ELITE PHARMACEUTICALS INC /NV/
Form 10-Q
August 09, 2016

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-Q

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

FOR THE QUARTERLY PERIOD ENDED JUNE 30, 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 incorporation or organization)	(I.R.S. Employer 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 x No ¨

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

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

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

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

Indicate the number of shares outstanding of each of the issuer's classes of common stock, as of the latest practicable date: 733,715,855 shares of common stock were issued and outstanding as of August 3, 2016.

PART 1 – FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

ELITE PHARMACEUTICALS, INC. AND SUBSIDIARY

CONDENSED CONSOLIDATED BALANCE SHEETS

	June 30, 2016 **(Unaudited)**	**March 31, 2016** **(Audited and Revised)**
ASSETS		
Current assets:		
Cash	$ 12,814,951	$ 11,512,179
Accounts receivable	1,220,245	1,530,296
Inventory	3,735,294	3,293,729
Prepaid expenses and other current assets	216,407	377,752
Total current assets	17,986,897	16,713,956
Property and equipment, net of accumulated depreciation of $6,898,916 and $6,726,401, respectively	8,222,527	8,110,721
Intangible assets, net of accumulated amortization of $-0-	6,411,974	6,411,799
Other assets		
Restricted cash – debt service for NJEDA bonds	388,959	388,959
Security deposits	48,714	48,714
Total other assets	437,673	437,673
Total assets	$ 33,059,071	$ 31,674,149

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

ELITE PHARMACEUTICALS, INC. AND SUBSIDIARY

CONDENSED CONSOLIDATED BALANCE SHEETS

	June 30, 2016 **(Unaudited)**	**March 31, 2016** **(Audited and Revised)**
LIABILITIES, MEZZANINE EQUITY AND STOCKHOLDERS' DEFICIT		
Current liabilities:		
Accounts payable	$ 1,457,761	$ 1,804,429
Accrued expenses	1,397,470	555,352
Deferred revenue, current portion	1,013,333	1,013,333
Bonds payable, current portion (net of bond issuance costs)	205,822	205,822
Line of credit, related party	-	718,309
Loans payable, current portion	304,756	342,944
Total current liabilities	4,379,142	4,640,189
Long-term liabilities:		
Deferred revenue, net of current portion	3,025,557	3,278,887
Bonds payable, net of current portion (net of bond issuance costs)	1,658,322	1,654,777
Loans payable, net current portion	450,001	520,829
Derivative financial instruments - warrants	7,968,646	10,368,567
Other long term liabilities	41,331	47,422
Total long term liabilities	13,143,857	15,870,482
Total liabilities	17,522,999	20,510,671
Mezzanine Equity		
Series I convertible preferred stock; par value $0.01; 500 shares authorized; 100 shares issued and outstanding as of June 30, 2016 and March 31, 2016	46,428,572	44,285,715
Stockholders' deficit:		
Common stock; par value $0.001; 995,000,000 shares authorized; 730,971,084 shares issued and 730,871,084 outstanding as of June 30, 2016; 711,544,352 shares issued and 711,444,352 outstanding as of March 31, 2016	730,974	711,546
Additional paid-in capital	110,254,090	109,137,805
Treasury stock; 100,000 shares as of June 30, 2016 and March 31, 2016; at cost	(306,841)	(306,841)
Accumulated deficit	(141,570,723)	(142,664,747)
Total stockholders' deficit	(30,892,500)	(33,122,237)
Total liabilities, mezzanine equity and stockholders' deficit	$ 33,059,071	$ 31,674,149

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 STATEMENTS OF OPERATIONS

(UNAUDITED)

	For the Three Months Ended June 30,	
	2016	2015 (As Restated)
Manufacturing fees	$2,551,858	$1,675,773
Licensing fees	719,288	487,332
Total revenue	3,271,146	2,163,105
Cost of revenue	2,147,552	1,196,968
Gross profit	1,123,594	966,137
Operating expenses:		
Research and development	1,550,370	2,366,262
General and administrative	699,011	754,444
Non-cash compensation through issuance of stock options	89,384	90,479
Depreciation and amortization	22,392	157,915
Total operating expenses	2,361,157	3,369,100
Loss from operations	(1,237,563)	(2,402,963)
Other income (expense):		
Interest expense and amortization of debt issuance costs	(68,943)	(76,228)
Change in fair value of derivative instruments	2,399,921	7,214,261
Interest Income	3,109	—
Other income (expense), net	2,334,087	7,138,033
Income from operations before income taxes	1,096,524	4,735,070
Income tax Provision	2,500	2,750
Net income	1,094,024	4,732,320
Change in carrying value of convertible preferred share mezzanine equity	(2,142,857)	6,428,571
Net (loss) income attributable to common stockholders	$(1,048,833)	$11,160,891
Basic (loss) income per share attributable to common stockholders	$(0.00)	$0.02

Diluted (loss) income per share attributable to common stockholders	$(0.00)	$(0.00)
Basic weighted average common shares outstanding	722,783,442	646,851,543
Diluted weighted average common shares outstanding	722,783,442	812,605,460

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

ELITE PHARMACEUTICALS, INC. AND SUBSIDIARY

CONDENSED CONSOLIDATED STATEMENT OF STOCKHOLDERS' DEFICIT

(UNAUDITED)

	COMMON STOCK			TREASURY STOCK			
	Shares	Amount	Additional Paid-In Capital	Shares	Amount	Accumulated Deficit	Stockholders' Deficit
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						1,094,024	1,094,024
Change in value of convertible preferred mezzanine equity			(2,142,857)				(2,142,857)
Issuance of common shares pursuant to the exercise of cash warrants	11,270,901	11,271	693,160				704,431
Issuance of common shares pursuant to the exercise of cash options	40,000	40	3,960				4,000
Common shares issued in payment of employee salaries	32,244	33	10,384				10,417
Common shares issued as commitment shares pursuant to the Lincoln Park purchase agreement	119,110	119	38,322				38,441

Costs associated with raising capital			(38,441)				(38,441)
Common shares sold pursuant to the Lincoln Park purchase agreement	7,964,477	7,965	2,462,373				2,470,338
Non-cash compensation through the issuance of employee stock options			89,384				89,384
Balance at June 30, 2016	730,971,084	$730,974	$110,254,090	100,000	$(306,841)	$(141,570,723)	$(30,892,500)

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 Three Months Ended June 30,	
	2016	2015 (As Restated)
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net Income	$ 1,094,024	$ 4,732,320
Adjustments to reconcile net (loss) income attributable to common stockholders to net cash used in operating activities:		
Depreciation and amortization	176,060	161,460
Change in fair value of derivative financial instruments - warrants	(2,399,921)	(7,214,261)
Non-cash compensation accrued	457,450	573,667
Non-cash compensation from the issuance of common stock and options	89,384	90,479
Non-cash rent expense and lease accretion	(6,087)	(5,099)
Change in operating assets and liabilities:		
Accounts receivable	310,051	397,822
Inventory	(441,565)	168,789
Prepaid expenses and other current assets	161,345	148,953
Accounts payable, accrued expenses and other current liabilities	48,417	(2,076,625)
Deferred revenue	(253,330)	4,913,333
Net cash (used in) provided by operating activities	(764,172)	1,890,838
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of property and equipment	(284,323)	(709,706)
Intellectual property costs	(175)	(6,637)
Net cash used in investing activities	(284,498)	(716,343)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from the issuance of stock	2,470,338	2,040,591
Proceeds from cash warrant and options exercises	708,431	1,199,671
Proceeds and repayments of line of credit, related party - net	(718,309)	(171,362)
Repayments of loans payable and other long term liabilities	(109,018)	(90,938)
Net cash provided by financing activities	2,351,442	2,977,962
Net change in cash	1,302,772	4,152,457
Cash, beginning of period	11,512,179	7,464,180
Cash, end of period	$ 12,814,951	$ 11,616,637

Supplemental disclosure of cash and non-cash transactions:		
Cash paid for interest	$ 31,422	$ 22,552
Commitment shares issued to Lincoln Park Capital	$ 38,441	$ 849,897
Change in carrying value of convertible preferred mezzanine equity	$ (2,142,857)	$ 6,428,571

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 ("US-FDA" or "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 months ended June 30, 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 September 30, 2015, should have been recorded as mezzanine equity at the maximum redemption amount each reporting period with changes recorded in additional paid in capital.

This Quarterly Report on Form 10-Q for the quarter ended June 30, 2016 includes the impact of the restatement on the comparative unaudited consolidated quarterly financial information for the quarter ended June 30, 2015. Accordingly, these unaudited condensed consolidated financial statements should be read in conjunction with the Company's unaudited condensed consolidated financial statements for the period ended June 30, 2015, included in the Company's amended Form 10-Q, for the period ended June 30, 2015, filed with the SEC on December 30, 2015; and 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.

ELITE PHARMACEUTICALS, INC. AND SUBSIDIARY

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(UNAUDITED)

Revenue Recognition

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

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

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

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

Arrangement consideration is allocated at the inception of the arrangement to all deliverables on the basis of their relative selling price (the relative selling price method). When applying the relative selling price method, the selling

price of each deliverable is determined using vendor-specific objective evidence of selling price, if such exists; otherwise, third-part 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 specific a 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.

ELITE PHARMACEUTICALS, INC. AND SUBSIDIARY

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(UNAUDITED)

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

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

Restricted Cash

As of June 30, 2016 and March 31, 2016, the Company had $388,959 of restricted cash, related to debt serve 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 June 30, 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* ("ASC Topic 718"). 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.

ELITE PHARMACEUTICALS, INC. AND SUBSIDIARY

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(UNAUDITED)

Earnings (Loss) Per Share Applicable to Common Stockholders

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

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

	For the Three Months Ended June 30,	
	2016	2015 (As Restated)
Numerator		
Net income (loss) attributable to common shareholders – basic	$(1,048,833)	$11,160,891
Effect of dilutive instruments on net income	n/a	(13,642,832)
Net loss attributable to common stockholders - diluted	$(1,048,833)	$(2,481,941)
Denominator		
Weighted average shares of common stock outstanding - basic	722,783,442	646,851,543
Dilutive effect of stock options, warrants and convertible securities	n/a	165,753,917
Weighted average shares of common stock outstanding – diluted	722,783,442	812,605,460
Net income (loss) per share		
Basic	$(0.00)	$0.02
Diluted	$(0.00)	$(0.00)

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.

ELITE PHARMACEUTICALS, INC. AND SUBSIDIARY

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(UNAUDITED)

The following table present information about our liabilities measured at fair value on a recurring basis as of June 30, 2016 and March 31, 2016, aggregated by the level in the fair value hierarchy within which those measurements fell:

		Fair Value Measurement Using		
	Amount at Fair Value	Level 1	Level 2	Level 3
June 30, 2016				
Liabilities				
Derivative financial instruments - warrants	$ 7,968,646	$ -	$ -	$ 7,968,646
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 stockholders' deficit.

Recently Issued Accounting Pronouncements

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.

In April 2016, the FASB issued ASU 2016-10, *Revenue from Contracts with Customers (Topic 606): Identifying Performance Obligations and Licensing* ("ASU 2016-10"). The amendments in ASU 2016-10 clarify the following two aspects of Topic 606: (a) identifying performance obligations; and (b) the licensing implementation guidance. The amendments do not change the core principle of the guidance in Topic 606. The effective date and transition requirements for the amendments are the same as the effective date and transition requirements in Topic 606: The guidance is effective for the Company beginning January 1, 2018, although early adoption is permitted beginning January 1, 2017. The Company is currently evaluating the effects of ASU 2016-10 on its unaudited condensed consolidated financial statements.

ELITE PHARMACEUTICALS, INC. AND SUBSIDIARY

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(UNAUDITED)

In May 2016, the FASB issued ASU 2016-12, *Revenue from Contracts with Customers (Topic 606): Narrow-Scope Improvements and Practical Expedients* ("ASU 2016-12"). The amendments in ASU 2016-12 provide clarifying guidance in certain narrow areas and add some practical expedients. Specifically, the amendments in this update (1) clarify the objective of the collectability criterion in step 1, and provides additional clarification for when to recognize revenue for a contract that fails step 1, (2) permit an entity, as an accounting policy election, to exclude amounts collected from customers for all sales (and other similar) taxes from the transaction price (3) specify that the measurement date for noncash consideration is contract inception, and clarifies that the variable consideration guidance applies only to variability resulting from reasons other than the form of the consideration, (4) provide a practical expedient that permits an entity to reflect the aggregate effect of all modifications that occur before the beginning of the earliest period presented when identifying the satisfied and unsatisfied performance obligations, determining the transaction price, and allocating the transaction price to the satisfied and unsatisfied performance obligations, (5) clarifies that a completed contract for purposes of transition is a contract for which all (or substantially all) of the revenue was recognized under legacy GAAP before the date of initial application. Further, accounting for elements of a contract that do not affect revenue under legacy GAAP are irrelevant to the assessment of whether a contract is complete. In addition, the amendments permit an entity to apply the modified retrospective transition method either to all contracts or only to contracts that are not completed contracts, and (6) clarifies that an entity that retrospectively applies the guidance in Topic 606 to each prior reporting period is not required to disclose the effect of the accounting change for the period of adoption. However, an entity is still required to disclose the effect of the changes on any prior periods retrospectively adjusted. The effective date and transition requirements for the amendments are the same as the effective date and transition requirements in Topic 606: The guidance is effective for the Company beginning January 1, 2018, although early adoption is permitted beginning January 1, 2017. The Company is currently evaluating the effects of ASU 2016-12 on its unaudited condensed consolidated financial statements.

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 restated 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:

	March 31, 2016		
	As previously Filed	Adjustments	Revised
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 June 30, 2016 and March 31, 2016 consisted of the following:

	June 30, 2016	March 31, 2016
Finished goods	$ 98,829	$ 225,698
Work-in-progress	144,690	222,784
Raw materials	3,491,775	2,845,247
	$ 3,735,294	$ 3,293,729

NOTE 4. PROPERTY AND EQUIPMENT, NET

Property and equipment as of June 30, 2016 and March 31, 2016 consisted of the following:

	June 30, 2016	March 31, 2016
Land, building and improvements	$ 6,447,815	$ 6,230,543
Laboratory, manufacturing and warehouse equipment	8,317,834	8,255,286
Office equipment and software	239,135	234,634
Furniture and fixtures	49,804	49,804
Transportation equipment	66,855	66,855
	15,121,443	14,837,122
Less: Accumulated depreciation	(6,898,916)	(6,726,401)
	$ 8,222,527	$ 8,110,721

Depreciation expense for the three months ended June 30, 2016 and 2015 was $172,515 and $157,915, respectively.

ELITE PHARMACEUTICALS, INC. AND SUBSIDIARY

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NOTE 5. INTANGIBLE ASSETS

The following table summarizes the Company's intangible assets as of June 30, 2016 and March 31, 2016:

	June 30, 2016				
	Estimated Useful Life	Gross Carrying Amount	Additions	Accumulated Amortization	Net Book Value
Patent application costs	*	$364,482	$175	$-	$364,657
ANDA acquisition costs	Indefinite	6,047,317	-	-	6,047,317
		$6,411,799	$175	$-	$6,411,974

	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 Food and Drug Administration ("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 1st based on the amount specified in the loan documents and semi-annual interest payments on March 1st and September 1st, equal to interest due on the outstanding principal. The annual interest rate on the Series A Note is 6.5%. The NJEDA Bonds are collateralized by a first lien on the Company's facility and equipment acquired with the proceeds of the original and refinanced bonds.

The following tables summarizes the Company's bonds payable liability as of June 30, 2016 and March 31, 2016, respectively.

	June 30, 2016	March 31, 2016
Gross Bonds payable		
NJEDA Bonds - Series A Notes	$2,065,000	$2,065,000
Less: Current portion of bonds payable (prior to deduction of bond offering costs)	(220,000)	(220,000)
Long-term portion of bonds payable, (prior to deduction of bond offering costs)	$1,845,000	$1,845,000
Bond Offering Costs	$354,453	$354,453
Less: Accumulated amortization	(153,597)	(150,052)
Bond offering costs, net	$200,856	$204,401
Current portion of bonds payable – net of bond offering costs		
Current portion of bonds payable	$220,000	$220,000
Less: Bond offering costs to be amortized in the next 12 months	(14,178)	(14,178)
Current portion of bonds payable, net of bond offering costs	$205,822	$205,822
Long term portion of bonds payable – net of bond offering costs		
Long term portion of bonds payable	$1,845,000	$1,845,000
Less: Bond offering costs to be amortized subsequent to the next 12 months	(186,678)	(190,223)
Long term portion of bonds payable, net of bond offering costs	$1,658,322	$1,654,777

Amortization expense related to the bond offering costs was $3,545 for the three months ended June 30, 2016 and 2015.

NOTE 7. LOANS PAYABLE

Loans Payable as of June 30, 2016 and March 31, 2016 consisted of the following:

	June 30, 2016	March 31, 2016
Equipment and insurance financing loans payable, between 6% and 13% interest and maturing between May 2017 and September 2020	$ 754,757	$ 863,773
Less: Current portion of loans payable	(304,756)	(342,944)
Long-term portion of loans payable	$ 450,001	$ 520,829

The interest expense associated with the loans payable for the three months ended June 30, 2016 and 2015 amounted to $21,151 and $21,641, respectively.

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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 and owing in principal balances outstanding during the period April 1, 2016 through May 23, 2016 was paid on May 24, 2016. Accordingly, as of June 30, 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 $4,038,890, consisting of a current component of $1,013,333 and a long term component of $3,025,557. These line items represent the unamortized amounts of a $200,000 advance payment received for a TAGI licensing agreement with a fifteen year term beginning in September 2010 and ending in August 2025 and the $5,000,000 advance payment Epic Collaborative Agreement with a five year term beginning in June 2015 and ending in May 2020. These advance payments were recorded as deferred revenue when received and are earned, on a straight line basis over the life of the licenses. The current component is equal to the amount of revenue

to be earned during the 12 month period immediately subsequent to the balance date and the long term component is equal to the amount of revenue to be earned thereafter.

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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.

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.

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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 June 30, 2016 and 2015 was $45,213 and $45,214, respectively and recorded in general and administrative expense in the audited condensed consolidated statements of operations. Deferred rent as of June 30, 2016 and March 31, 2016 was $13,015 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 June 30, 2016 and March 31, 2016, the Company had a liability of $28,316 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 500 shares of Series I Preferred are authorized and as of the current Balance Sheet Date, 100 shares are issued and outstanding, with a stated value of $100,000 and a par value of $0.01. The Certificate of Designations ("COD") for the Series I Preferred contain the following features:

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.

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

Based on Management's review of the COD, the host instrument, the Series I Preferred Shares, will be 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 will be 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 similar to the treatment of dividends paid on preferred stock), in arriving at net income (loss) available to common stockholders used in the calculation of earnings per share.

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

	June 30, 2016	March 31, 2016
Shares authorized	500	500
Shares outstanding	100	100
Par value	$0.01	$0.01
Stated value	$100,000	$100,000
Conversion price	$0.07	$0.07
Common shares to be issued upon redemption	142,857,143	142,857,143
Closing price on valuation date	$0.33	$0.31
Carrying value of Series, I convertible preferred stock	$46,428,572	$44,285,715

	For the Three Months Ended June 30,	
	2016	2015 **(As Restated)**
Change in value of Series I convertible preferred stock	$2,142,857	$(6,428,571)

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:

	June 30, 2016		March 31, 2016	
	Warrant Shares	Weighted Average Exercise Price	Warrant Shares	Weighted Average Exercise Price
Balance at beginning of period	41,586,066	$ 0.0625	89,870,034	$ 0.0625
Warrants exercised, forfeited and/or expired, net	(11,350,901)		(48,283,968)	
Balance at end of period	30,235,165	$ 0.0625	41,586,066	$ 0.0625

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

	June 30, 2016	March 31, 2016
Fair value of the Company's common stock	$0.33	$0.31
Volatility (based on the Company's historical volatility)	62% - 70%	52% - 81%
Exercise price	$0.0625	$0.0625 - 0.25
Estimated life (in years)	0.3 - 1.8	0.2 - 2.1
Risk free interest rate (based on 1-year treasury rate)	0.20% - 0.45%	0.18% - 0.73%

The changes in warrants (Level 3 financial instruments) measured at fair value on a recurring basis for the three months ended June 30, 2016 were as follows:

Balance as of March 31, 2016	$10,368,567
Change in fair value of derivative financial instruments - warrants	(2,399,921)
Balance as of June 30, 2016	$7,968,646

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NOTE 13. STOCKHOLDERS' 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.

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.

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.

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Common Stock

During the three months ended June 30, 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 11,310,901 shares of its common stock totaling $708,431 in connection with the exercise of warrants and stock options.

Issuance of shares of common stock in payment of employee salaries

The Company issued 32,244 shares of its common stock totaling $10,417 pursuant to employment contracts with certain employees.

Issuance of shares of common stock to Lincoln Park

The Company issued 119,110 shares of its common stock with a value totaling $38,441 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 7,964,477 shares of its common stock for proceeds totaling $2,470,338 in connection with the Purchase Agreement with Lincoln Park.

NOTE 14. STOCK-BASED COMPENSATION

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

Stock-based Director Compensation

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

During the three months ended June 30, 2016, the Company did not issue any shares of common stock to its Directors in payment of Director's fees.

During the three months ended June 30, 2016, the Company accrued Directors fees totaling $18,361, which will be paid via the issuance of 56,896 shares of Common Stock.

As of June 30, 2016, the Company owes its Directors a total of 103,020 shares of Common Stock in payment of Director fees totaling $33,361 due and owing. The Company anticipates that these shares of Common Stock will be issued during the next nine months.

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 three months ended June 30, 2016, the Company issued 32,244 shares of common stock a certain employee in payment of salaries in the aggregate amount of $10,417 for the three months ended June 30, 2016.

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During the three months ended June 30, 2016, the Company accrued salaries and fees totaling $213,667 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 661,857 shares of Common Stock.

As of June 30, 2016, the Company owes its President and Chief Executive Officer, Chief Financial Officer and certain other employees and consultants, a total of 1,296,397 shares of Common Stock in payment of salaries and fees totaling $419,167 due and owing. The Company anticipates that these shares of common stock will be issued during the next nine months.

Options

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

	Shares Underlying Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value
Outstanding at April 1, 2016	7,609,667	$ 0.48	6.5	$ 904,409
Granted	-	-	-	-
Forfeited and expired	-	-	-	-
Exercised	(40,000)	0.10		
Outstanding at June 30, 2016	7,569,667	0.48	6.3	975,699
Exercisable at June 30, 2016	4,453,001	0.54	5.5	683,411

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 June 30, 2016 and March 31, 2016 of $0.33 and $0.31.

NOTE 15. CONCENTRATIONS AND CREDIT RISK

Revenues

Five customers accounted for substantially all of the Company's revenues for the three months ended June 30, 2016 and 2015. Included in these customers for the three months ended June 30, 2016, are three customers that accounted for approximately 45%, 34%, and 13% of revenues each, respectively. Included in these customers for the three months ended June 30, 2015, are three customers that accounted for approximately 47%, 44%, and 5% of revenues each, respectively.

Accounts Receivable

Four customers accounted for substantially all of the Company's accounts receivable as of June 30, 2016. Included in these customers are three customers that accounted for approximately 53%, 32%, and 11% of revenues each, respectively.

Four customers accounted for substantially all of 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 revenues each, respectively.

Purchasing

Four suppliers accounted for more than 80% of the Company's purchases of raw materials for the three months ended June 30, 2016. Included in these four suppliers are three suppliers that accounted for approximately 63%, 9% and 6% of purchases each, respectively.

Seven suppliers accounted for more than 80% of the Company's purchases of raw materials for the three months ended June 30, 2015. Included in these seven suppliers are three suppliers that accounted for approximately 42%, 12% and 9% of purchases each, respectively.

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NOTE 16. SEGMENT RESULTS

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

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

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

The following represents selected information for the Company's reportable segments for the three months ended June 30, 2016 and 2015.

	For the Three Months Ended June 30,	
	2016	2015 (As Restated)
Revenue by Segment		

ANDA	$ 3,021,146	$ 2,079,772
NDA	250,000	83,333
	$ 3,271,146	$ 2,163,105

	For the Three Months Ended June 30,	
	2016	2015 (As Restated)
Operating Income (Loss) by Segment		
ANDA	$ 172,921	$ 854,473
NDA	(608,677)	(2,352,552)
	$ (435,756)	$ (1,498,079)

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.

	For the Three Months Ended June 30,	
	2016	2015 (As Restated)
Operating income (loss) by segment	$ (435,756)	$ (1,498,079)
Corporate unallocated costs	(462,125)	(370,075)
Interest revenue	3,109	409
Interest expense	(68,943)	(76,637)
Depreciation and amortization expense	(22,392)	(157,915)
Significant non-cash items	(317,290)	(376,894)
Change in fair value of derivative instruments	2,399,921	7,214,261
Income from operations before income taxes	$ 1,096,524	$ 4,735,070

ELITE PHARMACEUTICALS, INC. AND SUBSIDIARY

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(UNAUDITED)

NOTE 17. 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. 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 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 18. RELATED PARTY TRANSACTION AGREEMENTS WITH EPIC PHARMA LLC

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

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(UNAUDITED)

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.

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;

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(UNAUDITED)

- Stage of development of SequestOx™ and manufacturing site transfer and regulatory requirements relating to the commercialization of the generic products at the time of the discussions/negotiations, and an assessment of the risks, probability and time frames for achieving marketing authorizations from the FDA for each product.
- Assessment of consideration offered; and
- Comparison of the above factors among the various entities with whom the Company was engaged in discussions relating to the commercialization of SequestOx™ and the manufacture/marketing of the twelve generics related to the Epic Generic Agreement.

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

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

NOTE 19. MANUFACTURING, LICENSE AND DEVELOPMENT AGREEMENTS

The Company has entered into the following active agreements:

- License agreement with Precision Dose, dated September 10, 2010 (the "Precision Dose License Agreement")
- 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
- Development agreement with Akorn Pharmaceuticals, dated January 10, 2011 (the "Akorn 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:

ELITE PHARMACEUTICALS, INC. AND SUBSIDIARY

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(UNAUDITED)

- 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 products, all of which did not have FDA approval at the time of the discussions/negotiations and an assessment of the risks, probability and time frame for achieving marketing authorizations from the FDA for the products;
- Assessment of consideration offered by Precision and other entities with whom discussions were conducted; and
- Comparison of the above factors among the various entities with whom the Company was engaged in discussions relating to the commercialization of the generic products.

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

The Akorn Agreement was executed on January 10, 2011 between Hi-Tech Pharmacal Inc. (subsequently acquired by Akorn Pharmaceuticals) and provides for Elite to develop an intermediate product which will be incorporated into the finished formulation of a generic version of a prescription product for Akorn Pharmaceuticals (“Akorn”). There is currently no development activity being conducted pursuant to this agreement and there was no activity during the last 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.

NOTE 20. SUBSEQUENT EVENTS

The Company has evaluated subsequent events from the balance sheet date through August 9, 2016, the date the accompanying financial statements were issued. The following are material subsequent events:

FDA Issues Complete Response Letter relating to SequestOX™

On July 15, 2016, the Company announced that the U.S. Food and Drug Administration (the "FDA") has issued a Complete Response Letter (the "CRL") regarding the New Drug Application (the "NDA") for SequestOX™ (oxycodone hydrochloride and naltrexone hydrochloride), Elite's investigational abuse-deterrent opioid candidate for the management of moderate to severe acute pain where the use of an opioid analgesic is appropriate.

The FDA issues CRLs when the Agency considers the review cycle for an application is complete and whether the application is ready for approval in its present form. CRLs often include guidance that describes deficiencies that the FDA has identified in the application. When possible, the FDA recommends actions that the applicant may take to place the application in condition for approval. The CRL determined that the NDA was not ready for approval in its present form.

Common Stock sold pursuant to the Lincoln Park Purchase Agreement

Subsequent to June 30, 2016 and up to August 3, 2016 (the latest practicable date), a total of 2.71 million shares of Common Stock were sold and 0.03 million additional commitment shares were issued, pursuant to the Lincoln Park Purchase Agreement. Proceeds received from such transactions totaled $0.7 million.

Filing of ANDA for a 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.

ITEM 2.

MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

THREE MONTHS ENDED JUNE 30, 2016

COMPARED TO THE

THREE MONTHS ENDED JUNE 30, 2015 (RESTATED)

(UNAUDITED)

The following discussion of our financial condition and results of operations for the three months ended June 30, 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:

Product	Branded Product Equivalent	Therapeutic Category	Launch Date
Phentermine HCl 37.5mg tablets ("Phentermine 37.5mg")	Adipex-P®	Bariatric	April 2011
Lodrane D ® Immediate Release capsules ("Lodrane D")	n/a	OTC Allergy	September 2011
Methadone HCl 10mg tablets ("Methadone 10mg")	Dolophine®	Pain	January 2012
Hydromorphone HCl 8mg tablets ("Hydromorphone 8mg")	Dilaudid®	Pain	March 2012
Phendimetrazine Tartrate 35mg tablets ("Phendimetrazine 35mg")	Bontril®	Bariatric	November 2012
Phentermine HCl 15mg and 30mg capsules ("Phentermine 15mg" and "Phentermine 30mg")	Adipex-P®	Bariatric	April 2013
Naltrexone HCl 50mg tablets ("Naltrexone 50mg")	Revia®	Pain	September 2013
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 FDA approval. Within the past few years, the FDA has revised its enforcement policies, significantly limiting the circumstances under which these unapproved products may be marketed. If the FDA determines that a company is distributing an unapproved product that requires approval, the FDA may take enforcement action in a variety of ways, including, without limitation, product seizures and seeking a judicial injunction against distribution.

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

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

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

Methadone 10mg

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

On January 17, 2012, Elite commenced shipping Methadone 10mg tablets to Ascend pursuant to a commercial manufacturing and supply agreement dated June 23, 2011, as amended on September 24, 2012 and January 19, 2015, 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.