ELITE PHARMACEUTICALS INC /NV/
Form 10-Q
November 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 SEPTEMBER 30, 2018

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 every Interactive Data File required to be submitted 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 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. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

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

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: 819,489,751 shares of common stock were issued and outstanding as of November 2, 2018.

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PART 1 – FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

ELITE PHARMACEUTICALS, INC. AND SUBSIDIARY

CONDENSED CONSOLIDATED BALANCE SHEETS

	September 30, 2018 (Unaudited)	March 31, 2018 (Audited)
ASSETS		
Current assets:		
Cash	$ 4,705,189	$ 7,179,237
Accounts receivable, net of allowance for doubtful accounts of $-0-, respectively	1,015,846	675,879
Inventory	4,485,942	4,898,001
Prepaid expenses and other current assets	170,806	949,284
Total current assets	10,377,783	13,702,401
Property and equipment, net of accumulated depreciation of $9,022,541 and $8,408,979, respectively	8,755,340	8,993,708
Intangible assets, net of accumulated amortization of $-0-, respectively	7,713,001	7,713,001
Other assets:		
Restricted cash - debt service for NJEDA bonds	394,402	391,566
Security deposits	80,575	81,932
Total other assets	474,977	473,498
Total assets	$ 27,321,101	$ 30,882,608
LIABILITIES, MEZZANINE EQUITY AND SHAREHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 1,141,109	$ 1,658,137
Accrued expenses	2,662,385	1,788,571
Deferred revenue, current portion	1,013,333	1,013,333
Bonds payable, current portion, net of bond issuance costs	80,822	75,822
Loans payable, current portion	466,778	578,841
Total current liabilities	5,364,427	5,114,704

Long-term liabilities:		
Deferred revenue, net of current portion	745,557	1,252,223
Bonds payable, net of current portion and bond issuance costs	1,420,224	1,508,134
Senior secured promissory note - related party	1,200,000	1,200,000
Loans payable, net current portion	631,510	623,020
Derivative financial instruments - warrants	2,241,500	2,667,871
Other long-term liabilities	44,295	41,144
Total long-term liabilities	6,283,086	7,292,392
Total liabilities	11,647,513	12,407,096
Mezzanine equity		
Series J convertible preferred stock; par value $0.01; 50 shares authorized, 24.0344 issued and outstanding as of September 30, 2018; 50 shares authorized, 24.0344 issued and outstanding as of March 31, 2018	13,903,960	13,903,960
Shareholders' equity:		
Common stock; par value $0.001; 995,000,000 shares authorized 816,962,249 shares issued and 816,862,249 outstanding as of September 30, 2018; 802,626,761 shares issued and 802,526,761 outstanding as of March 31, 2018	816,965	802,629
Additional paid-in capital	148,057,540	146,602,502
Treasury stock; 100,000 shares as of September 30, 2018 and March 31, 2018; at cost	(306,841)	(306,841)
Accumulated deficit	(146,798,036)	(142,526,738)
Total shareholders' equity	1,769,628	4,571,552
Total liabilities, mezzanine equity and shareholders' equity	$ 27,321,101	$ 30,882,608

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

ELITE PHARMACEUTICALS, INC. AND SUBSIDIARY

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(UNAUDITED)

	For the Three Months Ended September 30,		For the Six Months Ended September 30,	
	2018	2017	2018	2017
Manufacturing fees	$806,487	$1,066,227	$2,348,345	$2,077,123
Licensing fees	556,562	557,354	1,182,402	1,249,228
Total revenue	1,363,049	1,623,581	3,530,747	3,326,351
Cost of revenue	542,551	614,941	2,118,950	1,630,001
Gross profit	820,498	1,008,640	1,411,797	1,696,350
Operating expenses:				
Research and development	2,455,466	2,286,514	3,782,094	4,108,504
General and administrative	614,937	594,073	1,497,749	1,453,034
Non-cash compensation through issuance of stock options	36,545	73,397	73,094	170,758
Depreciation and amortization	366,522	184,527	570,226	335,196
Total operating expenses	3,473,470	3,138,511	5,923,163	6,067,492
Loss from operations	(2,652,972)	(2,129,871)	(4,511,366)	(4,371,142)
Other income (expense):				
Interest expense and amortization of debt issuance costs	(106,002)	(82,541)	(189,140)	(153,272)
Change in fair value of derivative instruments	173,860	4,023,176	426,371	4,162,436
Interest income	1,582	4,419	2,837	8,401
Other income, net	69,440	3,945,054	240,068	4,017,565
Net (loss) income attributable to common shareholders	$(2,583,532)	$1,815,183	$(4,271,298)	$(353,577)
Basic (loss) income per share attributable to common shareholders	$(0.00)	$0.00	$(0.01)	$(0.00)
Diluted loss per share attributable to common shareholders	$(0.00)	$(0.00)	$(0.01)	$(0.01)
Basic weighted average Common Stock outstanding	812,256,006	782,424,624	807,677,777	800,772,162
Diluted weighted average Common Stock outstanding	812,256,006	788,793,861	807,677,777	807,141,399

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 Paid-In	Treasury Stock		Accumulated	Total Shareholders'
	Shares	Amount	Capital	Shares	Amount	Deficit	Equity
Balance at March 31, 2018	802,626,761	$802,629	$146,602,502	100,000	$(306,841)	$(142,526,738)	$4,571,552
Net loss	-	-	-	-	-	(4,271,298)	(4,271,298)
Common Stock sold pursuant to the Lincoln Park purchase agreement	14,142,083	14,142	1,382,142	-	-	-	1,396,284
Common Stock issued as additional commitment shares pursuant to the LPC purchase agreement	193,405	194	20,123	-	-	-	20,317
Costs associated with raising capital	-	-	(20,321)	-	-	-	(20,321)
Non-cash compensation through the issuance of employee stock options	-	-	73,094	-	-	-	73,094
Balance at September 30, 2018	816,962,249	$816,965	$148,057,540	100,000	$(306,841)	$(146,798,036)	$1,769,628

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

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ELITE PHARMACEUTICALS, INC. AND SUBSIDIARY

CONSOLIDATED STATEMENTS OF CASH FLOWS

(UNAUDITED)

	For the Six Months Ended September 30,	
	2018	2017
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$(4,271,298)	$(353,577)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	530,652	412,719
Change in fair value of derivative financial instruments - warrants	(426,371)	(4,162,436)
Non-cash compensation accrued	1,191,339	923,500
Non-cash compensation from the issuance of Common Stock and options	73,094	170,758
Non-cash rent expense and lease accretion	3,151	5,205
Change in operating assets and liabilities:		
Accounts receivable	(339,967)	(151,219)
Inventory	412,059	707,134
Prepaid expenses and other current assets	779,835	208,223
Accounts payable, accrued expenses and other current liabilities	(834,553)	(571,135)
Deferred revenue and customer deposits	(506,666)	(506,667)
Net cash used in operating activities	(3,388,725)	(3,317,495)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of property and equipment	-	(386,564)
Intellectual property costs	-	(75,274)
Net cash used in investing activities	-	(461,838)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from the issuance of stock	1,396,280	955,691
Proceeds from cash warrant and options exercises	-	181,908
Payment of bond principal	(90,000)	(85,000)
Other loan proceeds (payments), net	(388,767)	(260,432)
Costs associated with raising capital	-	(49,957)
Net cash provided by financing activities	917,513	742,210
Net change in cash and restricted cash	(2,471,212)	(3,037,123)
Cash and restricted cash, beginning of period	7,570,803	10,983,774
Cash and restricted cash, end of period	$5,099,591	$7,946,651
Supplemental disclosure of cash and non-cash transactions:		

Cash paid for interest	$24,044	$38,215
Financing of equipment purchases and insurance renewal	$375,194	$251,504
Issuance of Senior Secured Promissory Note pursuant ANDA asset acquisition	$-	$1,200,000
Commitment shares issued to Lincoln Park Capital	$20,321	$939,318
Retirement of Common Stock 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.

ELITE PHARMACEUTICALS, INC. AND SUBSIDIARY

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(UNAUDITED)

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 six months ended September 30, 2018 are not necessarily indicative of the results that may be expected for the entire year.

Reclassifications

Certain reclassifications have been made to the prior period financial statements to conform to the current period financial statement presentation. These reclassifications had no effect on net earnings or cash flows as previously reported.

Segment Information

Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC 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 generates revenue from the development of pain management products, manufacturing of a line of generic pharmaceutical products with approved ANDA, commercialization of products either by license and the collection of royalties, or through the manufacture of formulations and the development of new products and the expansion of licensing agreements with other pharmaceutical companies, including co-development projects, joint ventures and other collaborations. The Company also generates revenue through its focus on the development of various types of drug products, including branded drug products which require NDAs.

Under ASC 606, *Revenue from Contacts with Customers* ("ASC 606"), the Company recognizes revenue when the customer obtains control of promised goods or services, in an amount that reflects the consideration which is expected

to be received in exchange for those goods or services. The Company recognize revenues following the five-step model prescribed under ASC 606: (i) identify contract(s) with a customer; (ii) identify the performance obligation(s) in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligation(s) in the contract; and (v) recognize revenues when (or as) the Company satisfies a performance obligation. The Company only applies the five-step model to contracts when it is probable that the entity will collect the consideration it is entitled to in exchange for the goods or services it transfers to the customer. At contract inception, once the contract is determined to be within the scope of ASC 606, the Company assesses the goods or services promised within each contract and determines those that are performance obligations and assesses whether each promised good or service is distinct. The Company then recognizes as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied. Sales, value add, and other taxes collected on behalf of third parties are excluded from revenue.

ELITE PHARMACEUTICALS, INC. AND SUBSIDIARY

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(UNAUDITED)

Nature of goods and services

The following is a description of the Company's goods and services from which the Company generates revenue, as well as the nature, timing of satisfaction of performance obligations, and significant payment terms for each, as applicable:

a) Manufacturing Fees

The Company is equipped to manufacture controlled-release products on a contract basis for third parties, if and when the products are approved. These products include products using controlled-release drug technology and products utilizing abuse deterrent technologies. The Company also develops and markets (either on its own or by license to other companies) generic and proprietary controlled-release and abuse deterrent pharmaceutical products.

The Company recognizes revenue when the customer obtains control of the Company's product based on the contractual shipping terms of the contract. Revenue on product are presented gross because the Company is primarily responsible for fulfilling the promise to provide the product, is responsible to ensure that the product is produced in accordance with the related supply agreement and bears risk of loss while the inventory is in-transit to the commercial partner. Revenue is measured as the amount of consideration the Company expects to receive in exchange for transferring products to a customer.

b) License Fees

The Company enters into licensing and development agreements, which may include multiple revenue generating activities, including milestones payments, licensing fees, product sales and services. The Company analyzes each element of its licensing and development agreements in accordance with ASC 606 to determine appropriate revenue recognition. The terms of the license agreement may include payment to the Company of licensing fees, non-refundable upfront license fees, milestone payments if specified objectives are achieved, and/or royalties on

product sales.

If the contract contains a single performance obligation, the entire transaction price is allocated to the single performance obligation. Contracts that contain multiple performance obligations require an allocation of the transaction price based on the estimated relative standalone selling prices of the promised products or services underlying each performance obligation. The Company determines standalone selling prices based on the price at which the performance obligation is sold separately. If the standalone selling price is not observable through past transactions, the Company estimates the standalone selling price taking into account available information such as market conditions and internally approved pricing guidelines related to the performance obligations.

The Company recognizes revenue from non-refundable upfront payments at a point in time, typically upon fulfilling the delivery of the associated intellectual property to the customer. For those milestone payments which are contingent on the occurrence of particular future events (for example, payments due upon a product receiving FDA approval), the Company determined that these need to be considered for inclusion in the calculation of total consideration from the contract as a component of variable consideration using the most-likely amount method. As such, the Company assesses each milestone to determine the probability and substance behind achieving each milestone. Given the inherent uncertainty of the occurrence of future events, the Company will not recognize revenue from the milestone until there is not a high probability of a reversal of revenue, which typically occurs near or upon achievement of the event.

Significant management judgment is required to determine the level of effort required under an arrangement and the period over which the Company expects to complete its performance obligations under the arrangement. If the Company cannot reasonably estimate when its performance obligations either are completed or become inconsequential, then revenue recognition is deferred until the Company can reasonably make such estimates. Revenue is then recognized over the remaining estimated period of performance using the cumulative catch-up method.

When determining the transaction price of a contract, an adjustment is made if payment from a customer occurs either significantly before or significantly after performance, resulting in a significant financing component. Applying the practical expedient in paragraph 606-10-32-18, the Company does not assess whether a significant financing component exists if the period between when the Company performs its obligations under the contract and when the customer pays is one year or less. None of the Company’s contracts contained a significant financing component as of September 30, 2018.

ELITE PHARMACEUTICALS, INC. AND SUBSIDIARY

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(UNAUDITED)

In accordance with ASC 606-10-55-65, royalties are recognized when the subsequent sale of the customer's products occurs.

Disaggregation of revenue

In the following table, revenue is disaggregated by type of revenue generated by the Company and timing of revenue recognition. The table also includes a reconciliation of the disaggregated revenue with the reportable segments:

	For the Three Months Ended September 30,		For the Six Months Ended September 30,	
	2018	2017	2018	2017
NDA:				
Licensing fees	$ 250,000	$ 250,000	$ 500,000	$ 500,000
Total NDA revenue	250,000	250,000	500,000	500,000
ANDA:				
Manufacturing fees	$ 806,487	$ 1,066,227	$ 2,348,345	$ 2,077,123
Licensing fees	306,562	307,354	682,402	749,228
Total ANDA revenue	1,113,049	1,373,581	3,030,747	2,826,351
Total revenue	$ 1,363,049	$ 1,623,581	$ 3,530,747	$ 3,326,351

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 September 30, 2018, and March 31, 2018, the Company had $394,402 and $391,566, respectively, of restricted cash, related to debt service reserve in regard to the New Jersey Economic Development Authority ("NJEDA") bonds (see Note 5).

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.

ELITE PHARMACEUTICALS, INC. AND SUBSIDIARY

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(UNAUDITED)

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 September 30, 2018, 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 tax assets and liabilities are recognized for the estimated future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases. Deferred tax assets and liabilities are measured using enacted tax rates in effect for the year in which those temporary differences are expected to be recovered or settled. Where applicable, the Company records a valuation allowance to reduce any deferred tax assets that it determines will not be realizable in the future.

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.

ELITE PHARMACEUTICALS, INC. AND SUBSIDIARY

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(UNAUDITED)

Stock-Based Compensation

The Company accounts for stock-based compensation in accordance with ASC 718, *Compensation-Stock Compensation*. Under the fair value recognition provisions, 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 potential dilutive 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 September 30,		For the Six Months Ended September 30,	
	2018	2017	2018	2017
Numerator				
Net (loss) income attributable to common shareholders – basic	$(2,583,532)	$1,815,183	$(4,271,298)	$(353,577)
Effect of dilutive instrument on net (loss) income	-	(4,023,176)	-	(4,162,436)
Net loss attributable to common shareholders – diluted	$(2,583,532)	$(2,207,993)	$(4,271,298)	$(4,516,013)
Denominator				
Weighted average shares of common stock outstanding – basic	812,256,006	782,424,624	807,677,777	800,772,162
Dilutive effect of stock options warrants and convertible securities	-	6,369,237	-	6,369,237
Weighted average shares of common stock outstanding – diluted	812,256,006	788,793,861	807,677,777	807,141,399
Net (loss) income per share				
Basic	$(0.00)	$0.00	$(0.01)	$(0.00)
Diluted	$(0.00)	$(0.00)	$(0.01)	$(0.01)

Fair Value of Financial Instruments

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

ASC 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 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).

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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 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:

	Amount at	**Fair Value Measurement Using**		
	Fair Value	**Level 1**	**Level 2**	**Level 3**
September 30, 2018				
Liabilities				
Derivative financial instruments - warrants	$2,241,500	$-	$-	$2,241,500
March 31, 2018				
Liabilities				
Derivative financial instruments - warrants	$2,667,871	$-	$-	$2,667,871

See Note 11, 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 November 2016, the FASB issued ASU No. 2016-18*, Restricted Cash (ASC 230): Statement of Cash Flows ("ASU No. 2016-18").* ASU No. 2016-18 requires that a statement of cash flows explain the change during the period in the total of cash and amounts generally described as restricted cash. Restricted cash will be included with cash and cash equivalents when reconciling the beginning of period and end of period balances on the statement of cash flows upon adoption of this standard. As a result of the adoption of the new guidance, the Company increased the beginning of year total amount shown on the condensed consolidated statement of cash flows by $391,566 and $389,081 for the six months ended September 30, 2018 and 2017, respectively. These amounts represent the balance of restricted cash included in the consolidated balance sheets as of March 31, 2018 and 2017, respectively. Restricted cash is related to debt service reserve in regard to the NJEDA bonds (see Note 5).

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As of April 1, 2018, the Company adopted ASU 2017-09, *Compensation-Stock Compensation (ASC 718): Scope of Modification Accounting*, which clarifies when to account for a change to the terms or conditions of a share-based payment award as a modification. The new standard does not change the accounting for modifications but clarifies that modification accounting guidance should only be applied if the fair value, vesting conditions, or classification of the award changes as a result of the change in terms or conditions. The adoption of this standard did not materially impact the Company's stock-based compensation expense as no awards were modified during the six months ended September 30, 2018.

In August 2016, the FASB issued ASU 2016-15, *Statement of Cash Flows – Classification of Certain Cash Receipts and Cash Payments*, to clarify guidance on the classification of certain cash receipts and cash payments in the statement of cash flow. The standard is effective for annual reporting periods beginning after December 15, 2017, and interim periods within annual periods beginning after December 15, 2017. The Company's adoption of this standard as of April 1, 2018 had no impact to the Company's condensed consolidated financial statements for the six months ended September 30, 2018.

Recently Issued Accounting Pronouncements

In February 2016, the FASB issued ASU No. 2016-02, *Leases (ASC 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. In July 2018, the FASB issued ASU 2018-10, Codification Improvements to ASC 842 (Leases), and ASU 2018-11, Leases (ASC 842), Targeted Improvements, which provide (i) narrow amendments to clarify how to apply certain aspects of the new lease standard, (ii) entities with an additional transition method to adopt the new standard, and (ii) lessors with a practical expedient for separating components of a contract. All ASUs are effective for annual periods and interim periods within those annual periods beginning after December 15, 2018 and is effective for the Company for the year ending March 31, 2020. The Company is currently evaluating the effects of ASU 2016-02 on its financial statements and related disclosures.

In June 2018, the FASB issued ASU 2018-07, *Compensation-Stock Compensation (ASC 718): Improvements to Nonemployee Share-Based Payment Accounting*, which expands the scope of ASC 718 to include share-based payment transactions for acquiring goods and services from nonemployees and applies to all share-based payment transactions in which a grantor acquires goods or services to be used or consumed in a grantor's own operations by issuing share-based payment awards. ASC 718 does not apply to share-based payments used to effectively provide (1) financing to the issuer or (2) awards granted in conjunction with selling goods or services to customers as part of a contract accounted for under ASC 606. This update is effective for public business entities for fiscal years beginning after December 15, 2018, including interim periods within that fiscal year. Early adoption is permitted, but no earlier than an entity's adoption date of ASC 606. The Company is evaluating the effect that this update will have on its financial statements and related disclosures.

In August 2018, the FASB issued ASU 2018-13, *Fair Value Measurement (ASC 820): Disclosure Framework-Changes to the Disclosure Requirements for Fair Value Measurement*. ASU 2018-13 removes certain disclosures, modifies certain disclosures and adds additional disclosures. The ASU is effective for annual periods, including interim periods within those annual periods, beginning after December 15, 2019. Early adoption is permitted. The Company is evaluating the effect that this update will have on its financial statements and related disclosures.

Management has evaluated other recently issued accounting pronouncements and does not believe that any of these pronouncements will have a significant impact on our consolidated financial statements and related disclosures.

NOTE 2. INVENTORY

Inventory consisted of the following:

	September 30, 2018	March 31, 2018
Finished goods	$ 63,107	$ 229,204
Work-in-progress	112,285	297,350
Raw materials	4,310,550	4,371,447
	$ 4,485,942	$ 4,898,001

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NOTE 3. PROPERTY AND EQUIPMENT, NET

Property and equipment consisted of the following:

	September 30, 2018	March 31, 2018
Land, building and improvements	$ 7,675,317	$ 7,675,317
Laboratory, manufacturing and warehouse equipment	9,480,837	9,302,277
Office equipment and software	505,068	308,434
Furniture and fixtures	49,804	49,804
Transportation equipment	66,855	66,855
	17,777,881	17,402,687
Less: Accumulated depreciation	(9,022,541)	(8,408,979)
	$ 8,755,340	$ 8,993,708

Depreciation expense was $313,395 and $226,044 for the three months and $613,562 and $410,630 for the six months ended September 30, 2018 and 2017, respectively.

NOTE 4. INTANGIBLE ASSETS

The following table summarizes the Company’s intangible assets:

	September 30, 2018				
	Estimated Useful Life	**Gross Carrying Amount**	**Additions**	**Accumulated Amortization**	**Net Book Value**
Patent application costs	*	$465,684	$-	$ -	$465,684
ANDA acquisition costs	Indefinite	7,247,317	-	-	7,247,317
		$7,713,001	$-	$ -	$7,713,001

	March 31, 2018				
	Estimated Useful Life	Gross Carrying Amount	Additions	Accumulated Amortization	Net Book Value
Patent application costs	*	$371,774	$93,910	$ -	$465,684
ANDA acquisition costs	Indefinite	6,047,317	1,200,000	-	7,247,317
		$6,419,091	$1,293,910	$ -	$7,713,001

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 5. 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 September 1st based on the amount specified in the loan documents and semi-annual interest payments on March 1st and September 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.

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

	September 30, 2018	March 31, 2018
Gross bonds payable		
NJEDA Bonds - Series A Notes	$ 1,501,046	$ 1,760,000
Less: Current portion of bonds payable (prior to deduction of bond offering costs)	(80,822)	(90,000)
Long-term portion of bonds payable (prior to deduction of bond offering costs)	$ 1,420,224	$ 1,670,000
Bond offering costs	$ 354,453	$ 354,453
Less: Accumulated amortization	(185,497)	(178,409)
Bond offering costs, net	$ 168,956	$ 176,044
Current portion of bonds payable - net of bond offering costs		
Current portions of bonds payable	$ 95,000	$ 90,000
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	$ 80,822	$ 75,822
Long term portion of bonds payable - net of bond offering costs		
Long term portion of bonds payable	$ 1,575,000	$ 1,670,000
Less: Bond offering costs to be amortized subsequent to the next 12 months	(154,776)	(161,866)
Long term portion of bonds payable, net of bond offering costs	$ 1,420,224	$ 1,508,134

Amortization expense was $3,544 for the three months and $7,090 for the six months ended September 30, 2018 and 2017, respectively.

NOTE 6. LOANS PAYABLE

Loans payable consisted of the following:

	September 30, 2018	March 31, 2018
Equipment and insurance financing loans payable, between 3.5% and 12.73% interest and maturing between December 2018 and April 2023	$ 1,098,288	$ 1,201,861
Less: Current portion of loans payable	(466,778)	(578,841)
Long-term portion of loans payable	$ 631,510	$ 623,020

The interest expense associated with the loans payable was $27,559 and $19,022 for the three months and $58,720 and $40,781 for the six months ended September 30, 2018 and 2017, respectively.

NOTE 7. RELATED PARTY SECURED PROMISSORY NOTE WITH MIKAH PHARMA LLC

For consideration of the assets acquired on May 15, 2017, 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 $60,000 for the six months ended September 30, 2018. Accrued interest due and owing on this note was $165,000 and $105,000 as of September 30, 2018 and March 31, 2018, respectively.

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NOTE 8. DEFERRED REVENUE

Deferred revenues in the aggregate amount of $1,758,890 as of September 30, 2018, were comprised of a current component of $1,013,333 and a long-term component of $745,557. Deferred revenues in the aggregate amount of $2,265,556 as of March 31, 2018, were comprised of a current component of $1,013,333 and a long-term component of $1,252,223. 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 9. 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.

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 months ended September 30, 2018 and 2017 was $54,909, and $109,818 for the six months ended September 30, 2018 and 2017. Rent expense is recorded in general and administrative expense in the unaudited condensed consolidated statements of operations. Deferred rent as of September 30, 2018 and March 31, 2018 was $11,902 and $9,705, 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 September 30, 2018, and March 31, 2018, the Company had a liability of $32,398 and $31,443, respectively and recorded as a component of other long-term liabilities.

NOTE 10. MEZZANINE EQUITY

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 September 30, 2018.

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The issued shares were pursuant to an Exchange Agreement with Nasrat Hakim, ("Hakim") a related party and the Company's President, CEO and Chairman of the Board of Directors Pursuant 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 $0.1521 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 as of September 30, 2018 (See Note 11).

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 September 30, 2018, 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 Materials*. 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, $13,903,960 at April 28, 2017.

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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	%
Shareholder approval threshold	$0.1521	
Probability of approval is ending stock price is greater than threshold - midpoint	82.50	%
Probability of approval is ending stock price is less than threshold - midpoint	17.50	%
Trials	200,000	

Authorized, issued and outstanding shares, along with carrying value and change in value as of September 30, 2018 and March 31, 2018 are as follows:

Shares authorized	50.000
Shares outstanding	24.0344
Par value	$0.01
Stated value	$1,000,000
Conversion price	$0.1521
Common Stock to be issued upon conversion	158,017,321
Carrying value of Series J convertible preferred stock	$13,903,960

NOTE 11. 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:

	September 30, 2018		March 31, 2018	
	Warrant Shares	**Weighted Average Exercise Price**	**Warrant Shares**	**Weighted Average Exercise Price**
Balance at beginning of period	79,008,661	$ 0.1521	9,379,219	$ 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	-	-	(9,379,219)	0.0625
Balance at end of period	79,008,661	$ 0.1521	79,008,661	$ 0.1521

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 $6,474,674 upon issuance at April 28, 2017.

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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 10). As of September 30, 2018, 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.

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:

	September 30, 2018		March 31, 2018	
Fair value of the Company's common stock	$ 0.0900		$ 0.1000	
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	810,126,510		791,516,930	
Warrant term (in years)	8.58		9.08	
Risk-free rate	3.03	%	2.72	%
Volatility	90.00	%	90.00	%
Shareholder approval threshold	$ 0.1580		$ 0.1580	
Probability of approval is ending stock price is greater than threshold - midpoint	82.50	%	82.50	%
Probability of approval is ending stock price is greater than threshold - midpoint	17.50	%	17.50	%
Trials	100,000		100,000	
Fair value of derivative financial instruments - warrants	$ 2,241,500		$ 2,667,871	

The changes in warrants (Level 3 financial instruments) measured at fair value on a recurring basis for the six months ended September 30, 2018 were as follows:

Balance as of March 31, 2018	$2,667,871
Change in fair value of derivative financial instruments - warrants	(426,371)
Balance as of September 30, 2018	$2,241,500

NOTE 12. 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 2014 LPC Purchase Agreement, the Company issued 1,928,641 shares of its common stock to Lincoln Park 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.

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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 5,540,551 shares of common stock and are required to issue up to 5,540,551 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.

The Company, from time to time and at the Company's sole discretion but no more frequently than every other business day, could direct Lincoln Park to purchase (a "*Regular Purchase*") up to 500,000 shares of common stock on any such business day, increasing up to 800,000 shares, depending upon the closing sale price of the common stock, provided that in no event shall Lincoln Park purchase more than $760,000 worth of common stock on any single business day. The purchase price of shares of common stock related to the future Regular Purchase funding will be based on the prevailing market prices of such shares at the time of sales (or over a period of up to ten business days leading up to such time), but in no event, will shares be sold to Lincoln Park on a day the Common Stock closing price is less than the floor price of $0.10 per share, subject to adjustment.

In addition to Regular Purchases, on any business day on which the Company has properly submitted a Regular Purchase notice and the closing sale price is not below $0.15, the Company may purchase (an "*Accelerated Purchase*") an additional "accelerated amount" under certain circumstances. The amount of any Accelerated Purchase cannot exceed the lesser of three times the number of purchase shares purchased pursuant to the corresponding Regular Purchase; and 30% of the aggregate shares of the Company's common stock traded during normal trading hours on the purchase date. The purchase price per share for each such Accelerated Purchase will be equal to the lower of (i) 97% of the volume weighted average price during the purchase date; or (ii) the closing sale price of the Company's common stock on the purchase date.

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In the case of both Regular Purchases and Accelerated Purchases, the purchase price per share will be equitably adjusted for any reorganization, recapitalization, non-cash dividend, stock split, reverse stock split or other similar transaction occurring during the business days used to compute the purchase price.

Other than as set forth above, there are no trading volume requirements or restrictions under the Purchase Agreement, and the Company will control the timing and amount of any sales of the Company's common stock to Lincoln Park.

The Company's sales of shares of common stock to Lincoln Park under the 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 9.99% of the then outstanding shares of common stock.

The Purchase Agreement and the 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 Purchase Agreement at any time, at no cost or penalty. Actual sales of shares of common stock to Lincoln Park under the Purchase Agreement will depend on a variety of factors to be determined by the Company from time to time, including, without limitation, market conditions, the trading price of the Common Stock and determinations by the Company as to appropriate sources of funding for the Company and its operations. There are no trading volume requirements or 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 it directs in accordance with the Purchase Agreement. Lincoln Park has covenanted not to cause or engage in any manner whatsoever, any direct or indirect short selling or hedging of Company shares.

The net proceeds under the Purchase Agreement to the Company will depend on the frequency and prices at which the Company sells shares of its stock to Lincoln Park. During the six months ended September 30, 2018, a total of 14,142,083 shares were sold to Lincoln Park pursuant to the 2017 LPC Agreement for net proceeds totaling $14,142. In addition, 193,405 shares were issued to Lincoln Park as additional commitment shares, pursuant to the 2017 LPC Agreement.

NOTE 13. 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 six months ended September 30, 2018, the Company did not issue any shares of common stock to its Directors in payment of director's fees.

During the six months ended September 30, 2018, the Company accrued director's fees totaling $55,089, which will be paid via cash payments totaling $18,363 and the issuance of 377,296 shares of Common Stock.

As of September 30, 2018, the Company owed its Directors a total of $28,363 in cash payments and 559,682 shares of Common Stock in payment of director fees totaling $85,089 due and owing. The Company anticipates that these shares of Common Stock will be issued prior to the end of the current fiscal year.

Stock-based Employee/Consultant Compensation

Employment contracts with the Company's President and Chief Executive Officer, Chief Financial Officer and certain other employees and engagement contracts with certain consultants include provisions for a portion of each employee's salaries or consultant's fees 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 six months ended September 30, 2018, 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 six months ended September 30, 2018, the Company did not issue any shares pursuant to the engagement contracts with certain consultants.

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During the six months ended September 30, 2018, the Company accrued salaries totaling $402,500 owed to the Company's President and Chief Executive Officer, Chief Financial Officer and certain other employees which will be paid via the issuance of 4,130,412 shares of Common Stock.

As of September 30, 2018, the Company owed its President and Chief Executive Officer, Chief Financial Officer and certain other employees' salaries totaling $902,500 which will be paid via the issuance of 8,460,073 shares of Common Stock. 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 April 1, 2018	6,618,000	$ 0.16	6.1	$ 90,390
Forfeited and expired	403,000	$ 0.30		
Outstanding at September 30, 2018	6,215,000	$ 0.15	5.5	$ 60,000
Exercisable at September 30, 2018	5,628,334	$ 0.15	5.2	$ 60,000

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 September 30, 2018 and March 31, 2018 of $0.09 and $0.10, respectively.

NOTE 14. CONCENTRATIONS AND CREDIT RISK

Revenues

Two customers accounted for substantially all the Company's revenues for the six months ended September 30, 2018. These two customers accounted for approximately 56% and 25% of revenues each, respectively. The same two customers accounted for approximately 58% and 32% of revenues for the three months ended September 30, 2018.

Three customers accounted for substantially all the Company's revenues for the six months ended September 30, 2017. These three customers accounted for approximately 56%, 29% and 10% of revenues each, respectively. The same three customers accounted for approximately 53%, 28% and 9% of revenues for the three months ended September 30, 2017.

Accounts Receivable

Three customers accounted for substantially all the Company's accounts receivable as of September 30, 2018. These three customers accounted for approximately 39%, 20% and 17% of accounts receivable each, respectively.

Four customers accounted for substantially all the Company's accounts receivable as of March 31, 2018. These four customers accounted for approximately 52%, 14%, 12%, and 11% of accounts receivable each, respectively.

Purchasing

Seven suppliers accounted for more than 85% of the Company's purchases of raw materials for the six months ended September 30, 2018. Included in these seven suppliers are two suppliers that accounted for approximately 43% and 13% of purchases each, respectively.

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Seven suppliers accounted for more than 82% of the Company's purchases of raw materials for the six months ended September 30, 2017. Included in these seven suppliers are two suppliers that accounted for approximately 38% and 11% of purchases each, respectively.

NOTE 15. 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 September 30,		For the Six Months Ended September 30,	
	2018	2017	2018	2017

Operating Loss by Segment				
ANDA	$(410,581)	$(663,291)	$(546,502)	$(1,094,981)
NDA	(268,665)	(688,124)	(506,027)	(1,364,689)
	$(679,246)	$(1,351,415)	$(1,052,529)	$(2,459,670)

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

	For the Three Months Ended September 30,		For the Six Months Ended September 30,	
	2018	2017	2018	2017
Operating loss by segment	$(679,246)	$(1,351,415)	$(1,052,529)	$(2,459,670)
Corporate unallocated costs	(1,421,985)	(423,782)	(2,444,344)	(950,518)
Interest income	1,582	4,419	2,837	8,401
Interest expense and amortization of debt issuance costs	(106,002)	(82,541)	(189,140)	(153,272)
Depreciation and amortization expense	(366,522)	(184,527)	(570,226)	(335,196)
Significant non-cash items	(185,219)	(170,147)	(444,267)	(625,758)
Change in fair value of derivative instruments	173,860	4,023,176	426,371	4,162,436
(Loss) income from operations	$(2,583,532)	$1,815,183	$(4,271,298)	$(353,577)

NOTE 16. 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.

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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. These nonrefundable payments represent consideration for certain exclusive rights to ELI-200 and will be recognized ratably over the Epic Exclusivity Period. The Company determined that the performance obligations within the 2015 Epic License Agreement included the transfer of the license and the performance of the research and development services; the license is not distinct because the customer cannot obtain value from the license without the research and development services that the Company is uniquely able to perform.

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. 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. Based on subsequent meetings and communications with the FDA, the Company believes that there is a clear path forward to address the issues cited in the CRL. The Company believes that the meeting minutes, received from the FDA on January 23, 2017, supported a plan to address the issues cited by the FDA in the CRL by modifying the SequestOx™ formulation. Such plan includes, without limitation, conducting bioequivalence and bioavailability fed and fasted studies, comparing the modified formulation to the original formulation. the Company modified the SequestOx™ formulation and, on January 30, 2018 reported positive topline results from a pilot study indicating the likelihood of achieving the required bioequivalence in a pivotal trial under fed conditions. The Company is reviewing these results with the FDA and discussing pharmacokinetic study requirements for a re-submission of the NDA.

The 2015 Epic License Agreement expires on June 4, 2020, and Epic has previously advised the Company of their desire to extend this agreement. While discussions are ongoing, they are directly correlated to the regulatory status of SequestOx™. Furthermore, there can be no assurances that the parties will reach mutual agreement to extend the term of this agreement and no assurances that the terms and conditions of the agreement will be similar in all material aspects in the event that the agreement is extended by mutual consent of the parties. Non-receipt by the Company of the remaining $7.5 million milestone will have a material adverse effect on the Company's financial condition.

NOTE 17. COLLABORATIVE AGREEMENT WITH SUNGEN PHARMA LLC

On August 24, 2016, the Company entered into the SunGen Agreement. The SunGen Agreement, as amended, 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.

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On February 8, 2018, the Company filed an ANDA with the FDA for a generic version of an immediate release central nervous system ("*CNS*") stimulant. The ANDA represents the first filing for a product co-developed with SunGen under the SunGen Agreement.

On May 24, 2018, the Company filed an ANDA with the FDA for a generic version of an extended release CNS stimulant. The ANDA represents the second filing for a product co-developed with SunGen under the SunGen Agreement.

There can be no assurances that any of these products, including the two products for which ANDAs have already been filed, will receive marketing authorization and achieve commercialization within a reasonable 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.

NOTE 18. 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 16 above). The 2015 Epic License Agreement includes milestone payments totaling $10 million upon the filing with and approval of an 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. An additional $7.5 million is due upon approval by the FDA of the NDA filed for SequestOx™. 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 hours, with a range of 0.5 hour to 12 hours and a mean Tmax of the comparator, Roxicodone® of 3.4 hours with a range of 0.5 hour to 12 hours. 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 will pause, not proceed, with the rest of the clinical trials, and seek clarity from the FDA before deciding on the next steps for immediate release SequestOx™. 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 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 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.

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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. The Epic Generic Agreement expired on October 2, 2018 with Epic launching four of the six exclusive products and Elite collecting $1.0 million of the total $1.8 million fee.

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 19. 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")

- Master Development and License Agreement with SunGen Pharma LLC, dated August 24, 2016, as amended (the "SunGen Agreement") and,

- Strategic Marketing Alliance with Glenmark Pharmaceuticals, Inc. USA dated May 29, 2018 (the "Glenmark Alliance")

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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 SunGen Agreement provides for 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. To date, the Company has filed ANDAs with the FDA for the two CNS Products identified in the SunGen Agreement.

ELITE PHARMACEUTICALS, INC. AND SUBSIDIARY

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(UNAUDITED)

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.

The Glenmark Alliance, provides for the manufacture by Elite and marketing by Glenmark of identified generic products under license from Elite. In addition to the purchase prices for the products, Elite will receive license fees well in excess of 50% of gross profits. Gross profit is defined as net sales less the price paid to Elite for the products, distribution fees (less than 10%) and shipping costs. Glenmark will have semi-exclusive marketing rights to the ANDA approved generic product, phendimetrazine 35mg tablets, and exclusive marketing rights to generic Methadone HCl. Collectively, the brand products and their generic equivalents had total annual sales of approximately $33.6 million in 2017, according to Quintiles IMS Health data. The Agreement has an initial term of three years and automatically renews for one-year periods absent prior written notice of non-renewal. In addition to customary termination provisions, the Agreement permits Glenmark to terminate with regard to a product on at least three months' prior written notice if it determines to stop marketing and selling such product, and it permits Elite to terminate with regard to a product if at any time after the first twelvemonths from the first commercial sale, the average license fee paid by Glenmark for such product is less than $100,000 for a six-month sales period.

NOTE 20. RELATED PARTY AGREEMENTS WITH MIKAH PHARMA LLC

Pursuant to an asset acquisition**,** 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 "Reddy's 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 "Epic Trimipramine Manufacturing Agreement"). Pursuant to this agreement, Epic manufactured Trimipramine under license from Elite. In September 2018, Elite successfully transferred manufacturing of Trimipramine to the Northvale Facility, resulting in the irrelevance of the Epic Trimipramine Manufacturing Agreement. Trimipramine is currently manufactured by Elite.

Mikah is owned by Nasrat Hakim, the CEO, President and Chairman of the Board of the Company.

The Reddy's Distribution Agreement was concluded by mutual consent in August 2018.

Trimipramine is one of the products included in the Glenmark Strategic Alliance and is currently marketed and distributed by Glenmark.

NOTE 21. SUBSEQUENT EVENTS

The Company has evaluated subsequent events from the balance sheet date through November 9, 2018, the date the accompanying financial statements were issued. The following are material subsequent events.

Common Stock issued and sold pursuant to the Lincoln Park Purchase Agreement

Subsequent to September 30, 2018 and up to November 5, 2018 (the latest practicable date), a total of 2,527,502 shares of Common Stock were issued to Lincoln Park, with such shares consisting of 2,500,000 purchase shares and 27,502 additional commitment shares. Total proceeds from these transactions was $198,550.

Commercial launch of generic Methadone HCl 5mg and 10mg

On November 5, 2018, the Company announced the commercial launch of generic Methadone Hydrochloride 5mg and 10mg tablets by Glenmark Pharmaceuticals, Inc., USA ("Glenmark"), Elite's marketing alliance partner. Through this alliance, Glenmark will sell and distribute Elite's Methadone, for which Elite receives manufacturing and licensing fees.

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

THREE AND SIX MONTHS ENDED SEPTEMBER 30, 2018 (UNAUDITED)
COMPARED TO THE

THREE AND SIX MONTHS ENDED SEPTEMBER 30, 2017 (UNAUDITED)

The following discussion of our financial condition and results of operations for the three and six months ended September 30, 2018 and 2017 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, 2018, as filed on June 14, 2018 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 and the manufacture of generic pharmaceuticals. Our strategy includes improving off-patent drug products for life cycle management, developing generic versions of controlled-release drug products with high barriers to entry and the development of branded and generic products that utilize our proprietary and patented abuse resistance technologies.

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
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
Isradipine 2.5mg and 5mg capsules ("Isradipine 2.5mg" and "Isradipine 5mg")	n/a	Cardiovascular	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")	Roxycodone®	Pain	March 2016
Trimipramine Maleate Immediate Release 25mg, 50mg and 100mg capsules ("Trimipramine 25mg", "Trimipramine 50mg", "Trimipramine 100mg")	Surmontil®	Antidepressant	May 2017
Methadone HCl 5mg and 10mg tablets ("Methadone 5mg" and "Methadone 10mg")	Dolophine®	Pain	November 2018

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". Methadone 5mg and Methadone 10mg are collectively and individually referred to as "Methadone".

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.

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

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 it received approval of its abbreviated new drug application ("ANDA") from the FDA for Phendimetrazine Tartrate Tablets USP, 35mg. This product approval is from an ANDA that the Company filed approximately six years ago. This approval resulted in the Company having a second, approved ANDA for this product. The Company has been selling this product pursuant to the marketing authorization achieved from the first approved ANDA. The Company is currently considering strategic options for utilization of this approved ANDA, with such options including, without limitation, divestiture.

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.

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 2.5 mg 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. Trimipramine is currently manufactured by Elite and marketed by Glenmark pursuant to the Glenmark Strategic Alliance. 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. The ANDA purchased by Elite is currently the only marketed generic Trimipramine product.

Methadone 5mg and Methadone 10mg

Methadone 5mg and Methadone 10mg tablets were developed by us, with Elite receiving approval of the related ANDA in August 2018.

Sales and marketing rights for Methadone are included in the Glenmark Strategic Alliance. Please see the section below titled "*Strategic Marketing Alliance with Glenmark Pharmaceuticals, Inc. USA"* for further details of this agreement.

The first shipments of Methadone were made to Glenmark in November 2018. Methadone is currently manufactured by Elite and distributed by Glenmark under the Glenmark Strategic Alliance.

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.

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 hours with a range of 0.5 hour to 12 hours and the mean Tmax of the comparator, Roxicodone®, was 3.4 hours with a range of 0.5 hour to 12 hours. 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. Elite will pause, not proceed with the rest of the clinical trials, and seek clarity from FDA before deciding on the next steps for immediate release SequestOx™. 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 (see "*Licensing, Manufacturing and Development Agreements; Sales and Distribution Licensing Agreement with Epic Pharma LLC for SequestOx*™" below). 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.

Acetaminophen and codeine phosphate (generic version of Tylenol® with Codeine) 300mg/7.5mg, 300mg/15mg, 300mg/30mg, and 300mg/60mg tablets

On September 18, 2018, the Company filed an ANDA with the FDA for a generic version of Tylenol® with Codeine (acetaminophen and codeine phosphate) 300mg/7.5mg, 300mg/15mg, 300mg/30mg and 300mg/60mg tablets. The Company awaits the FDA's response.

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 FDA requested additional information relating to this filing, which was provided. The Company awaits the FDA's response.

Oxycodone Hydrochloride extended release (generic version of Oxycontin®)

On September 20, 2017, the Company filed an ANDA with the FDA for generic version of Oxycontin® (extended release Oxycodone Hydrochloride). 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 requested additional information relating to this filing. The Company's response to the FDA's request is in progress.

Generic version of immediate release Central Nervous System stimulant

On February 8, 2018, the Company filed an ANDA with the FDA for a generic version of an immediate release central nervous system ("CNS") stimulant. The ANDA represents the first filing for a product co-developed with SunGen Pharma LLC ("SunGen") under the Development and License Agreement between SunGen and the Company dated August 24, 2016 (the "SunGen Agreement"). According to IMS Health data, the branded product and its equivalents had total U.S. sales of more than $400 million for the twelve months ended September 30, 2017. The Company has not yet received a response from the FDA on this filing.

Under the terms of the SunGen Agreement, the product will be owned jointly by the Company and SunGen. Elite shall have exclusive rights to market and sell the product under its own label. Elite will also manufacture and package the product on a cost-plus basis.

Generic version of extended release Central Nervous System stimulant

On May 24, 2018, the Company filed an ANDA with the FDA for a generic version of an extended release CNS stimulant. The ANDA represents the second filing for a product co-developed with SunGen under the SunGen Agreement. According to IMS Health data, the branded product and its equivalents had total U.S. sales of approximately $1.6 billion for the twelve months ended September 30, 2017. The Company has not yet received a response from the FDA on this filing.

Under the terms of the SunGen Agreement, the product will be owned jointly by the Company and SunGen. Elite shall have exclusive rights to market and sell the product under its own label. Elite will also manufacture and package the product on a cost-plus basis.

Please see the section below titled “Master Development and License Agreement with SunGen Pharma LLC” for further details on the SunGen Agreement.

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

Oxycodone Hydrochloride and Acetaminophen, USP CII 5mg/325mg, 7.5mg/325mg and 10mg/325mg tablets

On July 3, 2018, the Company received approval by the FDA of its ANDA filed for generic Percocet® (Oxycodone Hydrochloride and Acetaminophen, USP CII) 5mg/325mg, 7.5mg/325mg and 10mg/325mg tablets. This product is indicated for the management of pain severe enough to require an opioid analgesic and for which alternative

treatments are inadequate. Based on Quintiles IMS Health data for the twelve months ending May 31, 2018, the retail sales for the brand and generic products were approximately $500 million. The Company is evaluating marketing options for this product.

In addition to the above, 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.

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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

These products were initially manufactured and marketed pursuant to the Epic Pharma Manufacturing and License Agreement, which expired in October 2018. Phendimetrazine and Isradipine are currently being marketed on a semi-exclusive and exclusive basis, respectively pursuant to the Glenmark Strategic Alliance. The Company is currently considering strategic options for continued commercial activities relating to Hydroxyzine, as well as evaluating other options, including, without limitation, divestiture. Please also see below for further details on the expired 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. The agreement with Dr. Reddy's Laboratories, Inc. was concluded by mutual consent and Trimipramine is currently marketed pursuant to the Glenmark Strategic Alliance.

Please see Note 20: 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 an 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 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. Based on subsequent meetings and communications with the FDA, the Company believes that there is a clear path forward to address the issues cited in the CRL. The Company believes that the meeting minutes, received from the FDA on January 23, 2017, supported a plan to address the issues cited by the FDA in the CRL by modifying the SequestOx™ formulation. Such plan includes, without limitation, conducting bioequivalence and bioavailability fed and fasted studies, comparing the modified formulation to the original formulation. the Company modified the SequestOx™ formulation and, on January 30, 2018 reported positive topline results from a pilot study indicating the likelihood of achieving the required bioequivalence in a pivotal trial under fed conditions. The Company is reviewing

these results with the FDA and discussing pharmacokinetic study requirements for a re-submission of the NDA.

The 2015 Epic License Agreement expires on June 4, 2020, and Epic has previously advised the Company of their desire to extend this agreement. While discussions are ongoing, they are directly correlated to the regulatory status of SequestOx™. Furthermore, there can be no assurances that the parties will reach mutual agreement to extend the term of this agreement and no assurances that the terms and conditions of the agreement will be similar in all material aspects in the event that the agreement is extended by mutual consent of the parties. Non-receipt by the Company of the remaining $7.5 million milestone will have a material adverse effect on the Company's financial condition.

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"), which expired on October 2, 2018.

Pursuant to this now expired agreement, the Company 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 had exclusive rights to market six products as listed in Schedule A of the Epic Manufacturing and License Agreement, and non-exclusive rights to market six products as listed in Schedule D of the Epic Manufacturing and License Agreement. Epic manufactured those products for which manufacturing site transfer was achieved and Epic was responsible for all regulatory and pharmacovigilance matters related to the products. The Company received a license fee and milestone payments, as provided for in this agreement. Upon expiration of this agreement, Epic ceased having rights to manufacture and market any of the products included therein. The Company has already successfully transferred manufacturing of Isradipine to the Northvale Facility and is in the process of transferring manufacturing of several of the other products included in this agreement to the Northvale Facility. The Company is also evaluating strategic options, in addition to manufacturing site transfer for several of the products, with such options including, without limitation, divestiture.

During the life of the Epic Manufacturing and License Agreement, the Company received license fees and milestone payments. The license fee was computed as a percentage of gross profit, as defined in the agreement, which was earned by Epic as a result of sales of the product. The milestones, which totaled $1.8 million were based upon Epic's signing and transfer of manufacturing to their manufacturing facilities. Please note that this agreement expired prior to successful transfer of manufacturing site for all products relating to the milestones, Elite received an aggregate of $1.0 million out of the total $1.8 million in milestones provided for in the agreement.

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 "Epic Trimipramine Manufacturing Agreement").

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

The Reddy's Trimipramine Distribution Agreement was concluded by mutual consent in August 2018.

Elite successfully transferred manufacturing of Trimipramine to the Northvale Facility in September 2018, resulting in the irrelevance of the Epic Manufacturing Agreement.

Methadone Manufacturing and Supply Agreement

On June 23, 2011 and as amended on September 24, 2012, January 19, 2015, July 20, 2015 and as extended on August 9, 2016, 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 is 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 manufacturing 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 and expired. We made our final shipments of Methadone to Ascend during the quarter ended June 30, 2018.

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.

On February 8, 2018, the Company filed an ANDA with the FDA for a generic version of an immediate release central nervous system (“CNS”) stimulant. The ANDA represents the first filing for a product co-developed with SunGen Pharma LLC (“SunGen”) under the Development and License Agreement between SunGen and the Company dated August 24, 2016 (the “SunGen Agreement”). According to IMS Health data, the branded product and its equivalents had total U.S. sales of more than $400 million for the twelve months ended September 30, 2017. The Company has not yet received a response from the FDA on this filing.

On May 24, 2018, the Company filed an ANDA with the FDA for a generic version of an extended release CNS stimulant. The ANDA represents the second filing for a product co-developed with SunGen under the SunGen Agreement. According to IMS Health data, the branded product and its equivalents had total U.S. sales of approximately $1.6 billion for the twelve months ended September 30, 2017. The Company has not yet received a response from the FDA on this 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.

Strategic Marketing Alliance with Glenmark Pharmaceuticals, Inc. USA

On May 29, 2018, we entered into a license, manufacturing and supply agreement with Glenmark Pharmaceuticals Inc. USA (“Glenmark”) to market the two Elite generic products described below in the United States with the option to add products in the future (the “Glenmark Alliance”).

Pursuant to the Glenmark Alliance, Glenmark will purchase the products from Elite and then sell and distribute them. In addition to the purchase prices for the products, Elite will receive license fees well in excess of 50% of gross profits. Gross profits are defined as net sales less the price paid to Elite for the products, distribution fees (less than 10%) and shipping costs. Glenmark will have semi-exclusive marketing rights to the ANDA approved generic product, phendimetrazine 35mg tablets, and exclusive marketing rights to Methadone 5mg and 10mg, products that were approved by the FDA on August 3, 2018. Collectively, the brand products and their generic equivalents had total annual sales of approximately $33.6 million in 2017, according to Quintiles IMS Health data. The Agreement has an initial term of three years and automatically renews for one-year periods absent prior written notice of non-renewal. In addition to customary termination provisions, the Agreement permits Glenmark to terminate with regard to a product on at least three months' prior written notice if it determines to stop marketing and selling such product, and it permits Elite to terminate with regard to a product if at any time after the first twelvemonths from the first commercial sale, the average license fee paid by Glenmark for such product is less than a defined minimum amount.

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. Please see "Filed products under FDA review; SequestOx™ - Immediate Release Oxycodone with sequestered Naltrexone" above.

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"). Please see "Filed products under FDA review; Hydrocodone bitartrate and acetaminophen tablets USP CII (generic version of Norco)" above. 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 generic version of Oxycontin® (extended release Oxycodone Hydrochloride). Please see “Filed products under FDA review; Oxycodone Hydrochloride extended release (generic version of Oxycontin®” above. 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 February 8, 2018, the Company filed an ANDA with the FDA for a generic version of an immediate release central nervous system (“CNS”) stimulant. The ANDA represents the first filing for a product co-developed with SunGen Pharma LLC (“SunGen”) under the SunGen Agreement. Please see “Filed products under FDA review Generic version of immediate release Central Nervous System stimulant” above. 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. Please also see the section below titled “Master Development and License Agreement with SunGen Pharma LLC”.

On May 30, 2018, the Company filed an ANDA with the FDA for a generic version of an extended release CNS stimulant. The ANDA represents the second filing for a product co-developed with SunGen under the SunGen Agreement. Please see “Filed products under FDA review Generic version of extended release Central Nervous System stimulant” above. 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. Please also see the section below titled “Master Development and License Agreement with SunGen Pharma LLC”.

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 and Generic Hydrocodone/APAP, 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.

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, 2018.

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 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 retain 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 6,926,909	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.

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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 Glenmark 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. Please see the Risk Factors in Part II, Item 1A entitled "*We depend on a limited number of customers and any reduction, delay or cancellation of an order from these customers or the loss of any of these customers could cause our revenue to decline*."

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 September 30, 2018 compared to September 30, 2017

Revenue, Cost of revenue and Gross profit:

	For the Three Months Ended September 30,		Change	
	2018	2017	Dollars	Percentage
Manufacturing fees	$ 806,487	$ 1,066,227	$ (259,740)	-24 %
Licensing fees	556,562	557,354	(792)	0 %
Total revenue	1,363,049	1,623,581	(260,532)	-16 %
Cost of revenue	542,551	614,941	(72,390)	-12 %
Gross profit	$ 820,498	$ 1,008,640	$ (188,142)	-19 %
Gross profit - percentage	60 %	62 %		

Total revenues for the three-month period ended September 30, 2018 decreased by $0.26 million or 16%, to $1.36 million, as compared to $1.62 million, for the corresponding period in 2017 primarily due to decreases in revenues derived from the manufacture and sale of generic methadone, hydromorphone and phentermine. Please note that during the three months ended September 30, 2017, the Company earned revenues from the contract manufacturing of methadone for Ascend Laboratories. This contract expired on December 31, 2017 and accordingly there were no revenues earned from the contract manufacturing of methadone during the three months ended September 30, 2018. Elite's ANDA for Methadone was approved in August 2013 and Elite achieved commercial launch of Methadone in November 2018 pursuant to the Glenmark Strategic Alliance. Revenues derived from the manufacture and sale of Methadone are expected to contribute to overall revenues earned during periods subsequent to September 30, 2018.

Manufacturing fees decreased by $0.26 million, or 24%, due to decreases in sales of generic methadone, hydromorphone and Phentermine, as more fully described above.

Licensing fees decreased by $0.001 million, or 0.1%. This decrease is primarily due to the timing of in-market sales of the Company's generic products, especially, without limitation, generic Isradipine, Phentermine and Naltrexone, 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 $0.07 million or 12%, to $0.54 million as compared to $0.61 million for the corresponding period in 2017. Costs of revenue consists of manufacturing and assembly costs. As such, the cost of revenue correlates directly with the decrease in manufacturing fees.

Our gross profit margin was 60% during the three months ended September 30, 2018 as compared to 62% during the three months ended September 30, 2017. The decrease in gross margin is due to the product mix of generics manufactured during the quarter.

Operating expenses:

	For the Three Months Ended September 30,		**Change**		
	2018	**2017**	**Dollars**	**Percentage**	
Operating expenses:					
Research and development	$2,455,466	$2,286,514	$168,952	7	%
General and administrative	614,937	594,073	20,864	4	%
Non-cash compensation	36,545	73,397	(36,852)	-50	%
Depreciation and amortization	366,522	184,527	181,995	99	%
Total operating expenses	$3,473,470	$3,138,511	$334,959	11	%

Operating expenses consist of research and development costs, general and administrative, non-cash compensation and depreciation and amortization expenses. Operating expenses for the three-month period ended September 30, 2018 increased by $0.33, or 11%, to $3.47 million, as compared to $3.14 million for the corresponding period in 2017.

Research and development costs for the three months ended September 30, 2018 was $2.46 million, an increase of $0.17 million, or 7%, from $2.29 million of such costs for the comparable period of the prior year. The increase was a result of additional resources being utilized in product development activities during the relevant quarterly periods from this fiscal year and the prior fiscal year.

General and administrative expenses for the three months ended September 30, 2018 and 2017 were $0.61 million, an increase of $0.02 million or 4% from $0.59 million of such costs for the comparable period of the prior year with such increase being attributed in large part to increased costs relating to compliance with various regulatory authorities.

Non-cash compensation expense for the three months ended September 30, 2018 and 2017 was $0.037 million and $0.073 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.

Depreciation and amortization expenses for the three months ended September 30,2018 was $0.367 million, an increase of $0.182 million or 99% from $0.185 million of such costs for the comparable period of the prior year. The increase was due to acquisitions of additional fixed assets as well as additional equipment being placed into service during the current fiscal quarter.

As a result of the foregoing, our loss from operations for the three months ended September 30, 2018 was $2.7, compared to a loss from operations of $2.1 million for the three months ended September 30, 2017.

Other income (expense):

	For the Three Months Ended September 30,		Change	
	2018	2017	Dollars	Percentage
Other income (expense):				
Interest expense and amortization of debt issuance costs	$ (106,002)	$ (82,541)	$ (23,461)	28 %
Change in fair value of derivative instruments	173,860	4,023,176	(3,849,316)	-96 %
Interest income	1,582	4,419	(2,837)	-64 %
Other income, net	$ 69,440	$ 3,945,054	$ (3,875,614)	-98 %

Other income, net for the three months ended September 30, 2018 was a net other income of $0.07 million, a decrease in net other income of $3.88 million from the net other income of $3.95 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 September 30, 2017. Please note that the change in the fair value of derivative instruments 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 the fair value of our derivatives instruments and increases in the closing price of the Company’s Common Stock. The warrants related to revenues earned in relation to the change in fair value of derivative instruments for the quarter ended September 30, 2017 expired prior to the quarter ended September 30, 2018 and accordingly had no impact on other income (expense) during the current fiscal quarter.

As a result of the foregoing, our net loss for the three months ended September 30, 2018 was $2.6 million, compared to net income of $1.8 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 loss attributable to common shareholders for the three months ended September 30, 2018, and September 30, 2017.

Six months ended September 30, 2018 compared to September 30, 2017

Revenue, Cost of revenue and Gross profit:

	For the Six Months Ended September 30,		Change	
	2018	2017	Dollars	Percentage
Manufacturing fees	$2,348,345	$2,077,123	$271,222	13 %
Licensing fees	1,182,402	1,249,228	(66,826)	-5 %
Total revenue	3,530,747	3,326,351	204,396	6 %
Cost of revenue	2,118,950	1,630,001	488,949	30 %
Gross profit	$1,411,797	$1,696,350	$(284,553)	-17 %
Gross profit - percentage	40 %	51 %		

Total revenues for the six-month period ended September 30, 2018 increased by $0.2 million or 6%, to $3.5 million, as compared to $3.3 million, for the corresponding period in 2017 primarily due to increases in revenues related to the manufacture and sale of generic Naltrexone as compared to the comparable period of the prior fiscal year.

Manufacturing fees increased by $0.3 million, or 13%, due to an increase in fees earned from the manufacture of generic Naltrexone.

Licensing fees decreased by $0.1 million, or 5%. This decrease is primarily due to the timing of in-market sales of the Company's generic products, especially, without limitation, generic Isradipine and Phentermine, 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 increased by $0.49 million or 30%, to $2.12 million as compared to $1.63 million for the corresponding period in 2017. Costs of revenue consists of manufacturing and assembly costs. As such, the cost of revenue correlates directly with the increase in manufacturing fees.

Our gross profit margin was 40% during the six months ended September 30, 2018 as compared to 51% during the six months ended September 30, 2017. The decrease in gross margin is due to the product mix of generics manufactured during the quarter.

Operating expenses:

	For the Six Months Ended September 30,		**Change**		
	2018	**2017**	**Dollars**	**Percentage**	
Operating expenses:					
Research and development	$3,782,094	$4,108,504	$(326,410)	-8	%
General and administrative	1,497,749	1,453,034	44,715	3	%
Non-cash compensation	73,094	170,758	(97,664)	-57	%
Depreciation and amortization	570,226	335,196	235,030	70	%
Total operating expenses	$5,923,163	$6,067,492	$(144,329)	-2	%

Operating expenses consist of research and development costs, general and administrative, non-cash compensation and depreciation and amortization expenses. Operating expenses for the six-month period ended September 30, 2018 decreased by $0.1, or 2%, to $5.9 million, as compared to $6.0 million for the corresponding period in 2017.

Research and development costs for the six months ended September 30, 2018 were $3.78 million, a decrease of $0.33 million or 8% from $4.11 million of such costs for the comparable period of the prior year. The decrease was due to the timing and composition of ongoing development of our abuse deterrent opioid, products under development pursuant to the SunGen Agreement and other products.

General and administrative expenses for the six months ended September 30, 2018 and 2017 were $1.49 million, an increase of $0.04 million or 3% from $1.45 million of such costs for the comparable period of the prior year with such increase being primarily due to increases in regulatory compliance costs.

Non-cash compensation expense for the six months ended September 30, 2018 and 2017 was $0.073 million and $0.171 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.

Depreciation and amortization expenses for the six months ended September 30,2018 was $0.570 million, an increase of $0.235 million or 70% from $0.335 million of such costs for the comparable period of the prior year. The increase was due to acquisitions of additional fixed assets as well as additional equipment being placed into service during the current fiscal quarter.

As a result of the foregoing, our loss from operations for the six months ended September 30, 2018 was $4.5 million**,** compared to a loss from operations of $4.4 million for the six months ended September 30, 2017.

Other income (expense):

	For the Six Months Ended September 30,		Change	
	2018	2017	Dollars	Percentage
Other income (expense):				
Interest expense and amortization of debt issuance costs	$(189,140)	$(153,272)	$(35,868)	23 %
Change in fair value of derivative instruments	426,371	4,162,436	(3,736,065)	-90 %

Interest income	2,837	8,401	(5,564)	-66	%
Other income (expense), net	$240,068	$4,017,565	$(3,777,497)	-94	%

Other income, net for the six months ended September 30, 2018 was net other income of $0.2 million, a decrease in net other income of $3.8 million from the net other income of $4.0 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 September 30, 2018 totaling a decrease in other income of $3.8 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. Please also note that the warrants related to revenues earned in relation to the change in fair value of derivative instruments for the six months ended September 30, 2017 had substantially been exercised or expired prior to the six-month period ended September 30, 2018 and accordingly had no impact on other income (expense) during the current fiscal quarter.

As a result of the foregoing, our net loss for the six months ended September 30, 2018 was $4.3 million, compared to $0.4 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 loss attributable to common shareholders for the six months ended September 30, 2018, and September 30, 2017.

Liquidity and Capital Resources

Capital Resources

	September 30, 2018	March 31, 2018	Change
Current assets	$ 10,377,783	$ 13,702,401	$(3,324,618)
Current liabilities	5,364,427	5,114,704	249,723
Working capital	5,013,356	8,587,697	(3,574,341)

The Company considers cash and working capital balances as several of the factors the Company uses in evaluating its performance, without limitation. As of September 30, 2018, the Company had cash on hand of $4.7 million and a working capital surplus of $5.0 million. We believe that such resources, combined with the Company's access to part or all of the remaining $37 million available pursuant to the $40 million equity line with Lincoln Park is sufficient to fund operations through the current operating cycle. For the six months ended September 30, 2018, we had losses from operations totaling $4.5 million, and net other income totaling $0.2 million, resulting in a net loss of $4.3 million.

The Company does not anticipate being profitable for the fiscal year ending March 31, 2019, 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 Six Months Ended September 30,	
	2018	2017
Net cash used in operating activities	$(3,388,725)	$(3,317,495)
Net cash used in investing activities	-	(461,838)
Net cash provided by financing activities	917,513	742,210

Net cash used in operating activities for the six months ended September 30, 2018 was $3.4 million, which included net losses of $4.3 million, change in fair value of derivative financial instruments – warrants of $0.4 million (non-cash), and changes in operating assets and liabilities of $0.5 million. These instances of decreases in cash are offset by change in non-cash compensation accrued of $1.3 million and depreciation and amortization of $0.5 million.

Net cash used in investing activities for the six months ended September 30, 2018 was $0.

Net cash provided by financing activities was $0.9 million for the six months ended September 30, 2018 which consist primarily from proceeds from the issuance of common stock pursuant to the 2017 LPC Purchase Agreement (see below).

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.

As of September 30, 2018, the Company issued 5,540,551 shares of its Common Stock as initial commitment shares and 470,414 shares of its Common Stock as additional commitment shares, both being pursuant to the 2017 LPC Purchase Agreement. In addition, as of September 30, 2018, the Company sold 31,961,033 shares of its common stock for proceeds totaling $3,396,162 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 10 to the financial statements) and Warrants (see Note 11 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 15,017,321 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").

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, 2018.

ITEM 1A. RISK FACTORS

We depend on a limited number of customers and any reduction, delay or cancellation of an order from these customers or the loss of any of these customers could cause our revenue to decline.

Each year we have had one or a few customers that have accounted for a large percentage of our limited revenues therefore the termination of a contract with a customer may result in the loss of 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, Glenmark and Precision Dose for the sales and distribution of products that we manufacture. We receive revenues to manufacture these products and also receive a profit split or royalties based on in-market sales of the products.

In addition, since a significant portion of our revenues is derived from a relatively few customers, any financial difficulties experienced by any one of these customers, or any delay in receiving payments from any one of these customers, could have a material adverse effect on our business, results of operations, financial condition, and cash flows. The contract manufacturing agreement with Ascend expired on December 31, 2017 and was not renewed or extended, with resultant adverse effects on revenues, results of operations, financial condition and cash flows. Furthermore, one of the agreements with Epic expired in October 2018 and the other one expires in June 2020. The agreement that expired in October 2018 has not been renewed or extended and there can be no assurances of the other agreement being renewed with Epic at all, or on terms that are not materially different from those currently in effect. The non-renewal of the current agreement with Epic or the renewal of the other agreement on terms that are materially different from those currently in effect could have a material adverse effect on our business, results of operations, financial condition and cash flows.

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, 2018, 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

None.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

ITEM 5. OTHER INFORMATION

On November 7, 2018, Dr. Aqeel Fatmi resigned from our Board of Directors.

ITEM 6. EXHIBITS

Exhibit No.	Description
2.1	Agreement and Plan of Merger between Elite Pharmaceuticals, Inc., a Delaware corporation ("Elite-Delaware") and Elite Pharmaceuticals, Inc., a Nevada corporation ("Elite-Nevada"), incorporated by reference to Exhibit 2.1 to the Current Report on Form 8-K filed with the SEC on January 9, 2012.
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 3.1 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 VGSPHARMA, 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.

10.1	Elite Pharmaceuticals, Inc. 2014 Equity Incentive Plan, incorporated by reference to Appendix B to the Company's Definitive Proxy Statement for its Annual Meeting of Shareholders, filed with the SEC on April 3, 2014.
10.2	Form of Confidentiality Agreement (corporate), incorporated by reference to Exhibit 10.7 to the Form SB-2.
10.3	Form of Confidentiality Agreement (employee), incorporated by reference to Exhibit 10.8 to the Form SB-2.
10.4	Loan Agreement, dated as of August 15, 2005, between New Jersey Economic Development Authority ("NJEDA") and the Company, incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K, dated August 31, 2005 and filed with the SEC on September 6, 2005.
10.5	Series A Note in the aggregate principal amount of $3,660,000.00 payable to the order of the NJEDA, incorporated by reference to Exhibit 10.2 to the Current Report on Form 8-K, dated August 31, 2005 and filed with the SEC on September 6, 2005.

10.6	Series B Note in the aggregate principal amount of $495,000.00 payable to the order of the NJEDA, incorporated by reference to Exhibit 10.3 to the Current Report on Form 8-K, dated August 31, 2005 and filed with the SEC on September 6, 2005.
10.7	Mortgage from the Company to the NJEDA, incorporated by reference to Exhibit 10.4 to the Current Report on Form 8-K, dated August 31, 2005 and filed with the SEC on September 6, 2005.
10.8	Indenture between NJEDA and the Bank of New York as Trustee, dated as of August 15, 2005, incorporated by reference to Exhibit 10.5 to the Current Report on Form 8-K, dated August 31, 2005 and filed with the SEC on September 6, 2005.
10.9	Consulting Agreement, dated as of July 27, 2007, between the Registrant and Willstar Consultants, Inc., incorporated by reference as Exhibit 10.1 to the Quarterly Report on Form 10-Q for the period ending September 30, 2007 and filed with the SEC on November 14, 2007.
10.10	Compensation Agreement, dated as of December 1, 2008, by and between the Company and Jerry I. Treppel, incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K, dated December 1, 2008 and filed with the SEC on December 4, 2008.
10.11	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 10.1 to the Current Report on Form 8-K, dated March 18, 2009 and filed with the SEC on March 23, 2009.
10.12	Amendment to Strategic Alliance Agreement, dated as of April 30, 2009, by and among the Company, Epic Pharma, LLC and Epic Investments, LLC, incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K, dated April 30, 2009 and filed with the SEC on May 6, 2009.
10.13	Second Amendment to Strategic Alliance Agreement, dated as of June 1, 2009, by and among the Company, Epic Pharma, LLC and Epic Investments, LLC, incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K, dated June 1, 2009, and filed with the SEC on June 5, 2009.
10.14	Third Amendment to Strategic Alliance Agreement, dated as of Aug 18, 2009, by and among the Company, Epic Pharma LLC and Epic Investments, LLC, incorporated by reference to Exhibit 10.3 to the Quarterly Report on Form 10-Q, for the period ending June 30, 2009 and filed with the SEC on August 19, 2009.
10.15	Employment Agreement, dated as of November 13, 2009, by and between the Company and Carter J. Ward, incorporated by reference to Exhibit 10.2 to the Quarterly Report on Form 10-Q, for the period ending September 30, 2009 and filed with the SEC on November 16, 2009.
10.16	Elite Pharmaceuticals Inc. 2009 Equity Incentive Plan, as adopted November 24, 2009, incorporated by reference to Exhibit 10.1 to the Registration Statement Under the Securities Act of 1933 on Form S-8, dated December 18, 2009 and filed with the SEC on December 22, 2009.
10.17	License Agreement, dated as of September 10, 2010, by and among Precision Dose Inc. and the Company, incorporated by reference to Exhibit 10.8 to the Quarterly Report on Form 10-Q, for the period ended September 30, 2010 and filed with the SEC on November 15, 2010 (Confidential Treatment granted with respect to portions of the Agreement).

10.18	Manufacturing and Supply Agreement, dated as of September 10, 2010, by and among Precision Dose Inc. and the Company, incorporated by reference to Exhibit 10.9 to the Quarterly Report on Form 10-Q, for the period ended September 30, 2010 and filed with the SEC on November 15, 2010 (Confidential Treatment granted with respect to portions of the Agreement).
10.19	Product Development Agreement between the Company and Hi-Tech Pharmacal Co., Inc. dated as of January 4, 2011, incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K, dated January 4, 2011 and filed with the SEC on January 10, 2011 (Confidential Treatment granted with respect to portions of the Agreement).
10.20	Manufacturing & Supply Agreement between the Company and ThePharmaNetwork, LLC, dated as of June 23, 2011, incorporated by reference to Exhibit 10.71 to the Annual Report on Form 10-K, for the period ended March 31, 2011 and filed with the SEC on June 29, 2011 (Confidential Treatment granted with respect to portions of the Agreement).

10.21	Treppel $500,000 Bridge Loan Agreement dated June 12, 2012, incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed with the SEC on June 13, 2012.
10.22	December 5, 2012 amendment to the Treppel Bridge Loan Agreement incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed with the SEC on December 10, 2012.
10.23	Letter Agreement between the Company and ThePharmaNetwork LLC, dated September 21, 2012 incorporated by reference to Exhibit 10.6 to the Quarterly Report on Form 10-Q filed with the SEC on November 14, 2012 (Confidential Treatment granted with respect to portions of the Agreement).
10.24	Purchase Agreement between the Company and Lincoln Park Capital LLC dated April 19, 2013, incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K, dated April 18, 2013 and filed with the SEC on April 22, 2013.
10.25	Registration Rights Agreement between the Company and Lincoln Park Capital LLC dated April 19, 2013, incorporated by reference to Exhibit 10.2 to the Current Report on Form 8-K, dated April 18, 2013 and filed with the SEC on April 22, 2013.
10.26	August 1, 2013 Employment Agreement with Nasrat Hakim, incorporated by reference to Exhibit 10.4 to the Current Report on Form 8-K, dated August 1, 2013 and filed with the SEC on August 5, 2013.
10.27	August 1, 2013 Mikah LLC Asset Purchase Agreement, incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K/A, dated August 1, 2013 and filed with the SEC on August 30, 2018. (Confidential Treatment granted with respect to portions of the Agreement).
10.28	August 1, 2013 Secured Convertible Note from the Company to Mikah Pharma LLC., incorporated by reference to Exhibit 10.2 to the Current Report on Form 8-K, dated August 1, 2013 and filed with the SEC on August 5, 2013.
10.29	August 1, 2013 Security Agreement from the Company to Mikah Pharma LLC., incorporated by reference to Exhibit 10.3 to the Current Report on Form 8-K, dated August 1, 2013 and filed with the SEC on August 5, 2013.
10.30	October 15, 2013 Hakim Credit Line Agreement, incorporated by reference to Exhibit 10.16 to the Quarterly Report on Form 10-Q for the period ended September 30, 2013.
10.31	October 2, 2013 Manufacturing and Licensing Agreement with Epic Pharma LLC, incorporated by reference to Exhibit 10.17 to the Amended Quarterly Report on Form 10-Q/A for the period ended September 30, 2013 and filed with the SEC on October 17, 2018.
10.32	August 19, 2013, Master Services Agreement with Camargo Pharmaceutical Services, LLC, incorporated by reference to Exhibit 10.18 to the Quarterly Report on Form 10-Q for the period ended September 30, 2013 and filed with the SEC on November 14, 2013.
10.33	November 21, 2013 Unsecured Convertible Note from the Company to Jerry Treppel, incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K, dated November 26, 2013 and filed with the SEC on November 26, 2013.

10.34	February 7, 2014 Amendment to Secured Convertible Note from the Company to Mikah, incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K, dated February 7, 2014 and filed with the SEC on February 7, 2014.
10.35	February 7, 2014 Amendment to Secured Convertible Note from the Company to Jerry Treppel, incorporated by reference to Exhibit 10.2 to the Current Report on Form 8-K, dated February 7, 2014 and filed with the SEC on February 7, 2014.
10.36	Purchase Agreement between the Company and Lincoln Park Capital LLC dated April 10, 2014, incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K, dated April 10, 2014 and filed with the SEC on April 14, 2014.
10.37	Registration Rights Agreement between the Company and Lincoln Park Capital LLC dated April 10, 2014, incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K, dated April 10, 2014 and filed with the SEC on April 14, 2014.

10.38	Employment Agreement with Dr. G. Kenneth Smith, dated October 20, 2014, incorporated by reference to Exhibit 10.82 to the Quarterly Report on Form 10-Q for the period ended September 30, 2014 and filed with the SEC on November 14, 2014.
10.39	January 19, 2015 Second Amendment to TPN-Elite Manufacturing and Supply Agreement dated June 23, 2011 and First Amendment to the TPN-Elite Manufacturing and Supply Agreement dated September 21, 2012, incorporated by reference to Exhibit 10.6 to the Quarterly Report on Form 10-Q/A for the period ended September 30, 2012, and filed with the SEC on November 17, 2016. Confidential Treatment granted with respect to portions of the Agreement.
10.40	January 28, 2015 First Amendment to the Loan Agreement between Nasrat Hakim and Elite Pharmaceuticals dated October 15, 2013, incorporated by reference to Exhibit 10.83 to the Quarterly Report on Form 10-Q for the period ended December 31, 2014 and filed with the SEC on February 17, 2015.
10.41	January 28, 2015 Termination of Development and License Agreement for Mikah-001 between Elite Pharmaceuticals, Inc. and Mikah Pharma LLC and Transfer of Payment, incorporated by reference to Exhibit 10.84 to the Quarterly Report on Form 10-Q for the period ended December 31, 2014 and filed with the SEC on February 17, 2015.
10.42	June 4, 2015 License Agreement with Epic Pharma LLC, incorporated by reference to Exhibit 10.85 to Amendment No. 1 to the Annual Report on Form 10-K for the fiscal year ended March 31, 2015 and filed with the SEC on July 11, 2016. (Confidential Treatment granted with respect to portions of the Agreement).
10.43	Amendment No. 1 to Hakim Employment Agreement, incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed with the SEC on January 29, 2016.
10.44	August 24, 2016 Master Development and License Agreement between Elite and SunGen Pharma LLC. incorporated by reference to Exhibit 10.44 to the Quarterly Report on Form 10-Q for the period ended September 30, 2016 and filed with the SEC on November 9, 2016. (Confidential Treatment granted with respect to portions of the Agreement).
10.45	August 9, 2016 Amendment to Manufacturing and Supply Agreement between the Company and ThePharmaNetwork, LLC, dated as of June 23, 2011 incorporated by reference to Exhibit 10.45 to the Quarterly Report on Form 10-Q for the period ended September 30, 2016 and filed with the SEC on November 9, 2016.
10.46	July 20, 2015 Third Amendment to TPN-Elite Manufacturing and Supply Agreement dated June 23, 2011 incorporated by reference to Exhibit 10.46 to the Quarterly Report on Form 10-Q for the period ended September 30, 2016 and filed with the SEC on November 9, 2016. (Confidential Treatment granted with respect to portions of the Agreement).
10.47	Purchase Agreement between the Company and Lincoln Park Capital LLC dated May 1, 2017, incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K, dated May 2, 2017 and filed with the SEC on May 2, 2017.
10.48	Registration Rights Agreement between the Company and Lincoln Park Capital LLC dated May 1, 2017, incorporated by reference to Exhibit 10.2 to the Current Report on Form 8-K, dated May 2, 2017 and filed with

	the SEC on May 2, 2017.
10.49	April 28, 2017 Exchange Agreement between the Company and Nasrat Hakim, incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K, dated April 28, 2017 and filed with the SEC on April 28, 2017.
10.50	May 2017 Trimipramine Acquisition Agreement from Mikah Pharma, incorporated by reference to Exhibit 10.50 to the Annual Report on Form 10-K, for the period ended March 31, 2017 and filed with the SEC on June 14, 2017.
10.51	May 2017 Secured Promissory Note from the Company to Mikah Pharma, incorporated by reference to Exhibit 10.51 to the Annual Report on Form 10-K, for the period ended March 31, 2017 and filed with the SEC on June 14, 2017.
10.52	May 2017 Security Agreement between the Company to Mikah Pharma, incorporated by reference to Exhibit 10.52 to the Annual Report on Form 10-K, for the period ended March 31, 2017 and filed with the SEC on June 14, 2017.
10.53	May 2017 Assignment of Supply and Distribution Agreement between Dr. Reddy's Laboratories and Mikah Pharma, incorporated by reference to Exhibit 10.53 to the Annual Report on Form 10-K, for the period ended March 31, 2017 and filed with the SEC on June 14, 2017.

10.54	May 2017 Assignment of Manufacturing and Supply Agreement between Epic and Mikah Pharma, incorporated by reference to Exhibit 10.54 to the Annual Report on Form 10-K, for the period ended March 31, 2017 and filed with the SEC on June 14, 2017.
10.55	Supply and Distribution Agreement between Dr. Reddy's Laboratories and Mikah Pharma, incorporated by reference to Exhibit 10.55 to the Annual Report on Form 10-K, for the period ended March 31, 2017 and filed with the SEC on June 14, 2017. (Confidential Treatment granted with respect to portions of the Agreement).
10.56	Manufacturing and Supply Agreement between Epic and Mikah Pharma, incorporated by reference to Exhibit 10.56 to the Annual Report on Form 10-K, for the period ended March 31, 2017 and filed with the SEC on June 14, 2017. (Confidential Treatment granted with respect to portions of the Agreement).
10.57	Master Development and License Agreement for Products Between Elite Pharmaceuticals, Inc. And Sungen dated July 6, 2017, 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	Second Amendment to Master Development and License Agreement for Products Between Elite Pharmaceuticals, Inc. 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	First Amendment to Master Development and License Agreement for Products Between Elite Pharmaceuticals, Inc. 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).
10.60	May 29, 2018 License, Manufacturing and Supply Agreement with Glenmark Pharmaceuticals Inc. USA., incorporated by reference to Exhibit 10.60 to the Annual Report on Form 10-K for the fiscal year ended March 31, 2018 and filed with the SEC on June 14, 2018. (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.

November 9, 2018 By: /s/ Nasrat Hakim
Nasrat Hakim

Chief Executive Officer, President and Chairman of the Board of Directors

(Principal Executive Officer)

November 9, 2018 By: /s/ Carter J. Ward
Carter J. Ward

Chief Financial Officer, Treasurer and Secretary

(Principal Financial and Accounting Officer)