDA for an end-of-review meeting to discuss steps that it could take to obtain approval of SequestOx™. Based on this and the meeting minutes received from the FDA on January 23, 2017, the Company formulated a plan to address the issues cited by the FDA in the CRL, with such plan including, without limitation, modifying the SequestOx™ formulation, conducting bioequivalence and bioavailability fed and fasted studies, comparing the modified formulation to the original formulation.

On July 7, 2017, the Company reported topline results from a pivotal bioequivalence fed study for or SequestOx™. The mean Tmax (the amount of time that a drug is present at the maximum concentration in serum) of SequestOx ™ was 4.6 hr. with a range of 0.5 hr. to 12 hr. and the mean Tmax of the comparator, Roxicodone®, was 3.4 hr. with a range of 0.5 hr. to 12 hr. A key objective for the study was to determine if the reformulated SequestOx ™ had a similar Tmax to the comparator when taken with a high fat meal. Based on these results, the Company paused clinical trials for this formulation of SequestOx™.

On January 30, 2018, the Company reported positive topline results from a pilot study conducted for a modified SequestOx™ wherein, based on the results of this pilot study, the modified SequestOx™ formulation is expected to achieve bioequivalence with a Tmax range equivalent to the reference product when conducted in a pivotal trial under fed conditions. The Company intends to review these study results with the FDA and discuss pharmacokinetic study requirements for a re-submission of the NDA.

The Company will continue to pursue extended release products with its proprietary abuse deterrent technology.

There can be no assurances of the success of any future clinical trials, or if such trials are successful, there can be no assurances that an intended future resubmission of the NDA product filing, if made, will be accepted by or receive marketing approval from the FDA, and accordingly, there can be no assurances that the Company will earn and receive the additional $7.5 million or future license fees. If the Company does not receive these payments or fees, it will materially and adversely affect our financial condition. In addition, even if marketing authorization is received, there can be no assurances that there will be future revenues or profits, or that any such future revenues or profits would be in amounts that provide adequate return on the significant investments made to secure this marketing authorization.

Manufacturing and License Agreement with Epic Pharma LLC

On October 2, 2013, we executed the Epic Pharma Manufacturing and License Agreement (the "Epic Manufacturing and License Agreement"). This agreement granted Epic certain rights to manufacture, market and sell in the United States and Puerto Rico the twelve approved ANDAs acquired by us pursuant to the Mikah Thirteen ANDA Acquisition. Of the twelve approved ANDAs, Epic will have the exclusive right to market six products as listed in Schedule A of the Epic Manufacturing and License Agreement, and a non-exclusive right to market six products as listed in Schedule D of the Epic Manufacturing and License Agreement. Epic will manufacture the products and is responsible for all regulatory and pharmacovigilance matters related to the products and for all costs related to the site transfer for all products. We have no further obligations or deliverables under the Epic Manufacturing and License Agreement. Pursuant to the Epic Manufacturing and License Agreement, we will receive a license fee and milestone payments. The license fee will be computed as a percentage of the gross profit, as defined in the Epic Manufacturing and License Agreement, earned by Epic a result of sales of the products. The manufacturing cost used for the calculation of the license fee is a predetermined amount per unit plus the cost of the drug substance (API) and the sales cost for the calculation is predetermined based on net sales.

If we manufacture any product for sale by Epic, then Epic shall pay us the same predetermined manufacturing cost per unit plus the cost of the API. The license fee is payable monthly for the term of the Epic Manufacturing and License Agreement. Epic shall pay to us certain milestone payments as defined by the Epic Manufacturing and License Agreement. The term of the Epic Manufacturing and License Agreement is five years and may be extended for an additional five years upon mutual agreement of the parties. Twelve months following the launch of a product covered by the Epic Manufacturing and License Agreement, we may terminate the marketing rights for any product if the license fee paid, by Epic, falls below a designated amount for a nine-month period of that product. We may also terminate the exclusive marketing rights if Epic is unable to meet the annual unit volume forecast for a designated product group for any year, subject to the ability of Epic, during the succeeding nine-month period, to achieve at least one-half of the prior year's minimum annual unit forecast. The Epic Manufacturing and License Agreement may be terminated by mutual agreement, as a result of a breach by either party that is not cured within 60 days' notice of the breach, or by us as a result of Epic Pharma becoming a party to a bankruptcy, reorganization or other insolvency proceeding that continues for a period of 30 days or more.

Trimipramine Acquisition

On May 16, 2017, we executed an asset purchase agreement with Mikah Pharma, and acquired from Mikah Pharma (the "Trimipramine Acquisition") an FDA approved ANDA for Trimipramine for aggregate consideration of $1,200,000, payable pursuant to a senior secured note due on December 31, 2020 (the "Trimipramine Note"). Mikah Pharma is owned by Nasrat Hakim, the Chairman of the Board of Directors, President and Chief Executive Officer (CEO) of the Company.

The Trimipramine Note bears interest at the rate of 10% per annum, payable quarterly. All principal and unpaid interest is due and payable on December 31, 2020. Pursuant to a security agreement, repayment of the Trimipramine Note is secured by the ANDA acquired in the Acquisition.

Trimipramine Distribution Agreement with Dr. Reddy's Laboratories, Inc. and Manufacturing Agreement with Epic

On May 17, 2017, in conjunction with the Trimipramine Acquisition, the Company executed an assignment agreement with Mikah Pharma, pursuant to which the Company acquired all rights, interests, and obligations under a supply and distribution agreement (the "Reddy's Trimipramine Distribution Agreement") with Dr. Reddy's Laboratories, Inc. ("Dr. Reddy's") originally entered into by Mikah Pharma on May 7, 2017 and relating to the supply, sale and distribution of generic Trimipramine Maleate Capsules 25mg, 50mg and 100mg.

On May 22, 2017, the Company executed an assignment agreement with Mikah Pharma, pursuant to which the Company acquired all rights, interests and obligations under a manufacturing and supply agreement with Epic originally entered into by Mikah in 2011 and amended on June 30, 2015 and relating to the manufacture and supply of Trimipramine (the "Trimipramine Manufacturing Agreement").

Under the Trimipramine Manufacturing Agreement, Epic will manufacture Trimipramine under license from the Company pursuant to the FDA approved and currently marketed Abbreviated New Drug Application that was acquired in conjunction with the Company's entry into these agreements.

Under the Reddy's Trimipramine Distribution Agreement, the Company will supply Trimipramine on an exclusive basis to Dr. Reddy's and Dr. Reddy's will be responsible for all marketing and distribution of Trimipramine in the United States, its territories, possessions, and commonwealth. The Trimipramine will be manufactured by Epic and transferred to Dr. Reddy's at cost, without markup.

Dr. Reddy's will pay to the Company a share of the profits, calculated without any deduction for cost of sales and marketing, derived from the sale of Trimipramine. The Company's share of these profits is in excess of 50%.

Methadone Manufacturing and Supply Agreement

On June 23, 2011, as amended and extended, we entered into an agreement to manufacture and supply Methadone 10mg to ThePharmaNetwork LLC (the "Methadone Manufacturing and Supply Agreement"). ThePharmaNetwork LLC was subsequently acquired by Alkem Laboratories Ltd ("Alkem") and now goes by the name Ascend Laboratories LLC ("Ascend") and is a wholly owned subsidiary of Alkem.

Ascend in the owner of the approved ANDA for Methadone 10mg, and the Northvale Facility is an approved manufacturing site for this ANDA. The Methadone Manufacturing and Supply Agreement provides for the manufacture and packaging by the Company of Ascend's methadone hydrochloride 10mg tablets.

The initial shipment of Methadone 10mg pursuant to the Methadone Manufacturing and Supply Agreement occurred in January 2012.

On August 26, 2016, the Methadone Manufacturing and Supply Agreement was amended and extended through December 31, 2017. The Company is discussing further extension of this agreement. We continue to manufacture this product pursuant to the terms of the agreement[?].

Precision Dose License Agreement

On September 10, 2010, we executed a License Agreement with Precision Dose (the "Precision Dose License Agreement") to market and distribute Phentermine 37.5mg, Phentermine 15mg, Phentermine 30mg, Hydromorphone 8mg, Naltrexone 50mg, and certain additional products that require approval from the FDA, through its wholly-owned subsidiary, TAGI, in the United States, Puerto Rico and Canada. Phentermine 37.5mg was launched in April 2011. Hydromorphone 8mg was launched in March 2012. Phentermine 15mg and Phentermine 30mg were launched in April 2013. Naltrexone 50mg was launched in September 2013. Precision Dose will have the exclusive right to market these products in the United States and Puerto Rico and a non-exclusive right to market the products in Canada.

Pursuant to the Precision Dose License Agreement, Elite will receive a license fee and milestone payments. The license fee will be computed as a percentage of the gross profit, as defined in the Precision Dose License Agreement, earned by Precision Dose as a result of sales of the products. The license fee is payable monthly for the term of the Precision Dose License Agreement. The milestone payments will be paid in six installments. The first installment was paid upon execution of the Precision Dose License Agreement. The remaining installments are to be paid upon FDA approval and initial shipment of the products to Precision Dose. The term of the Precision Dose License Agreement is 15 years and may be extended for 3 successive terms, each of 5 years.

Master Development and License Agreement with SunGen Pharma LLC

On August 24, 2016, as amended we entered into an agreement with SunGen Pharma LLC ("SunGen") (the "SunGen Agreement") to undertake and engage in the research, development, sales and marketing of eight generic

pharmaceutical products. Two of the products are classified as CNS stimulants (the “CNS Products”), two of the products are classified as beta blockers and the remaining four products consist of antidepressants, antibiotics and antispasmodics.

Under the terms of the SunGen Agreement, Elite and SunGen will share in the responsibilities and costs in the development of these products and will share substantially in the profits from sales. Upon approval, the know-how and intellectual property rights to the products will be owned jointly by Elite and SunGen. Three of the eight products will be jointly owned, three products will be owned by SunGen, with Elite having exclusive marketing rights and the remaining two products will be owned by Elite, with SunGen having exclusive marketing rights. Elite will manufacture and package all eight products on a cost-plus basis.

On January 10, 2018, the Company reported positive topline results from pivotal bioequivalence studies for an undisclosed extended-release generic product in co-development with SunGen Pharma. The topline results indicate that the generic product is bioequivalent to the branded product. The studies were single dose crossover comparative bioavailability studies in healthy male and female volunteers in both the fed and fasting states. A fasting study with product beads sprinkled on to applesauce also demonstrated bioequivalence to the branded product. MS Health reported approximately $1.6 billion in revenue for the generic market for this product in 2017.

Products Under Development

Elite’s research and development activities are primarily focused on developing its proprietary abuse deterrent technology and the development of a range of abuse deterrent opioid products that utilize this technology or other approaches to abuse deterrence.

Elite’s proprietary abuse-deterrent technology, utilizes the pharmacological approach to abuse deterrence and consists of a multi-particulate capsule which contains an opioid agonist in addition to naltrexone, an opioid antagonist used primarily in the management of alcohol dependence and opioid dependence. When this product is taken as intended, the naltrexone is designed to pass through the body unreleased while the opioid agonist releases over time providing therapeutic pain relief for which it is prescribed. If the multi-particulate beads are crushed or dissolved, the opioid antagonist, naltrexone, is designed to release. The absorption of the naltrexone is intended to block the euphoria by preferentially binding to same receptors in the brain as the opioid agonist and thereby reducing the incentive for abuse or misuse by recreational drug abusers.

We filed an NDA for the first product to utilize our abuse deterrent technology, Immediate Release Oxycodone 5mg, 10mg, 15mg, 20mg and 30mg with sequestered Naltrexone (collectively and individually referred to as "SequestOx™"), on January 14, 2016.

On July 15, 2016, the FDA issued a Complete Response Letter, or CRL, regarding the NDA. The CRL stated that the review cycle for the SequestOx™ NDA is complete and the application is not ready for approval in its present form.

On December 21, 2016, the Company met with the FDA for an end-of-review meeting to discuss steps that it could take to obtain approval of SequestOx™. Based on this and the meeting minutes received from the FDA on January 23, 2017, the Company formulated a plan to address the issues cited by the FDA in the CRL, with such plan including, without limitation, modifying the SequestOx™ formulation, conducting bioequivalence and bioavailability fed and fasted studies, comparing the modified formulation to the original formulation.

On July 7, 2017, the Company reported topline results from a pivotal bioequivalence fed study for or SequestOx™. The mean Tmax (the amount of time that a drug is present at the maximum concentration in serum) of SequestOx™ was 4.6 hr. with a range of 0.5 hr. to 12 hr. and the mean Tmax of the comparator, Roxicodone®, was 3.4 hr. with a range of 0.5 hr. to 12 hr. A key objective for the study was to determine if the reformulated SequestOx™ had a similar Tmax to the comparator when taken with a high fat meal. Based on these results, the Company paused clinical trials for this formulation of SequestOx™. On January 30, 2018, the Company reported positive topline results from a pilot study conducted for a modified SequestOx™ wherein, based on the results of this pilot study, the modified SequestOx™ formulation is expected to achieve bioequivalence with a Tmax range equivalent to the reference product when conducted in a pivotal trial under fed conditions. The Company intends to review these study results with the FDA and discuss pharmacokinetic study requirements for a re-submission of the NDA. The Company will continue to pursue extended release products with its proprietary abuse deterrent technology.

There can be no assurances of the success of any future clinical trials, or if such trials are successful, there can be no assurances that an intended future resubmission of the NDA product filing, if made, will be accepted by or receive marketing approval from the FDA, and accordingly, there can be no assurances that the Company will earn and receive the additional $7.5 million or future license fees. If the Company does not receive these payments or fees, it will materially and adversely affect our financial condition. In addition, even if marketing authorization is received, there can be no assurances that there will be future revenues or profits, or that any such future revenues or profits would be in amounts that provide adequate return on the significant investments made to secure this marketing authorization.

On August 9, 2016, the Company filed an ANDA with the FDA for a generic version of Percocet® (oxycodone hydrochloride and acetaminophen, USP CII) 5mg, 7.5mg and 10mg tablets with 325mg of acetaminophen ("Generic Oxy/APAP"). Percocet® is a combination medication, with abuse deterrence, and is used to help relieve moderate to

severe pain. On September 7, 2017, the Company received a CRL from the FDA for the ANDA filed for this product. The Company has responded to the CRL and submitted the required amendment which the Company believes addresses the deficiencies identified in the CRL. As of the date of filing of this Quarterly Report on Form 10-Q, the Company has received no further communication from the FDA in relation to this product. Please note that there can be no assurances of this product receiving marketing authorization, or achieving commercialization. In addition, even if marketing authorization is received and the product is commercialized, there can be no assurances of future revenues or profits in such amounts that would provide adequate return on the significant investments made to secure marketing authorization for this product.

On December 12, 2016, the Company filed an ANDA with the FDA for a generic version of Norco ® (hydrocodone bitartrate and acetaminophen tablets USP CII) 2.5mg/325mg, 5mg/325mg, 7.5mg/325mg and 10mg/325mg tablets ("Generic Hydrocodone/APAP"). Norco® is a combination medication and is used to help relieve moderate to moderately severe pain. The Company received a CRL from the FDA in October 2017 regarding this ANDA filing with actions required to resolve the deficiencies being in process. The Company intends to submit a response to the FDA addressing the deficiencies noted in the CRL and expects such response to be submitted prior to year end. Please note that there can be no assurances of this product receiving marketing authorization, or achieving commercialization. In addition, even if marketing authorization is received and the product is commercialized, there can be no assurances of future revenues or profits in such amounts that would provide adequate return on the significant investments made to secure marketing authorization for this product.

On September 20, 2017, the Company filed an ANDA with the FDA for a generic version of OxyContin® (extended release Oxycodone Hydrochloride) tablets ("Generic Extended Release Oxycodone"). OxyContin® is approved for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate. OxyContin ® is formulated such that the tablets provide physical abuse deterrent properties. IMS reported approximately $2.3 billion in revenue for OxyContin® and its equivalents in 2016. The FDA has requested additional information related to this filing and the Company expects to submit a response to the FDA's request later this year. Please note that there can be no assurances of this product receiving marketing authorization, or achieving commercialization. In addition, even if marketing authorization is received and the product is commercialized, there can be no assurances of future revenues or profits in such amounts that would provide adequate return on the significant investments made to secure marketing authorization for this product.

The Company believes that the abuse deterrent technology can be applied to and incorporated into a wide range of opioids used today for pain management and has, to date, identified 10 additional products for potential development. All of these products are at early stages of development, with research and development activities mainly consisting of in-house process development and laboratory studies. Extensive efficacy and safety studies, similar to those conducted for SequestOx™, Generic Oxy/APAP, Generic Hydrocodone/APAP, and Generic Extended Release Oxycodone have not yet been conducted for these other products. As a result, costs incurred in relation to the development of these 10 products have not been material.

Research and development costs were $2.7 and $1.5 million for the three months ended December 31, 2017 and 2016, respectively and $7.1 million and $4.3 million for the nine months ended December 31, 2017 and 2016, respectively. Costs incurred during the prior fiscal year relate almost entirely to the development of the abuse deterrent opioid product, SequestOx,™ Generic Oxy/APAP, Generic Hydrocodone/APAP and costs incurred during the current fiscal year relate almost entirely to the development of the abuse deterrent opioid products, SequestOx™, Generic Oxy/APAP, Generic Hydrocodone/APAP, Generic Extended Release Oxycodone, and the generic, undisclosed pain product.

On June 4, 2015, the Company entered into a sales and distribution licensing agreement which included a non-refundable payment of $5 million to Elite for prior research and development activities, with such representing the first material net cash inflows being generated by ELI-200. On January 14, 2016, the Company filed an NDA with the FDA for SequestOx™, thereby earning a non-refundable $2.5 million milestone. An additional $7.5 million non-refundable milestone is due upon the FDA's approval of Elite's NDA. Please note, as further detailed above, there can be no assurances of the Company receiving marketing authorization for SequestOx™, and accordingly, there can be no assurances that the Company will earn and receive the additional $7.5 million or future license fees. The non-receipt by the Company of these payments and or fees will materially and adversely affect our financial condition.

Please note that, while the FDA is required to review applications within certain timeframes, during the review process, the FDA frequently requests that additional information be submitted. The effect of such request and subsequent submission can significantly extend the time for the NDA review process. Until an NDA is actually approved, there can be no assurances that the information requested and submitted will be considered adequate by the FDA to justify approval. The packaging and labeling of our developed products are also subject to FDA regulation. Based on the foregoing, it is impossible to anticipate the amount of time that will be needed to obtain FDA approval to market any product. In addition, there can be no assurances of the Company filing the required application(s) with the FDA or of the FDA approving such application(s) if filed, and the Company's ability to successfully develop and commercialize products incorporating its abuse deterrent technology is subject to a high level of risk as detailed in "Item 1A-Risk Factors-Risks Related to our Business" of the Annual Report on Form 10-K filed with the SEC on June 14, 2017, and further detailed in "Item 1A-Risk Factors" in this quarterly report on Form 10-Q.

Abuse-Deterrent and Sustained Release Opioids

The abuse-deterrent opioid products utilize our patented abuse-deterrent technology that is based on a pharmacological approach. These products are combinations of a narcotic agonist formulation intended for use in patients with pain, and an antagonist, formulated to deter abuse of the drug. Both, agonist and antagonist, have been on the market for a number of years and sold separately in various dose strengths. We have filed Investigational New Drug applications ("INDs") for two abuse resistant products under development and have tested products in various pharmacokinetic and efficacy studies. We expect to continue to develop multiple abuse resistant products. Products utilizing the pharmacological approach to deter abuse such as Suboxone®, a product marketed in the United States by Reckitt Benckiser Pharmaceuticals, Inc., and Embeda®, a product marketed in the United States by Pfizer, Inc., have been approved by the FDA and are being marketed in the United States.

We have developed, licensed to Epic the marketing rights to SequestOx™, immediate release Oxycodone with Naltrexone, and have retained the rights to the remainder of these abuse resistant and sustained release opioid products. We may license these products at a later date to a third party who could provide funding for the remaining clinical studies and who could provide sales and distribution for the product.

We also developed controlled release technology for oxycodone under a joint venture with Elan which terminated in 2002. According to the Elan Termination Agreement, we acquired all proprietary, development and commercial rights for the worldwide markets for the products developed by the joint venture, including the sustained release opioid products. Upon licensing or commercialization of an oral controlled release formulation of oxycodone for the treatment of pain, we will pay a royalty to Elan pursuant to the Elan Termination Agreement. If we were to sell the product itself, we will pay a 1% royalty to Elan based on the product's net sales, and if we enter into an agreement with another party to sell the product, we will pay a 9% royalty to Elan based on our net revenues from this product. We are allowed to recoup all development costs including research, process development, analytical development, clinical development and regulatory costs before payment of any royalties to Elan.

Patents

Since our incorporation, we have secured the following patents, of which two have been assigned for a fee to another pharmaceutical company. Our patents are:

PATENT	EXPIRATION DATE
U.S. patent 5,837,284 (assigned to Celgene Corporation)	November 2018
U.S. patent 6,620,439	October 2020
U.S. patent 6,635,284 (assigned to Celgene Corporation)	March 2018
U.S. patent 6,926,909	April 2023
U.S. patent 8,182,836	April 2024
U.S. patent 8,425,933	April 2024
U.S. patent 8,703,186	April 2024
Canadian patent 2,521,655	April 2024
Canadian patent 2,541,371	September 2024
U.S. patent 9,056,054	June 2030
E.P. patent 1615623	April 2024

We also have pending applications for two additional U.S. patents and two foreign patents. We intend to apply for patents for other products in the future; however, there can be no assurance that any of the pending applications or other applications which we may file will be granted. We have also filed corresponding foreign applications for key patents.

Prior to the enactment in the United States of new laws adopting certain changes mandated by the General Agreement on Tariffs and Trade (“GATT”), the exclusive rights afforded by a U.S. Patent were for a period of 17 years measured from the date of grant. Under GATT, the term of any U.S. Patent granted on an application filed subsequent to June 8, 1995 terminates 20 years from the date on which the patent application was filed in the United States or the first priority date, whichever occurs first. Future patents granted on an application filed before June 8, 1995, will have a term that terminates 20 years from such date, or 17 years from the date of grant, whichever date is later.

Under the Drug Price Competition Act, a U.S. product patent or use patent may be extended for up to five years under certain circumstances to compensate the patent holder for the time required for FDA regulatory review of the product. Such benefits under the Drug Price Competition Act are available only to the first approved use of the active ingredient in the drug product and may be applied only to one patent per drug product. There can be no assurance that we will be able to take advantage of this law.

Also, different countries have different procedures for obtaining patents, and patents issued by different countries provide different degrees of protection against the use of a patented invention by others. There can be no assurance, therefore, that the issuance to us in one country of a patent covering an invention will be followed by the issuance in other countries of patents covering the same invention, or that any judicial interpretation of the validity, enforceability, or scope of the claims in a patent issued in one country will be similar to the judicial interpretation given to a corresponding patent issued in another country. Furthermore, even if our patents are determined to be valid, enforceable, and broad in scope, there can be no assurance that competitors will not be able to design around such patents and compete with us using the resulting alternative technology.

Trademarks

SequestOx™ is a trademark owned by Elite, which received a Notice of Allowance by the United States Patent and Trademark Office on December 22, 2015.

We currently plan to license at least some of our products to other entities in the marketing of pharmaceuticals, but may also sell products under our own brand name in which case we may register trademarks for those products.

Sources and Availability of Raw Materials; Manufacturing

A significant portion of our raw materials may be available only from foreign sources. Foreign sources can be subject to the special risks of doing business abroad, including:

- greater possibility for disruption due to transportation or communication problems;
- the relative instability of some foreign governments and economies;
- interim price volatility based on labor unrest, materials or equipment shortages, export duties, restrictions on the transfer of funds, or fluctuations in currency exchange rates; and,
- uncertainty regarding recourse to a dependable legal system for the enforcement of contracts and other rights.

While we currently obtain the raw materials that we need from over 20 suppliers, some materials used in our products are currently available from only one supplier or a limited number of suppliers. The FDA requires identification of raw material suppliers in applications for approval of drug products. If raw materials were unavailable from a specified supplier, FDA approval of a new supplier could delay the manufacture of the drug involved.

We have acquired pharmaceutical manufacturing equipment for manufacturing our products. We have registered our facilities with the FDA and the DEA.

Dependence on One or a Few Major Customers

Each year we have had one or a few customers that have accounted for a large percentage of our limited revenues, therefore the termination or restructuring of a contract with a customer may result in the loss of material amount or substantially all of our revenues. We are constantly working to develop new relationships with existing or new customers, but despite these efforts we may not, at the time that any of our current contracts expire, have other contracts in place generating similar or material revenue. We have agreements with Epic, Precision Dose and Ascend for the licensing, sales and distribution of products that we manufacture. We are currently renegotiating a licensing contract with Epic, which may result in the termination of an existing contract or an amended licensing contract that is materially different from that already in place. We receive revenues to manufacture these products and also receive a profit split or royalties based on in-market sales of the products.

Critical Accounting Policies and Estimates

The preparation of the unaudited condensed consolidated financial statements and related disclosures in conformity with GAAP, and our discussion and analysis of its financial condition and operating results require our management to make judgments, assumptions and estimates that affect the amounts reported in its condensed consolidated financial statements and accompanying notes. Note 1 – Summary of Significant Accounting Policies, of the Notes to Condensed Consolidated Financial Statements of this Quarterly Report on Form 10-Q describes the significant accounting policies and methods used in the preparation of our unaudited condensed consolidated financial statements. Management bases its estimates on historical experience and on various other assumptions it believes to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities. Actual results may differ from these estimates and such differences may be material.

Results of Operations

The following set forth our results of operations for the periods presented. The period-to-period comparison of financial results is not necessarily indicative of future results.

Three months ended December 31, 2017 compared to December 31, 2016

Revenue, Cost of revenue and Gross profit:

	For the Three Months Ended December 31,		Change	
	2017	2016	Dollars	Percentage
Manufacturing fees	$ 2,083,826	$ 1,885,765	$198,061	11 %
Licensing fees	451,628	444,884	6,744	2 %
Total revenue	2,535,454	2,330,649	204,805	9 %
Cost of revenue	1,419,829	1,726,751	(306,922)	-18 %
Gross profit	$ 1,115,625	$ 603,898	$511,727	85 %
Gross profit - percentage	44 %	26 %		

Total revenues for the three-month period ended December 31, 2017 increased by $0.2 million or 9%, to $2.5 as compared to $2.3 million, for the corresponding period in 2016 primarily due to the following:

Manufacturing fees increased by $0.2 million, or 11%, due to a growth in the generic product lines manufactured during the quarter.

Licensing fees increased by $0.006 million, or 2%. This increase is primarily due to the timing of in-market sales of the Company's generic products, as well as margins achieved by the Company's licensed marketing partners. License fees earned are based on in-market sales and accordingly, there is a natural lag between manufacturing revenues earned by the Company and related license fees being earned from in market sales occurring subsequent to the Company's shipment of licensed generic products to its marketing partners. In market profits achieved by the Company's marketing partners are also a factor, with a direct correlation to the license fee revenues earned by the Company.

Costs of revenue consists of manufacturing costs. Our costs of revenue decreased by $0.3 million or 18%, to $1.4 million as compared to $1.7 million for the corresponding period in 2016. Costs of revenue consists of manufacturing and assembly costs, with each product having a unique cost profile correlating to the underlying cost of the materials consumed, direct labor hours expended and overhead resources utilized. The decrease in overall costs of revenues is due in large part to manufacturing operations in the current quarter consisting of a lower cost profile product mix, as compared to manufacturing operations in the same quarter of the prior year, despite there being an increase in overall manufacturing revenues for the current quarter as compared to the same quarter of the prior year.

Our gross profit margin was 44% during the three months ended December 31, 2017 as compared to 26% during the three months ended December 31, 2016. The increase in gross margin is due to the product mix of generics manufactured during the quarter.

Operating expenses:

	For the Three Months Ended December 31,		Change		
	2017	2016	Dollars	Percentage	
Operating expenses:					
Research and development	$ 2,514,435	$ 1,526,183	$988,252	65	%
General and administrative	614,994	694,321	(79,327)	-11	%
Non-cash compensation	37,961	84,785	(46,824)	-55	%
Depreciation and amortization	7,196	21,032	(13,836)	-66	%
Total operating expenses	$ 3,174,586	$ 2,326,321	$848,265	36	%

Operating expenses consist of research and development costs, general and administrative, non-cash compensation through the issuance of stock options and depreciation and amortization expenses. Operating expenses for the three-month period ended December 31, 2017 increased by $0.9 million, or 36%, to $3.2 million, as compared to $2.3 million for the corresponding period in 2016.

Research and development costs for the three months ended December 31, 2017 were $2.5 million, an increase of $1.0 million or 65% from $1.5 million of such costs for the comparable period of the prior year. The increase was due to increased product development activities culminating in positive topline results from pivotal and pilot studies for several products and progress made towards the filing of additional ANDA applications.

General and administrative expenses for the three months ended December 31, 2017 and 2016 were $0.6 million and $0.7 million, respectively. The decrease is due to ongoing cost reduction efforts. Please note however, that regulatory fees and compliance costs, including, without limitation, fees and costs related to compliance with FDA, DEA and Sarbanes Oxley regulations have significantly increased and represent areas of costs that have a weak correlation to the Company’s cost reduction efforts.

Non-cash compensation expense through the issuance of stock options for the three months ended December 31, 2017 and 2016 was $0.04 million and $0.08 million, respectively. The decrease in non-cash compensation expense derives from the timing in amortization of the value of employee stock options issued over the course of the last three years and a decrease in the number of options granted as compared to the corresponding period in 2016.

Depreciation and amortization expense for the three months ended December 31, 2017 was $0.01 million, a decrease of $0.01 million, or 66% from $0.02 million of such costs for the comparable period of the prior year. The decrease was due to the combination of increased facility utilization and higher depreciation absorption rates currently as a result of facility expansion and improvements over the last year, and the application of resources between commercial and product development activity.

As a result of the foregoing, our loss from operations for the three months ended December 31, 2017 was $2.1 million, compared to a loss from operations of $1.7 million for the three months ended December 31, 2016.

Other income (expense):

	For the Three Months Ended December 31,		Change	
	2017	2016	Dollars	Percentage
Other income (expense):				
Interest expense and amortization of debt issuance costs	$ (92,458)	$ (55,563)	$(36,895)	66 %
Change in fair value of derivative instruments	605,448	1,571,471	(966,023)	-61 %
Interest income	4,461	3,151	1,310	42 %
Other income (expense), net	$ 517,451	$ 1,519,059	$(1,001,608)	-66 %

Other income (expense), net for the three months ended December 31, 2017 was net other income of $0.5 million, a decrease in net other income of $1.0 million from the net other income of $1.5 million for the comparable period of the prior year. The decrease in other income was due to other income relating to changes in the fair value of our outstanding warrants during the three months ended December 31, 2017 totaling a decrease in other income of $1.0 million, as compared to the prior period. Please note that derivative income (expenses) is determined in large part by the number of warrants outstanding and the change in the closing price of the Company’s Common Stock as of the end of the period, as compared to the closing price at the beginning of the period, with a strong inverse relationship between derivative income (expenses) and increases in the closing price of the Company’s Common Stock.

As a result of the foregoing, our net loss for the three months ended December 31, 2017 was $0.5 million, compared to a net income of $1.7 million for the comparable period of the prior year.

Change in value of convertible preferred share mezzanine equity:

There were no changes in the value of our convertible preferred stock, which is included in the calculation of net income (loss) attributable to common shareholders for the three months ended December 31, 2017 and 2016, respectively. Accordingly, net income attributable to common shareholders for the three months ended December 31, 2017 was a net loss of $0.5 million, compared to net income of $1.7 million for the comparable period of the prior year.

Nine months ended December 31, 2017 compared to December 31, 2016

Revenue, Cost of revenue and Gross profit:

	For the Nine Months Ended December 31,		Change	
	2017	2016	Dollars	Percentage
Manufacturing fees	$ 4,160,949	$ 6,470,697	$(2,309,748)	-36 %
Licensing fees	1,700,856	1,816,796	(115,940)	-6 %
Total revenue	5,861,805	8,287,493	(2,425,688)	-29 %
Cost of revenue	3,049,830	5,755,997	(2,706,167)	-47 %
Gross profit	$ 2,811,975	$ 2,531,496	$280,479	11 %
Gross profit - percentage	48 %	31 %		

Total revenues for the nine-month period ended December 31, 2017 decreased by $2.4 million or 29%, to $5.9 million, as compared to $8.3 million, for the corresponding period in 2016 primarily due to the following:

Manufacturing fees decreased by $2.3 million, or 36%, due to a decrease (in the first two quarters of the year) related to generic Methadone and Naltrexone sales.

Licensing fees decreased by $0.1 million, or 6%. This decrease is primarily due to the timing of in-market sales of the Company’s generic products, as well as margins achieved by the Company’s licensed marketing partners. License fees earned are based on in-market sales and accordingly, there is a natural lag between manufacturing revenues earned by the Company and related license fees being earned from in market sales occurring subsequent to the Company’s shipment of licensed generic products to its marketing partners. In market profits achieved by the Company’s marketing partners are also a factor, with a direct correlation to the license fee revenues earned by the Company.

Costs of revenue consists of manufacturing and assembly costs. Our costs of revenue decreased by $2.7 million or 47%, to $3.0 million as compared to $5.7 million for the corresponding period in 2016. In addition to the direct correlation between manufacturing revenues and costs of revenues, please note that cost of revenue consists of manufacturing and assembly costs, with each product having a unique cost profile correlating to the underlying cost of the materials consumed, direct labor hours expended and overhead resources utilized. The decrease in costs of revenues is due in large part to the strong correlation between manufacturing revenues and these costs, combined with effects of the difference in products manufactured as compared between the years.

Our gross profit margin was 48% during the nine months ended December 31, 2017 as compared to 31% during the nine months ended December 31, 2016. The increase in gross margin is due to the product mix of generics manufactured during the quarter and the application of resources between commercial and product development activity.

Operating expenses:

	For the Nine Months Ended December 31,		Change	
	2017	2016	Dollars	Percentage
Operating expenses:				
Research and development	$ 6,944,182	$ 4,312,337	$2,631,845	61 %
General and administrative	2,068,028	2,060,380	7,648	0 %
Non-cash compensation	208,719	258,954	(50,235)	-19 %
Depreciation and amortization	21,149	64,408	(43,259)	-67 %
Total operating expenses	$ 9,242,078	$ 6,696,079	$2,545,999	38 %

Operating expenses consist of research and development costs, general and administrative, non-cash compensation and depreciation and amortization expenses. Operating expenses for the nine-month period ended December 31, 2017 increased by $2.5 million, or 38%, to $9.2 million, as compared to $6.7 million for the corresponding period in 2016.

Research and development costs for the nine months ended December 31, 2017 were $6.9 million, an increase of $2.6 million or 61% from $4.3 million of such costs for the comparable period of the prior year. The increase was due to increased product development activities culminating in positive topline results from pivotal and pilot studies of several products and the filing of two ANDA’s and progress made toward additional ANDA filings.

General and administrative expenses for the nine months ended December 31, 2017 and 2016 were $2.1 million and $2.1 million, respectively. Although these costs are almost unchanged as compared to the prior year, please note that while the Company continues diligent cost reduction efforts in this area, there have been significant increases in

regulatory fees and costs relating to compliance with FDA, DEA and Sarbanes Oxley regulations, which have a weak correlation to the Company's cost reduction efforts, and which have offset, in large part, cost reductions achieved elsewhere.

Non-cash compensation expense for the nine months ended December 31, 2017 and 2016 was $0.2 million and $0.3 million, respectively. The decrease in non-cash compensation expense derives from the timing in amortization of the value of employee stock options issued over the course of the last three years and a decrease in the number of options granted as compared to the corresponding period in 2016.

Depreciation and amortization expense for the nine months ended December 31, 2017 was $0.02 million, a decrease of $0.04 million, or 67% from $0.06 million of such costs for the comparable period of the prior year. The decrease was due to the combination of increased facility utilization and higher depreciation absorption rates currently as a result of facility expansion and improvements over the last year, and the application of resources between commercial and product development activity.

As a result of the foregoing, our loss from operations for the nine months ended December 31, 2017 was $6.4 million, compared to a loss from operations of $4.2 million for the nine months ended December 31, 2016.

Other income (expense):

	For the Nine Months Ended December 31,		Change	
	2017	2016	Dollars	Percentage
Other income (expense):				
Interest expense and amortization of debt issuance costs	$ (245,730)	$ (181,883)	$(63,847)	35 %
Change in fair value of derivative instruments	4,767,884	9,468,320	(4,700,436)	-50 %
Interest income	12,862	9,407	3,455	37 %
Other income (expense), net	$ 4,535,016	$ 9,295,844	$(4,760,828)	-51 %

Other income (expense), net for the nine months ended December 31, 2017 was net other income of $4.5 million, a decrease in net other income of $4.8 million from net other income of $9.3 million for the comparable period of the prior year. The decrease in other income was due to derivative income relating to changes in the fair value of our outstanding warrants during the quarter ended December 31, 2017 totaling a decrease in other income of $4.7 million, as compared to the prior period. Please note that derivative income (expenses) is determined in large part by the number of warrants outstanding and the change in the closing price of the Company's Common Stock as of the end of the period, as compared to the closing price at the beginning of the period, with a strong inverse relationship between derivative revenues and increases in the closing price of the Company's Common Stock.

As a result of the foregoing, our net loss for the nine months ended December 31, 2017 was $0.8 million, compared to a net income of $7.0 million for the comparable period of the prior year.

Change in value of convertible preferred share mezzanine equity:

There was no change in the value of our convertible preferred stock, which is included in the calculation of net income (loss) attributable to common shareholders for the nine months ended December 31, 2017, and an increase of $20.7 million for the nine months ended December 31, 2016. Accordingly, net income attributable to common shareholders for the nine months ended December 31, 2017 was a net loss of $0.8 million, compared to net income of $27.7 million for the comparable period of the prior year.

Liquidity and Capital Resources

Capital Resources

	December 31, 2017	March 31, 2017	Change
Current assets	$ 14,763,967	$ 18,412,720	$(3,648,753)
Current liabilities	4,743,096	3,344,746	1,398,350
Working capital	10,020,871	15,067,974	(5,047,103)

The Company considers cash and working capital balances as several of the factors the Company uses in evaluating its performance, without limitation. As of December 31, 2017, the Company had cash on hand of $7.2 million and a working capital surplus of $10.0 million. We believe that such resources, combined with the Company's access to part or all of the remaining $38.8 million available pursuant to the $40.0 million equity line with Lincoln Park is sufficient to fund operations through the current operating cycle. For the nine months ended December 31, 2017, we had losses

from operations totaling $6.4 million, and net other income totaling $4.5 million, resulting in a net loss of $0.8 million.

The Company does not anticipate being profitable for the fiscal year ending March 31, 2018, due in large part to its plans to conduct clinical development and commercialization activities on a range of abuse deterrent opioid products, on an accelerated and simultaneous basis. Such activities require the investment of significant amounts in clinical trials, safety and efficacy studies, bioequivalence studies, product manufacturing, regulatory expertise and filings, as well as investments in manufacturing and lab equipment and software. In order to finance these significant expenditures, the Company entered into a new purchase agreement with Lincoln Park Capital Fund, with such agreement providing the Company with an equity line totaling $40 million. We believe this amount of financing, if received, is sufficient to fund the commercialization of the abuse deterrent opioid products identified. Please see below for further details on the financing transactions with Lincoln Park.

Summary of Cash Flows:

	For the Nine Months Ended December 31,	
	2017	2016
Net cash used in operating activities	$ (3,795,644)	$ (3,807,871)
Net cash used in investing activities	(378,206)	(812,054)
Net cash provided by financing activities	823,545	6,391,108

Net cash used in operating activities for the nine months ended December 31, 2017 was $3.8 million, which included net losses of $1.0 million, and change in fair value of derivative financial instruments – warrants of $4.8 million (non-cash). These instances of decreases in cash are offset by change in non-cash compensation accrued of $0.9 million, non-cash compensation from the issuance of common stock and options of $0.2 million and depreciation and amortization of $0.7 million.

Net cash used in investing activities for the nine months ended December 31, 2017 was $0.4 million. This consisted primarily of the purchase of property and equipment of $0.3 million.

Net cash provided by financing activities was $0.8 million for the nine months ended December 31, 2017. This consisted of proceeds from the issuance of common stock of $1.2 million, proceeds from the exercise of cash warrants and stock options of $0.2 million; offset by payments of other loans of $0.4 million.

Lincoln Park Capital – May 1, 2017 Purchase Agreement

On May 1, 2017, the Company entered into a purchase agreement (the "2017 LPC Purchase Agreement"), together with a registration rights agreement (the "2017 LPC Registration Rights Agreement"), with Lincoln Park.

Under the terms and subject to the conditions of the 2017 LPC Purchase Agreement, the Company has the right to sell to and Lincoln Park is obligated to purchase up to $40 million in shares of common stock, subject to certain limitations, from time to time, over the 36-month period commencing on June 5, 2017.

The Company may direct Lincoln Park, at its sole discretion and subject to certain conditions, to purchase up to 500,000 shares of Common Stock on any business day, provided that at least one business day has passed since the most recent purchase, increasing to up to 1,000,000 shares, depending upon the closing sale price of the Common Stock (such purchases, "Regular Purchases"). However, in no event shall a Regular Purchase be more than $1,000,000. The purchase price of shares of common stock related to the future funding will be based on the prevailing market prices of such shares at the time of sales. In addition, the Company may direct Lincoln Park to purchase additional amounts as accelerated purchases under certain circumstances. Sales of shares of common stock to Lincoln Park under the 2017 LPC Purchase Agreement are limited to no more than the number of shares that would result in the beneficial ownership by Lincoln Park and its affiliates, at any single point in time, of more than 4.99% of the then outstanding shares of common stock.

In connection with the 2017 LPC Purchase Agreement, the Company issued to Lincoln Park 5,540,550 shares of common stock and the Company is required to issue up to 5,540,550 additional shares of common stock pro rata as the Company requires Lincoln Park to purchase shares under the 2017 LPC Purchase Agreement over the term of the agreement. Lincoln Park has represented to us, among other things, that it is an "accredited investor" (as such term is defined in Rule 501(a) of Regulation D under the Securities Act of 1933, as amended (the "Securities Act")). We sold the securities in reliance upon an exemption from registration contained in Section 4(a)(2) under the Securities Act. The securities sold may not be offered or sold in the United States absent registration or an applicable exemption from registration requirements.

The 2017 LPC Purchase Agreement and the 2017 LPC Registration Rights Agreement contain customary representations, warranties, agreements and conditions to completing future sale transactions, indemnification rights and obligations of the parties. The Company has the rights to terminate the 2017 LPC Purchase Agreement at any time, at no cost or penalty. Actual sales of shares of common stock to Lincoln Park under the 2017 LPC Purchase Agreement will depend on a variety of factors to be determined by us from time to time, including, among others, market conditions, the trading price of the common stock and determinations by us as to the appropriate sources of funding for us and our operations. There are no trading volume requirements or, other than the limitation on beneficial ownership discussed above, restrictions under the Purchase Agreement. Lincoln Park has no right to require any sales by the Company, but is obligated to make purchases from the Company as directed in accordance with the 2017 LPC Purchase Agreement Lincoln Park has covenanted not to cause or engage in any manner whatsoever, any direct or indirect short selling or hedging of the Company's shares.

The net proceeds received by under the 2017 LPC Purchase Agreement will depend on the frequency and prices at which the Company sells shares of common stock to Lincoln Park.

A registration statement on form S-3 was filed with the SEC on May 10, 2017 and was declared effective on June 5, 2017.

The Company issued 5,540,551 shares of its common stock as initial commitment shares pursuant to the 2017 LPC Purchase Agreement, 167,336 shares of its common stock as additional commitment shares, pursuant to the 2017 LPC Purchase Agreement with Lincoln Park, as consideration for their commitment to purchase additional shares of the Company's common stock. In addition, the Company issued 10,169,281 shares of its common stock for proceeds totaling $1,208,100 in connection with the 2017 LPC Purchase Agreement with Lincoln Park.

Exchange Agreement

On April 28, 2017, we entered into an exchange agreement (the "Exchange Agreement") with Nasrat Hakim, our Chief Executive Officer, pursuant to which we issued to Mr. Hakim 23.0344 shares of our newly designated Series J Convertible Preferred Stock ("Series J Preferred") (see Note 11 to the financial statements) and Warrants (see Note 12 to the financial statements) to purchase an aggregate of 79,008,661 shares of our Common Stock (the "Warrants" and, along with the Series J Preferred issued to Mr. Hakim, the "Securities") in exchange for 158,017,321 shares of our common stock owned by Mr. Hakim.

The exchange was conducted pursuant to the exemption from registration provided by Section 3(a)(9) of the Securities Act of 1933, as amended (the "Securities Act").

Series J Preferred

Each share of Series J Preferred has a stated value of $1,000,000 (the "Stated Value"). Commencing on the earlier of three years from the date of issuance of the Series J Preferred or the date that Shareholder Approval of an increase in authorized shares is obtained and the requisite corporate action has been effected, each share of Series J Preferred is convertible into shares of Company Common Stock at a rate calculated by dividing the Stated Value by $0.1521 (the "Conversion Price") (prior to any adjustment, 6,574,622 shares of Common Stock per whole share of Series J Preferred). At present, there is not a sufficient number of authorized but unissued or unreserved shares of Common Stock to permit full conversion of the Securities (the "Authorized Share Deficiency"). Accordingly, the Series J Preferred will not be convertible to the extent that there are not a sufficient number of shares available for issuance upon conversion unless and until Shareholder Approval has been obtained and the requisite corporate action has been effected. Subject to certain exceptions, the Conversion Price is subject to adjustment for any issuances or deemed issuances of common stock or common stock equivalents at an effective price below the then Conversion Price. The Conversion price also is adjustable upon the happening of certain customary events such as stock dividends and splits, pro rata distributions and fundamental transactions.

Holders of Series J Preferred vote, along with the holders of Common Stock, on any matter presented to the shareholders. Each holder of Series J Preferred is entitled to cast the number of votes equal to the number of whole shares of Common Stock into which the shares of Series J Preferred held by such holder are convertible regardless of whether an Authorized Share Deficiency Exists.

The Series J Preferred ranks senior to the Common Stock with respect to the payment of dividends. So long as any shares of Series J Preferred remain outstanding, the Company cannot declare, pay or set aside any dividends on shares of any other of its capital stock, unless the holders receive, a dividend on each outstanding share of Series J Preferred in an amount equal to the dividend the holders would have been entitled to receive upon conversion, in full, of the shares of Series J Preferred regardless of whether an Authorized Share Deficiency Exists. In addition, solely during any period commencing four years after the issuance of the Series J Preferred, provided that the Authorized Share Deficiency still exists, until such time as the Authorized Share Deficiency no longer exists, holders of the Series J Preferred are entitled to receive dividends at the rate per share (as a percentage of the Stated Value per share) of 20% per annum, payable quarterly.

Upon liquidation, dissolution or winding up of the Company, holders of Series J Preferred are entitled to receive for each share of Series J Preferred Stock, pari passu and pro rata with the holders of Common Stock, out of the Company’s assets, an amount equal to the amount distributable with regard to the number of whole shares of Common Stock into which the shares of Series J Preferred held by the holders are convertible as of the date of the Liquidation regardless of whether an Authorized Share Deficiency exists.

Warrants

The Warrants are exercisable for a period of 10 years from the date of issuance, commencing on the earlier of (i) the date that Shareholder Approval is obtained and the requisite corporate action has been effected; or (ii) April 28, 2020. The initial exercise price is $0.1521 per share and the Warrants can be exercised for cash or on a cashless basis. The exercise price is subject to adjustment for any issuances or deemed issuances of common stock or common stock equivalents at an effective price below the then exercise price. The Warrants provide for other standard adjustments upon the happening of certain customary events. The Warrants are not exercisable during any period when an Authorized Share Deficiency exists and will expire on the expiry date, without regards to the existence of an Authorized Shares Deficiency.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

We believe that our market risk exposures are immaterial as we do not have instruments for trading purposes, and reasonable possible near-term changes in market rates or prices will not result in material near-term losses in earnings, material changes in fair values or cash flows for all instruments.

We maintain all our cash, cash equivalents and restricted cash in three financial institutions, and we perform periodic evaluations of the relative credit standing of these institutions. However, no assurances can be given that the third-party institutions will retain acceptable credit ratings or investment practices.

Item 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

We maintain "disclosure controls and procedures," as such term is defined in Rule 13a-15(e) under the Securities Exchange Act of 1934, as amended (the "Exchange Act"). In designing and evaluating our disclosure controls and procedures, our management recognized that disclosure controls and procedures, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of disclosure controls and procedures are met. Additionally, in designing disclosure controls and procedures, our management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible disclosure controls and procedures. The design of any disclosure controls and procedures also is based in part upon 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.

As of the end of the period covered by this Quarterly Report on Form 10-Q, we carried out an evaluation, under the supervision and with the participation of our management, including our Chief Executive Officer and our Chief Financial Officer, of the effectiveness of our disclosure controls and procedures as defined in Rule 13a-15(e) and 15d-15(e) of the Exchange Act. Based on the controls evaluation, our Chief Executive Officer and Chief Financial Officer concluded that as of the date of their evaluation, our disclosure controls and procedures were effective to provide reasonable assurance that (a) the information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and (b) such information is accumulated and communicated to our management, including our Chief Executive Officer and President and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure.

Changes in Internal Controls

There were no changes in our internal control over financial reporting (as defined in Rule 13a-15(f) and Rule 15d-15(f) under the Exchange Act) during our most recent fiscal quarter that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II - OTHER INFORMATION

Item 1. Legal Proceedings.

Pending Litigation

There have been no material developments in any of the legal proceedings discussed in Item 3 of our Annual Report on Form 10-K for the year ended March 31, 2017.

Item 1A. Risk Factors.

While results of the recent pilot study for a modified formulation of SequestOx™ indicated the expected bioequivalence with a Tmax range equivalent to the reference product when conducted in a pivotal trial under fed conditions, there can be no assurances that such pivotal trials, when conducted, will produce such expected results.

As disclosed in this Report, the topline results from a pilot study on a modified formulation of SequestOx™ indicated expected bioequivalence with a Tmax range equivalent to the reference product when conducted in a pivotal trial under fed conditions. As a result, the Company intends to review the pilot study results with the FDA and discuss pharmacokinetic study requirements for a re-submission of the SequestOx™ NDA. Please note, we cannot assure if or whether our efforts to re-submit the NDA and receive approval from the FDA will be successful. If we are unable to obtain approval for SequestOx™, or if we incur significant costs or delays in obtaining such approval, our ability to commercialize SequestOx™ may be materially adversely affected.

Please see “We received a Complete Response Letter from the FDA that indicated that our SequestOx™ NDA is not ready for approval in its present form. While we plan on proceeding with our application for SequestOx™, we cannot assure if or whether our efforts will be successful. If we are unable to obtain approval for SequestOx™ or if we incur significant costs or delays in obtaining such approval, our ability to commercialize SequestOx™ may be materially adversely affected” in Part I, “Item 1A. Risk Factors” in our Annual Report on Form 10-K for the year ended March 31, 2017.

Impact of New Tax Legislation

On December 22, 2017, President Trump signed into law new tax legislation, the Tax Act, that significantly changes the Internal Revenue Code of 1986, as amended. The Tax Act, among other things, contains significant changes to corporate taxation, including reduction of the corporate tax rate from a top marginal rate of 35% to a flat rate of 21%, limitation of the tax deduction for interest expense to 30% of adjusted earnings (except for certain small businesses), limitation of the deduction for net operating losses to 80% of current year taxable income and elimination of net operating loss carrybacks, one time taxation of offshore earnings at reduced rates regardless of whether they are repatriated, immediate deductions for certain new investments instead of deductions for depreciation expense over time, and modifying or repealing many business deductions and credits. Any federal net operating loss carryovers created in 2018 and thereafter will be carried forward indefinitely pursuant to the Tax Act. We continue to examine the impact this tax legislation may have on our business.

In addition to the other information set forth in this report, you should carefully consider the factors discussed in Part I, “Item 1A. Risk Factors” in our Annual Report on Form 10-K for the year ended March 31, 2017, which could materially affect our business, financial condition, or future results. The risks described herein and in our Annual Report on Form 10-K are not the only risks we face. Additional risks and uncertainties not currently known to us or that we currently deem to be immaterial also may materially adversely affect our business, financial condition and operating results.

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

During the nine months ended December 31, 2017, we issued 18,787,000 shares of common stock that were unregistered, all of which were issued pursuant to the exercise of cash warrants, with proceeds received totaling $2,332,662. We relied on the exemption provided by Section 4(a)(2) of the Securities Act of 1933 to issue the common stock. The securities were offered and sold without any form of general solicitation or general advertising and the offerees made representations that they were accredited investors.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

None.

Item 6. Exhibits

Exhibit No.	Description
3.1(a)	Articles of Incorporation of Elite-Nevada, incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K filed with the SEC on January 9, 2012.
3.1(b)	Certificate of Incorporation of Elite-Delaware, together with all other amendments thereto, as filed with the Secretary of State of the State of Delaware, incorporated by reference to (a) Exhibit 4.1 to the Registration Statement on Form S-4 (Reg. No. 333-101686), filed with the SEC on December 6, 2002 (the "Form S-4"), (b) Exhibit 3.1 to the Company's Current Report on Form 8-K dated July 28, 2004 and filed with the SEC on July 29, 2004, (c) Exhibit 3.1 to the Company's Current Report on Form 8-K dated June 26, 2008 and filed with the SEC on July 2, 2008, and (d) Exhibit 3.1 to the Company's Current Report on Form 8-K dated December 19, 2008 and filed with the SEC on December 23, 2008.*
3.1(c)	Certificate of Designations, Preferences and Rights of Series A Preferred Stock, as filed with the Secretary of the State of Delaware, incorporated by reference to Exhibit 4.5 to the Current Report on Form 8-K dated October 6, 2004, and filed with the SEC on October 12, 2004.*
3.1(d)	Certificate of Retirement with the Secretary of the State of the Delaware to retire 516,558 shares of the Series A Preferred Stock, as filed with the Secretary of State of Delaware, incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K dated March 10, 2006, and filed with the SEC on March 14, 2006.*
3.1(e)	Certificate of Designations, Preferences and Rights of Series B 8% Convertible Preferred Stock, as filed with the Secretary of the State of Delaware, incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K dated March 15, 2006, and filed with the SEC on March 16, 2006.*
3.1(f)	Amended Certificate of Designations of Preferences, Rights and Limitations of Series B 8% Convertible Preferred Stock, as filed with the Secretary of State of the State of Delaware, incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K dated April 24, 2007, and filed with the SEC on April 25, 2007.*
3.1(g)	Certificate of Designations, Preferences and Rights of Series C 8% Convertible Preferred Stock, as filed with the Secretary of the State of Delaware, incorporated by reference to Exhibit 3.2 to the Current Report on Form 8-K dated April 24, 2007, and filed with the SEC on April 25, 2007.*
3.1(h)	Amended Certificate of Designations, Preferences and Rights of Series C 8% Convertible Preferred Stock, as filed with the Secretary of the State of Delaware, incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K dated April 24, 2007, and filed with the SEC on April 25, 2007.*
3.1(i)	

	Amended Certificate of Designations of Preferences, Rights and Limitations of Series B 8% Convertible Preferred Stock, as filed with the Secretary of State of the State of Delaware, incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K dated September 15, 2008, and filed with the SEC on September 16, 2008.*
3.1(j)	Amended Certificate of Designations, Preferences and Rights of Series C 8% Convertible Preferred Stock, as filed with the Secretary of the State of Delaware, incorporated by reference to Exhibit 3.2 to the Current Report on Form 8-K dated September 15, 2008, and filed with the SEC on September 16, 2008.*
3.1(k)	Amended Certificate of Designations of Preferences, Rights and Limitations of Series D 8% Convertible Preferred Stock, as filed with the Secretary of State of the State of Delaware, incorporated by reference to Exhibit 3.3 to the Current Report on Form 8-K dated September 15, 2008, and filed with the SEC on September 16, 2008.*
3.1(l)	Certificate of Designation of Preferences, Rights and Limitations of Series E Convertible Preferred Stock, as filed with the Secretary of State of the State of Delaware, incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K dated June 1, 2009, and filed with the SEC on June 5, 2009.*
3.1(m)	Amended Certificate of Designations of the Series D 8% Convertible Preferred Stock as filed with the Secretary of State of the State of Delaware on June 29, 2010, incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K, dated June 24, 2010 and filed with the SEC on July 1, 2010.*

3.1(n)	Amended Certificate of Designations of the Series E Convertible Preferred Stock as filed with the Secretary of State of the State of Delaware on June 29, 2010, incorporated by reference to Exhibit 3.2 to the Current Report on Form 8-K, dated June 24, 2010 and filed with the SEC on July 1, 2010.*
3.1(o)	Certificate of Designations of the Series G Convertible Preferred Stock as filed with the Secretary of State of the State of Nevada on April 18, 2013, incorporated by reference to Exhibit 4.1 to the Current Report on Form 8-K, dated April 18, 2013 and filed with the SEC on April 22, 2013.
3.1(p)	Certificate of Designation of the Series H Junior Participating Preferred Stock, incorporated by reference to Exhibit 2 (contained in Exhibit 1) to the Registration Statement on Form 8-A filed with the SEC on November 15, 2013.
3.1(q)	Certificate of Designations of the Series I Convertible Preferred Stock as filed with the Secretary of State of the State of Nevada on February 6, 2014, incorporated by reference to Exhibit 4.1 to the Current Report on Form 8-K, dated February 6, 2014 and filed with the SEC on February 7, 2014.
3.1(r)	Certificate of Designations of the Series J Convertible Preferred Stock as filed with the Secretary of State of the State of Nevada on May 3, 2017, incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K, dated April 28, 2017 and filed with the SEC on April 28, 2017.
3.2(a)	Amended and Restated By-Laws of the Company, incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K dated March 17, 2014 and filed with the SEC on March 18, 2014.
3.2(b)	By-Laws of Elite-Delaware, as amended, incorporated by reference to Exhibit 3.2 to the Company's Registration Statement on Form SB-2 (Reg. No. 333-90633) made effective on February 28, 2000 (the "Form SB-2").*
4.1	Form of specimen certificate for Common Stock of the Company, incorporated by reference to Exhibit 4.1 to the Form SB-2.*
4.2	Form of specimen certificate for Series B 8% Convertible Preferred Stock of the Company, incorporated by reference to Exhibit 4.1 to the Current Report on Form 8-K, dated March 15, 2006 and filed with the SEC on March 16, 2006.*
4.3	Form of specimen certificate for Series C 8% Convertible Preferred Stock of the Company, incorporated by reference to Exhibit 4.1 to the Current Report on Form 8-K, dated April 24, 2007 and filed with the SEC on April 25, 2007.*
4.4	Form of Warrant to purchase shares of Common Stock issued to purchasers in the private placement which closed on March 15, 2006 (the "Series B Financing"), incorporated by reference to Exhibit 4.2 to the Current Report on Form 8-K, dated March 15, 2006 and filed with the SEC on March 16, 2006.*
4.5	Form of Warrant to purchase shares of Common Stock issued to purchasers in the Series B Financing, incorporated by reference to Exhibit 4.3 to the Current Report on Form 8-K, dated March 15, 2006 and filed with the SEC on March 16, 2006.*

4.6	Form of Warrant to purchase shares of Common Stock issued to the Placement Agent, in connection with the Series B Financing, incorporated by reference to Exhibit 4.4 to the Current Report on Form 8-K, dated March 15, 2006 and filed with the SEC on March 16, 2006.*
4.7	Form of Warrant to purchase 600,000 shares of Common Stock issued to Indigo Ventures, LLC, incorporated by reference to Exhibit 4.1 to the Current Report on Form 8-K, dated July 12, 2006 and filed with the SEC on July 18, 2006.*
4.8	Form of Warrant to purchase up to 478,698 shares of Common Stock issued to VGS PHARMA, LLC, incorporated by reference as Exhibit 3(a) to the Current Report on Form 8-K, dated December 6, 2006 and filed with the SEC on December 12, 2006.*
4.9	Form of Non-Qualified Stock Option Agreement for 1,750,000 shares of Common Stock granted to Veerappan Subramanian, incorporated by reference as Exhibit 3(b) to the Current Report on Form 8-K, dated December 6, 2006 and filed with the SEC on December 12, 2006.*

4.10	Form of Warrant to purchase shares of Common Stock issued to purchasers in the private placement which closed on April 24, 2007 (the "Series C Financing"), incorporated by reference to Exhibit 4.2 to the Current Report on Form 8-K, dated April 24, 2007 and filed with the SEC on April 25, 2007.*
4.11	Form of Warrant to purchase shares of Common Stock issued to the placement agent in the Series C Financing, incorporated by reference to Exhibit 4.3 to the Current Report on Form 8-K, dated April 24, 2007 and filed with the SEC on April 25, 2007.*
4.12	Form of specimen certificate for Series D 8% Convertible Preferred Stock of the Company, incorporated by reference to Exhibit 4.1 to the Current Report on Form 8-K, dated September 15, 2008 and filed with the SEC on September 16, 2008.*
4.13	Form of Warrant to purchase shares of Common Stock issued to purchasers in the private placement which closed on September 15, 2008 (the "Series D Financing"), incorporated by reference to Exhibit 4.2 to the Current Report on Form 8-K, dated September 15, 2008 and filed with the SEC on September 16, 2008.*
4.14	Form of Warrant to purchase shares of Common Stock issued to the placement agent in the Series D Financing, incorporated by reference to Exhibit 4.3 to the Current Report on Form 8-K, dated September 15, 2008 and filed with the SEC on September 16, 2008.*
4.15	Form of specimen certificate for Series E Convertible Preferred Stock of the Company, incorporated by reference to Exhibit 4.1 to the Current Report on Form 8-K, dated June 1, 2009, and filed with the SEC on June 5, 2009.*
4.16	Warrant to purchase shares of Common Stock issued to Epic Investments, LLC in the initial closing of the Strategic Alliance Agreement, dated as of March 18, 2009, by and among the Company, Epic Pharma, LLC and Epic Investments, LLC, incorporated by reference to Exhibit 4.2 to the Current Report on Form 8-K, dated June 1, 2009, and filed with the SEC on June 5, 2009.*
4.17	Form of specimen certificate for Series G Convertible Preferred Stock of the Company, incorporated by reference to Exhibit 4.2 to the Current Report on Form 8-K, dated April 18, 2013 and filed with the SEC on April 22, 2013.
4.18	Form of specimen certificate for Series I Convertible Preferred Stock of the Company, incorporated by reference to Exhibit 4.2 to the Current Report on Form 8-K, dated February 6, 2014 and filed with the SEC on February 7, 2014.
4.19	Rights Agreement, dated as of November 15, 2013, between the Company and American Stock Transfer & Trust Company, LLC., incorporated by reference to Exhibit 1 to the Registration Statement on Form 8-A filed with the SEC on November 15, 2013.
4.20	Form of Series H Preferred Stock Certificate, incorporated by reference to Exhibit 1 to the Registration Statement on Form 8-A filed with the SEC on November 15, 2013.
4.21	Warrant to purchase shares of Common Stock issued to Nasrat Hakim dated April 28, 2017 incorporated by reference to Exhibit 4.1 to the Current Report on Form 8-K, dated April 28, 2017, and filed with the SEC on April 28, 2017.

10.57	Master Development and License Agreement for Products dated July 6, 2017 between Elite Laboratories, Inc. and SunGen Pharma LLC ("SunGen"), incorporated by reference to Exhibit 10.57 to the Quarterly Report on Form 10-Q for the period ended June 30, 2017 and filed with the SEC on August 9, 2017. (Confidential Treatment granted with respect to portions of the Agreement).
10.58	July 24, 2017 Amendment to August 24, 2016 Master Development and License Agreement between Elite and SunGen Pharma LLC."), incorporated by reference to Exhibit 10.58 to the Quarterly Report on Form 10-Q for the period ended June 30, 2017 and filed with the SEC on August 9, 2017. (Confidential Treatment granted with respect to portions of the Agreement).
10.59	December 1, 2016 Amendment to August 24, 2016 Master Development and License Agreement between Elite and SunGen Pharma LLC."), incorporated by reference to Exhibit 10.59 to the Quarterly Report on Form 10-Q for the period ended June 30, 2017 and filed with the SEC on August 9, 2017. (Confidential Treatment granted with respect to portions of the Agreement).

31.1	Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002**
31.2	Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002**
32.1	Certification of Chief Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002**
32.2	Certification of Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002**
101.INS**	XBRL Instance Document
101.SCH**	XBRL Taxonomy Schema Document
101.CAL**	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF**	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB**	XBRL Taxonomy Extension Label Linkbase Document
101.PRE**	XBRL Taxonomy Extension Presentation Linkbase Document

* On January 5, 2011, the Company changed its domicile from Delaware to Nevada. All corporate documents from Delaware have been superseded by Nevada corporate documents filed or incorporated by reference herein. All outstanding Delaware securities certificates are now outstanding Nevada securities certificates.

** 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.

ELITE PHARMACEUTICALS, INC.

February 9, 2018 By: /s/ Nasrat Hakim
Nasrat Hakim
Chief Executive Officer, President and Chairman of the

Board of Directors
(Principal Executive Officer)

February 9, 2018 By: /s/ Carter J. Ward
Carter J. Ward
Chief Financial Officer, Treasurer and Secretary
(Principal Financial and Accounting Officer)