

ELITE PHARMACEUTICALS INC /NV/  
Form 10-Q  
February 09, 2017

**UNITED STATES**

**SECURITIES AND EXCHANGE COMMISSION**

**WASHINGTON, D.C. 20549**

**FORM 10-Q**

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

FOR THE QUARTERLY PERIOD ENDED DECEMBER 31, 2016

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    (I.R.S. Employer  
incorporation or organization) Identification No.)

**165 LUDLOW AVENUE**

**07647**

**NORTHVALE, NEW JERSEY**

(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  No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes  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   
Non-accelerated filer  Smaller reporting company

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

Indicate the number of shares outstanding of each of the issuer's classes of common stock, as of the latest practicable date: 917,898,440 shares of common stock were issued and outstanding as of February 1, 2017.

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**PART 1 – FINANCIAL INFORMATION****ITEM 1. FINANCIAL STATEMENTS****ELITE PHARMACEUTICALS, INC. AND SUBSIDIARY****CONDENSED CONSOLIDATED BALANCE SHEETS**

	December 31, 2016 (Unaudited)	March 31, 2016 (Audited)
<b>ASSETS</b>		
Current assets:		
Cash	\$ 13,283,362	\$ 11,512,179
Accounts receivable	544,677	1,530,296
Inventory	6,028,814	3,293,729
Prepaid expenses and other current assets	764,535	377,752
Total current assets	20,621,388	16,713,956
Property and equipment, net of accumulated depreciation of \$7,231,333 and \$6,726,401, respectively	8,719,385	8,110,721
Intangible assets, net of accumulated amortization of \$-0-	6,419,091	6,411,799
Other assets:		
Restricted cash - debt service for NJEDA bonds	388,959	388,959
Security deposits	50,846	48,714
Total other assets	439,805	437,673
Total assets	\$ 36,199,669	\$ 31,674,149
<b>LIABILITIES, MEZZANINE EQUITY AND SHAREHOLDERS' EQUITY (DEFICIT)</b>		
Current liabilities:		
Accounts payable	\$ 1,355,371	\$ 1,804,429
Accrued expenses	1,802,475	555,352
Deferred revenue, current portion	1,013,333	1,013,333
Bonds payable, current portion (net of bond issuance costs)	70,822	205,822
Line of credit, related party	-	718,309
Loans payable, current portion	439,265	342,944

Total current liabilities	4,681,266	4,640,189
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*The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.*

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**ELITE PHARMACEUTICALS, INC. AND SUBSIDIARY****CONDENSED CONSOLIDATED BALANCE SHEETS**

	<b>December 31, 2016 (Unaudited)</b>	<b>March 31, 2016 (Audited)</b>
Long-term liabilities:		
Deferred revenue, net of current portion	2,518,890	3,278,887
Bonds payable, net of current portion and bond issuance costs	1,580,411	1,654,777
Loans payable, net current portion	443,151	520,829
Derivative financial instruments - warrants	900,247	10,368,567
Other long term liabilities	29,175	47,422
Total long-term liabilities	5,471,874	15,870,482
 Total liabilities	 10,153,140	 20,510,671
 Mezzanine Equity		
Series I convertible preferred stock; par value \$0.01; 395.758 shares authorized, -0- issued and outstanding as of December 31, 2016; 495.758 shares authorized, 100 shares issued and outstanding as of March 31, 2016	-	44,285,715
 Shareholders' equity (deficit):		
Common stock; par value \$0.001; 995,000,000 shares authorized; 911,245,171 shares issued and 911,145,171 outstanding as of December 31, 2016; 711,544,352 shares issued and 711,444,352 outstanding as of March 31, 2016	911,247	711,546
Additional paid-in capital	161,105,495	109,137,805
Treasury stock; 100,000 shares as of December 31, 2016 and March 31, 2016; at cost	(306,841	) (306,841 )
Accumulated deficit	(135,663,372	) (142,664,747 )
Total shareholders' equity (deficit)	26,046,529	(33,122,237 )
Total liabilities, mezzanine equity and shareholders' equity (deficit)	\$36,199,669	\$31,674,149

*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 December 31,		For the Nine Months Ended December 31,	
	2016	2015	2016	2015
Manufacturing fees	\$ 1,885,765	\$ 1,622,052	\$ 6,470,697	\$ 5,851,020
Licensing fees	444,884	571,824	1,816,796	1,452,468
Total revenue	2,330,649	2,193,876	8,287,493	7,303,488
Cost of revenue	1,726,751	835,675	5,755,997	3,447,172
Gross profit	603,898	1,358,201	2,531,496	3,856,316
Operating expenses:				
Research and development	1,526,183	3,174,311	4,312,337	10,012,623
General and administrative	694,321	654,839	2,060,380	1,991,219
Non-cash compensation through issuance of stock options	84,785	75,025	258,954	246,495
Depreciation and amortization	21,032	166,825	64,408	492,625
Total operating expenses	2,326,321	4,071,000	6,696,079	12,742,962
Loss from operations	(1,722,423 )	(2,712,799 )	(4,164,583 )	(8,886,646 )
Other income (expense):				
Interest expense and amortization of debt issuance costs	(55,563 )	(68,119 )	(181,883 )	(207,376 )
Change in fair value of derivative instruments	1,571,471	(9,452,046 )	9,468,320	(87,999 )
Interest income	3,151	-	9,407	-
Other income (expense), net	1,519,059	(9,520,165 )	9,295,844	(295,375 )
(Loss) income from operations before the benefit from sale of state net operating loss credits	(203,364 )	(12,232,964 )	5,131,261	(9,182,021 )
Benefit from sale of state net operating loss credits	1,870,114	-	1,870,114	-
Net income (loss)	1,666,750	(12,232,964 )	7,001,375	(9,182,021 )
Change in carrying value of convertible preferred share mezzanine equity	-	(24,785,740 )	20,714,286	(23,428,573 )

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Net income (loss) attributable to common shareholders'	\$ 1,666,750	\$ (37,018,704	) \$ 27,715,661	\$ (32,610,594	)
Basic income (loss) per share attributable to common shareholders'	\$ 0.00	\$ (0.05	) \$ 0.03	\$ (0.05	)
Diluted income (loss) per share attributable to common shareholders'	\$ 0.00	\$ (0.05	) \$ (0.00	) \$ (0.05	)
Basic weighted average common shares outstanding	904,763,117	684,773,829	811,794,206	665,720,299	
Diluted weighted average common shares outstanding	910,505,291	684,773,829	817,536,320	665,720,299	

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



**ELITE PHARMACEUTICALS, INC. AND SUBSIDIARY****CONDENSED CONSOLIDATED STATEMENT OF SHAREHOLDERS' EQUITY (DEFICIT)****(UNAUDITED)**

	Common Stock			Treasury Stock		Accumulated Deficit	Total Shareholders' Equity (Deficit)
	Shares	Amount	Additional Paid-In Capital	Shares	Amount		
Balance at March 31, 2016	711,544,352	\$ 711,546	\$ 109,137,805	100,000	\$(306,841)	\$(142,664,747)	\$(33,122,237)
Net income						7,001,375	7,001,375
Change in value of convertible preferred mezzanine equity			20,714,286				20,714,286
Issuance of common shares pursuant to the exercise of cash warrants	29,562,876	29,563	1,818,117				1,847,680
Issuance of common shares pursuant to the exercise of cash options	100,000	100	8,700				8,800
Common shares issued in payment of employee salaries	42,938	43	13,707				13,750
	278,215	278	69,147				69,425

Common shares issued as commitment shares pursuant to the Lincoln Park purchase agreement							
Costs associated with raising capital			(87,096	)		(87,096	)
Common shares sold pursuant to the Lincoln Park purchase agreement	26,859,647	26,860	5,743,303			5,770,163	
Non-cash compensation through the issuance of employee stock options			258,954			258,954	
Conversion of Series I convertible preferred stock into common shares	142,857,143	142,857	23,428,572			23,571,429	
Balance at December 31, 2016	911,245,171	\$911,247	\$161,105,495	100,000	\$(306,841)	\$(135,663,372	) \$26,046,529

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

**ELITE PHARMACEUTICALS, INC. AND SUBSIDIARY****CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS****(UNAUDITED)**

	For the Nine Months Ended December	
	31,	
	2016	2015
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>		
Net income (loss)	\$ 7,001,375	\$ (9,182,021 )
Adjustments to reconcile net income (loss) to net cash used in operating activities:		
Depreciation and amortization	504,932	492,625
Change in fair value of derivative financial instruments - warrants	(9,468,320 )	87,999
Non-cash compensation accrued	1,232,950	586,167
Non-cash compensation from the issuance of common stock and options	272,705	246,494
Milestone shares issued pursuant to Epic Strategies Alliance Agreement	-	840,000
Non-cash rent expense	(19,528 )	(16,488 )
Non-cash lease accretion	1,278	1,206
Bad debt recovery	-	(117,095 )
Change in operating assets and liabilities:		
Accounts receivable	985,619	816,579
Inventory	(2,735,085 )	(149,611 )
Prepaid expenses and other current assets	(388,915 )	148,712
Accounts payable, accrued expenses and other current liabilities	(434,885 )	(1,533,080 )
Deferred revenue and customer deposits	(759,997 )	4,406,666
Net cash used in operating activities	(3,807,871 )	(3,371,847 )
<b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>		
Purchase of property and equipment	(804,762 )	(1,351,847 )
Intellectual property costs	(7,292 )	(26,158 )
Net cash used in investing activities	(812,054 )	(1,378,005 )
<b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>		
Proceeds from the issuance of stock	5,770,163	3,289,198
Proceeds from cash warrant and options exercises	1,856,480	2,455,753
Proceeds and repayments of line of credit, related party - net	(718,309 )	135,238
Payment of bonds principal	(209,366 )	(210,000 )
Other loan payments	(290,189 )	(281,237 )
Costs associated with raising capital	(17,671 )	-
Net cash provided by financing activities	6,391,108	5,388,952
Net change in cash	1,771,183	639,100

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Cash, beginning of period	11,512,179	7,464,180
Cash, end of period	\$ 13,283,362	\$ 8,103,280
Supplemental disclosure of cash and non-cash transactions:		
Cash paid for interest	\$ 142,351	\$ 127,912
Financing of equipment purchases and insurance renewal	\$ 308,834	\$ 384,699
Commitment shares issued to Lincoln Park Capital	\$ 69,425	\$ 37,067
Change in carrying value of convertible preferred mezzanine equity	\$ 20,714,286	\$ (23,428,573 )
Conversion of Series I convertible preferred stock into common shares	\$ 23,571,429	\$ -

*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 nine months ended December 31, 2016 are not necessarily indicative of the results that may be expected for the entire year.

*Restatement of Previously Issued Consolidated Financial Statements*

As disclosed in the Company's Annual Report on Form 10-K for the year ended March 31, 2016, the Company has restated the consolidated financial statements as of and for the years ended March 31, 2015 and 2014 and unaudited quarterly financial information for the first two quarters in the year ended March 31, 2016 and the first three quarters in the year ended March 31, 2015, to correct prior periods primarily related to (i) an error in accounting treatment for license agreement with Epic, in which the Company determined that revenue relating to a \$5,000,000 non-refundable payment, which was originally recognized in full during the quarterly period ended June 30, 2015, should have been recognized, on a straight line basis, over the exclusivity period, coinciding with the five year term of the Epic Collaborative Agreement, as this payment is attributed to the exclusive license and other rights granted to Epic in the Epic Collaborative Agreement; and (ii) a determination that the Series I convertible preferred stock, which had originally been classified as a derivative liability prior to the quarter ended December 31, 2015, should have been recorded as mezzanine equity at the maximum redemption amount each reporting period with changes recorded in additional paid in capital.

These unaudited condensed consolidated financial statements should be read in conjunction with the Company's audited consolidated financial statements for the year ended March 31, 2016 included in the Company's Fiscal 2016 Annual Report on Form 10-K, filed with the SEC on June 15, 2016. In addition, the Company's future Quarterly Reports on Form 10-Q for subsequent quarterly periods during the current fiscal year will reflect the impact of the restatement in the comparative prior quarter and year-to-date periods.

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

The Company has determined that its reportable segments are products whose marketing approvals were secured via an Abbreviated New Drug Applications ("ANDA") and products whose marketing approvals were secured via a New

Drug Application (“NDA”). ANDA products are referred to as generic pharmaceuticals and NDA products are referred to as branded pharmaceuticals.

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

### ***Revenue Recognition***

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

**ELITE PHARMACEUTICALS, INC. AND SUBSIDIARY**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

**(UNAUDITED)**

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

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

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

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

When determining the selling price for significant deliverables under a multiple-element revenue arrangement, the Company considers any or all of the following, without limitation, depending on information available or information that could be reasonably available without undue cost and effort: vendor-specific objective evidence, third party evidence or best estimate of selling price. More specifically, factors considered can include, without limitation and as appropriate, size of market for a specific product, number of suppliers and other competitive market factors, forecast



market shares and gross profits, barriers/time frames to market entry/launch, intellectual property rights and protections, exclusive or non-exclusive arrangements, costs of similar/identical deliverables from third parties, contractual terms, including, without limitation, length of contract, renewal rights, commercial terms, profit allocations, and other commercial, financial, tangible and intangible factors that may be relevant in the valuation of a specific deliverable.

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

· It must be either commensurate with the Company's performance in achieving the milestone or the enhancement of the value of the delivered item(s) as a result of a specific outcome resulting from the Company's performance to achieve the milestone; and

· It relates solely to past performance; and

· It is reasonable relative to all of the deliverables and payment terms (including other potential milestone consideration) within the arrangement.

### ***Collaborative Arrangements***

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

· The parties to the contract must actively participate in the joint operating activity; and

· The joint operating activity must expose the parties to the possibility of significant risk and rewards, based on whether or not the activity is successful.

**ELITE PHARMACEUTICALS, INC. AND SUBSIDIARY**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

**(UNAUDITED)**

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.

***Restricted Cash***

As of December 31, 2016 and March 31, 2016, the Company had \$388,959 of restricted cash, related to debt service reserve in regards to the New Jersey Economic Development Authority (“NJEDA”) bonds (see Note 6).

***Inventory***

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

***Intangible Assets***

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

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

As of December 31, 2016, the Company did not identify any indicators of impairment.

### ***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.

### ***Stock-Based Compensation***

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

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

### ***Earnings (Loss) Per Share Applicable to Common Shareholders'***

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

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**ELITE PHARMACEUTICALS, INC. AND SUBSIDIARY****NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS****(UNAUDITED)**

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

	For the Three Months Ended December 31,		For the Nine Months Ended December 31,	
	2016	2015	2016	2015
<b>Numerator</b>				
Net income (loss) attributable to common shareholders - basic	\$1,666,750	\$(37,018,704)	\$27,715,661	\$(32,610,594)
Effect of dilutive instrument on net income (loss)	(1,571,471)	34,237,786	(30,182,606)	23,516,572
Net income (loss) attributable to common shareholders - diluted	\$95,279	\$(2,780,918)	\$(2,466,945)	\$(9,094,022)
<b>Denominator</b>				
Weighted average shares of common stock outstanding - basic	904,763,177	684,773,829	811,794,206	665,720,299
Dilutive effect of stock options, warrants and convertible securities	5,742,114	151,761,342	5,742,114	151,761,342
Weighted average shares of common stock outstanding - diluted	910,505,291	836,535,171	817,536,320	817,481,641
<b>Net income (loss) per share</b>				
Basic	\$0.00	\$(0.05)	\$0.03	\$(0.05)
Diluted	\$0.00	\$(0.05)	\$(0.00)	\$(0.05)

***Fair Value of Financial Instruments***

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

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

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

Level 1 — Unadjusted quoted prices in active markets for identical assets or liabilities that are accessible at the measurement date.

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

Level 3 — Inputs that are unobservable for the asset or liability.

**ELITE PHARMACEUTICALS, INC. AND SUBSIDIARY****NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS****(UNAUDITED)***Measured on a Recurring Basis*

The following table presents information about our liabilities measured at fair value on a recurring basis as of December 31, 2016 and March 31, 2016, aggregated by the level in the fair value hierarchy within which those measurements fell:

	Amount at Fair Value	Fair Value Measurement Using		
		Level 1	Level 2	Level 3
December 31, 2016				
Liabilities				
Derivative financial instruments - warrants	\$ 900,247	\$ -	\$ -	\$ 900,247
March 31, 2016				
Liabilities				
Derivative financial instruments - warrants	\$ 10,368,567	\$ -	\$ -	\$ 10,368,567

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

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

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

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

### ***Treasury Stock***

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

### ***Recently Issued Accounting Pronouncements***

In May 2014, the FASB issued ASU 2014-09, *Revenue from Contracts with Customers (Topic 606)*. The core principle of ASU 2014-09 is that an entity should recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods and services. This standard is effective for fiscal years and interim reporting periods beginning after December 15, 2016. In August 2015, the FASB issued ASU 2015-14, *Revenue from Contracts with Customers (Topic 606): Deferral of the Effective Date*. The amendments in this update deferred the effective date for implementation of ASU 2014-09 by one year and is now effective for annual reporting periods beginning after December 15, 2017. Early application is permitted only as of annual reporting periods beginning after December 15, 2016 including interim reporting periods within that period. Topic 606 is effective for the Company in the first quarter of fiscal 2019. The Company is currently evaluating the effects of ASU 2014-09 and related ASUs noted below on its unaudited condensed financial statements.

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

In April 2015, the FASB issued ASU 2015-3, *Simplifying the Presentation of Debt Issuance Costs* ("ASU 2015-3"). ASU 2015-3 revises previous guidance to require that debt issuance costs be reported in the unaudited condensed consolidated financial statements as a direct deduction from the face amount of the related liability, consistent with the presentation of debt discounts. Prior to the amendments, debt issuance costs were presented as a deferred charge (i.e. an asset) on the unaudited condensed consolidated financial statements. This new guidance is effective for the annual period ending after December 15, 2015, and for annual periods and interim periods thereafter. The amendments must be applied retrospectively. The Company has adopted the provisions of ASU 2015-03. Refer to Note 2 Change in Accounting Principle for the effect of adopting ASU 2015-03 on the condensed consolidated balance sheet as of March 31, 2016.



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**ELITE PHARMACEUTICALS, INC. AND SUBSIDIARY**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

**(UNAUDITED)**

In July 2015, the FASB issued ASU 2015-11, *Simplifying the Measurement of Inventory (Topic 330)* (“ASU 2015-11”). The amendments in ASU 2015-11 clarify the determination of net realizable value of inventory, applicable to measurement of inventory asset value on the balance sheet. The amendments do not change the core principal of the guidance provided in Topic 330, specifically the valuation of inventory at the lower of cost or market value, with market value being determined by the net realizable value of the inventory item(s). The amendments clarify, however, that net realizable value is to be measured as the estimated selling price in the ordinary course of business, less reasonably predicible costs of completion, disposal and transportation. The guidance is effective for the annual period beginning after December 15, 2016, and for annual periods and interim periods thereafter, with early adoption being optional and permitted as of the beginning of an interim or annual reporting period. The Company is currently evaluating the effects of ASU 2015-11 on its unaudited condensed financial statements.

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

In March 2016, the FASB issued ASU 2016-09, *Improvements to Employee Share-Based Payment Accounting (Topic 718)* (“ASU 2016-09”). The amendments in ASU 2016-09 provide revised guidance in relation to the following with regards to share based payments: i) Accounting for forfeitures, ii) Income tax effects, and iii) classification of excess tax benefits. The guidance is effective for the annual period beginning after December 15, 2016, and for annual periods and interim periods thereafter, with early adoption being optional and permitted as of the beginning of an interim or annual reporting period. The Company is currently evaluating the effects of ASU 2016-09 on its unaudited condensed financial statements.

In August 2016, the FASB issued ASU 2016-15, *Statement of Cash Flows (Topic 230) Classification of Certain Cash Receipts and Cash Payments* (“ASU 2016-15”). ASU 2016-15 eliminates the diversity in practice related to the classification of certain cash receipts and payments for debt prepayment or extinguishment costs, the maturing of a zero-coupon bond, the settlement of contingent liabilities arising from a business combination, proceeds from insurance settlements, distributions from certain equity method investees and beneficial interests obtained in a financial asset securitization. ASU 2016-15 designates the appropriate cash flow classification, including requirements

to allocate certain components of these cash receipts and payments among operating, investing and financing activities. The guidance is effective for the Company beginning after December 15, 2017, although early adoption is permitted. The Company is currently evaluating the effects of ASU 2016-15 on its unaudited condensed consolidated financial statements.

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

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.

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**ELITE PHARMACEUTICALS, INC. AND SUBSIDIARY****NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS****(UNAUDITED)****NOTE 2. CHANGE IN ACCOUNTING PRINCIPLE**

As noted in Note 1 Summary of Significant Accounting Policies, the Company adopted the provisions of ASU 2015-03 and has retroactively reclassified its consolidated balance sheet for the year ended March 31, 2016. During the fiscal year ended March 31, 2016, the Company had accounted for bond offering costs associated with its NJEDA Bonds as an other asset within the Company's consolidated balance sheet.

The following table is a summary of the effect of the reclassification on the consolidated balance sheet as of March 31, 2016:

	<b>March 31, 2016</b>		
	As previously filed	Adjustments	As Reclassified
Other assets:			
EDA bond offering costs	\$204,401	\$ (204,401 )	\$ -
Current liabilities:			
Current portion of EDA bonds payable	\$220,000	\$ (14,178 )	\$ 205,822
Long term liabilities:			
EDA bonds payable- non-current	\$1,845,000	\$ (190,223 )	\$ 1,654,777

**NOTE 3. INVENTORY**

Inventory as of December 31, 2016 and March 31, 2016 consisted of the following:

	December 31, 2016	March 31, 2016
Finished goods	\$ 304,672	\$ 225,698
Work-in-progress	132,529	222,784
Raw materials	5,591,613	2,845,247
	\$ 6,028,814	\$ 3,293,729

**NOTE 4. PROPERTY AND EQUIPMENT, NET**

Property and equipment as of December 31, 2016 and March 31, 2016 consisted of the following:

	December 31, 2016	March 31, 2016
Land, building and improvements	\$ 6,841,191	\$ 6,230,543
Laboratory, manufacturing and warehouse equipment	8,733,843	8,255,286
Office equipment and software	259,025	234,634
Furniture and fixtures	49,804	49,804
Transportation equipment	66,855	66,855
	15,950,718	14,837,122
Less: Accumulated depreciation	(7,231,333 )	(6,726,401 )
	\$ 8,719,385	\$ 8,110,721

Depreciation expense was \$166,602 and \$173,914 for the three months and \$504,932 and \$492,625 for the nine months ended December 31, 2016 and 2015, respectively.

**ELITE PHARMACEUTICALS, INC. AND SUBSIDIARY****NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS****(UNAUDITED)****NOTE 5. INTANGIBLE ASSETS**

The following table summarizes the Company's intangible assets as of December 31, 2016 and March 31, 2016:

	December 31, 2016				
	Estimated Useful Life	Gross Carrying Amount	Additions	Accumulated Amortization	Net Book Value
Patent application costs	*	\$364,482	\$7,292	\$-	\$371,774
ANDA acquisition costs	Indefinite	6,047,317	-	-	6,047,317
		\$6,411,799	\$7,292	\$-	\$6,419,091

	March 31, 2016				
	Estimated Useful Life	Gross Carrying Amount	Additions	Accumulated Amortization	Net Book Value
Patent application costs	*	\$334,457	\$30,025	\$ -	\$364,482
ANDA acquisition costs	Indefinite	6,047,317	-	-	6,047,317
		\$6,381,774	\$30,025	\$ -	\$6,411,799

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

**NOTE 6. NJEDA BONDS**

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

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

The following tables summarizes the Company’s bonds payable liability as of December 31, 2016 and March 31, 2016, respectively.

	December 31, 2016	March 31, 2016
Gross bonds payable		
NJEDA Bonds - Series A Notes	\$ 1,845,000	\$ 2,065,000
Less: Current portion of bonds payable (prior to deduction of bond offering costs)	(85,000 )	(220,000 )
Long-term portion of bonds payable (prior to deduction of bond offering costs)	\$ 1,760,000	\$ 1,845,000
Bond offering costs	\$ 354,453	\$ 354,453
Less: Accumulated amortization	(160,686 )	(150,052 )
Bond offering costs, net	\$ 193,767	\$ 204,401
Current portion of bonds payable - net of bond offering costs		
Current portions of bonds payable	\$ 85,000	\$ 220,000
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	\$ 70,822	\$ 205,822
Long term portion of bonds payable - net of bond offering costs		
Long term portion of bonds payable	\$ 1,760,000	\$ 1,845,000
Less: Bond offering costs to be amortized subsequent to the next 12 months	(179,589 )	(190,223 )
Long term portion of bonds payable, net of bond offering costs	\$ 1,580,411	\$ 1,654,777

**ELITE PHARMACEUTICALS, INC. AND SUBSIDIARY****NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS****(UNAUDITED)**

Amortization expense was \$3,544 for the three months and \$10,633 for the nine months ended December 31, 2016 and 2015, respectively.

**NOTE 7. LOANS PAYABLE**

Loans Payable as of December 31, 2016 and March 31, 2016 consisted of the following:

	<b>December 31, 2016</b>	<b>March 31, 2016</b>
Equipment and insurance financing loans payable, between 6% and 13% interest and maturing between May 2017 and January 2022	\$ 882,416	\$ 863,773
Less: Current portion of loans payable	(439,265 )	(342,944 )
Long-term portion of loans payable	\$ 443,151	\$ 520,829

The interest expense associated with the loans payable was \$21,603 and \$26,081 for the three months and \$64,932 and \$68,986 for the nine months ended December 31, 2016 and 2015, respectively.

**NOTE 8. LINE OF CREDIT – RELATED PARTY**

During October 2013, the Company entered into a bridge loan agreement (the “Hakim Loan Agreement”) with Mr. Nasrat Hakim, the Company’s President and CEO. Under the terms of the Hakim Loan Agreement, the Company has the right, at its sole discretion, to a line of credit (“Hakim Credit Line”) in the maximum principal amount of up to \$1,000,000 at any one time. The purpose of the Hakim Credit Line is to support the acceleration of the Company’s product development activities. The outstanding amount is evidenced by a promissory note, which matured on March 31, 2016, as amended. On March 31, 2016, the entire unpaid principal balance plus accrued interest thereon was due and payable in full. The Company could have prepaid any amounts owed without penalty. Any such prepayments shall first be attributable to interest due and owing and then to principal. Interest only shall be payable quarterly on



January 1, April 1, July 1 and October 1 of each year. Prior to maturity or the occurrence of an Event of Default as defined in the Hakim Loan Agreement, the Company may borrow, repay, and re-borrow under the Hakim Credit Line through maturity. Amounts borrowed under the Hakim Credit Line bore interest at the rate of 10% per annum.

As of March 31, 2016, the principal balance owed under the Hakim Credit Line was \$718,309, with an additional \$70,784 in accrued interest being also owed, in accordance with the terms and conditions of the Hakim Credit Line. This principal balance was paid in full on May 23, 2016. Accrued interest consisting of \$70,784 due and owed on March 31, 2016, plus \$9,134 in interest due, owed and expensed during the period April 1, 2016 through May 23, 2016 was paid on May 24, 2016. Accordingly, as of December 31, 2016, there are no amounts due and owing under the Hakim Loan Agreement or the Hakim Line of Credit and both have expired.

#### **NOTE 9. DEFERRED REVENUE**

Deferred revenues in the aggregate amount of \$3,532,223 as of December 31, 2016, were comprised of a current component of \$1,013,333 and a long-term component of \$2,518,890. Deferred revenues in the aggregate amount of \$4,292,220 as of March 31, 2016, were comprised of a current component of \$1,013,333 and a long-term component of \$3,278,887. These line items represent the unamortized amounts of a \$200,000 advance payment received for a TAGI licensing agreement with a fifteen-year term beginning in September 2010 and ending in August 2025 and the \$5,000,000 advance payment Epic Collaborative Agreement with a five-year term beginning in June 2015 and ending in May 2020. These advance payments were recorded as deferred revenue when received and are earned, on a straight-line basis over the life of the licenses. The current component is equal to the amount of revenue to be earned during the 12-month period immediately subsequent to the balance date and the long-term component is equal to the amount of revenue to be earned thereafter.

#### **NOTE 10. COMMITMENTS AND CONTINGENCIES**

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

**ELITE PHARMACEUTICALS, INC. AND SUBSIDIARY**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

**(UNAUDITED)**

*Legal Proceedings*

*Arbitration with Precision Dose, Inc.*

On May 9, 2014, Precision Dose Inc., the parent company of TAGI Pharmaceuticals, Inc., commenced an arbitration against the Company alleging that the Company failed to properly supply, price and satisfy gross profit minimums regarding Phentermine 37.5mg tablets, as required by the parties' agreements. Elite denied Precision Dose's allegations and has counterclaimed that Precision Dose is no longer entitled to exclusivity rights with respect to Phentermine 37.5mg tablets, and is responsible for certain costs, expenses, price increases and lost profits relating to Phentermine 37.5mg tablets and the parties' agreements. The parties have reached agreement in settlement of these issues, with Precision Dose agreeing to pay certain amounts to the Company in exchange for Elite agreeing to restore exclusivity rights with respect to Phentermine 37.5mg tablets, subject to certain defined conditions. Both parties have been complying with the agreed settlement terms and the Company has notified the Arbitrator of this settlement, requesting the issuance of proceeding termination documents.

Due to the agreements reached and adhered to with regards to this issue, the Company has determined that no contingency loss needs to be recorded.

*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 expires on December 31, 2016 with two tenant renewal options of five years each, at the sole discretion of the Company. On June 22, 2016, the Company exercised the first of these renewal options, with such option including a term that begins on January 1, 2017 and expires on December 31, 2021.

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

Rent expense is recorded on the straight-line basis. Rents paid in excess is recognized as deferred rent. Rent expense under the 135 Ludlow Ave. modified lease for the three-month ended December 31, 2016 and 2015 was \$45,213 and \$45,214, respectively and \$135,639 and \$90,427 for the nine months ended December 31, 2016 and 2015 respectively. Rent expense is recorded in general and administrative expense in the unaudited condensed consolidated statements of operations. Deferred rent as of December 31, 2016 and March 31, 2016 was zero and \$19,528, respectively and recorded as a component of other long-term liabilities.

The Company has an obligation for the restoration of its leased facility and the removal or dismantlement of certain property and equipment as a result of its business operation in accordance with ASC 410, *Asset Retirement and Environmental Obligations – Asset Retirement Obligations*. The Company records the fair value of the asset retirement obligation in the period in which it is incurred. The Company increases, annually, the liability related to this obligation. The liability is accreted to its present value each period and the capitalized cost is depreciated over the useful life of the related asset. Upon settlement of the liability, the Company records either a gain or loss. As of December 31, 2016 and March 31, 2016, the Company had a liability of \$29,177 and \$27,895, respectively and recorded as a component of other long-term liabilities.

#### **NOTE 11. MEZZANINE EQUITY - SERIES I CONVERTIBLE PREFERRED STOCK**

On February 6, 2014, the Company created the Series I Convertible Preferred Stock ("Series I Preferred"). A total of 495.758 shares of Series I Preferred were authorized, 100 shares are issued and outstanding, with a stated value of \$100,000 per share and a par value of \$0.01 as of March 31, 2016. On August 16, 2016, the 100 shares issued and outstanding were converted into 142,857,143 shares of common stock at the stated conversion price of \$0.07 (See Note 13). In conjunction with the Certificate of Designations ("COD"), the shares converted were retired, canceled and returned to the status of authorized by unissued preferred stock, leaving a total of 395.758 shares of Series I Preferred authorized and no shares of Series I Preferred outstanding at December 31, 2016.

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



**ELITE PHARMACEUTICALS, INC. AND SUBSIDIARY**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

**(UNAUDITED)**

***Background***

Conversion feature - the Series I Preferred Shares may be converted, at the option of the Holder, into the Company's Common Stock at a stated conversion price of \$0.07.

Subsequent dilutive issuances - if the Company issues options at a price below the Conversion Price, then the Conversion Price will be reduced.

Subsequent dividend issuances - if the Company issues Common Stock in lieu of cash in satisfaction of its dividend obligation on its Series C Certificate, the applicable Conversion Price of the Series I Preferred is adjusted.

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

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

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

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

	December 31, 2016	March 31, 2016
Shares authorized	395.758	495.758
Shares outstanding	-	100
Par value	\$ 0.01	\$0.01
Stated value per share	\$ 100,000	\$ 100,000
Conversion price	\$ 0.07	\$0.07
Common shares to be issued upon redemption	-	142,857,143
Closing price on valuation date	N/A	\$0.31
Carrying value of Series I convertible preferred stock	\$ -	\$ 44,285,715

	For the Three Months Ended December 31,		For the Nine Months Ended December 31,	
	2016	2015	2016	2015
Change in carrying value of convertible preferred share mezzanine equity	\$ -	\$ (24,785,740	) \$20,714,286	\$(23,428,573)

#### NOTE 12. DERIVATIVE FINANCIAL INSTRUMENTS – WARRANTS

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

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

A summary of warrant activity is as follows:

**ELITE PHARMACEUTICALS, INC. AND SUBSIDIARY****NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS****(UNAUDITED)**

	December 31, 2016		March 31, 2016	
	Warrant Shares	Weighted Average Exercise Price	Warrant Shares	Weighted Average Exercise Price
Balance at beginning of year	41,586,066	\$ 0.0625	89,870,034	\$ 0.0625
Warrants exercised, forfeited and/or expired, net	(32,206,847)		(48,283,968)	
Balance at end of year	9,379,219	\$ 0.0625	41,586,066	\$ 0.0625

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

	December 31, 2016	March 31, 2016
Fair value of the Company's common stock	\$ 0.15	\$0.31
Volatility (based on the Company's historical volatility)	75% - 76%	52% - 81%
Exercise price	\$ 0.0625	\$ 0.0625 - 0.25
Estimated life (in years)	1.2 - 1.3	0.2 - 2.1
Risk free interest rate (based on 1-year treasury rate)	0.81 %	0.18% - 0.73%

The changes in warrants (Level 3 financial instruments) measured at fair value on a recurring basis for the nine months ended December 31, 2016 were as follows:

Balance as of March 31, 2016	\$10,368,567
Change in fair value of derivative financial instruments - warrants	(9,468,320)
Balance as of December 31, 2016	\$900,247

**NOTE 13. SHAREHOLDERS' EQUITY (DEFICIT)***Lincoln Park Capital*

On April 10, 2014, the Company entered into a Purchase Agreement (the “Lincoln Park Purchase Agreement” and/or “Purchase Agreement”) and a Registration Rights Agreement (the “Registration Rights Agreement”) with Lincoln Park Capital Fund, LLC (“Lincoln Park”). Pursuant to the terms of the Purchase Agreement, Lincoln Park has 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. Pursuant to the terms of the Registration Rights Agreement, we have filed with the SEC registration statements to register for resale under the Securities Act the shares that have been or may be issued to Lincoln Park under the Purchase Agreement. The latest registration statement, which updates the prior registration statements, was declared effective by the SEC on July 13, 2016.

Upon execution of the Purchase Agreement, the Company issued 1,928,641 shares of common stock to Lincoln Park pursuant to the Purchase Agreement as consideration for its commitment to purchase additional shares of common stock under that agreement and the Company is obligated to issue up to an additional 1,928,641 commitment shares to Lincoln Park pro rata as up to \$40 million of common stock purchased by Lincoln Park. Through December 31, 2016, we have sold to Lincoln Park an aggregate of 89.7 million shares under the Purchase Agreement for aggregate gross proceeds of approximately \$24.0 million. In addition, we have issued an additional 1.2 million Commitment Shares.

The Company, from time to time and at the Company’s sole discretion but no more frequently than every other business day, 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.



**ELITE PHARMACEUTICALS, INC. AND SUBSIDIARY**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

**(UNAUDITED)**

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.

***Common Stock***

During the nine months ended December 31, 2016, the Company issued the following shares of common stock:

*Issuance of shares of common stock pursuant to the exercise of warrants and stock options*

The Company issued 29,662,876 shares of its common stock totaling \$1,856,480 in connection with the exercise of warrants and stock options.

*Issuance of shares of common stock in payment of employee salaries*

The Company issued 42,938 shares of its common stock totaling \$13,750 pursuant to employment contracts with certain employees.

*Issuance of shares of common stock to Lincoln Park*

The Company issued 278,215 shares of its common stock with a value totaling \$69,425 on the date of issuance, in connection with the Purchase Agreement with Lincoln Park as consideration for their commitment to purchase additional shares of the Company's common stock. In addition, the Company issued 26,859,647 shares of its common stock for proceeds totaling \$5,770,163 in connection with the Purchase Agreement with Lincoln Park.

*Conversion of Series I convertible preferred stock*

On August 16, 2016, Mr. Nasrat Hakim, the Company's President and CEO, converted 100 shares of the Series I convertible preferred stock, such shares having a total stated value of \$10 million, at the stated conversion price of \$0.07 into 142,857,143 shares of the Company's common stock, with such shares being valued at \$23,571,429, based upon the closing price of the Company's Common Stock on the date of the conversion.

**NOTE 14. STOCK-BASED COMPENSATION**

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

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**ELITE PHARMACEUTICALS, INC. AND SUBSIDIARY**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

**(UNAUDITED)**

*Stock-based Director Compensation*

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

During the nine months ended December 31, 2016, the Company did not issue any shares of common stock to its Directors in payment of director's fees.

During the nine months ended December 31, 2016, the Company accrued director's fees totaling \$58,361, which will be paid via the issuance of 288,172 shares of Common Stock.

As of December 31, 2016, the Company owes its Directors a total of 334,295 shares of Common Stock in payment of director fees totaling \$73,361 due and owing. The Company anticipates that these shares of Common Stock will be issued during prior to the end of the current fiscal year.

*Stock-based Employee Compensation*

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

During the nine months ended December 31, 2016, the Company issued 42,938 shares of common stock to certain employees in payment of salaries in the aggregate amount of \$13,750, consisting of \$6,250 of related employee salaries earned during the nine months ended December 31, 2016 and \$7,500 in related employee salaries due and owing as of March 31, 2016, the end of the immediately prior fiscal year. Please note that these shares were issued to employees that resigned from their positions with the Company and represented those shares due and owing as of the date of such resignations.

During the nine months ended December 31, 2016, the Company accrued salaries and fees totaling \$631,000 owed to the Company's President and Chief Executive Officer, Chief Financial Officer and certain other employees and consultants, which are to be paid via the issuance of a total of 3,073,032 shares of Common Stock, inclusive of shares issued to employees that resigned from the Company during the nine months ended December 31, 2016.

As of December 31, 2016, the Company owes its President and Chief Executive Officer, Chief Financial Officer and certain other employees and consultants, a total of 3,696,875 shares of Common Stock in payment of salaries and fees totaling \$833,167 due and owing. The Company anticipates that these shares of common stock will be issued prior to the end of the current fiscal year.

### *Options*

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

	Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value
Outstanding at April 1, 2016	7,609,667	\$ 0.48	6.5	\$ 904,409
Granted	870,000	0.23		
Forfeited and expired	(1,907,000 )	1.29		
Exercised	(100,000 )	0.09		
Outstanding at December 31, 2016	6,472,667	\$ 0.21	6.9	\$ 361,298
Exercisable at December 31, 2016	5,019,335	\$ 0.19	6.4	\$ 211,665

**ELITE PHARMACEUTICALS, INC. AND SUBSIDIARY****NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS****(UNAUDITED)**

The aggregate intrinsic value for outstanding options is calculated as the difference between the exercise price of the underlying awards and the quoted price of the Company common stock as of December 31, 2016 and March 31, 2016 of \$0.15 and \$0.31.

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

	December 31, 2016	March 31, 2016
Volatility (based on the Company's historical volatility)	119% - 121%	119% - 120%
Exercise price	\$ 0.17 - 0.42	\$0.23 - 0.42
Estimated term (in years)	10	10
Risk free interest rate (based on 1-year treasury rate)	2.4% - 1.8%	2.1% - 2.2%
Forfeiture rate	0.0	% 2.7 %
Fair value of options granted	\$ 317,634	\$ 129,913
Non-cash compensation through issuance of stock options	\$ 258,954	\$ 333,363

**NOTE 15. SALE OF NEW JERSEY STATE NET OPERATING LOSSES**

During the three months ended December 31, 2016, Elite Labs, a wholly owned subsidiary of Elite, received final approval from the New Jersey Economic Development Authority for the sale of net tax benefits of \$1,286,842 relating to New Jersey net operating losses and net tax benefits of \$745,891 relating to R&D tax credits. The Company sold the net tax benefits approved for sale at a transfer price equal to ninety-two cents for every benefit dollar for total proceeds of \$1,870,114.

**NOTE 16. CONCENTRATIONS AND CREDIT RISK*****Revenues***

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

Three customers accounted for substantially all the Company's revenues for the three months ended December 31, 2015. These three customers accounted for approximately 49%, 29% and 15% of revenues each, respectively. The same three customers accounted for approximately 46%, 34% and 12% of revenues for the nine months ended December 31, 2015.

### ***Accounts Receivable***

Three customers accounted for all the Company's accounts receivable as of December 31, 2016. These three customers accounted for approximately 41%, 35%, and 24% of accounts receivable as of December 31, 2016.

Four customers accounted for substantially all the Company's accounts receivable as of March 31, 2016. Included in these customers are three customers that accounted for approximately 54%, 30% and 8% of accounts receivable as of March 31, 2016.

### ***Purchasing***

Three suppliers accounted for more than 65% of the Company's purchases of raw materials for the nine months ended December 31, 2016. These three suppliers accounted for approximately 48%, 9% and 8% of purchases each, respectively.

For the nine months ended December 31, 2015, the same three suppliers accounted for more than 69% of the Company's purchases. These three suppliers accounted for approximately 30%, 28% and 11% of purchases each, respectively.

## **NOTE 17. SEGMENT RESULTS**

FASB ASC 280-10-50 requires use of the "management approach" model for segment reporting. The management approach is based on the way a company's management organized segments within the company for making operating

decisions and assessing performance. Reportable segments are based on products and services, geography, legal structure, management structure, or any other manner in which management disaggregates a company.

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**ELITE PHARMACEUTICALS, INC. AND SUBSIDIARY****NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS****(UNAUDITED)**

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 and nine months ended December 31, 2016 and 2015.

	For the Three Months Ended December 31,		For the Nine Months Ended December 31,	
	2016	2015	2016	2015
Revenue by Segment				
ANDA	\$ 2,080,649	\$ 1,943,876	\$ 7,537,493	\$ 6,720,155
NDA	250,000	250,000	750,000	583,333
	\$ 2,330,649	\$ 2,193,876	\$ 8,287,493	\$ 7,303,488

	For the Three Months Ended December 31,		For the Nine Months Ended December 31,	
	2016	2015	2016	2015
<i>Operating (Loss) Income by Segment</i>				
ANDA	\$ (302,110	) \$ 1,065,439	\$ (38,576	) \$ 3,134,402
NDA	(351,186	) (2,895,668	) (1,240,085	) (9,316,110
	\$ (653,296	) \$ (1,830,229	) \$ (1,278,661	) \$ (6,181,708

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

	<b>For the Three Months Ended</b>		<b>For the Nine Months Ended</b>	
	<b>December 31,</b>		<b>December 31,</b>	
	<b>2016</b>	<b>2015</b>	<b>2016</b>	<b>2015</b>
Operating loss by segment	\$ (653,296 )	\$ (1,830,229 )	\$ (1,278,661 )	\$ (6,181,708 )
Corporate unallocated costs	(1,017,047 )	(367,147 )	(2,017,976 )	(1,113,997 )
Interest income	3,151	-	9,407	-
Interest expense and amortization of debt issuance costs	(55,563 )	(68,119 )	(181,883 )	(207,376 )
Depreciation and amortization expense	(21,032 )	(166,825 )	(64,408 )	(492,625 )
Significant non-cash items	(31,048 )	(348,598 )	(803,538 )	(1,098,316 )
Change in fair value of derivative instruments	1,571,471	(9,452,046 )	9,468,320	(87,999 )
(Loss) income from operations	\$ (203,364 )	\$ (12,232,964 )	\$ 5,131,261	\$ (9,182,021 )

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**ELITE PHARMACEUTICALS, INC. AND SUBSIDIARY**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

**(UNAUDITED)**

**NOTE 18. COLLABORATIVE AGREEMENT WITH EPIC PHARMA LLC**

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

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

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

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

Please note that on July 15, 2016, the FDA issued a Complete Response Letter, or CRL, regarding the NDA. The CRL stated that the review cycle for the SequestOx™ NDA is complete and the application is not ready for approval in its present form. Please see Note 21, “Subsequent Events” below regarding the Company’s End of Review meeting held with the FDA subsequent to the end of the December 31, 2016 quarter.

There can be no assurances that this product 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 this marketing authorization.

#### **NOTE 19. RELATED PARTY TRANSACTION AGREEMENTS WITH EPIC PHARMA LLC**

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

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

- The Company’s performance is required to achieve each milestone; and
- The milestones will relate to past performance, when achieved; and

The milestones are reasonable relative to all of the deliverables and payment terms within the 2015 Epic License Agreement

After marketing authorization is received from the FDA, Elite will receive a license fee which is based on profits achieved from the commercial sales of ELI-200. On January 14, 2016, the Company filed an NDA with the FDA for SequestOx™, thereby earning a \$2.5 million milestone pursuant to the 2015 Epic License Agreement. The Company has received payment of this amount from Epic. Please note that on July 15, 2016, the FDA issued a Complete Response Letter, or CRL, regarding the NDA. The CRL stated that the review cycle for the SequestOx™ NDA is complete and the application is not ready for approval in its present form. The Company currently is evaluating the points raised in the CRL and intends to request an End of Review meeting with the FDA to determine the pathway forward for SequestOx™. 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. If the Company does not receive these payments or fees, it will materially and adversely affect our financial condition.

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**ELITE PHARMACEUTICALS, INC. AND SUBSIDIARY**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

**(UNAUDITED)**

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

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

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

Assessment of the opportunity for each product in the market, including consideration of the following, without limitation: market size, number of competitors, the current and estimated future regulatory, legislative and social environment for abuse deterrent opioids and the other generic products to which the underlying contracts are relevant;

· Assessment of various avenues for monetizing SequestOx™ and the twelve ANDA's owned by the Company, including the various combinations of sites of manufacture and marketing options;

· Elite's resources and capabilities with regards to the concurrent development of abuse deterrent opioids and expansion of its generic business segment, including financial and operational resources required to achieve manufacturing site transfers for twelve approved ANDA's;

· Capabilities of each party with regards to various factors, including, one or more of the following: manufacturing, marketing, regulatory and financial resources, distribution capabilities, ownership structure, personnel, assessments of operational efficiencies and entity stability, company culture and image;

· Stage of development of SequestOx™ and manufacturing site transfer and regulatory requirements relating to the commercialization of the generic products at the time of the discussions/negotiations, and an assessment of the risks, probability and time frames for achieving marketing authorizations from the FDA for each product.

· Assessment of consideration offered; and

· Comparison of the above factors among the various entities with whom the Company was engaged in discussions relating to the commercialization of SequestOx™ and the manufacture/marketing of the twelve generics related to the Epic Generic Agreement.

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

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

**ELITE PHARMACEUTICALS, INC. AND SUBSIDIARY**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

**(UNAUDITED)**

**NOTE 20. 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”)

· Manufacturing and Supply Agreement with Ascend Laboratories Inc., dated June 23, 2011 and as amended on September 24, 2012 and January 19, 2015 (the “Ascend Manufacturing Agreement”) and

· Master Development and License Agreement with SunGen Pharma LLC dated August 24, 2016 (the “SunGen Agreement”)

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

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

The milestones, totaling \$500k (with \$405k already received), consist of amounts due upon the first shipment of each identified product, as follows: Phentermine 37.5mg tablets (\$145k), Phentermine 15 & 30mg capsules (\$45k), Hydromorphone 8mg (\$125k), Naltrexone 50mg (\$95k) and the balance of \$95k due in relation to the first shipment



of generic products which still require marketing authorizations from the FDA, and to which there can be no assurances of such marketing authorizations being granted and accordingly there can be no assurances that the Company will earn and receive these milestone amounts. These milestones have been determined to be substantive, with such determination being made by the Company after assessments based on the following:

- The Company's performance is required to achieve each milestone; and

- The milestones will relate to past performance, when achieved; and

- The milestones are reasonable relative to all of the deliverables and payment terms within the Precision Dose License Agreement.

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

- Assessment of the opportunity for each generic product in the market, including consideration of the following, without limitation: market size, number of competitors, the current and estimated future regulatory, legislative and social environment for each generic product, and the maturity of the market;

- Assessment of various avenues for monetizing the generic products, including the various combinations of sites of manufacture and marketing options;

- Capabilities of each party with regards to various factors, including, one or more of the following: manufacturing resources, marketing resources, financial resources, distribution capabilities, ownership structure, personnel, assessment of operational efficiencies and stability, company culture and image;

- Stage of development of each generic product, all of which did not have FDA approval at the time of the discussions/negotiations and an assessment of the risks, probability and time frame for achieving marketing authorizations from the FDA for the products;

- Assessment of consideration offered by Precision and other entities with whom discussions were conducted; and

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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.

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**ELITE PHARMACEUTICALS, INC. AND SUBSIDIARY**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

**(UNAUDITED)**

The Ascend Manufacturing Agreement provides for the manufacturing by Elite of Methadone 10mg for supply to Ascend Laboratories LLC (“Ascend”). Ascend is the owner of the approved ANDA for Methadone 10mg, and the Northvale Facility is an approved manufacturing site for this ANDA. There are no license fees or milestones relating to this agreement. All revenues earned are recognized as manufacturing revenues on the date of shipment of the product, when title for the goods is transferred, and for which the price is agreed to and it has been determined that collectability is reasonably assured. The initial shipment of Methadone 10mg pursuant to the Ascend Manufacturing Agreement occurred in January 2012.

The SunGen Agreement executed on August 24, 2016 provides that Elite and SunGen Pharma LLC will engage in the research, development, sales and marketing of four generic pharmaceutical products. Two of the products are classified as CNS stimulants (the “CNS Products”) and two of the products are classified as beta blockers (the “Beta Blocker Products”).

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 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.

**NOTE 21. SUBSEQUENT EVENTS**

The Company has evaluated subsequent events from the balance sheet date through February 9, 2017, the date the accompanying financial statements were issued. The following are material subsequent events.

**Common Stock sold pursuant to the Lincoln Park Purchase Agreement**

Subsequent to December, 2016 and up to February 1, 2017 (the latest practicable date), a total of 6,604,914 shares of Common Stock were sold and 48,354 additional commitment shares were issued, pursuant to the Lincoln Park Purchase Agreement. Proceeds received from such transactions totaled \$1.0 million.

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

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

**COMPARED TO THE**

**THREE AND NINE MONTHS ENDED DECEMBER 31, 2015 (UNAUDITED)**

*The following discussion of our financial condition and results of operations for the three and nine months ended December 31, 2016 and 2015 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, 2016, as filed on June 15, 2016 with the SEC. We use words such as "anticipate," "estimate," "plan," "project," "continuing," "ongoing," "expect," "believe," "intend," "may," "will," "should," "could," and similar expressions to identify forward-looking statements.*

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

### **Background**

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

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

## **Strategy**

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

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

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

## **Commercial Products**

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

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

*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”.*

*Phentermine 37.5mg*

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

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

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

#### Lodrane D®

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

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

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

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



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

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Methadone 10mg

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

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

Hydromorphone 8mg

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

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

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

Phendimetrazine Tartrate 35mg

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

agreement with Mikah Pharma, dated June 1, 2011.

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

*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 2.5mg and Isradipine 5mg

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

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

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

*Hydroxyzine 10mg, Hydroxyzine 25mg and Hydroxyzine 50mg*

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

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

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

*Oxycodone 5mg, Oxycodone 10mg, Oxycodone 15mg, Oxycodone 20mg and Oxycodone 30mg (“Oxy IR”)*

We received notification from Epic in October 2015 of the approval by the FDA of Epic’s ANDA for Oxy IR. This product was an Identified IR Product in the Epic Strategic Alliance Agreement Dated March 18, 2009 (the “Epic Strategic Alliance”). Oxy IR was developed at the Northvale Facility pursuant to the Epic Strategic Alliance, in which we are entitled to a Product Fee of 15% of Profits as defined in the Epic Strategic Alliance.

Epic advised us that the first commercial sale of Oxy IR occurred in March 2016 and such sales are ongoing.

**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 the Company could take to obtain approval of SequestOx™. Based on the FDA response, 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. The Company plans on proceeding immediately with the in vitro and in vivo studies required and expect to resubmit the SequestOx™ application later this year. The in vivo studies include bioequivalence and bioavailability fed and fasted studies comparing the modified formulation to the original formulation.

Please note, however, that there can be no assurances that the Company's intended future resubmission of the NDA product filing will be accepted by or receive marketing approval from the FDA. In addition, even if the Company receives marketing approval, there can be no assurances of future revenues or profits relating to this product, or that any such future revenues and profits would be in amounts that provide adequate return on the significant investments made to secure this marketing authorization.

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

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

*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.

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

### **Approved Products Not Yet Commercialized**

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

### **Asset Acquisition Agreements**

Generic Phentermine Capsules

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

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

Generic Hydromorphone HCl Product

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

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

Generic Naltrexone Product

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





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

*Thirteen Abbreviated New Drug Applications*

On August 1, 2013, Elite executed the Mikah ANDA Purchase with Mikah Pharma and acquired a total of thirteen ANDAs, consisting of twelve ANDAs approved by the FDA and one ANDA under active review with the FDA, and all amendments thereto (the “Mikah Thirteen ANDA Acquisition”) for aggregate consideration of \$10,000,000, payable pursuant to a secured convertible note due in August 2016.

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

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

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

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

**Licensing, Manufacturing and Development Agreements**

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

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

The remaining \$7.5 million in non-refundable payments due pursuant to the 2015 SequestOx™ License Agreement is due on the FDA’s approval of SequestOx™ for commercial sale in the United States of America (please see the paragraph below for further details). In addition, we will receive a license fee computed as a percentage (50%) of net sales of the products as defined in the 2015 SequestOx™ License Agreement and is entitled to multi-million-dollar minimum annual license fees we will manufacture the product for sale by Epic on a cost-plus basis and both parties agree to execute a separate Manufacturing and Supply Agreement. The license fee is payable quarterly for the term of the 2015 SequestOx™ License Agreement. The term of the 2015 SequestOx™ License Agreement is five years and may be extended for an additional five years upon mutual agreement of the parties. Elite can terminate the 2015 SequestOx™ License Agreement on 90 days’ written notice in the event that Epic does not pay us certain minimum annual license fees over the initial five-year term of the 2015 SequestOx™ License Agreement. Either party may terminate this 2015 SequestOx™ License Agreement upon a material breach and failure to cure that breach by the other party within a specified period. Please note that there was a change in management of Epic that occurred in May 2016, concurrent with a change in ownership of Epic. The new management of Epic has advised us of their desire to renegotiate the 2015 SequestOx™ License Agreement. While the 2015 SequestOx™ License Agreement is still in effect, as a prudent business practice, we are currently cooperating with Epic and are engaged in such negotiations with Epic, which are ongoing, as well as pursuing other options relating to the license and/or distribution of Sequest-Ox™. We believe that if agreement is reached with Epic on revised terms and conditions and amendment is made to the 2015 SequestOx™ License Agreement, such amendment may materially differ from the current 2015 SequestOx™ License Agreement.

In addition, 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 the Company could take to obtain approval of SequestOx™. Based on the FDA response, 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. The Company plans on proceeding immediately with the in vitro and in vivo studies required and expect to resubmit the SequestOx™ application later this year. The in vivo studies include bioequivalence and bioavailability fed and fasted studies comparing the modified formulation to the original formulation.

There can be no assurances that the Company's intended future resubmission of the NDA product filing will be accepted by or receive marketing approval from the FDA. In addition, even if the Company receives marketing approval, there can be no assurances of future revenues or profits relating to this product, or that any such future revenues and profits would be in amounts that provide adequate return on the significant investments made to secure this marketing authorization.

*Manufacturing and License Agreement with Epic Pharma LLC*

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

If we manufacture any product for sale by Epic, then Epic shall pay us the same predetermined manufacturing cost per unit plus the cost of the API. The license fee is payable monthly for the term of the Epic Manufacturing and License Agreement. Epic shall pay to us certain milestone payments as defined by the Epic Manufacturing and License Agreement. The term of the Epic Manufacturing and License Agreement is five years and may be extended for an additional five years upon mutual agreement of the parties. Twelve months following the launch of a product covered by the Epic Manufacturing and License Agreement, we may terminate the marketing rights for any product if the

license fee paid, by Epic, falls below a designated amount for a six-month period of that product. We may also terminate the exclusive marketing rights if Epic is unable to meet the annual unit volume forecast for a designated product group for any year, subject to the ability of Epic, during the succeeding six-month period, to achieve at least one-half of the prior year's minimum annual unit forecast. The Epic Manufacturing and License Agreement may be terminated by mutual agreement, as a result of a breach by either party that is not cured within 60 days' notice of the breach, or by us as a result of Epic Pharma becoming a party to a bankruptcy, reorganization or other insolvency proceeding that continues for a period of 30 days or more.

*Methadone Manufacturing and Supply Agreement*

On June 23, 2011 and as amended on September 24, 2012 and January 19, 2015, we entered into an agreement to manufacture and supply Methadone 10mg to ThePharmaNetwork LLC (the "Methadone Manufacturing and Supply Agreement"). ThePharmaNetworkLLC 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 manufacture and packaging by the Company of Ascend's methadone hydrochloride 10mg tablets.

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

On August 26, 2016, the Methadone Manufacturing and Supply Agreement was amended and extended through December 31, 2017.

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.

Development Agreement with Akorn Pharmaceuticals

On January 10, 2011, we entered into an agreement for us to develop an intermediate product for a generic version of a prescription product for Hi-Tech Pharmaceutical Co, Inc. (subsequently acquired by Akorn Pharmaceuticals) (“Akorn”). Under the terms of the agreement, we will undertake a development program for an intermediate product that Akorn shall then incorporate into a final product. Akorn or its designees, shall be responsible for the filing of the ANDA for the finished product and the ANDA will be filed under the Akorn name. Upon approval of the ANDA, Elite will manufacture the intermediate product. Akorn will manufacture the final product and will be responsible for the marketing and sales of the final product. Akorn will pay us milestone payments for the development work. Upon commercialization, we will receive payment for the manufacturing of the intermediate product and a percentage of the profits generated from the sale of the product.

Please note that there is currently no development activity being conducted pursuant to this agreement and there was no activity during the prior fiscal year as well. There can be no assurances that development activities will resume or that a resumption of development activities will result in the successful development of the relevant product. Furthermore, there can be no assurances that the development program will result in an intermediate product that can be incorporated into a final product. There can be no assurances that an ANDA will be filed by Akorn or its designees or that any such ANDA filed will receive marketing approval by the FDA. Furthermore, there can be no assurances of the commercialization of a final product containing the intermediate relating to this agreement or that such

commercialization will result in profits being generated from the sale of the product.

*Master Development and License Agreement with SunGen Pharma LLC*

On August 24, 2016, 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 four generic pharmaceutical products. Two of the products are classified as CNS stimulants (the “CNS Products”) and two of the products are classified as beta blockers (the “Beta Blocker Products”).

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 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. 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.

**Products Under Development**

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

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

We filed an NDA for the first product to utilize our abuse deterrent technology, Immediate Release Oxycodone 5mg, 10mg, 15mg, 20mg and 30mg with sequestered Naltrexone (collectively and individually referred to as “SequestOx™”), on January 14, 2016. On July 15, 2016, the FDA issued a Complete Response Letter, or CRL, regarding the NDA. The CRL stated that the review cycle for the SequestOx™ NDA is complete and the application is not ready for approval in its present form. On December 21, 2016, the Company met with the FDA for an end-of-review meeting to discuss steps that the Company can take to obtain approval of SequestOx™. Based on the FDA response, the Company believes there is a clear path forward to address the issues cited in the CRL. 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. The Company plans on proceeding immediately with the in vitro and in vivo studies required and expects to resubmit the SequestOx™ application later this year. The in vivo studies include bioequivalence and bioavailability fed and fasted studies comparing the modified formulation to the original formulation. Please note that 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. If the Company does not receive these payments or fees, it will materially and adversely affect our financial condition.

On August 9, 2016, the Company filed an ANDA with the FDA for a generic version of Percocet® (oxycodone hydrochloride and acetaminophen, USP CII) 5mg, 7.5mg and 10mg tablets with 325mg of acetaminophen (“Generic Oxy/APAP”). Percocet® is a combination medication, with abuse deterrence, and is used to help relieve moderate to severe pain. Please note that there can be no assurances of this product receiving marketing authorization, or achieving commercialization. In addition, even if marketing authorization is received and the product is commercialized, there can be no assurances of future revenues or profits in such amounts that would provide adequate return on the significant investments made to secure marketing authorization for this product.

On December 12, 2016, the Company filed an ANDA with the FDA for a generic version of Norco® (hydrocodone bitartrate and acetaminophen tablets USP CII) 2.5mg/325mg, 5mg/325mg, 7.5mg/325mg and 10mg/325mg tablets (“Generic Hydrocodone/APAP”). Norco is a combination medication and is used to help relieve moderate to moderately severe pain. Please note that there can be no assurances of this product receiving marketing authorization, or achieving commercialization. In addition, even if marketing authorization is received and the product is commercialized, there can be no assurances of future revenues or profits in such amounts that would provide adequate return on the significant investments made to secure marketing authorization for this product.

The Company believes that the abuse deterrent technology can be applied to and incorporated into a wide range of opioids used today for pain management and has, to date, identified 10 additional products for potential development. All of these products are at early stages of development, with research and development activities mainly consisting of in-house process development and laboratory studies. Extensive efficacy and safety studies, similar to those conducted for SequestOx™, Generic Oxy/APAP 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.



Research and development costs were \$1.5 million and \$3.2 million for the three months ended December 31, 2016 and 2015, respectively and \$4.3 million and \$10.0 million for the nine months ended December 31, 2016 and 2015, respectively. Costs incurred during the prior fiscal year relate almost entirely to the development of the abuse deterrent opioid product, SequestOx<sup>TM</sup>, and costs incurred during the current fiscal year relate almost entirely to the development of the abuse deterrent opioid products, SequestOx<sup>TM</sup>, Generic Oxy/APAP and Generic Hydrocodone/APAP.

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<sup>TM</sup>, 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<sup>TM</sup>, 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 may 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 15, 2016, and further detailed in "Item 1A-Risk Factors" in this quarterly report on Form 10-Q.

### **Abuse-Deterrent and Sustained Release Opioids**

The abuse-deterrent opioid products utilize our patented abuse-deterrent technology that is based on a pharmacological approach. These products are combinations of a narcotic agonist formulation intended for use in patients with pain, and an antagonist, formulated to deter abuse of the drug. Both, agonist and antagonist, have been on the market for a number of years and sold separately in various dose strengths. We have filed INDs for two abuse resistant products under development and has tested products in various pharmacokinetic 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, and retain the rights to these abuse resistant and sustained release opioid products. We may license these products at a later date to a third party who could provide funding for the remaining clinical studies and who could provide sales and distribution for the product.

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

## Patents

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

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

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

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

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

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

## **Trademarks**

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

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

### **Sources and Availability of Raw Materials; Manufacturing**

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

- greater possibility for disruption due to transportation or communication problems;

- the relative instability of some foreign governments and economies;

- interim price volatility based on labor unrest, materials or equipment shortages, export duties, restrictions on the transfer of funds, or fluctuations in currency exchange rates; and

- uncertainty regarding recourse to a dependable legal system for the enforcement of contracts and other rights.

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

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

### **Dependence on One or a Few Major Customers**

Each year we have had one or a few customers that have accounted for a large percentage of our limited revenues, therefore the termination or restructuring of a contract with a customer may result in the loss of material amount or substantially all of our revenues. We are constantly working to develop new relationships with existing or new customers, but despite these efforts we may not, at the time that any of our current contracts expire, have other

contracts in place generating similar or material revenue. We have agreements with Epic, Precision Dose and Ascend for the licensing, sales and distribution of products that we manufacture. We are currently renegotiating a licensing contract with Epic, which may result in the termination of an existing contract or an amended licensing contract that is materially different from that already in place. We receive revenues to manufacture these products and also receive a profit split or royalties based on in-market sales of the products.

### **Critical Accounting Policies and Estimates**

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

### **Results of Operations**

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

#### ***Three months ended December 31, 2016 compared to December 31, 2015***

*Revenue, Cost of revenue and Gross profit:*

	For the Three Months Ended December 31,		Change		
	2016	2015	Dollars	Percentage	
Manufacturing fees	\$ 1,885,765	\$ 1,622,052	\$263,713	16	%
Licensing fees	444,884	571,824	(126,940)	-22	%
Total revenue	2,330,649	2,193,876	136,773	6	%
Cost of revenue	1,726,751	835,675	891,076	107	%
Gross profit	\$ 603,898	\$ 1,358,201	\$(754,303)	-56	%
Gross profit - percentage	26	% 62			%

Total revenues for the three-month period ended December 31, 2016 increased by \$0.1 million or 6%, to \$2.3, as compared to \$2.2 million, for the corresponding period in 2015 due to the timing of generic product shipments.

Manufacturing fees increased by \$0.3 million, or 16%, due to timing of generic product shipments.

Licensing fees decreased by \$0.1 million, or 22%. This decrease is primarily due to the timing of in-market sales of the Company's generic products, as well as margins achieved by the Company's licensed marketing partners. License fees earned are based on in-market sales and accordingly, there is a natural lag between manufacturing revenues earned by the Company and related license fees being earned from in market sales occurring subsequent to the Company's shipment of licensed generic products to its marketing partners. In market profits achieved by the Company's marketing partners are also a factor, with a direct correlation to the license fee revenues earned by the Company.

Costs of revenue consists of manufacturing and assembly costs. Our costs of revenue increased by \$0.9 million or 107%, to \$1.7 million as compared to \$0.8 million for the corresponding period in 2015. The increase in costs of revenue is primarily due to increased and continued investments in Company's facility and resources leading to higher overhead absorption rates.

Our gross profit margin was 26% during the three months ended December 31, 2016 as compared to 62% during the three months ended December 31, 2015. The decrease in gross margin is due to the product mix of generics manufactured during the quarter, combined with higher overhead absorption rates.

*Operating expenses:*

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	For the Three Months Ended December 31,		Change		
	2016	2015	Dollars	Percentage	
Operating expenses:					
Research and development	\$ 1,526,183	\$ 3,174,311	\$(1,648,128)	-52	%
General and administrative	694,321	654,839	39,482	6	%
Non-cash compensation	84,785	75,025	9,760	13	%
Depreciation and amortization	21,032	166,825	(145,793 )	-87	%
Total operating expenses	\$ 2,326,321	\$ 4,071,000	\$(1,744,679)	-43	%

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 December 31, 2016 decreased by \$1.8 million, or 43%, to \$2.3 million, as compared to \$4.1 million for the corresponding period in 2015.

Research and development costs for the three months ended December 31, 2016 were \$1.5 million, a decrease of \$1.7 million or 52% from \$3.2 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 and other products.

General and administrative expenses for the three months ended December 31, 2016 and 2015 was \$0.7 million. The Company has continued to increase the utilization of the Company's manufacturing facilities resulting in lower unallocated overheads.

Non-cash compensation expense for the three months ended December 31, 2016 and 2015 was \$0.08 million. 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 expense for the three months ended December 31, 2016 was \$0.02 million, a decrease of \$0.18 million, or 87% from \$0.2 million of such costs for the comparable period of the prior year. The decrease was due to the combination of increased facility utilization and higher depreciation absorption rates currently as a result of facility expansion and improvements over the last year.

As a result of the foregoing, our loss from operations for the three months ended December 31, 2016 was \$1.7 million, compared to a loss from operations of \$2.7 million for the three months ended December 31, 2015.



*Other income (expense):*

	For the Three Months Ended December 31,		Change	
	2016	2015	Dollars	Percentage
Other income (expense):				
Interest expense and amortization of debt issuance costs	\$ (55,563	) \$ (68,119	) \$12,556	-18 %
Change in fair value of derivative instruments	1,571,471	(9,452,046	) 11,023,517	-117 %
Interest income	3,151	-	3,151	
Other income (expense), net	\$ 1,519,059	\$ (9,520,165	) \$11,039,224	-116 %

Other income (expense), net for the three months ended December 31, 2016 was net other income of \$1.5 million, an increase in net other income of \$11.0 million from the net other (expense) of \$(9.5) million for the comparable period of the prior year. The increase in other income was due to derivative income relating to changes in the fair value of our outstanding warrants during the quarter ended December 31, 2016 totaling other income of \$1.6 million, as compared to other (expense) of \$(9.5) million for the comparable period of the prior year. Please note that derivative income (expenses) is determined in large part by the number of warrants outstanding and the change in the closing price of the Company's Common Stock as of the end of the period, as compared to the closing price at the beginning of the period, with a strong inverse relationship between derivative revenues and increases in the closing price of the Company's Common Stock.

As a result of the foregoing, our net income for the three months ended December 31, 2016 was \$1.7 million, compared to a net loss of \$12.2 million for the comparable period of the prior year.

*Change in value of Series I convertible preferred stock:*

Changes in the value in our Series I convertible preferred stock, which is included in the calculation of net income (loss) attributable to common shareholders resulted in no change for the three months ended December 31, 2016, as compared to an increase in net loss of \$24.8 million for the comparable period of the prior year. Accordingly, net income attributable to common shareholders for the three months ended December 31, 2016 was a net income of \$1.7 million, compared to a net loss of \$37.0 million for the comparable period of the prior year.

*Nine months ended December 31, 2016 compared to December 31, 2015*

*Revenue, Cost of revenue and Gross profit:*

	For the Nine Months Ended December 31,		Change	
	2016	2015	Dollars	Percentage
Manufacturing fees	\$ 6,470,697	\$ 5,851,020	\$619,677	11 %
Licensing fees	1,816,796	1,452,468	364,328	25 %
Total revenue	8,287,493	7,303,488	984,005	13 %
Cost of revenue	5,755,997	3,447,172	2,308,825	67 %
Gross profit	\$ 2,531,496	\$ 3,856,316	\$(1,324,820)	-34 %
Gross profit - percentage	31	% 53		%

Revenues for the nine-month period ended December 31, 2016 increased by \$1.0 million, or 13%, to \$8.3 million as compared to \$7.3 million for the corresponding period in 2015 due to continued growth in the Company's generic product lines.

Manufacturing fees increased by \$0.6 million, or 11%, due to continued growth in the Company's generic product lines.

Licensing fees increased by \$0.4 million, or 25%. This increase is primarily due to the inclusion of nine months of license fees earned from the SequestOx™ license agreement where the corresponding prior period included only seven months of such revenues. In addition, license fees relating to the sale of the Company's generic product lines have increased, consistent with the increase in manufacturing revenues.

Costs of revenue consists of manufacturing and assembly costs. Our costs of revenue increased by \$2.3 million or 67%, to \$5.7 million as compared to \$3.4 million for the corresponding period. The increase in costs of revenue is primarily due to increased investments in Company's facility leading to higher overhead absorption rates.

Our gross profit margin was 31% during the nine months ended December 31, 2016 as compared to 53% during the nine months ended December 31, 2015. The decrease in gross margin is due to the product mix of generics manufactured during the quarter.

*Operating expenses:*

	For the Nine Months Ended December 31,		Change		
	2016	2015	Dollars	Percentage	
Operating expenses:					
Research and development	\$ 4,312,337	\$ 10,012,623	\$(5,700,286)	-57	%
General and administrative	2,060,380	1,991,219	69,161	3	%
Non-cash compensation	258,954	246,495	12,459	5	%
Depreciation and amortization	64,408	492,625	(428,217 )	-87	%
Total operating expenses	\$ 6,696,079	\$ 12,742,962	\$(6,046,883)	-47	%

Operating expenses consist of research and development costs, general and administrative, non-cash compensation and depreciation and amortization expenses. Operating expenses for the nine-month period ended December 31, 2016 decreased by \$6.0 million, or 47%, to \$6.7 million, as compared to \$12.7 million for the corresponding period in 2015.

Research and development costs for the nine months ended December 31, 2016 were \$4.3 million, a decrease of \$5.7 million or 57% from \$10.0 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 Elite's abuse deterrent opioid and other products.

General and administrative expenses for the nine months ended December 31, 2016 were \$2.1 million, a decrease of \$0.1 million or 3% from \$2.0 million of such costs for the comparable period of the prior year. The decrease was due to the increased utilization of the Company's manufacturing facilities resulting in lower unallocated overheads.

Non-cash compensation expense for the nine months ended December 31, 2016 and 2015 was \$0.2 million. 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 expense for the nine months ended December 31, 2016 was \$0.1 million, a decrease of \$0.4 million, or 87% from \$0.5 million of such costs for the comparable period of the prior year. The decrease was due to the combination of increased facility utilization and higher depreciation absorption rates currently because of facility expansion and improvements over the last year.

Due to the foregoing, our loss from operations for the nine months ended December 31, 2016 was \$4.2 million, compared to a loss from operations of \$8.9 million for the nine months ended December 31, 2015.

*Other income (expense):*

	For the Nine Months Ended December		Change	
	31, 2016	2015	Dollars	Percentage
Other income (expense):				
Interest expense and amortization of debt issuance costs	\$ (181,883	) \$ (207,376	) \$25,493	-12 %
Change in fair value of derivative instruments	9,468,320	(87,999	) 9,556,319	-10860 %
Interest income	9,407	-	9,407	
Other income (expense), net	\$ 9,295,844	\$ (295,375	) \$9,591,219	-3247 %

Other income (expense), net for the nine months ended December 31, 2016 was net other income of \$9.3 million, an increase in net other income of \$9.6 million from the net other expense of \$(0.3) million for the comparable period of the prior year. The increase in other income was due to derivative income relating to changes in the fair value of our outstanding warrants during the quarter ended December 31, 2016 totaling other income of \$9.5 million, as compared to other expense of \$(0.09) million for the comparable period of the prior year. Please note that derivative income (expenses) are determined in large part by the number of warrants outstanding and the change in the closing price of the Company's Common Stock as of the end of the period, as compared to the closing price at the beginning of the period, with a strong inverse relationship between derivative revenues and increases in the closing price of the Company's Common Stock.

As a result, of the foregoing, our net income for the nine months ended December 31, 2016 was \$7.0 million, compared to net loss of \$9.2 million for the comparable period of the prior year.

*Change in value of Series I convertible preferred stock:*

Changes in the value in our Series I convertible preferred stock, which is included in the calculation of net income (loss) attributable to common shareholders resulted in no change for the nine months ended December 31, 2016, as compared to an increase in net loss of \$23.4 million for the comparable period of the prior year. Accordingly, net income attributable to common shareholders for the nine months December 31, 2016 was a net income of \$27.7 million, compared to net loss of \$32.6 million for the comparable period of the prior year.

**Liquidity and Capital Resources***Capital Resources*

	December 31, 2016	March 31, 2016	Change
Current assets	\$ 20,621,388	\$ 16,713,956	\$3,907,432
Current liabilities	4,681,266	4,640,189	41,077
Working capital	15,940,122	12,073,767	3,866,355

As of December 31, 2016, the Company had cash on hand of \$13.3 million and a working capital surplus of \$15.9 million. We believe that such resources, combined with the Company's access to part or all of the remaining \$14.8 million available pursuant to the \$40 million equity line with Lincoln Park is sufficient to fund operations through the current operating cycle. For the nine months ended December 31, 2016, we had losses from operations totaling \$4.2 million, and net other income totaling \$9.3 million, resulting in a net income of \$7.0 million.

The Company does not anticipate being profitable for the fiscal year ending March 31, 2017, 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. To finance these significant expenditures, the Company entered into two purchase agreements with Lincoln Park, with such agreements providing the company with equity lines totaling \$50 million, with approximately \$14.8 million of this amount being available under the remaining equity line. We believe this amount of financing, if received, is sufficient to fund the commercialization of the abuse deterrent opioid products identified. Please also note that the realization of the full \$14.8 million is dependent on several factors, including the trading price and volume of the Common Stock. There can be no assurances that such price and volumes would be sufficient for the Company to realize, in full, the remaining \$14.8 million balance

available under the Lincoln Park Purchase Agreement, prior to its expiration in April of 2017.

*Summary of Cash Flows:*

	For the Nine Months Ended December 31,	
	2016	2015
Net cash used in operating activities	\$ (3,807,871	) \$ (3,371,847
Net cash used in investing activities	(812,054	) (1,378,005
Net cash provided by financing activities	6,391,108	5,388,952

Net cash used in operating activities for the nine months ended December 31, 2016 was \$3.8 million, which included net income of \$7.0 million, change in fair value of derivative financial instruments – warrants of \$9.5 million (non-cash) and changes in operating assets and liabilities of \$3.6 million. These instances of decreases in cash are offset by change in non-cash compensation accrued of \$1.2 million, and non-cash compensation from the issuance of common stock and options of \$0.3 million.

Net cash used in investing activities for the nine months ended December 31, 2016 was \$0.8 million. This consisted primarily of the purchase of property and equipment of \$0.8 million.

Net cash provided by financing activities was \$6.4 million for the nine months ended December 31, 2016. This consisted of proceeds from the issuance of common stock of \$5.8 million, proceeds from the exercise of cash warrants and stock options of \$1.9 million; offset by repayments of bonds principal of \$0.2 million, payments of other loans of \$0.3 million and repayments from related party line of credit \$0.7 million.

### **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 that evaluation and the material weaknesses described below, our Chief Executive Officer and Chief Financial Officer have concluded that our disclosure controls and procedures were not effective such that the information relating to our Company required to be disclosed in our SEC reports (i) is not recorded, processed, summarized and reported within the time periods specified in SEC rules and forms and (ii) is not accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, to allow timely decisions regarding required disclosure. A material weakness is a deficiency, or combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of our financial statements will not be prevented or detected on a timely basis.

The material weaknesses relate to inadequate segregation of duties in our financial reporting process and disclosure controls and procedures and internal controls over financial reporting of complex accounting issues.

*Changes in Internal Controls*

During Fiscal 2017, our management has taken the following actions that materially affect, or are reasonably likely to materially affect, our internal control over financial reporting and to remediate the material weaknesses described in our 2016 Annual Report on Form 10-K filed on June 15, 2016 with the SEC.

We have hired a third-party to assist us (1) in identifying remediations to material weaknesses in internal controls, (2) with the planning and implementation of such remediations and (3) to support the testing and documentation of our complete internal control environment, including those remediating actions taken/implemented to address the material weakness in internal controls.

Other than discussed above, there have not been any changes in our internal control over financial reporting during the quarter ended December 31, 2016 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, 2016.

### **Item 1A. Risk Factors.**

**We have identified material weaknesses in our internal control over financial reporting which could, if not remediated, adversely affect our ability to report our financial condition, cash flows and results of operations in a timely and accurate manner and/or increase the risk of future misstatements, which could have a material adverse effect on our business, financial condition, cash flows and results of operations and could cause the market value of our common shares and/or debt securities to decline.**

Our management is responsible for establishing and maintaining adequate internal control over our financial reporting, as defined in Rule 13a-15(f) under the Exchange Act. Based on reviews conducted by management, our Independent Auditors and specific guidance from subject matter experts engaged by us, we have concluded that material weaknesses in our internal controls over financial reporting existed that contributed to the errors in accounting that necessitated the restatement of previously issued financial statements. A material weakness is a deficiency, or a combination of deficiencies, in internal controls over financial reporting such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis.

Management determined that we did not maintain effective internal controls over financial reporting as of the fiscal year ended March 31, 2016 due to the existence of the following material weaknesses identified by management: We did not maintain adequate segregation of duties in our accounting and financial reporting process. We have not appropriately restricted access to our accounting applications to appropriate users and we do not have processes in place that ensure that appropriate segregation of duties is maintained. Certain personnel have access to financial applications, programs and data beyond that needed to perform their individual job responsibilities and without independent monitoring. This allows for the creation, review and processing of certain financial data without

independent review and authorization. There are also certain financial personnel that have incompatible duties, including in the areas of cash disbursements, payroll, and journal entry reviews. We have not yet completed the process of assigning different people the responsibilities of authorizing transactions, recording transactions, and maintaining custody of assets to sufficiently reduce the opportunities to allow any person to be in a position to both perpetrate and conceal errors or fraud in the normal course of the person's duties. Particularly in the areas of purchases, cash disbursements, journal entry review and payroll, certain individuals have incompatible duties that limit our ability to identify and detect errors or fraud that may occur.

We have identified certain remediation actions and are in the process of implementing them. During Fiscal 2016, we created and staffed a new accounting position, with such position contributing improved segregation of duties in the areas of purchasing, accounts payable processing, and timesheet management. In addition, improved segregation of duties has been achieved in the areas of cash disbursements, banking management, inventory control and manufacturing accounting, through increased delegation of duties to a staff accounting position that was created and staffed in Fiscal 2015. We intend to focus more resources on internal control procedures during Fiscal 2017. We have engaged a third-party consultant to assist with the enhancement of our control documentation as well as with developing a more robust control environment that once implemented would help remediate the material weaknesses described above. As part of this process, we have begun developing a Segregation of Duties Matrix and updating to enhance business processes, documentation and job roles to fully implement this matrix. We will also be evaluating an enhancement in the financial and enterprise resource planning systems for some point in the future but will also focus on effective compensating controls until the financial/ERP software can be upgraded or replaced.

As we continue to evaluate and work to improve internal controls over financial reporting, we may determine to take additional measures to address the material weaknesses or determine to modify the remediation efforts described above. Until the remediation efforts discussed above, including any additional remediation efforts that we identify as necessary, are implemented, tested and deemed to be operating effectively, the material weaknesses described above will continue to exist.

If we do not complete our remediation in a timely manner or if our remedial measures are insufficient to address the material weaknesses, or if additional material weaknesses in our internal controls are discovered or occur in the future, it may materially adversely affect our ability to report our financial condition and results of operations in a timely and accurate manner and there will continue to be an increased risk of future misstatements. Although we regularly review and evaluate internal controls systems to allow management to report on the effectiveness of our internal controls over financial reporting, we may discover additional weaknesses in our internal controls over financial reporting or disclosure controls and procedures. The next time we evaluate our internal controls over financial reporting and disclosure controls and procedures, if we identify one or more new material weaknesses or have been unable to timely remediate our existing material weaknesses, we would be unable to conclude that our internal controls over financial reporting or disclosure controls and procedures are effective. If we are unable to conclude that our internal controls over financial reporting or our disclosure controls and procedures are effective, or if our independent registered public accounting firm expresses an opinion that our internal controls over financial reporting is ineffective, we may not be able to report our financial condition and results of operations in a timely and accurate manner, which could have a material adverse effect on our business, financial condition, cash flows and results of operations and could cause the market value of our common shares to decline. In addition, any potential future restatements could subject us to additional adverse consequences, including sanctions by the SEC, shareholder litigation and other adverse actions. Moreover, we may be the subject of further negative publicity focusing on such financial statement adjustments and resulting restatement and negative reactions from our shareholders, creditors or others with whom we do business.

The occurrence of any of the foregoing could have a material adverse effect on our business, financial condition, cash flows and results of operations and could cause the market value of our common shares to decline.

**We received a Complete Response Letter from the FDA that indicated that our SequestOx NDA is not ready for approval in its present form. While we plan on proceeding with our application for SequestOx, we cannot assure if or whether our efforts will be successful. If we are unable to obtain approval for SequestOx or if we incur significant costs or delays in obtaining such approval, our ability to commercialize SequestOx may be materially adversely affected.**

In July 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, we met with the FDA for an end-of-review meeting to discuss steps that we could take to obtain approval of SequestOx. Based on the FDA response, we believe there is a path forward to address the issues cited in the CRL, with such path forward including modification of the SequestOx formulation, and the successful completion of in vitro and in vivo studies. If we are unable to modify the formulation or if we are unable to successfully complete the required studies, we will not meet the requirements specified by the FDA for resubmission of the NDA. Furthermore, there can be no assurances given that the FDA will eventually approve our NDA. If we are unable to obtain approval for SequestOx, or if we incur significant costs or delays in obtaining such approval, our ability to commercialize SequestOx may be materially adversely affected.

**We received a Warning Letter from the U.S. Food and Drug Administration (“FDA”) regarding Postmarketing Adverse Drug Experience reporting. The Warning Letter does not restrict the production or shipment of any of the Company’s products, or the sale or marketing of the Company’s products, however, unless and until the Company is able to correct the outstanding issues identified, to the FDA’s satisfaction, the FDA may withhold approval of pending drug applications or take other actions that would have a material adverse impact on the Company.**

On August 26, 2016, Elite received a Warning Letter from the FDA regarding Postmarketing Adverse Drug Experience (PADE) reporting. The Warning Letter relates to certain observations that the FDA believes were inadequately addressed by the Company’s response to a Form 483 issued by the FDA from a recent inspection at its facility. The Warning Letter cites that Elite’s Standard Operating Procedures (SOPs) do not adequately address how to monitor and receive adverse drug experiences (ADEs). While Elite has a contract with an external service provider for follow-up to ADEs, Elite remains responsible for ensuring the ADEs are appropriately investigated and that follow-up information is submitted in a timely manner to the FDA. The FDA believes that Elite does not have adequate SOPs for ADEs, and failed to investigate, evaluate, and timely report ADEs.

Elite takes the matters identified in the Warning Letter seriously and is currently addressing the deficiencies cited in the letter. The Company intends to work closely with the FDA to resolve any outstanding issues. The Warning Letter does not restrict the production or shipment of any of the Elite’s products, or the sale or marketing of the Company’s products, however unless and until the Company is able to correct outstanding issues to the FDA’s satisfaction, the FDA may withhold approval of pending drug applications or take other actions that would have a material adverse impact on the Company. Please note that there can be no assurances that the Company will correct outstanding issues

to the FDA's satisfaction, nor can there be any assurances of the FDA granting approval of pending drug applications in the event of the Company's successful resolution, to the satisfaction of the FDA of the issues identified in the Warning Letter.

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, 2016, which could materially affect our business, financial condition, or future results. The risks described herein and in our Annual Report on Form 10-K are not the only risks we face. Additional risks and uncertainties not currently known to us or that we currently deem to be immaterial also may materially adversely affect our business, financial condition and operating results.

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

During the nine months ended December 31, 2016, we issued 199,700,819 shares of common stock that were unregistered, consisting of 29,562,876 shares being issued pursuant to the exercise of cash warrants, with proceeds received totaling \$1,847,680 and 142,857,143 shares being issued in conversion of Series I convertible preferred stock into common shares. We relied on the exemption provided by Section 4(a)(2) of the Securities Act of 1933 to issue the common stock. The securities were offered and sold without any form of general solicitation or general advertising and the offerees made representations that they were accredited investors.

**Item 3. Defaults Upon Senior Securities.**

None.

**Item 4. Mine Safety Disclosures.**

Not applicable.

**Item 5. Other Information.**

None.

**Item 6. Exhibits.**

<b>Exhibit No.</b>	<b>Description</b>
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
- 3.2(a) Amended and Restated By-Laws of the Company, incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K dated March 17, 2014 and filed with the SEC on March 18, 2014.
- 3.2(b) By-Laws of Elite-Delaware, as amended, incorporated by reference to Exhibit 3.2 to the Company's Registration Statement on Form SB-2 (Reg. No. 333-90633) made effective on February 28, 2000 (the "Form SB-2").\*
- 4.1 Form of specimen certificate for Common Stock of the Company, incorporated by reference to Exhibit 4.1 to the Form SB-2.\*



- 4.2 Form of specimen certificate for Series B 8% Convertible Preferred Stock of the Company, incorporated by reference to Exhibit 4.1 to the Current Report on Form 8-K, dated March 15, 2006 and filed with the SEC on March 16, 2006.\*
- 4.3 Form of specimen certificate for Series C 8% Convertible Preferred Stock of the Company, incorporated by reference to Exhibit 4.1 to the Current Report on Form 8-K, dated April 24, 2007 and filed with the SEC on April 25, 2007.\*
- 4.4 Form of Warrant to purchase shares of Common Stock issued to purchasers in the private placement which closed on March 15, 2006 (the "Series B Financing"), incorporated by reference to Exhibit 4.2 to the Current Report on Form 8-K, dated March 15, 2006 and filed with the SEC on March 16, 2006.\*
- 4.5 Form of Warrant to purchase shares of Common Stock issued to purchasers in the Series B Financing, incorporated by reference to Exhibit 4.3 to the Current Report on Form 8-K, dated March 15, 2006 and filed with the SEC on March 16, 2006.\*

- 4.6 Form of Warrant to purchase shares of Common Stock issued to the Placement Agent, in connection with the Series B Financing, incorporated by reference to Exhibit 4.4 to the Current Report on Form 8-K, dated March 15, 2006 and filed with the SEC on March 16, 2006.\*
- 4.7 Form of Warrant to purchase 600,000 shares of Common Stock issued to Indigo Ventures, LLC, incorporated by reference to Exhibit 4.1 to the Current Report on Form 8-K, dated July 12, 2006 and filed with the SEC on July 18, 2006.\*
- 4.8 Form of Warrant to purchase up to 478,698 shares of Common Stock issued to VGS PHARMA, LLC, incorporated by reference as Exhibit 3(a) to the Current Report on Form 8-K, dated December 6, 2006 and filed with the SEC on December 12, 2006.\*
- 4.9 Form of Non-Qualified Stock Option Agreement for 1,750,000 shares of Common Stock granted to Veerappan Subramanian, incorporated by reference as Exhibit 3(b) to the Current Report on Form 8-K, dated December 6, 2006 and filed with the SEC on December 12, 2006.\*
- 4.10 Form of Warrant to purchase shares of Common Stock issued to purchasers in the private placement which closed on April 24, 2007 (the "Series C Financing"), incorporated by reference to Exhibit 4.2 to the Current Report on Form 8-K, dated April 24, 2007 and filed with the SEC on April 25, 2007.\*
- 4.11 Form of Warrant to purchase shares of Common Stock issued to the placement agent in the Series C Financing, incorporated by reference to Exhibit 4.3 to the Current Report on Form 8-K, dated April 24, 2007 and filed with the SEC on April 25, 2007.\*
- 4.12 Form of specimen certificate for Series D 8% Convertible Preferred Stock of the Company, incorporated by reference to Exhibit 4.1 to the Current Report on Form 8-K, dated September 15, 2008 and filed with the SEC on September 16, 2008.\*
- 4.13 Form of Warrant to purchase shares of Common Stock issued to purchasers in the private placement which closed on September 15, 2008 (the "Series D Financing"), incorporated by reference to Exhibit 4.2 to the Current Report on Form 8-K, dated September 15, 2008 and filed with the SEC on September 16, 2008.\*
- 4.14 Form of Warrant to purchase shares of Common Stock issued to the placement agent in the Series D Financing, incorporated by reference to Exhibit 4.3 to the Current Report on Form 8-K, dated September 15, 2008 and filed with the SEC on September 16, 2008.\*
- 4.15 Form of specimen certificate for Series E Convertible Preferred Stock of the Company, incorporated by reference to Exhibit 4.1 to the Current Report on Form 8-K, dated June 1, 2009, and filed with the SEC on June 5, 2009.\*
- 4.16 Warrant to purchase shares of Common Stock issued to Epic Investments, LLC in the initial closing of the Strategic Alliance Agreement, dated as of March 18, 2009, by and among the Company, Epic Pharma, LLC and Epic Investments, LLC, incorporated by reference to Exhibit 4.2 to the Current Report on Form 8-K, dated June 1, 2009, and filed with the SEC on June 5, 2009.\*
- 4.17 Form of specimen certificate for Series G Convertible Preferred Stock of the Company, incorporated by reference to Exhibit 4.2 to the Current Report on Form 8-K, dated April 18, 2013 and filed with the SEC on

April 22, 2013.

4.18 Form of specimen certificate for Series I Convertible Preferred Stock of the Company, incorporated by reference to Exhibit 4.2 to the Current Report on Form 8-K, dated February 6, 2014 and filed with the SEC on February 7, 2014.

4.19 Rights Agreement, dated as of November 15, 2013, between the Company and American Stock Transfer & Trust Company, LLC., incorporated by reference to Exhibit 1 to the Registration Statement on Form 8-A filed with the SEC on November 15, 2013.

4.20 Form of Series H Preferred Stock Certificate, incorporated by reference to Exhibit 1 to the Registration Statement on Form 8-A filed with the SEC on November 15, 2013.

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- Elite Pharmaceuticals, Inc. 2014 Equity Incentive Plan, incorporated by reference to Appendix B to the
- 10.1 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.
- Loan Agreement, dated as of August 15, 2005, between New Jersey Economic Development Authority
- 10.4 ("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.
- Series A Note in the aggregate principal amount of \$3,660,000.00 payable to the order of the NJEDA,
- 10.5 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.
- Series B Note in the aggregate principal amount of \$495,000.00 payable to the order of the NJEDA,
- 10.6 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.
- Indenture between NJEDA and the Bank of New York as Trustee, dated as of August 15, 2005, incorporated by
- 10.8 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.
- Consulting Agreement, dated as of July 27, 2007, between the Registrant and Willstar Consultants, Inc.,
- 10.9 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.
- Compensation Agreement, dated as of December 1, 2008, by and between the Company and Jerry I. Treppel,
- 10.10 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.
- Strategic Alliance Agreement, dated as of March 18, 2009, by and among the Company, Epic Pharma, LLC and
- 10.11 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.
- Amendment to Strategic Alliance Agreement, dated as of April 30, 2009, by and among the Company, Epic
- 10.12 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.
- Second Amendment to Strategic Alliance Agreement, dated as of June 1, 2009, by and among the Company,
- 10.13 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.

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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 Amended Annual Report on Form 10-K/A, for the period ended March, 31, 2011 and filed with the SEC on November 17, 2016.
- 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 Amended Quarterly Report on Form 10-Q/A filed with the SEC on November 17, 2016.
- 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, dated August 1, 2013 and filed with the SEC on August 5, 2013. (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 April 25, 2014. Confidential Treatment granted with respect to portions of the Agreement.
- 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 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.
- 10.40 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.
- 10.41 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).
- 10.42 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.
- 10.43 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).
- 10.44 August 26, 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



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Quarterly Report on Form 10-Q for the period ended September 30, 2016 and filed with the SEC on November 9, 2016.

10.45 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).

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

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

\*\* Filed herewith.

**SIGNATURES**

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

ELITE PHARMACEUTICALS, INC.

February 9, 2017      By:     /s/ Nasrat Hakim  
  Nasrat Hakim  
  
  Chief Executive Officer, President and Chairman of the Board of  
  Directors  
  
  (Principal Executive Officer)

February 9, 2017      By:     /s/ Carter J. Ward  
  Carter J. Ward  
  
  Chief Financial Officer, Treasurer and Secretary  
  
  (Principal Financial and Accounting Officer)