

ELITE PHARMACEUTICALS INC /NV/  
Form 10-Q/A  
December 30, 2015

U.S. SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q/A

(Amendment No. 2)

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

For the quarterly period ended September 30, 2015

or

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

For the transition period ended \_\_\_\_\_ to \_\_\_\_\_

Commission File Number: 001-15697

ELITE PHARMACEUTICALS, INC.  
(Exact name of registrant as specified in its charter)

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

165 Ludlow Avenue, Northvale, New Jersey 07647  
(Address of principal executive offices) (Zip Code)

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

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(Former name, former address and former fiscal year, if changed since last report)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15 (d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes  No

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

Yes  No

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

Large Accelerated filer  Accelerated Filer  Non-Accelerated Filer  Smaller Reporting Company

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).

Yes  No

Indicate the number of shares outstanding of each of the issuer’s classes of common stock, as of the latest practicable date. As of November 5, 2015, the issuer had outstanding 684,756,279 shares of common stock, \$0.001 par value (exclusive of 100,000 shares held in treasury).

**EXPLANATORY NOTE**

**This amended Form 10-Q for the quarter ended September 30, 2015 (“Form 10-Q/A”) only amends information in Part I, Item 1 and Item 2 of the Form 10-Q/A (amendment 1), previously filed with the Commission on November 10, 2015 (the “Original Filing”).**

**Specifically, we have restated our financial statement and revised our Management’s Discussion and Analysis of Financial Condition and Results of Operations to (i) correct our treatment of revenue recognition for the non-refundable \$5,000,000 payment from Epic Pharma LLC (“Epic”) pursuant to our Licensing Agreement dated June 4, 2015 with Epic; (ii) correct our accounting treatment for Convertible Preferred Stock for periods prior to the quarter ended September 30, 2015; and (iii) in response to certain comments received from the Securities and Exchange Commission.**

**All other information and items as presented in the Original Filing and as included herein are unchanged. Except for the foregoing amended and restated information, this Amendment does not amend, update or change any other information presented in the Original Filing.**

**In addition, as required by Rule 12b-15 of the Securities Exchange Act of 1934, this Form 10-Q/A contains new certifications by our principal executive officer and our principal financial and accounting officer, filed as exhibits hereto**

**ELITE PHARMACEUTICALS, INC. AND SUBSIDIARY**

**INDEX**

	<b>Page No.</b>
<b>PART I – FINANCIAL INFORMATION</b>	
Item 1. Financial Statements (Restated)	
<u>Condensed Consolidated Balance Sheets as of September 30, 2015 (unaudited) and March 31, 2015 (audited)</u>	F-1
<u>Condensed Consolidated Statements of Operations for the six months ended September 30, 2015 (unaudited) and September 30, 2014 (unaudited)</u>	F-3
<u>Condensed Consolidated Statement of Changes in Stockholders’ Deficit for the six months ended September 30, 2015 (unaudited)</u>	F-4
<u>Condensed Consolidated Statements of Cash Flows for the six months ended September 30, 2015 (unaudited) and September 30, 2014 (unaudited)</u>	F-5
<u>Notes to Condensed Consolidated Financial Statements</u>	F-6
Item 2. <u>Management’s Discussion and Analysis of Financial Condition and Results of Operations</u>	1
Item 3. <u>Quantitative and Qualitative Disclosures about Market Risk</u>	17
Item 4. <u>Controls and Procedures</u>	17
<b>PART II – OTHER INFORMATION</b>	
Item 1. <u>Legal Proceedings</u>	18
Item 1A. <u>Risk Factors</u>	18
Item 2. <u>Unregistered Sales of Equity Securities and Use of Proceeds</u>	19
Item 3. <u>Defaults upon Senior Securities</u>	19
Item 4. <u>Mine Safety Disclosures</u>	19
Item 5. <u>Other Information</u>	19

Item 6.	<u>Exhibits</u>	19
	<u>SIGNATURES</u>	30

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

	<b>September 30,</b>	<b>March 31,</b>
	<b>2015</b>	<b>2015</b>
	<b>(Unaudited)</b>	<b>(Audited)</b>
<b>ASSETS</b>		
<b>CURRENT ASSETS</b>		
Cash	\$ 9,031,088	\$ 7,464,180
Accounts receivable (net of allowance for doubtful accounts of \$0 and \$272,620, respectively)	1,415,886	1,446,441
Inventories	3,353,313	3,032,002
Prepaid expenses and other current assets	295,108	388,061
Total Current Assets	14,095,395	12,330,684
PROPERTY AND EQUIPMENT, <u>net of accumulated depreciation of \$6,392,827 and \$6,074,117, respectively</u>	7,554,519	6,401,802
<u>INTANGIBLE ASSETS</u> – net of accumulated amortization of \$-0-	6,399,667	6,381,774
<b>OTHER ASSETS</b>		
Security deposits	48,714	198,481
Restricted cash – debt service for EDA bonds	388,959	388,959
EDA bond offering costs, net of accumulated amortization of \$142,963 and \$135,874, respectively	211,490	218,579
Total Other Assets	649,163	806,019
<b>TOTAL ASSETS</b>	<b>\$ 28,698,744</b>	<b>\$ 25,920,279</b>

*The accompanying notes are an integral part of the condensed consolidated financial statements*

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

	<b>September 30,</b>	<b>March 31,</b>
	<b>2015</b>	<b>2015</b>
	<b>(Unaudited)</b>	<b>(Audited)</b>
<b>LIABILITIES AND STOCKHOLDERS' DEFICIT</b>		
<b>CURRENT LIABILITIES</b>		
Current portion of EDA bonds payable	\$ 220,000	\$ 210,000
Short term loans and current portion of long-term debt	251,835	265,165
Related Party Line of Credit	411,709	583,071
Accounts payable and accrued expenses	3,611,073	3,997,528
Deferred revenues	1,013,333	13,333
<b>Total Current Liabilities</b>	<b>5,507,950</b>	<b>5,069,097</b>
<b>LONG TERM LIABILITIES</b>		
EDA bonds payable – non current	1,845,000	2,065,000
Deferred revenues	3,785,557	125,557
Other long term liabilities	549,486	629,138
Derivative liabilities	9,184,216	17,762,573
<b>Total Long Term Liabilities</b>	<b>15,364,259</b>	<b>20,582,268</b>
<b>TOTAL LIABILITIES</b>	<b>20,872,209</b>	<b>25,651,365</b>
<b>MEZZANINE EQUITY</b>		
Convertible preferred shares	32,857,145	35,000,000
<b>STOCKHOLDERS' DEFICIT</b>		
Common stock – par value \$0.001, Authorized 995,000,000 shares and 690,000,000 shares, respectively. Issued 681,756,279 shares and 631,160,701 shares, respectively. Outstanding 680,756,279 shares and 630,060,701 shares, respectively	681,759	631,162
Additional paid-in-capital	113,525,265	106,926,328

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Accumulated deficit	(138,930,793 )	(141,981,735)
Treasury stock at cost (100,000 common shares)	(306,841 )	(306,841 )
TOTAL STOCKHOLDERS' DEFICIT	(25,030,610 )	(34,731,086 )
TOTAL LIABILITIES, MEZZANINE EQUITY AND STOCKHOLDERS' DEFICIT	\$28,698,744	\$25,920,279

*The accompanying notes are an integral part of the condensed consolidated financial statements*

F-2



**CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS***(Unaudited and Restated)*

	<b>THREE MONTHS ENDED</b>		<b>SIX MONTHS ENDED</b>	
	<b>September 30,</b>		<b>September 30,</b>	
	2015	2014	2015	2014
<b>REVENUES</b>				
Manufacturing Fees	\$2,553,195	\$850,934	\$4,228,968	\$1,799,971
Licensing Fees	393,312	405,483	880,644	613,128
Lab Fee Revenues	—	—	—	5,000
Total Revenues	2,946,507	1,256,417	5,109,612	2,418,099
<b>COSTS OF REVENUES</b>	1,414,529	681,669	2,611,497	1,410,199
Gross Profit	1,531,978	574,748	2,498,115	1,007,900
<b>OPERATING EXPENSES</b>				
Research and Development	4,172,419	3,583,563	6,614,063	7,623,403
General and Administrative	881,566	722,229	1,560,630	1,329,268
Non-cash compensation through issuance of stock options	80,992	53,481	171,470	77,143
Depreciation and Amortization	164,340	276,812	325,800	470,696
Total Operating Expenses	5,299,317	4,636,085	8,671,963	9,500,510
<b>(LOSS) FROM OPERATIONS</b>	<b>(3,767,339 )</b>	<b>(4,061,337 )</b>	<b>(6,173,848 )</b>	<b>(8,492,610 )</b>
<b>OTHER INCOME / (EXPENSES)</b>				
Interest expense	(63,824 )	(70,075 )	(136,507 )	(148,281 )
Change in fair value of derivative liabilities	2,149,787	10,379,665	9,364,047	11,121,624
Gain on Sale on Investment	—	—	—	1,670,678
Other Income (Expense)	—	—	(2,750 )	3,248
Total Other Income / (Expense)	2,085,963	10,309,590	9,224,790	12,647,269
<b>NET INCOME (LOSS)</b>	<b>\$(1,681,376 )</b>	<b>\$6,248,253</b>	<b>\$3,050,942</b>	<b>\$4,154,658</b>
Change in value of convertible preferred share mezzanine equity	(5,071,406 )	15,131,571	1,357,167	12,823,356
<b>NET INCOME (LOSS) ATTRIBUTABLE TO COMMON SHAREHOLDERS</b>	<b>\$(6,752,782 )</b>	<b>\$21,379,824</b>	<b>\$4,408,109</b>	<b>\$16,978,014</b>
<b>NET INCOME (LOSS) PER SHARE</b>				
Basic	\$(0.01 )	\$0.04	\$0.01	\$0.03
Diluted	\$(0.00 )	\$(0.01 )	\$(0.00 )	\$(0.01 )

WEIGHTED AVERAGE NUMBER OF COMMON  
SHARES OUTSTANDING

Basic	665,330,431	577,691,292	656,141,476	565,150,231
Diluted	823,495,279	739,869,496	814,306,324	733,912,128

*The accompanying notes are an integral part of the condensed consolidated financial statements*

F-3

**ELITE PHARMACEUTICALS, INC. AND SUBSIDIARY****CONDENSED CONSOLIDATED STATEMENT OF CHANGES IN STOCKHOLDERS' DEFICIT***(Unaudited and Restated)*

	COMMON STOCK		TREASURY STOCK		Accumulated Deficit	Stockholders' Deficit
	Shares	Amount	Paid-In Capital	Shares		
<b>Balance at March 31, 2015</b>	631,160,701	\$631,162	\$106,926,328	100,000	\$(306,841)	\$(141,981,735) \$(34,731,086 )
Net Income					3,050,942	3,050,942
Change in value of convertible preferred mezzanine equity			1,357,167			1,357,167
Common shares sold pursuant to the Lincoln Park Capital purchase agreement	13,155,283	13,157	2,766,985			2,780,142
Non-cash compensation through the issuance of stock options			171,470			171,470
Common shares issued as commitment shares pursuant to the Lincoln Park Capital purchase agreement	134,047	134	(134 )			—
	37,252,079	37,252	2,291,003			2,328,255

Common shares  
issued pursuant to  
the exercise of  
cash warrants

Common Shares Issued Pursuant to Director Salaries	54,169	54	12,446				12,500
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<b>Balance at September 30, 2015</b>	681,756,279	\$681,759	\$113,525,265	100,000	\$(306,841)	\$(138,930,793)	\$(25,030,610 )
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*The accompanying notes are an integral part of the condensed consolidated financial statements*

F-4

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

	<b>SIX MONTHS ENDED</b>	
	<b>SEPTEMBER 30</b>	
	2015	2014
<b>CASH FLOWS FROM OPERATING ACTIVITIES</b>		
Net Income	\$3,050,942	\$4,154,659
Adjustments to reconcile net income to cash used in operating activities:		
Depreciation and amortization	325,799	435,537
Change in fair value of derivative liabilities	(9,364,047)	(11,121,624)
Non-cash compensation accrued	586,167	679,771
Non-cash compensation from the issuance of common stock and options	171,470	83,333
Non-cash rent expense	(10,991 )	5,189
Non-cash lease accretion	798	752
Gain on Sale of Investment	—	(1,670,678 )
Bad debt recovery	(117,095 )	—
Changes in Assets and Liabilities		
Accounts receivable	147,650	(365,708 )
Inventories	(321,311 )	(591,130 )
Prepaid and other current assets	242,721	(60,862 )
Accounts payable, accrued expenses and other current liabilities	(960,122 )	(183,608 )
Deferred revenues and Customer deposits	4,660,000	(6,667 )
<b>NET CASH PROVIDED BY (USED) IN OPERATING ACTIVITIES</b>	<b>(1,588,019)</b>	<b>(8,641,036 )</b>
<b>CASH FLOWS FROM INVESTING ACTIVITIES</b>		
Purchases of property, equipment and leasehold improvements	(1,405,633)	(1,005,087 )
Costs incurred for intellectual property assets	(17,893 )	(8,549 )
Deposits to / (withdrawals from) restricted cash, net	—	(123,909 )
Proceeds from Sale of Investment	—	5,000,000
<b>NET CASH PROVIDED BY (USED IN) INVESTING ACTIVITIES</b>	<b>(1,423,526)</b>	<b>3,862,455</b>
<b>CASH FLOWS FROM FINANCING ACTIVITIES</b>		
Proceeds from sale of common shares	2,780,142	6,227,485
Proceeds from exercise of cash warrants and options	2,328,255	290,231
Proceeds / (Payments) from draws against credit lines from related parties	(171,362 )	137,579
Payment of bonds Principal	(210,000 )	(1,110,000 )
Other loan payments	(148,582 )	(65,049 )
Costs associated with raising capital	—	(16,364 )
<b>NET CASH PROVIDED BY FINANCING ACTIVITIES</b>	<b>4,578,453</b>	<b>5,463,882</b>
<b>NET CHANGE IN CASH AND CASH EQUIVALENTS</b>	<b>1,566,908</b>	<b>685,301</b>

CASH AND CASH EQUIVALENTS – beginning of period	7,464,180	6,941,777
CASH AND CASH EQUIVALENTS – end of period	\$9,031,088	\$7,627,078
SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION		
Cash paid for interest	\$110,372	\$141,342
Non-Cash Financing Transactions		
Financing of equipment purchases and insurance renewal	\$65,794	\$495,753
Commitment shares issued to Lincoln Park Capital	\$830,515	\$756,053
Conversion of Preferred Shares to Common Shares	\$—	\$2,272,500
Change in maximum redemption value of convertible preferred mezzanine equity	\$1,357,167	\$12,823,356

*The accompanying notes are an integral part of the condensed consolidated financial statements*

**ELITE PHARMACEUTICALS, INC. AND SUBSIDIARY**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

**THREE AND SIX MONTHS ENDED SEPTEMBER 30, 2015 AND 2014**

**(UNAUDITED and RESTATED)**

**NOTE 1 - DEFINITIONS**

**“Current Balance Sheet Date”** means September 30, 2015

**“Current Fiscal Year”** means the twelve months ended March 31, 2016

**“Current Quarter”** means the three months ended September 30, 2015

**“Current YTD”** means the six months ended September 30, 2015

**“EPIC”** means Epic Pharma LLC

**“FDA”** means the U.S. Food and Drug Administration

**“Hakim Credit Line Limit”** equals \$1,000,000

**“Hakim Credit Line Balance”** equals \$411,709

**“Hakim Credit Line Interest Due”** equals \$41,658

“**Prior Year Balance Sheet Date**” means September 30, 2014

“**Prior Fiscal Year**” means the twelve months ended March 31, 2015

“**Prior Year Quarter**” means the three months ended September 30, 2014

“**SEC**” means the Securities and Exchange Commission

**NOTE 2 - BASIS OF PRESENTATION**

The financial statements in this amended quarterly report on Form 10-Q are restated to correct errors in accounting that were identified in the previously issued quarterly report on Form 10-Q which was filed with the SEC on November 9, 2015. Please refer to note 4 for further details on the specifics and effects of these corrections of accounting error.

The information in this quarterly report on Form 10-Q includes the results of operations of Elite Pharmaceuticals, Inc. and its consolidated subsidiaries (collectively the “Company” or “Elite”) for the Current Quarter and Prior Year Quarter. The accompanying unaudited and restated condensed consolidated financial statements have been prepared pursuant to rules and regulations of the SEC in accordance with accounting principles generally accepted for interim financial statement presentation. Accordingly, they do not include all of the information and footnotes required by accounting principles generally accepted in the United States of America (“GAAP”) for complete financial statements. In the opinion of management, all adjustments (consisting of normal recurring accruals) considered necessary for a fair presentation of the condensed consolidated financial position, results of operations and cash flows of the Company for the periods presented have been included.

The financial results for the interim periods are not necessarily indicative of the results to be expected for the full year or future interim periods.



The accompanying unaudited and restated condensed consolidated financial statements should be read in conjunction with the consolidated financial statements and notes included in the Company's Annual Report on Form 10-K for the year ended March 31, 2015 and filed with the SEC on June 15, 2015.

There have been no changes in significant accounting policies since March 31, 2015, other than the accounting for license fees received pursuant to the license agreement between the Company and Epic Pharma LLC dated June 4, 2015 and the accounting for convertible preferred share mezzanine as discussed in Note 4 to these financial statements. The changes for accounting for convertible preferred share mezzanine equity are to be considered when reviewing the Annual Report on Form 10-K filed with the SEC on June 15, 2015. The change in accounting for the license fees received pursuant to the license agreement between the Company and Epic Pharma LLC dated June 4, 2015 apply to a transaction that occurred subsequent to the period included in the Annual Report on Form 10-K filed with the SEC on June 15, 2015, and accordingly is not relevant to the financials reported therein.

The Company does not anticipate being profitable for the Current Fiscal Year; therefore a current provision for income tax was not established for the Current Quarter. Only the minimum liability required for state corporation taxes was considered.

### **Collaborative Arrangements**

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

- The parties to the contract must actively participate in the joint operating activity; and
- The joint operating activity must expose the parties to the possibility of significant risks 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 "Epic Collaborative Agreement"), which has been determined to satisfy the criteria for consideration as a collaborative agreement, and is accounted for accordingly, in accordance with GAAP.

### **Revenue Recognition**

The Company enters into licensing, manufacturing and development agreements which may include multiple revenue generating activities, including, without limitation, milestones, license fees, product sales and services. These multiple elements are assessed in accordance ASC 605-25 Revenue Recognition for 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 and the fair value can be determined, 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, or if the fair value cannot be determined, 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, we determine the period over which the performance obligations will be performed and revenue will be recognized. If we cannot reasonably estimate the timing and the level of effort to complete our 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.

F-7

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

When determining the selling price for significant deliverables under a multiple-element revenue arrangement, the Company considers any or all of the following, 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.

## **Segment Reporting**

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 organizes 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 disaggregates its product revenues into the type of marketing authorization relating to each product, specifically the following two reportable segments:

1. ANDA’s for generic products; or
2. NDA’s for branded products.

During the three and six months ended September 30, 2015 and 2014, the Company recognized \$4,776k and \$2,696k from the sale of generic products respectively. The Company had no revenues relating to the sale of branded products during the three and six months ended September 30, 2015 and 2014.

**NOTE 3 - SIGNIFICANT ACCOUNTING POLICIES AND ESTIMATES**

Management's discussion addresses our Consolidated Financial Statements, which have been prepared in accordance with accounting principles generally accepted in the United States of America. The preparation of these financial statements requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of financial statements and the reported amounts of revenues and expenses during the reporting period. On an ongoing basis, management evaluates its estimates and judgment, including those related to bad debts, intangible assets, income taxes, workers compensation, and contingencies and litigation. Management bases its estimates and judgments on historical experience and on various other factors that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

F-8

Management believes the following critical accounting policies, among others, affect its more significant judgments and estimates used in the preparation of its Consolidated Financial Statements. Our most critical accounting policies include the recognition of revenue upon completion of certain phases of projects under research and development contracts. We also assess a need for an allowance to reduce our deferred tax assets to the amount that we believe is more likely than not to be realized. We assess the recoverability of inventory, long-lived assets and intangible assets whenever events or changes in circumstances indicate that the carrying value of the asset may not be recoverable. We assess our exposure to current commitments and contingencies. It should be noted that actual results may differ from these estimates under different assumptions or conditions.

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

The accounting treatment of warrants and preferred share series issued is determined pursuant to the guidance provided by subtopics 470, 480, 815 and 270 of the Accounting Standard Codification. Each feature of these instruments, including, without limitation, any rights relating to subsequent dilutive issuances, dividend issuances, equity sales, rights offerings, forced conversions, optional redemptions, automatic monthly conversions, dividends and exercise are assessed with determinations made regarding the proper classification on the Company's statement of financial position, results of operations, cash flow statement and statement of changes in equity.

#### **NOTE 4 - RESTATEMENT OF PRIOR FINANCIAL INFORMATION**

After receiving a comment letter from the SEC in connection with its standard periodic review of our Form 10-K for the Fiscal Year Ended March 31, 2015, our Form 10-Q for the Quarterly Period Ended June 30, 2015 and, in the process of review, our Form 10-Q, as amended, for the Quarterly Period Ended September 30, 2015, we conducted further reviews of our financial statements. Based on such reviews, the following determinations were made:

##### **Error in Accounting for License Agreement with EPIC**

During our review, we determined that the accounting treatment for the recognition of revenue relating to a \$5 million, non-refundable payment received from EPIC pursuant to our Licensing Agreement dated June 4, 2015 (the "Epic Collaborative Agreement") was incorrect. Specifically, it has been determined that revenue relating to the \$5 million, non-refundable payment, which was originally recognized in full during the quarterly period ended June 30, 2015, should instead be recognized, on a straight line basis, over the exclusivity period, currently 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

The correction of this accounting error has no effect on periods prior to the quarter ended June 30, 2015.

	As of September 30, 2015		
	As Previously Reported	Adjustments	As Restated
Condensed Consolidated Balance Sheet			
Deferred Revenues, Current	\$ 13,333	\$ 1,000,000	\$ 1,013,333
Deferred Revenues, Long Term	\$ 118,890	\$ 3,666,667	\$ 3,785,557
Accumulated deficit	\$ (136,943,114)	\$ (1,987,679 ) <sup>1</sup>	\$ (138,930,793)

F-9

	Six Months Ended September 30, 2015		
	As		
	Previously	Adjustments	As Restated
	Reported		Reported
Condensed Consolidated Statement of Operations			
Licensing fee	\$547,311	\$333,333	\$880,644
Product Development Licensing	\$5,000,000	\$(5,000,000)	\$—
Change in fair value of derivative liabilities	\$8,578,358	\$785,689 <sup>2</sup>	\$9,364,047
Change in carrying value of convertible preferred share mezzanine equity	2,142,857	(785,690)	1,357,167
Net Income (Loss) attributable to common shareholders	9,074,777	(4,594,668)	4,480,109
Net Income (Loss) Per Share			
Basic	\$0.01	\$—	\$0.01
Diluted	\$0.00	\$—	\$0.00

	Six Months Ended September 30, 2015		
	As		
	Previously	Adjustments	As Restated
	Reported		Reported
Condensed Consolidated Statement of Cash Flows			
Net Income (Loss)	\$6,931,921	\$(3,880,979)	\$3,050,942
Change in fair value of derivative liabilities	\$(8,578,358)	\$(785,689)	\$(9,364,047)
Change in deferred revenues and customer deposits	\$(6,667)	\$4,666,667	\$4,660,000
Net cash used in operating activities	\$(1,588,019)	\$—	\$(1,588,019)

Adjustments to accumulated deficit include those amounts relating to the correction of accounting error for the 1 convertible preferred stock (see below) as well as relating to the correction of accounting error for revenue recognition from the Epic Collaborative Agreement (see above).

<sup>2</sup>See below for details on correction to accounting error relating to convertible preferred shares

#### Accounting for convertible preferred shares prior to the quarter ended September 30, 2015

We determined that our accounting for Convertible Preferred Stock (“Preferred Derivatives”) for periods prior to the quarter ended September 30, 2015 was incorrect. Specifically, it has been determined the Preferred Derivatives which had originally been classified as derivative liabilities prior to the quarter ended September 30, 2015, should instead be accounted for as quasi equity instruments and recorded as mezzanine equity. In addition, the preferred derivatives which were recorded at fair value each reporting period, with changes recorded in net income, will instead be recorded at the maximum redemption amount each reporting period with changes recorded in additional paid in capital. Accordingly, the change in carrying value of the Preferred Derivatives, was originally included in the calculation of net income as well as the calculation of net income attributable to common shareholders prior to the quarter ended September 30, 2015, should instead be included only in the calculation of net income attributable to common shareholders. Accordingly, correction of this error in accounting has no effect on earnings per share.

In accordance with the guidance provided by the SEC's Staff Accounting Bulletin 99, *Materiality* ("SAB 99") and Staff Accounting Bulletin 108, *Considering the Effects of Prior Year Misstatements when Quantifying Misstatements in Current Year Financial Statements* ("SAB 108"), the Company has determined that the impact of adjustments relating to the corrections of this accounting error are not material to previously issued annual audited and unaudited consolidated financial statements. Accordingly, these changes are disclosed herein and will be disclosed prospectively.



	As of September 30, 2015		
	As Previously Reported	Adjustments	As Corrected
Condensed Consolidated Balance Sheet			
Additional paid-in capital	\$ 116,204,254	\$(2,678,989 )	\$ 113,525,265

	As of March 31, 2015		
	As Previously Reported	Adjustments	As Corrected
Condensed Consolidated Balance Sheet			
Derivative liabilities	\$ 52,762,573	\$(35,000,000)	\$ 17,762,573
Convertible preferred shares	\$—	\$ 35,000,000	\$ 35,000,000
Additional paid-in capital	\$ 161,021,568	\$(54,095,240)	\$ 106,926,328
Accumulated deficit	\$(196,076,975)	\$ 54,095,240	\$(141,981,735)

	Year Ended March 31, 2015		
	As Previously Reported	Adjustments	As Corrected
<u>Condensed Consolidated Statement of Operations</u>			
Change in fair value of derivative liabilities	\$ 25,602,370	\$(23,709,070)	\$ 1,893,300
Change in carrying value of convertible preferred share mezzanine equity	\$—	\$ 23,709,070	\$ 23,709,070
Net Income (Loss) Attributable to common shareholders	\$ 28,929,674	\$—	\$ 28,929,674
Net Income (Loss) Per Share			
Basic	\$ 0.05	\$—	\$ 0.05
Diluted	\$(0.02 )	\$—	\$(0.02 )

	Year Ended March 31, 2015		
	As Previously Reported	Adjustments	As Corrected
<u>Condensed Consolidated Statement of Cash Flows</u>			
Net Income (Loss)	\$ 28,929,674	\$—	\$ 28,929,674
Change in fair value of derivative liabilities	\$(25,602,370)	\$ 23,709,070	\$(1,893,300 )
Change in carrying value of convertible preferred share mezzanine equity	\$—	\$(23,709,070)	\$(23,709,070)
Net cash used in operating activities	\$(15,103,233)	\$—	\$(15,103,233)

**NOTE 5 - CASH AND CASH EQUIVALENTS**

Cash consists of cash on deposit with banks and money market instruments. The Company places its cash with high quality, U.S. financial institutions and, to date, has not experienced losses on any of its balances.

F-11

**NOTE 6 - INVENTORIES**

Inventories consist of raw materials, work in process and finished goods and are stated at the lower of cost (first-in, first-out basis) or market (net realizable value), and summarized as follows:

	September 30, 2015	March 31, 2015
Raw Materials	\$ 3,015,384	\$ 2,850,459
Work-in-Process	160,080	58,771
Finished Goods	177,849	122,772
Total Inventory	\$ 3,353,313	\$ 3,032,002

**NOTE 7 - NJEDA BONDS**

Bond financing consisting of the following, as of:

	September 30,	March 31,
	2015	2015
Refinanced NJEDA Bonds	\$ 2,065,000	\$2,275,000
Current portion	(220,000 )	(210,000 )
Long term portion, net of current maturities	\$ 1,845,000	\$2,065,000

Maturities of Bonds for the next five years are as follows:

YEAR ENDING SEPTEMBER 30,	AMOUNT
2016	\$220,000
2017	85,000
2018	90,000
2019	95,000
2020	105,000
Thereafter	1,470,000
	\$2,065,000

**NOTE 8 - INTANGIBLE ASSETS**

Costs to acquire intangible assets are capitalized and if such assets are determined to have a finite useful life, amortized to expense on a straight-line method over this finite useful life. Costs to acquire intangible assets that are determined to be indefinitely lived, such as Abbreviated New Drug Applications (“ANDA’s”) are capitalized, but not amortized to expense.

Patent application costs capitalized were incurred in relation to the Company’s abuse deterrent opioid technology. Amortization of such patent costs will begin upon the issuance of marketing authorization by the FDA of a product incorporating such patented technology and be calculated on a straight line basis through the expiry of the related patent(s).

All intangible assets are tested for impairment on at least an annual basis, or sooner should events or changes in circumstances occur that may indicate a potential impairment of a listed intangible asset.

F-12

As of September 31, 2015 and March 31, 2015, the following costs were recorded as intangible assets on the Company's balance sheet:

	September 30, 2015	March 31, 2015
Intangible assets at beginning of fiscal year		
Patent application costs	\$ 334,457	\$302,602
ANDA acquisitions	6,047,317	6,047,317
Less: Accumulated Amortization	—	—
Net Intangible Assets at beginning of fiscal year	\$ 6,381,774	\$6,349,917
Intangible asset costs capitalized during the fiscal year		
Patent application costs	\$ 17,893	\$31,855
ANDA acquisition costs	—	—
Total cost of intangible assets capitalized	\$ 17,893	\$31,855
Intangible assets at end of fiscal period		
Patent application costs	\$ 352,350	\$334,457
ANDA acquisitions	6,047,317	6,047,317
Less: Accumulated Amortization	—	—
Net Intangible Assets	\$ 6,399,667	\$6,381,774

#### **NOTE 9 - PROPERTY AND EQUIPMENTS**

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

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

As of September 31, 2015 and March 31, 2015, the following costs were recorded as Property and Equipment on the Company's balance sheet:

September 30, 2015	March 31, 2015
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Computer Equipment	\$ 135,003	\$ 132,917
Furniture and Fixtures	49,804	49,804
Land	300,000	300,000
Building Improvement	3,245,307	2,938,212
Lease Improvement	1,959,753	1,318,480
Lab Equipment	1,280,932	1,096,905
Manufacturing Equipment	6,664,696	6,179,960
Warehouse Equipment	168,342	316,351
Office Equipment	76,654	76,454
Vehicles	66,855	66,855
Total	13,947,346	\$ 12,475,938
Less: Accumulated depreciation and amortization	6,392,827	6,074,136
Property and equipment, net	\$ 7,554,519	\$ 6,401,802

Depreciation Expense for six months ended on September 30, 2015 and 2014 was \$318,711 and \$463,609 respectively.

Fixed assets with a cost of \$1.96 million have not yet been placed in service as of the Current Balance Sheet Date.

**NOTE 10 - LOANS PAYABLE**

During the ordinary course of business, the Company has secured loans to support the collateralized financing of fixed asset acquisitions, or the renewal of insurance policies. During the six months ended September 30, 2015, the Company has secured such loans with initial principal amounts totaling \$66k and with payment terms of 60 months.

Loans Payable consisted of the following as of:

	<b>September 30,</b>	<b>March 31,</b>
	<b>2015</b>	<b>2015</b>
Total loans	\$ 742,716	\$ 825,503
Current Portion	251,835	265,165
Long-term portion, net of current maturities	\$ 490,881	\$ 560,338

Principal payments on loans for 12 months ending September 30:

2016	\$251,835
2017	228,006
2018	114,994
2019	105,148
2020	42,733
Thereafter	—
Total Principal Payments	\$742,716

**NOTE 11 - WARRANT DERIVATIVE LIABILITIES**

Accounting Standard Codification “ASC” 815 – *Derivatives and Hedging*, which provides guidance on determining what types of instruments or embedded features in an instrument issued by a reporting entity can be considered indexed to its own stock for the purpose of evaluating the first criteria of the scope exception in the pronouncement on accounting for derivatives. These requirements can affect the accounting for warrants issued by the Company. As the warrants issued by the Company do not have fixed settlement provisions because their exercise prices may be lowered if the Company issues securities at lower prices in the future, we have concluded that the instruments are not indexed to the Company’s stock and are to be treated as derivative liabilities.

The portion of derivative liabilities related to outstanding warrants was valued using the Black-Scholes option valuation model and the following assumptions on the following dates:

FAIR VALUE OF WARRANT DERIVATIVE LIABILITY

**September 30,    March 31,**

	<b>2015</b>	<b>2015</b>
Risk-Free interest rate	0.1% - 0.9%	0.05% - 0.89%
Expected volatility	68% - 95%	93% - 113%
Expected life (in years)	0.0 – 2.6	1.2 – 3.1
Expected dividend yield	—	—
Number of warrants	52,617,955	89,870,034
Fair Value of Warrant Derivative Liability	\$9,184,206	\$17,762,573

CHANGE IN VALUE OF WARRANT DERIVATIVE LIABILITY

**Three months ended                      Six months ended**

	<b>September 30</b>		<b>September 30</b>	
	2015	2014	2015	2014
Change in Warrant Derivative Liability	\$(2,149,787)	\$10,379,665	\$(9,364,047)	\$11,121,624



The risk free interest rate was based on rates established by the U.S. Treasury Department. The expected volatility was based on the historical volatility of the Company's share price for periods equal to the expected life of the outstanding warrants at each valuation date. The expected dividend rate was based on the fact that the Company has not historically paid dividends on common stock and does not expect to pay dividends on common stock in the future.

**NOTE 12 - MEZZANINE EQUITY - CONVERTIBLE PREFERRED SHARES**

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:

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, (in a manner similar to the treatment of dividends paid on preferred stock), in arriving at income available to common stockholders used in the calculation of earnings per share.

**CONVERTIBLE PREFERRED MEZZANINE  
EQUITY**

**March 31,**

	<b>September 30, 2015</b>	<b>2015</b>
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	\$ 0.2300	\$ 0.2450
<b>Carrying value of convertible preferred mezzanine equity</b>	<b>\$ 32,857,143</b>	<b>\$ 35,000,000</b>

F-15

	(Increase)/Decrease in Value of Convertible Preferred Stock			
	Three Months Ended Sept 30,		Six Months Ended Sept 30,	
	2015	2014	2015	2014
Series I Preferred	\$ (4,285,714 )	\$ 15,131,571	\$ 2,142,857	\$ 12,823,355

**NOTE 13 - OPERATING LEASES**

The Company entered into a lease for a portion of a one-story warehouse, located at 135-137 Ludlow Avenue, Northvale, New Jersey, consisting of approximately 15,000 square feet of floor space. The lease term began on July 1, 2010.

On July 29, 2014, the Company modified this operating lease, with the material terms of the modification including the Company being permitted to occupy the entire 35,000 square feet in the building.

The lease terms, as modified, include an initial term that expires on December 31, 2016, and the Company has the option to renew the lease for two additional terms of five years each. The lease is classified as an operating lease.

The property related to this lease is used for the storage of pharmaceutical finished goods, raw materials, equipment and documents, as well as a site at which the Company engages in manufacturing packaging and distribution activities, inclusive of regulatory support and compliance activities.

Minimum 5 year payments\* for the initial term for the leasing of 35,000 square feet at 135 Ludlow are as follows:

12 Months Ending September 30,	Amount
2016	\$205,878
2017	51,723
2018	—
2019	—
2020	—
Total Minimum 5 year lease payments	\$257,601

\* Minimum lease payments are exclusive of additional expenses related to certain expenses incurred in the operation and maintenance of the premises, including, without limitation, real estate taxes and common area charges which may be due under the terms and conditions of the lease, but which are not quantifiable at the time of filing of this quarterly report on Form 10-Q.

Rent expense relating to the operating lease is recorded using the straight line method, and is summarized as follows:

	RENT EXPENSE			
	Three months ended		<b>Six months ended</b>	
	September 30,		<b>September 30,</b>	
	2015	2014	2015	2014
Rent Expense	\$45,214	\$45,214	\$90,427	\$63,003
Change in deferred rent liability	\$(5,496 )	\$24,010	\$(10,991)	\$20,595

DEFERRED RENT LIABILITY (LONG-TERM LIABILITY)		
	<b>June 30</b>	<b>September 30</b>
	<b>2015</b>	<b>2015</b>
Balance of Deferred Rent Liability	\$ 37,027	\$ 31,533

**NOTE 14 - COMMON STOCK**

During the Current YTD, the Company issued shares of Common Stock, as follows:

Description	Shares Of Common Stock
Common shares sold pursuant to the LPC-40 Purchase Agreement	13,155,283
Common shares issued as commitment shares pursuant to the LPC-40 Purchase Agreement	134,047
Common shares issued pursuant to the exercise of cash warrants	37,252,079
Common Shares issued in payment of employee salaries	54,169
Total Common Shares issued during the Current YTD	50,595,578

**Options**

**Options issued and outstanding as of the Current Balance Sheet Date are summarized as follows:**

	Number of Options	Range of Exercise Prices
Vested Options	4,355,500	\$0.07 to \$2.50
Non-Vested Options	3,226,667	\$0.07 to \$0.46

Each option represents the right to purchase one share of common stock. The non-vested options are scheduled to vest in various increments during dates that are within the period beginning on July 23, 2016 and through October 20, 2017, or upon the occurrence of certain defined events and require that employees awarded such options be employed

by the Company on the vesting date.

**NOTE 15 - PER SHARE INFORMATION**

Basic earnings per share of common stock (“Basic EPS”) is computed by dividing the net (loss) income by the weighted-average number of shares of common stock outstanding. Diluted earnings per share of common stock (“Diluted EPS”) are computed by dividing the net (loss) income by the weighted-average number of shares of common stock, and dilutive common stock equivalents and convertible securities then outstanding. GAAP requires the presentation of both Basic and Diluted EPS, if such Diluted EPS is not anti-dilutive, on the face of Company’s Condensed Statements of Operations.

F-17

The calculation of Basic EPS and Diluted EPS is summarized as follows:

	<b>For the Three Months</b>		<b>For the Six Months</b>	
	<b>Ended September 30</b>		<b>Ended September 30</b>	
	2015	2014	2015	2014
<b>Numerator</b>				
Net Income (loss) attributable to common shareholders – Basic	\$(6,752,782 )	\$21,379,824	\$4,408,109	\$16,978,014
Effect of dilutive instruments on Net Income	2,921,619	(25,511,236 )	(10,721,215 )	(23,944,980 )
Net Income (loss) attributable to common shareholders - Diluted	\$(3,831,163 )	\$(4,131,412 )	\$(6,313,106 )	\$(6,966,966 )
<b>Denominator</b>				
Weighted-average shares of common stock outstanding – basic	665,330,431	577,691,292	656,141,476	565,150,231
Dilutive effect of stock options, warrants and convertible securities	158,164,848	162,178,204	158,164,848	168,761,897
Weighted average shares of common stock outstanding – diluted	823,495,279	739,869,496	814,306,324	733,912,128
<b>Net (loss) income per share</b>				
Basic	\$(0.01 )	\$0.04	0.01	\$0.03
Diluted	\$(0.00 )	\$(0.01 )	\$(0.01 )	\$(0.01 )

#### **NOTE 16 - COLLABORATIVE AGREEMENT WITH EPIC PHARMA LLC**

On June 4, 2015, the Company entered into the Epic Collaborative Agreement, which provides for the exclusive right to product development sales and distribution by Epic Pharma LLC (“Epic”) of ELI-200, an abuse deterrent opioid which employs the Company’s proprietary pharmacological abuse-deterrent technology. Epic will be responsible for payment of product development costs, sales and marketing of ELI-200, and Elite will be responsible for the manufacture of the product. Under the Epic Collaborative 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 net product sales. 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.

During the three months ended June 30, 2015, Elite received non-refundable payments totaling \$5 million from Epic for the exclusive right to product development sales and distribution of ELI-200 pursuant to the Epic Collaborative Agreement, under which it agreed to not permit marketing or selling of ELI-200 within the United States of America to any other party. Such exclusive rights are considered a 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.

Additional payments under the Epic Collaborative Agreement will be recognized as the defined elements are completed and collectability is reasonably assured.

F-18



**NOTE 17 - RELATED PARTY TRANSACTION AGREEMENTS**

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.

On June 4, 2015, the Company entered into the Epic Collaborative Agreement (please see Note 16 above)

The Epic Collaborative 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 Epic Collaborative 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 Epic Collaborative 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. There can be no assurances of the Company filing an NDA and receiving marketing authorization for ELI-200, and accordingly, there can be no assurances that the Company will earn and receive the additional \$10 million or future license fees. If the Company does not receive these payments or fees, it most likely 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 which are based

on profits achieved from commercial sales of the products. 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 Epic Collaborative 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 ELI-200 and the twelve ANDA's owned by the Company, including the various combinations of sites of manufacture and marketing options;

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

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

Stage of development of ELI-200 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 ELI-200 and the manufacture/marketing of the twelve generics related to the Epic Generic Agreement.

#### **NOTE 18 - MANUFACTURING, LICENSE AND DEVELOPMENT AGREEMENTS**

The Company has entered into the following 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")

Development and license agreement with a private, Hong Kong based company, dated March 16, 2012 (the "Hong Kong Development 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.

F-20

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

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

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

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

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

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

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

Stage of development of each generic 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 Hong Kong Development Agreement provides for Elite to develop a branded prescription pharmaceutical product (the “Prescription Product”) for a private Hong Kong-based company (the “Hong Kong Customer”). There is currently no development activity being conducted pursuant to this agreement, and there was no activity conducted 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.

F-21

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 19 - SALE OF INVESTMENT IN NOVEL LABORATORIES**

At the end of 2006, Elite entered into a joint venture with VGS Pharma, LLC (“VGS”) and created Novel Laboratories, Inc. (“Novel”), a privately-held company specializing in pharmaceutical research, development, manufacturing, licensing, acquisition and marketing of specialty generic pharmaceuticals.

On June 10, 2014, the Company received \$5 million in exchange for its investment in Novel’s Class A Voting Common Stock.

#### **NOTE 20 - CONCENTRATIONS**

##### Revenue Concentrations

Three customers accounted for approximately 90% of the Company’s revenues for the six months ended September 30, 2015. Included in these are three customers that accounted for approximately 54%, 24% and 19% of revenues each, respectively.

Three customers accounted for more than 90% of the Company’s revenues for the six months ended September 30, 2014. Included in these are three customers that accounted for approximately 60%, 18% and 60% of revenues each, respectively.

##### Accounts Receivable Concentrations

Two customers accounted for more than 90% of the Company’s accounts receivable as of September 30, 2015. Included in these are two customers that accounted for approximately 56% and 36% of accounts receivable, respectively.

Three customers accounted for more than 90% of the Company's accounts receivable as of September 30, 2014. Included in these are three customers that accounting for approximately 44%, 36% and 10% of accounts receivable, respectively.

Purchasing Concentrations

Five suppliers accounted for more than 80% of the Company's purchases of raw materials for the six months ended September 30, 2015. Included in these five suppliers are two suppliers that accounted for approximately 44% and 17% of raw material purchases for the period, respectively.

Five suppliers accounted for more than 80% of the Company's purchases of raw materials for the six months ended September 30, 2014. Included in these five suppliers are three suppliers that accounted for approximately 44%, 14% and 11% of raw material purchases for this period, respectively.



**NOTE 21 - LEGAL PROCEEDINGS**

In the ordinary course of business we may be subject to litigation from time to time. Except as discussed below, there is no current, pending or, to our knowledge, threatened litigation or administrative action to which we are a party or of which our property is the subject (including litigation or actions involving our officers, directors, affiliates, or other key personnel, or holders of record or beneficially of more than 5% of any class of our voting securities, or any associate of any such party) which in our opinion has, or is expected to have, a material adverse effect upon our business, prospects financial condition or operations.

**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 denies 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. As of the date of filing of this current report on Form 10-Q 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. The Company has notified the Arbitrator of this settlement and is awaiting the Arbitrators issuance of the proceeding termination document.

GAAP requires that a contingency loss may only be recognized if the event is (1) probable and (2) the amount of the loss can be reasonably estimated. There were no liabilities of this type at September 30, 2015.

**NOTE 22 - EQUITY LINE WITH LINCOLN PARK CAPITAL FUND LLC**

On April 10, 2014, we entered into a purchase agreement (the "LPC-40 Purchase Agreement"), together with a registration rights agreement (the "Registration Rights Agreement"), with Lincoln Park Capital Fund, LLC ("Lincoln Park").

Under the terms and subject to the conditions of the LPC-40 Purchase Agreement, the Company has the right to sell to and Lincoln Park is obligated to purchase up to \$40 million in shares of the Company's common stock ("Common Stock"), subject to certain limitations, from time to time, over the 36-month period commencing on the date that a registration statement, which the Company agreed to file with the SEC pursuant to the Registration Rights Agreement,

is declared effective by the SEC and a final prospectus in connection therewith is filed. The Company may direct Lincoln Park, at its sole discretion and subject to certain conditions, to purchase up to 500,000 shares of Common Stock on any business day, provided that at least one business day has passed since the most recent purchase, increasing to up to 800,000 shares, depending upon the closing sale price of the Common Stock (such purchases, "Regular Purchases"). However, in no event shall a Regular Purchase be more than \$760,000. The purchase price of shares of Common Stock related to the future funding will be based on the prevailing market prices of such shares at the time of sales, 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 as set forth in the LPC-40 Purchase Agreement. In addition, the Company may direct Lincoln Park to purchase additional amounts as accelerated purchases if on the date of a Regular Purchase the closing sale price of the Common Stock is not below the threshold price as set forth in the LPC-40 Purchase Agreement. 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 the Common Stock.

F-23

In connection with the LPC-40 Purchase Agreement, the Company issued to Lincoln Park 1,928,641 shares of Common Stock and is required to issue up to 1,928,641 additional shares of Common Stock pro rata as the Company requires Lincoln Park to purchase the Company's shares under the Purchase Agreement over the term of the agreement. Lincoln Park represented to the Company, among other things, that it was an "accredited investor" (as such term is defined in Rule 501(a) of Regulation D under the Securities Act of 1933, as amended (the "Securities Act")), and the Company sold the securities in reliance upon an exemption from registration contained in Section 4(2) under the Securities Act. The securities sold may not be offered or sold in the United States absent registration or an applicable exemption from registration requirements.

The LPC-40 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 LPC-40 Purchase Agreement at any time, at no cost or penalty. Actual sales of shares of Common Stock to Lincoln Park under the LPC-40 Purchase Agreement will depend on a variety of factors to be determined by the Company from time to time, including, among others, market conditions, the trading price of the Common Stock and determinations by the Company as to the appropriate sources of funding for the Company and its operations. There are no trading volume requirements or restrictions under the LPC-40 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 LPC-40 Purchase Agreement. Lincoln Park has covenanted not to cause or engage in any manner whatsoever, any direct or indirect short selling or hedging of our shares.

The net proceeds under the LPC-40 Purchase Agreement to the Company will depend on the frequency and prices at which the Company sells shares of its stock to Lincoln Park. The Company expects that any proceeds received by the Company from such sales to Lincoln Park under the Purchase Agreement will be used for general corporate purposes and working capital requirements.

A Registration Statement on Form S-1 was filed with the SEC in relation to this transaction with Lincoln Park and it was declared effective by the SEC as of May 1, 2014. A post-effective amendment to the Registration Statement was subsequently filed with the SEC and declared effective on July 1, 2014.

During the six months ended September 30, 2015, a total of 13,155,283 shares of Common Stock were sold to Lincoln Park pursuant to the Purchase Agreement, with the proceeds of such sales of Common Stock totaling \$2,780,142. An additional 134,047 shares of Common Stock were issued to Lincoln Park during this same period with such shares constituting additional commitment shares issued pursuant to the Purchase Agreement.

During the six months ended September 30, 2014, a total of 19,004,103 shares of Common Stock were sold to Lincoln Park pursuant to the Purchase Agreement, with the proceeds of such sales of Common Stock totaling \$6,227,485. An

additional 300,269 shares of Common Stock were issued to Lincoln Park during this same period with such constituting initial commitment shares and additional commitment shares issued pursuant to the Purchase Agreement.

**NOTE 23 - SUBSEQUENT EVENTS**

**Common shares issued pursuant to the strategic alliance agreement with Epic Investments LLC.**

A total of 3 million shares of Common Stock were issued to Epic Investments LLC pursuant to the Strategic Alliance Agreement dated March 18, 2009, as amended on April 30, 2009, June 1, 2009, and July 28, 2009 (the “Epic Strategic Alliance”), upon Epic’s notification to the Company of the FDA’s approval of the ANDA filed by Epic for immediate release oxycodone tablets. This product was developed at the Northvale facility. As per the Epic Strategic Alliance, Elite is entitled to 15% of the profits achieved from the commercial sales of this product for a 10 year period commencing on the date of first commercial shipment and Epic is to receive 3 million shares of Common Stock upon approval by the FDA of the ANDA.

**ITEM 2.**

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

**THREE AND SIX MONTHS ENDED SEPTEMBER 30, 2015 (RESTATED)**

**COMPARED TO THE**

**THREE AND SIX MONTHS ENDED SEPTEMBER 30, 2014 (RESTATED)**

**(UNAUDITED)**

The following discussion and analysis should be read with the financial statements and accompanying notes included elsewhere in this Form 10-Q and in the Annual Report on Form 10-K for the year ended March 31, 2015. It is intended to assist the reader in understanding and evaluating our financial position.

*This Quarterly Report on Form 10-Q and the documents incorporated herein contain "forward-looking statements". Such forward-looking statements involve known and unknown risks, uncertainties and other factors which may cause the actual results, performance or achievements of the Company, or industry results, to be materially different from any future results, performance or achievements expressed or implied by such forward-looking statements. When used in this Form 10-Q, statements that are not statements of current or historical fact may be deemed to be forward-looking statements. Without limiting the foregoing, the words "plan", "intend", "may," "will," "expect," "believe", "could," "anticipate," "estimate," or "continue" or similar expressions or other variations or comparable terminology are intended to identify such forward-looking statements. All statements other than statements of historical fact included in this Form 10-Q regarding our financial position, business strategy and plans or objectives for future operations are forward-looking statements. Without limiting the broader description of forward-looking statements above, we specifically note, without limitation, that statements regarding the preliminary nature of the clinical program results and the potential for further product development, that involve known and unknown risks, delays, uncertainties and other factors not under our control, the requirement of substantial future testing, clinical trials, regulatory reviews and approvals by the Food and Drug Administration and other regulatory authorities prior to the commercialization of products under development, and our ability to manufacture and sell any products, gain market acceptance, earn a profit from sales or licenses of any drugs or our ability to discover new drugs in the future, are all forward-looking in nature. These risks and other factors are discussed in our filings with the Securities and Exchange Commission. Readers are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof. Except as required by law, the Company undertakes no obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise.*

*Any reference to “Elite”, the “Company”, “we”, “us”, “our” or the “Registrant” refers to Elite Pharmaceuticals Inc. and its subsidiaries.*

## **Overview**

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. Our strategy includes improving off-patent drug products for life cycle management and developing generic versions of controlled-release drug products with high barriers to entry.

We own and 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

Elite is focusing its efforts on the following areas: (i) development of Elite’s pain management products; (ii) manufacturing of a line of generic pharmaceutical products with approved 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.

Elite is focusing 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.

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

## Commercial Products

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

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

(“Phendimetrazine 35mg”) Phentermine HCl 15mg and 30mg capsules	Adipex-P®	Bariatric	April 2013
(“Phentermine 15mg” and “Phentermine 30mg”) Naltrexone HCl 50mg tablets	Revia®	Pain	September 2013
(“Naltrexone 50mg”) Isradipine 2.5mg and 5mg capsules	n/a	Cardiovascular	January 2015
(“Isradipine 2.5mg” and “Isradipine 5mg”) Hydroxyzine HCl 10mg, 25mg and 50mg tablets	Atarax®, Vistaril®	Antihistamine	April 2015
(“Hydroxyzine 10mg” and “Hydroxyzine 25mg” and “Hydroxyzine 50mg”)			

*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”.*

**Phentermine 37.5mg**

The approved Abbreviated New Drug Application “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”). For further details on the Phentermine Purchase Agreement, please see exhibit 10.7 to the Quarterly Report on Form 10-Q, filed with the SEC on November 15, 2010, with such filing being herein incorporated by reference.



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® Immediate Release capsules**

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.

ECR products have since been divested so that Lodrane D® is promoted and distributed in the 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.

Lodrane D® is marketed under the Over-the-Counter Monograph (the “OTC Monograph”) and accordingly, under the Code of Federal Regulations can be lawfully marketed in the US without prior approval. Under the Federal Food Drug and Cosmetic Act (“FDCA”), FDA regulations and statements of FDA policy, certain drug products are permitted to be marketed in the U.S. without prior 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.

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 revenues for the manufacturing, packaging and laboratory stability study services for the product, as well as royalties on sales.

**Methadone 10mg tablets**

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 tablets**

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

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

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

### **Phendimetrazine Tartrate 35mg tablets**

The ANDA for Phendimetrazine 35mg was acquired by Elite as part of the asset purchase agreement between the Company and Mikah Pharma, dated August 1, 2013 (the “Mikah ANDA Purchase”). Please see “Elite’s Acquisition of 13 Abbreviated New Drug Applications (“ANDAs”)” below for more information on this agreement. The Northvale Facility was already an approved manufacturing site for this product as of the date of the Mikah ANDA Purchase. Prior to the acquisition of this ANDA, Elite had been manufacturing this product on a contract basis pursuant to a manufacturing and supply agreement with Mikah Pharma, dated June 1, 2011.

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

### **Phentermine 15mg and 30mg capsules**

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

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

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

**Naltrexone 50mg**

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

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

**Isradipine 2.5mg and Isradipine 5mg**

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

Sales and marketing rights for Isradipine 2.5mg and Isradipine 5mg are included in the manufacturing and license agreement between the Company and Epic Pharma LLC, dated October 2, 2013 (the “Epic Manufacturing and License Agreement”). Please see the section below titled “Epic Manufacturing and License Agreement” for further details of this agreement.

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

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

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

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

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

### **Approved products not yet commercialized**

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

### **Asset Acquisition Agreements**

#### **Elite's Purchase of a Generic Phentermine Product**

On September 10, 2010, Elite, together with its subsidiary, Elite Laboratories, Inc., executed a Purchase Agreement (the "Phentermine Purchase Agreement") with Epic Pharma, LLC ("Epic") for the purpose of acquiring from Epic an ANDA for a generic phentermine product (the "Phentermine ANDA"), with such being filed with the FDA at the time the Phentermine Purchase Agreement was executed. On February 4, 2011, the FDA approved the Phentermine

ANDA. The acquisition of the Phentermine ANDA closed on March 31, 2011 and Elite paid the full acquisition price of \$450,000 from the purchase agreement with Epic Pharma.

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

#### **Elite’s Purchase of a Generic Hydromorphone HCl Product**

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

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

### **Elite's Purchase of a Generic Naltrexone Product**

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

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

### **Elite's Acquisition of 13 Abbreviated New Drug Applications**

On August 1, 2013, Elite executed an asset purchase agreement (the "Mikah ANDA Purchase") with Mikah and acquired from Mikah a total of 13 ANDAs, consisting of 12 ANDAs approved by the FDA and one ANDA under active review with the FDA, and all amendments thereto (the "Mikah 13 ANDA Acquisition") for aggregate consideration of \$10,000,000, payable pursuant to a secured convertible note due in August 2016.

Each of the products referenced in the 12 approved ANDAs require manufacturing site approval with the FDA. Elite believes that the site transfers qualify for CBE 30 review, with one exception, which would allow for the product manufacturing transfer on an expedited basis. However, Elite can give no assurances that all will qualify for CBE 30 review, or on the timing of these transfers of manufacturing site, or on the approval by the FDA of the transfers of manufacturing site.

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

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

Elite has executed a Manufacturing and License Agreement with Epic Pharma dated October 2, 2013 (the "Epic Pharma Manufacturing and License Agreement"), relating to the manufacturing, marketing and sale of these 12 ANDAs. Please see below for further details on the Epic Pharma Manufacturing and License Agreement.

## **Licensing, Manufacturing and Development Agreements**

### **Sales and Distribution Licensing Agreement with Epic for Abuse-Deterrent ELI-200**

On June 4, 2015, Elite Pharmaceuticals Inc. and its wholly-owned subsidiary Elite Laboratories, Inc. (collectively, “Elite”) executed an exclusive License Agreement (the “Agreement”) with Epic Pharma LLC. (“Epic”), to market and sell in the United States, ELI-200, an undisclosed opioid with sequestered naltrexone capsules, owned by Elite. Epic will have the exclusive right to market ELI-200 and its various dosage forms as listed in Schedule A of the Agreement (the “Products”). Epic is responsible for all regulatory and pharmacovigilance matters related to the products. Pursuant to the 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, the filing of a New Drug Application (“NDA”) with the U.S. Food and Drug Administration (“FDA”) and the receipt of the approval letter for the NDA from the FDA. In addition, Elite will receive a license fee computed as a percentage of net sales of the Products as defined in the Agreement. Elite will manufacture the product for sale by Epic on a cost plus basis and both parties agree to execute a separate Manufacturing and Supply Agreement. The license fee is payable quarterly for the term of the Agreement. The term of the License Agreement is five years and may be extended for an additional five years upon mutual agreement of the parties. Elite can terminate the Agreement on 90 days’ written notice in the Event that Epic does not pay to Elite certain minimum annual license fees over the initial five year term of the Agreement. Either party may terminate this Agreement upon a material breach and failure to cure that breach by the other party within a specified period.



### **Manufacturing and License Agreement with Epic Pharma LLC**

On October 2, 2013, Elite executed the Epic Pharma Manufacturing and License Agreement (the “Epic Generic Agreement”). This agreement granted Epic Pharma certain rights to manufacture, market and sell in the United States and Puerto Rico the 12 approved ANDAs acquired by Elite pursuant to the Mikah Purchase Agreement. Of the 12 approved ANDAs, Epic Pharma will have the exclusive right to market six products as listed in Schedule A of the Epic Pharma Manufacturing and License Agreement, and a non-exclusive right to market six products as listed in Schedule D of the Epic Pharma Manufacturing and License Agreement. Epic Pharma will manufacture the products and Epic is responsible for all regulatory and pharmacovigilance matters related to the products and for all costs related to the site transfer for all products. Elite has no further obligations or deliverables under the Epic Generic Agreement. Pursuant to the Epic Generic Agreement, Elite will receive a license fee and milestone payments. The license fee will be computed as a percentage of the gross profit, as defined in the Epic Pharma Manufacturing and License Agreement, earned by Epic Pharma a result of sales of the products. The manufacturing cost used for the calculation of the license fee is a predetermined amount per unit plus the cost of the drug substance (API) and the sales cost for the calculation is predetermined based on net sales. If Elite manufactures any product for sale by Epic Pharma, then Epic Pharma shall pay to Elite that same predetermined manufacturing cost per unit plus the cost of the API. The license fee is payable monthly for the term of the Epic Pharma Manufacturing and License Agreement. Epic Pharma shall pay to Elite certain milestone payments as defined by the Epic Pharma Manufacturing and License Agreement. To date, milestones totaling \$1,000,000 have been earned and received in relation to the signing of the Epic Pharma Manufacturing and License Agreement and the filing and approval by the FDA of supplements relating to the transfer of manufacturing site for Isradipine 2.5mg and Isradipine 5mg. The term of the Epic Pharma Manufacturing and License Agreement is five years and may be extended for an additional five years upon mutual agreement of the parties. Twelve months following the launch of a product covered by the Epic Pharma Manufacturing and License Agreement, Elite may terminate the marketing rights for any product if the license fee paid by Epic Pharma falls below a designated amount for a six month period of that product. Elite may also terminate the exclusive marketing rights if Epic Pharma is unable to meet the annual unit volume forecast for a designated product group for any year, subject to the ability of Epic Pharma, during the succeeding six month period, to achieve at least one-half of the prior year’s minimum annual unit forecast. The Epic Pharma Manufacturing and License Agreement may be terminated by mutual agreement of Elite and Epic Pharma, as a result of a breach by either party that is not cured within 60 days notice of the breach, or by Elite as a result of Epic Pharma becoming a party to a bankruptcy, reorganization or other insolvency proceeding that continues for a period of 30 days or more.

### **Methadone Manufacturing and Supply Agreement**

On June 23, 2011 and as amended on September 24, 2012 and January 19, 2015, Elite entered into an agreement to manufacture and supply Methadone 10mg to ThePharmaNetwork LLC (the “Methadone Manufacturing and Supply Agreement”). ThePharmaNetworkLLC was subsequently acquired by Alkem Laboratories Ltd (“Alkem”) and now goes by the name Ascend Laboratories LLC (“Ascend”) and is a wholly owned subsidiary of Alkem.

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

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

**Licensing Agreement with Precision Dose Inc.**

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

Pursuant to the Precision Dose License Agreement, Elite will receive a license fee and milestone payments. The license fee will be computed as a percentage of the gross profit, as defined in the Precision Dose License Agreement, earned by Precision Dose as a result of sales of the products. The license fee is payable monthly for the term of the Precision Dose License Agreement. The milestone payments will be paid in six installments. The first installment was paid upon execution of the License Agreement. The remaining installments are to be paid upon FDA approval and initial shipment of the products to Precision Dose. The term of the License Agreement is 15 years and may be extended for 3 successive terms, each of 5 years. Please see Part II, Item 1, Legal Proceedings below for details of an arbitration proceeding commenced by Precision Dose related to certain terms and conditions of the Precision Dose License Agreement.

### **Development agreement with Akorn Pharmaceuticals**

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

Please note that there can be no assurances that the development program will result in an intermediate product that can be incorporated into a final product. There can be no assurances that an ANDA will be filed by Akorn or its designees or that any such ANDA filed will receive marketing approval by the FDA. Furthermore, there can be no assurances of the commercialization of a final product containing the intermediate relating to this agreement or that such commercialization will result in profits being generated from the sale of the product.

For further details, please refer to the Current Report on Form 8-K filed with the SEC on January 10, 2011, such filing being herein incorporated by reference.

### **Products Under Development**

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

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

The first product to utilize our abuse deterrent technology, ELI-200, has successfully completed Phase III studies, and, subject to the risks described below, the Company believes that it will be able to file a New Drug Application ("NDA") with the FDA during this fiscal year. The Company believes that, when this application is accepted by the FDA and subject to the risks described below, it will be granted expedited review by the FDA, and accordingly believes that any such approval could be received during the fiscal year ended March 31, 2017.

The Company believes that the abuse deterrent technology can be applied to and incorporated into a wide range of opioids used today for pain management and has, to date, identified 10 additional products for potential development. All of these products are at early stages of development, with research and development activities mainly consisting of in-house process development and laboratory studies. Extensive efficacy and safety studies, similar to those conducted for ELI-200 have not yet been conducted for these other products. As a result, costs incurred in relation to the development of these 10 products have not been material.

Research and development costs were \$6.6 million for the six months ended September 30, 2015 and \$14.8 million and \$4.0 million for the fiscal years ended March 31, 2015 and 2014, respectively, with such costs relating almost entirely to the development of ELI-200, the first product developed by Elite that incorporates the technology.

On June 4, 2015, the Company entered into a sales and distribution licensing agreement which included a payment of \$5 million to Elite for prior research and development activities, with such representing the first material net cash inflows being generated by ELI-200. The agreement also includes an additional \$10 million to be paid upon the filing with and approval by the FDA of the NDA, and license fees based on the commercial sales achieved by ELI-200, once marketing authorization has been granted by the FDA. Please note, as further detailed below, there can be no assurances of the Company filing an NDA and receiving marketing authorization for ELI-200, and accordingly, there can be no assurances that the Company will earn and receive the additional \$10 million or future license fees. If the Company does not receive these payments or fees, it most likely will materially adversely affect our financial condition.

Please note that, while the FDA is required to review applications within certain timeframes, during the review process, the FDA frequently requests that additional information be submitted. The effect of such request and subsequent submission can significantly extend the time for the NDA review process. Until an NDA is actually approved, there can be no assurances that the information requested and submitted will be considered adequate by the FDA to justify approval. The packaging and labeling of our developed products are also subject to FDA regulation. Based on the foregoing, it is impossible to anticipate the amount of time that will be needed to obtain FDA approval to market any product. In addition, there can be no assurances of the Company filing the required application(s) with the FDA or of the FDA approving such application(s) if filed, and the Company's ability to successfully develop and commercialize products incorporating its abuse deterrent technology is subject to a high level of risk as detailed in "Item 1A-Risk Factors-Risks Related to our Business" of this Annual Report on Form 10-K filed with SEC on June 15, 2015.

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

The abuse-deterrent opioid products utilize our patented abuse-deterrent technology that is based on a pharmacological approach. These products are combinations of a narcotic agonist formulation intended for use in patients with pain, and an antagonist, formulated to deter abuse of the drug. Both, agonist and antagonist, have been on the market for a number of years and sold separately in various dose strengths. Elite has filed INDs for two abuse

resistant products under development and has tested products in various pharmacokinetic studies. Elite expects to continue to develop multiple abuse resistant products. Products utilizing the pharmacological approach to deter abuse such as Suboxone®, a product marketed in the United States by Reckitt Benckiser Pharmaceuticals, Inc., and Embeda®, a product marketed in the United States by Pfizer, Inc., have been approved by the FDA and are being marketed in the United States.

Elite has developed, and retains the rights to these abuse resistant and sustained release opioid products. Elite may license these products at a later date to a third party who could provide funding for the remaining clinical studies and who could provide sales and distribution for the product.

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

## Patents

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

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

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

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

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

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



We also rely upon unpatented proprietary and trade secret technology that we seek to protect, in part, by confidentiality agreements with our collaborative partners, employees, consultants, outside scientific collaborators, sponsored researchers, and other advisors. There can be no assurance that these agreements provide meaningful protection or that they will not be breached, that we will have adequate remedies for any such breach, or that our trade secrets, proprietary know-how, and technological advances will not otherwise become known to others. In addition, there can be no assurance that, despite precautions taken by us, others have not and will not obtain access to our proprietary technology.

### **Trademarks**

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

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

Management's discussion addresses our Consolidated Financial Statements, which have been prepared in accordance with accounting principles generally accepted in the United States of America. The preparation of these financial statements requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of financial statements and the reported amounts of revenues and expenses during the reporting period. On an ongoing basis, management evaluates its estimates and judgment, including those related to bad debts, intangible assets, income taxes, workers compensation, and contingencies and litigation. Management bases its estimates and judgments on historical experience and on various other factors that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

Management believes the following critical accounting policies, among others, affect its more significant judgments and estimates used in the preparation of its Consolidated Financial Statements. Our most critical accounting policies include the recognition of revenue upon completion of certain phases of projects under research and development contracts. We also assess a need for an allowance to reduce our deferred tax assets to the amount that we believe is more likely than not to be realized. We assess the recoverability of inventory, long-lived assets and intangible assets whenever events or changes in circumstances indicate that the carrying value of the asset may not be recoverable. We assess our exposure to current commitments and contingencies. It should be noted that actual results may differ from these estimates under different assumptions or conditions.

### **Results of Consolidated Operations**

**Three Months Ended September 30, 2015 Compared to Three Months Ended September 30, 2014**

Our revenues for the three months ended September 30, 2015 were \$2,947k, an increase of \$1,691k or approximately 135% over revenues for the comparable period of the prior year, and consisted of \$2,553k in manufacturing fees and \$393k in licensing fees. Revenues for the three months ended September 30, 2014, consisted of \$851k in manufacturing fees and \$405k in licensing fees.

Manufacturing fees Increased by \$1,702k, or approximately 200%, mostly due to the continued growth of the Company's generic product lines.

Licensing fees decreased by \$12k, or approximately 3%, with this decrease being mostly due to the timing of in-market sales of generic products being marketed by Tagi Pharma under license from Elite.

Research and development costs for the three months ended September 30, 2015 were \$4,172k, an increase of \$589k or approximately 16% from \$3,583k of such costs for the comparable period of the prior year. The increase was due to the timing of ongoing clinical trials related to the development of Elite's abuse deterrent opioid products.

General and administrative expenses for the three months ended September 30, 2015, were \$881k, an increase of \$159k, or approximately 22% from \$722k of general and administrative expenses for the comparable period of the prior year. The increase was primarily due to increases in the general cost of operation. Please note that these higher levels of overhead costs are expected to continue.

Depreciation and amortization for the three months ended September 30, 2015 was \$164k, a decrease of \$113k, or approximately 41%, from \$277k for the comparable period of the prior year. The decrease was primarily due to a decrease in the overall basis of depreciable assets resulting from the expiry of the economic life of equipment since June 2014. The expansion and upgrade of the Northvale Facility, which has required significant investments in property, plant and equipment, has not yet been placed in service. Accordingly, depreciation expenses relating to these investments have not yet been recorded. When commissioned, the investments relating to the expansion of the Northvale Facility will result in increased depreciation expense.

Non-cash compensation through the issuance of stock options and warrants for the three months ended September 30, 2015 was \$81k, an increase of \$28k, or approximately 51% from \$53k for the comparable period of the prior year. The increase is due to the issuance of employee stock options subsequent to the quarter ended June 30, 2014.

As a result of the foregoing, our loss from operations for the three months ended September 30, 2015 was \$3,767k, compared to a loss from operations of \$4,061k for the three months ended September 30, 2014.

Other income/expenses for the three months ended September 30, 2015 was net other income of \$2,086k, a decrease in other income of \$8,224k from the net other income of \$10,310k for the comparable period of the prior year. The decrease in other income/expense was due to derivative income relating to changes in the fair value of our derivative liabilities during the three months ended September 30, 2015 \$2,150k, as compared to a derivative income of \$10,380k for the comparable period of the prior year. Please note that derivative income/(expenses) are determined in large part by the change in fair value of the warrants outstanding.

As a result of the foregoing, our net loss for the three months ended September 30, 2015 was \$1,681k, compared to a net income of \$6,248k for the comparable period of the prior year.

Changes in maximum redemption value in our convertible preferred mezzanine equity, which is included in the calculation of net income (loss) attributable to common shareholders resulted in net loss being increased by \$5,071k for the three months ended September 30, 2015, as compared to an increase in net income of \$15,132k for the comparable period of the prior year. Accordingly, net income (loss) attributable to common shareholders for the three months ended September 30, 2015 was a net loss of \$(6,753)k, compared to a net income of \$21,380 for the comparable period of the prior year. Please note that the change in maximum redemption value of convertible preferred mezzanine equity is significantly influenced by the trading price of our Common Stock, with a strong, inverse correlation existing between the price of our Common Stock and additions/reductions in net income to determine net income attributable to common shareholders.

#### **Six Months Ended September 30, 2015 Compared to Six Months Ended September 30, 2014**

Our revenues for the six months ended September 30, 2015 were \$5,110k, an increase of \$2,692k or approximately 111% over revenues for the comparable period of the prior year, and consisted of \$4,229k in manufacturing fees and \$881k in licensing fees. Revenues for the six months ended September 30, 2014, consisted of \$1,800k in manufacturing fees, \$613k in licensing fees and \$5k in lab fees.

Manufacturing fees Increased by \$2,429k, or approximately 135%, mostly due to the continued growth of the Company's generic product lines.

Licensing fees increased by \$268k, or approximately 44%, with this increase being due to increased profit splits earned from product sales relating to the TAGI and Epic licensing agreements.

Research and development costs for the six months ended September 30, 2015 were \$6,614k, a decrease of \$1,009k or approximately 13% from \$7,623k of such costs for the comparable period of the prior year. The decrease was due to the timing of ongoing clinical trials related to the development of Elite's abuse deterrent opioid products.

General and administrative expenses for the six months ended September 30, 2015, were \$1,561k, an increase of \$231k, or approximately 17% from \$1,330k of general and administrative expenses for the comparable period of the prior year. The increase was primarily due to significant increases in the hiring of additional staff to support regulatory compliance activities, additional costs incurred in relation to insurance and employee benefits. Please note that these higher levels of overhead costs are expected to continue.

Depreciation and amortization for the six months ended September 30, 2015 was \$326k, a decrease of \$145k, or approximately 31%, from \$471k for the comparable period of the prior year. The decrease was primarily due to a decrease in the overall basis of depreciable assets resulting from the expiry of the economic life of equipment since June 2014. The expansion and upgrade of the Northvale Facility, which has required significant investments in property, plant and equipment, has not yet been placed in service. Accordingly, depreciation expenses relating to these investments have not yet been recorded. When commissioned, the investments relating to the expansion of the Northvale Facility will result in increased depreciation expense.

Non-cash compensation through the issuance of stock options and warrants for the six months ended September 30, 2015 was \$171k, an increase of \$94k, or approximately 122% from \$77k for the comparable period of the prior year. The increase is due to the issuance of employee stock options subsequent to the three months ended June 30, 2014.

As a result of the foregoing, our loss from operations for the six months ended September 30, 2015 was \$6,174k, compared to a loss from operations of \$8,493k for the six months ended September 30, 2014.

Other income/expenses for the six months ended September 30, 2015 was net other income of \$9,225k, a decrease in other income of \$3,422k from the net other income of \$12,647k for the comparable period of the prior year. The decrease in other income/expense was due to derivative income relating to changes in the fair value of derivative liabilities during the six months ended September 30, 2015 totaling an income of \$9,364k, as compared to a derivative income of \$11,122k and the gain on sale of investment totaling \$1,671k for the comparable period of the prior year. Please note that derivative income/(expenses) are determined in large part by the change in fair value of the warrants outstanding.

As a result of the foregoing, our net income for the six months ended September 30, 2015 was \$3,051k, compared to a net income of \$4,155k for the comparable period of the prior year.

Changes in maximum redemption value in our convertible preferred mezzanine equity, which is included in the calculation of net income (loss) attributable to common shareholders resulted in net income being increased by \$1,357k for the six months ended September 30, 2015, as compared to an increase in net income of \$12,823k for the comparable period of the prior year. Accordingly, net income (loss) attributable to common shareholders for the six months ended September 30, 2015 was net income of \$4,408k, compared to net income of \$16,978 for the comparable period of the prior year.

### **Material Changes in Financial Condition**

Our working capital (total current assets less total current liabilities), increased to a surplus of \$8.6 million as of September 30, 2015 from a working capital surplus of \$7.3 million as of March 31, 2015, primarily due to working capital generated by sales of common stock and proceeds from the exercise of cash warrants and options totaling \$5.1 million, both of which are accretive to working capital.

Net cash used in operations was \$1.6million for the six months ended September 30, 2015, primarily due to our net income from continuing operations of \$3.1 million, offset by non-cash credits totaling \$8.4 million, which included, without limitation, depreciation and amortization charges of \$0.33 million, net income credits from the change in fair value of derivative liabilities of \$9.36 million. In addition, net cash provided by operations was effected by changes in the balances of assets and liabilities, including, without limitation, decrease in account receivables and prepaid expenses totaling \$0.39 million, and an increase in deferred revenues of \$4.66 million, each of which result in a net increase in cash, offset by increases in inventories of \$0.3 million and decreases in accounts payables and other current liabilities of \$1.0 million, each of which result in a net decrease in cash.

## **LIQUIDITY AND CAPITAL RESOURCES**

### **Cash and Working Capital**

As of September 30, 2015, the Company had cash on hand of \$9.0 million and a working capital surplus of \$9.6million. The Company believes that such resources, combined with the Company's access to the remaining \$24.0 million available pursuant to the \$40 million equity line with Lincoln Park, and approximately \$0.6 million available under the Hakim Credit Line are sufficient to fund operations through the current operating cycle. For the six months ended September 30, 2015, we had loss from operations totaling \$6.2 million, net other income totaling \$9.2 million and a net income of \$3.1 million. Please note that the Company's other income/expenses are significantly influenced by the change in fair value of the warrants outstanding.

The Company does not anticipate being profitable for the fiscal year ending March 31, 2016, due in large part to its plans to conduct clinical development and commercialization activities on a range of abuse deterrent opioid products, on an accelerated and simultaneous basis. Such activities require the investment of significant amounts in clinical trials, safety and efficacy studies, bioequivalence studies, product manufacturing, regulatory expertise and filings, as well as investments in manufacturing and lab equipment and software. In order to finance these significant expenditures, the Company entered into two purchase agreements with Lincoln Park, with such agreements providing the company with equity lines totaling \$50 million. We believe this amount of financing, if received, is sufficient to fund the commercialization of the abuse deterrent opioid products identified. Please see below for further details on the financing transactions with Lincoln Park.

### **Lincoln Park Capital**

On April 10, 2014, we entered into a Purchase Agreement and a Registration Rights Agreement with Lincoln Park Capital (the "LPC 40 Purchase Agreement"). Pursuant to the terms of the Purchase Agreement, Lincoln Park has agreed to purchase from us up to \$40 million of our 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 a

registration statement to register for resale under the Securities Act the shares that have been or may be issued to Lincoln Park under the Purchase Agreement. That registration statement was declared effective by the SEC on May 1, 2014. A post-effective amendment to that Registration Statement was subsequently filed with the SEC and declared effective on July 1, 2014.

Upon execution of the Purchase Agreement, we have issued 1,928,641 shares of our common stock to Lincoln Park pursuant to the Purchase Agreement as consideration for its commitment to purchase additional shares of our common stock under that agreement and we are obligated to issue up to an additional 1,928,641 commitment shares to Lincoln Park pro rata as up to \$40 million of our common stock is purchased by Lincoln Park. Through November 9, 2015, we have sold to Lincoln Park an aggregate of 60.3 million shares under the Purchase Agreement for aggregate gross proceeds of approximately \$16.0 million. In addition, we have issued an additional 0.8 million Commitment Shares.

We may, from time to time and at our 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 our 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 our 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 10 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 we have properly submitted a Regular Purchase notice and the closing sale price is not below \$0.15, we 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 our 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 our 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 we will control the timing and amount of any sales of our common stock to Lincoln Park.

Our sales of shares of Common Stock to Lincoln Park under the Lincoln Park 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 Lincoln Park Purchase Agreement and the Lincoln Park 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 Lincoln Park Purchase Agreement at any time, at no cost or penalty. Actual sales of shares of Common Stock to Lincoln Park under the Lincoln Park 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 Lincoln Park 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 Lincoln Park Purchase Agreement. Lincoln Park has covenanted not to cause or engage in any manner whatsoever, any direct or indirect short selling or hedging of our shares.

The net proceeds 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. The Company expects that any proceeds received by the Company from such sales to Lincoln Park under the Lincoln Park Purchase Agreement will be used for general corporate purposes and working capital requirements.

The foregoing descriptions of the LPC 40 Purchase Agreement, and the Registration Rights Agreement are qualified in their entirety by reference to the full text of the LPC 40 Purchase Agreement, and the Registration Rights Agreement, copies of which are attached to the Current Report on Form 8-K, filed with the SEC on April 14, 2014 as Exhibit 10.1 and 10.2, respectively, and each of which is incorporated herein in its entirety by reference. The representations, warranties and covenants contained in such agreements, were made only for purposes of such agreements and as of specific dates, were solely for the benefit of the parties to such agreements, and may be subject to limitations agreed upon by the contracting parties, including being qualified by confidential disclosures exchanged between the parties in connection with execution of the agreements.

### **Hakim \$1,000,000 Bridge Revolving Credit Line**

On October 15, 2013 (the “Hakim Credit Line Effective Date”), and as amended on January 28, 2015, we entered into a bridge loan agreement (the “Hakim Loan Agreement”) with Nasrat Hakim, our President and CEO. Under the terms of the Hakim Loan Agreement, we have the right, in our 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. Mr. Hakim provided the Credit Line for the purpose of supporting the acceleration of our product development activities. The outstanding amount will be evidenced by a promissory note which shall mature on March 31, 2016, at which time the entire unpaid principal balance plus accrued interest thereon shall be due and payable in full. We may prepay 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, we may borrow, repay, and reborrow under the Hakim Credit Line through maturity. Amounts borrowed under the Hakim Credit Line will bear interest at the rate of ten percent (10%) per annum. As of September 30, 2015, the principal balance owed under the Credit Line was \$411,709 with an additional \$41,658 in accrued interest being also owed, in accordance with the terms and conditions of the Credit Line. On January 28, 2015, The Development and License Agreement dated August 27, 2010 and between the Company and Mikah Pharma LLC (the “Mikah Development Agreement”) was terminated. Pursuant to the Mikah Development Agreement, Mikah Pharma LLC (“Mikah”) made advance consideration payments to the Company totaling \$200,000 in exchange for product development services to be provided at a future date. Subsequent to the execution of the Mikah Development Agreement, and before any development milestones were achieved, the sole owner of Mikah, Mr. Nasrat Hakim, became the President and Chief Executive Officer of the Company. Mikah has accordingly ceased operating and is in the process of winding down and liquidating its assets. Any further development of the product related to this agreement will belong to the Company, although there can be no assurances that such development will occur or be successful. The Mikah Development Agreement requires that the consideration paid in advance to the Company be refunded in the event of no milestones being achieved. Mr. Hakim, as owner of Mikah, has directed that the \$200,000 refund due to Mikah not be paid currently, but rather be added to the amounts due under the Hakim Credit Line.

### **NJEDA Bonds**

On August 31, 2005, the Company successfully completed a refinancing of a prior 1999 bond issue through the issuance of new tax-exempt bonds (the “Bonds”). The refinancing involved borrowing \$4,155,000, evidenced by a 6.5% Series A Note in the principal amount of \$3,660,000 maturing on September 1, 2030 and a 9% Series B Note in the principal amount of \$495,000 maturing on September 1, 2012. The net proceeds, after payment of issuance costs, were used (i) to redeem the outstanding tax-exempt Bonds originally issued by the Authority on September 2, 1999, (ii) refinance other equipment financing and (iii) for the purchase of certain equipment to be used in the manufacture of pharmaceutical products. As of September 30, 2015, all of the proceeds were utilized by the Company for such stated purposes.

Interest is payable semiannually on March 1 and September 1 of each year. The 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 related Indenture requires the maintenance of a \$415,500 Debt Service Reserve Fund consisting of \$366,000 from the Series A Notes proceeds and \$49,500 from the Series B Notes proceeds. The Debt Service Reserve is maintained in

restricted cash accounts that are classified in Other Assets.

Bond issue costs of \$354,000 were paid from the bond proceeds and are being amortized over the life of the bonds. Amortization of bond issuance costs amounted to \$7,089 for the six months ended September 30, 2015.

The NJEDA Bonds require the Company to make an annual principal payment on September 1st of varying amounts as specified in the loan documents and semi-annual interest payments on March 1st and September 1st, equal to interest due on the outstanding principal at the applicable rate for the semi-annual period just ended.

As of the date of filing of this Quarterly Report on Form 10-Q, the Series B Note has been paid in full and retired and all principal and interest payments due and owing under the Series A Note have been paid in full.

The Company has classified the principal amounts with a maturity of not more than twelve months from September 30, 2015, totaling \$220,000, as current liabilities. Principal amounts with maturities in excess of twelve months from September 30, 2016, totaling \$1,845,000 have been recorded as non-current liabilities.

### **Off-Balance Sheet Arrangements**

We have not entered into any off-balance sheet arrangements that have or are reasonably likely to have a current or future effect on our financial condition, changes in financial condition, revenues or expenses, results of operations, liquidity, capital expenditures, or capital resources that would be considered material to investors.

### **Effects of Inflation**

We are subject to price risks arising from price fluctuations in the market prices of the products that we sell. Management does not believe that inflation risk is material to our business or our consolidated financial position, results of operations, or cash flows.

## **ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK**

Market risk is the potential loss arising from adverse changes in the financial markets, including interest rates and foreign currency exchange rates.

### Interest rate risk

As of September 30, 2015, our principal debt obligations included EDA bonds payable with a total principal balance of \$2.065 million, loans payable with principal balances totaling \$0.743 million, and principal balances owed pursuant to related party lines of credit totaling \$0.411 million. Interest rates for all such indebtedness are fixed and accordingly there is no significant interest rate sensitivity related to these liabilities.

### Foreign Currency Exchange Risk

We operate and transact business in US Dollars, accordingly, the Company is not exposed to any significant foreign currency exchange risk.

## **ITEM 4. CONTROLS AND PROCEDURES**

### **Evaluation of Disclosure Controls and Procedures**

The Company has established disclosure controls and procedures that are designed to ensure that information required to be disclosed in reports filed or submitted under the Securities Exchange Act of 1934 (“the Exchange Act”), (i) recorded, processed, summarized and reported within the time periods specified in the SEC’s rules and forms, and (ii)

accumulated and communicated to our management to allow for timely decisions regarding disclosure. A controls system cannot provide absolute assurance, however, that the objectives of the controls system are met, and no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within a company have been detected.

Under the supervision and with the participation of our management, including the Chief Executive and Chief Financial Officers, we evaluated the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rule 13a-15(e) and 15d-15(e) under the Exchange Act as of the end of the period covered by this Quarterly Report on Form 10-Q. Based upon that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures as of the end of the period covered by this report were not effective so that the information required to be disclosed by us in reports filed under the Exchange Act is (i) recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and (ii) accumulated and communicated to our management in order to allow for timely decisions regarding disclosure.

As of Fiscal Year Ended March 31, 2015 we had identified certain matters that constituted material weaknesses in our internal control over financial reporting which resulted from a lack of segregation of duties in the Payroll, Accounting and Procure to Pay cycles.

After receiving a comment letter from the SEC in connection with standard periodic reviews of our Form 10-K for the Fiscal Year Ended March 31, 2015, our Form 10-Q for the Quarterly Period Ended June 30, 2015 and, in the process of review, our Form 10-Q, as amended, for the Quarterly Period Ended September 30, 2015, we identified additional material weaknesses in internal control over financial reporting. The specific material weaknesses include the fact that we experienced difficulty in applying complex accounting and financial reporting and disclosure rules required under GAAP and SEC reporting regulations related to (i) the recognition of revenue relating to a \$5 million non-refundable payment received in relation to a licensing agreement and (ii) the accounting treatment of convertible preferred stock and preferred derivative liabilities associated with the share issuances.

We are in the process of designing and implementing policies and procedures to remediate our ineffective internal control over financial reporting in fiscal 2015, including hiring a third-party expert to aid in identifying and applying GAAP rules to our complex transactions.

### **Changes in Internal Controls**

During Fiscal 2016, our management has taken the following actions that materially affect, or are reasonably likely to materially affect, our internal control over financial reporting and to remediate the material weaknesses described in our 2015 Form 10-K.

- We have hired a third-party to aid us in identifying and applying GAAP rules related to our complex transactions.

Other than discussed above, there have not been any changes in our internal control over financial reporting during the quarter ended September 30, 2015 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

## **PART II. OTHER INFORMATION**

### **ITEM 1. LEGAL PROCEEDINGS**

In the ordinary course of business we may be subject to litigation from time to time. Except as discussed below, there is no current, pending or, to our knowledge, threatened litigation or administrative action to which we are a party or of which our property is the subject (including litigation or actions involving our officers, directors, affiliates, or other

key personnel, or holders of record or beneficially of more than 5% of any class of our voting securities, or any associate of any such party) which in our opinion has, or is expected to have, a material adverse effect upon our business, prospects financial condition or operations.

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 denies 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. As of the date of filing of this current report on Form 10-Q 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. The Company has notified the Arbitrator of this settlement and is awaiting the Arbitrators issuance of the proceeding termination document.

**ITEM 1A. RISK FACTORS**

There have been no material changes from the Risk Factors described in our Annual Report on Form 10-K for the fiscal year ended March 31, 2015.



**ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS.**

During the six months ended September 30, 2015, we issued 37,306,248 shares of Common Stock that were unregistered, consisting of 37,252,079 shares being issued pursuant to the exercise of cash warrants and options, with proceeds received totaling \$2,328,255 and 54,169 shares being issued in payment of salaries as per related employment agreements, with such salaries paid totaling \$12,500. We relied on the exemption provided by Section 4(a)(2) of the Securities Act of 1933 to issue the common stock. The securities were offered and sold without any form of general solicitation or general advertising and the offerees made representations that they were accredited investors.

Subsequent to September 30, 2015 and up to and including November 5, 2015 (the latest practicable date), we issued a total of 3 million shares of Common Stock that were unregistered, with all such unregistered shares being issued pursuant to the Strategic Alliance Agreement between the Company and Epic Investments LLC (“Epic Investments”) dated March 18, 2009, as amended on April 30, 2009, June 1, 2009, and July 28, 2009 (the “Epic Strategic Alliance”), which for obligation, which require the issuance of 3 million shares of Common Stock to Epic Investments upon their notification to the Company of the FDA’s approval of the ANDA filed by Epic Pharma LLC for immediate release oxycodone tablets

**ITEM 3. DEFAULTS UPON SENIOR SECURITIES**

None.

**ITEM 4. Mine Safety Disclosures.**

Not applicable.

**ITEM 5. Other Information**

None.

**Item 6. Exhibits**

The exhibits listed in the index below are filed as part of this report.

**Exhibit**

<b>No.</b>	<b>Description</b>
2.1	Agreement and Plan of Merger between Elite Pharmaceuticals, Inc., a Delaware corporation (“Elite-Delaware”) and Elite Pharmaceuticals, Inc., a Nevada corporation (“Elite-Nevada”), incorporated by reference to Exhibit 2.1 to the Current Report on Form 8-K filed with the SEC on January 9, 2012.
3.1(a)	Articles of Incorporation of Elite-Nevada, incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K filed with the SEC on January 9, 2012.
3.1(b)	Certificate of Incorporation of Elite-Delaware, together with all other amendments thereto, as filed with the Secretary of State of the State of Delaware, incorporated by reference to (a) Exhibit 4.1 to the Registration Statement on Form S-4 (Reg. No. 333-101686), filed with the SEC on December 6, 2002 (the “Form S-4”), (b) Exhibit 3.1 to the Company’s Current Report on Form 8-K dated July 28, 2004 and filed with the SEC on July 29, 2004, (c) Exhibit 3.1 to the Company’s Current Report on Form 8-K dated June 26, 2008 and filed with the SEC on July 2, 2008, and (d) Exhibit 3.1 to the Company’s Current Report on Form 8-K dated December 19, 2008 and filed with the SEC on December 23, 2008.*
3.1(c)	Certificate of Designations, Preferences and Rights of Series A Preferred Stock, as filed with the Secretary of the State of Delaware, incorporated by reference to Exhibit 4.5 to the Current Report on Form 8-K dated October 6, 2004, and filed with the SEC on October 12, 2004.*

3.1(d) Certificate of Retirement with the Secretary of the State of the Delaware to retire 516,558 shares of the Series A Preferred Stock, as filed with the Secretary of State of Delaware, incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K dated March 10, 2006, and filed with the SEC on March 14, 2006.\*

3.1(e) Certificate of Designations, Preferences and Rights of Series B 8% Convertible Preferred Stock, as filed with the Secretary of the State of Delaware, incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K dated March 15, 2006, and filed with the SEC on March 16, 2006.\*

3.1(f) Amended Certificate of Designations of Preferences, Rights and Limitations of Series B 8% Convertible Preferred Stock, as filed with the Secretary of State of the State of Delaware, incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K dated April 24, 2007, and filed with the SEC on April 25, 2007.\*

3.1(g) Certificate of Designations, Preferences and Rights of Series C 8% Convertible Preferred Stock, as filed with the Secretary of the State of Delaware, incorporated by reference to Exhibit 3.2 to the Current Report on Form 8-K dated April 24, 2007, and filed with the SEC on April 25, 2007.\*

3.1(h) Amended Certificate of Designations, Preferences and Rights of Series C 8% Convertible Preferred Stock, as filed with the Secretary of the State of Delaware, incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K dated April 24, 2007, and filed with the SEC on April 25, 2007.\*

3.1(i) Amended Certificate of Designations of Preferences, Rights and Limitations of Series B 8% Convertible Preferred Stock, as filed with the Secretary of State of the State of Delaware, incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K dated September 15, 2008, and filed with the SEC on September 16, 2008.\*

3.1(j) Amended Certificate of Designations, Preferences and Rights of Series C 8% Convertible Preferred Stock, as filed with the Secretary of the State of Delaware, incorporated by reference to Exhibit 3.2 to the Current Report on Form 8-K dated September 15, 2008, and filed with the SEC on September 16, 2008.\*

3.1(k) Amended Certificate of Designations of Preferences, Rights and Limitations of Series D 8% Convertible Preferred Stock, as filed with the Secretary of State of the State of Delaware, incorporated by reference to Exhibit 3.3 to the Current Report on Form 8-K dated September 15, 2008, and filed with the SEC on September 16, 2008.\*

3.1(l) Certificate of Designation of Preferences, Rights and Limitations of Series E Convertible Preferred Stock, as filed with the Secretary of State of the State of Delaware, incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K dated June 1, 2009, and filed with the SEC on June 5, 2009.\*

3.1(m) Amended Certificate of Designations of the Series D 8% Convertible Preferred Stock as filed with the Secretary of State of the State of Delaware on June 29, 2010, incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K, dated June 24, 2010 and filed with the SEC on July 1, 2010.\*

3.1(n) Amended Certificate of Designations of the Series E Convertible Preferred Stock as filed with the Secretary of State of the State of Delaware on June 29, 2010, incorporated by reference to Exhibit 3.2 to the Current Report on Form 8-K, dated June 24, 2010 and filed with the SEC on July 1, 2010.\*

3.1(o) Certificate of Designations of the Series G Convertible Preferred Stock as filed with the Secretary of State of the State of Nevada on April 18, 2013, incorporated by reference to Exhibit 4.1 to the Current Report on Form 8-K, dated April 18, 2013 and filed with the SEC on April 22, 2013 .

20

- 3.1(p) Certificate of Designation of the Series H Junior Participating Preferred Stock, incorporated by reference to Exhibit 2 (contained in Exhibit 1) to the Registration Statement on Form 8-A filed with the SEC on November 15, 2013.
- 3.1(q) Certificate of Designations of the Series I Convertible Preferred Stock as filed with the Secretary of State of the State of Nevada on February 6, 2014, incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K, dated February 6, 2014 and filed with the SEC on February 7, 2014
- 3.2(a) Amended and Restated By-Laws of the Company, incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K dated March 17, 2014 and filed with the SEC on March 18, 2014.
- 3.2(b) By-Laws of Elite-Delaware, as amended, incorporated by reference to Exhibit 3.2 to the Company's Registration Statement on Form SB-2 (Reg. No. 333-90633) made effective on February 28, 2000 (the "Form SB-2").\*
- 4.1 Form of specimen certificate for Common Stock of the Company, incorporated by reference to Exhibit 4.1 to the Form SB-2.\*
- 4.2 Form of specimen certificate for Series B 8% Convertible Preferred Stock of the Company, incorporated by reference to Exhibit 4.1 to the Current Report on Form 8-K, dated March 15, 2006 and filed with the SEC on March 16, 2006.\*
- 4.3 Form of specimen certificate for Series C 8% Convertible Preferred Stock of the Company, incorporated by reference to Exhibit 4.1 to the Current Report on Form 8-K, dated April 24, 2007 and filed with the SEC on April 25, 2007.\*
- 4.4 Form of Warrant to purchase shares of Common Stock issued to purchasers in the private placement which closed on March 15, 2006 (the "Series B Financing"), incorporated by reference to Exhibit 4.2 to the Current Report on Form 8-K, dated March 15, 2006 and filed with the SEC on March 16, 2006.\*
- 4.5 Form of Warrant to purchase shares of Common Stock issued to purchasers in the Series B Financing, incorporated by reference to Exhibit 4.3 to the Current Report on Form 8-K, dated March 15, 2006 and filed with the SEC on March 16, 2006.\*
- 4.6 Form of Warrant to purchase shares of Common Stock issued to the Placement Agent, in connection with the Series B Financing, incorporated by reference to Exhibit 4.4 to the Current Report on Form 8-K, dated March 15, 2006 and filed with the SEC on March 16, 2006.\*
- 4.7 Form of Warrant to purchase 600,000 shares of Common Stock issued to Indigo Ventures, LLC, incorporated by reference to Exhibit 4.1 to the Current Report on Form 8-K, dated July 12, 2006 and filed with the SEC on July 18, 2006.\*
- 4.8 Form of Warrant to purchase up to 478,698 shares of Common Stock issued to VGS PHARMA, LLC, incorporated by reference as Exhibit 3(a) to the Current Report on Form 8-K, dated December 6, 2006 and filed with the SEC on December 12, 2006.\*
- 4.9

Form of Non-Qualified Stock Option Agreement for 1,750,000 shares of Common Stock granted to Veerappan Subramanian, incorporated by reference as Exhibit 3(b) to the Current Report on Form 8-K, dated December 6, 2006 and filed with the SEC on December 12, 2006.\*

4.10 Form of Warrant to purchase shares of Common Stock issued to purchasers in the private placement which closed on April 24, 2007 (the "Series C Financing"), incorporated by reference to Exhibit 4.2 to the Current Report on Form 8-K, dated April 24, 2007 and filed with the SEC on April 25, 2007.\*

- 4.11 Form of Warrant to purchase shares of Common Stock issued to the placement agent in the Series C Financing, incorporated by reference to Exhibit 4.3 to the Current Report on Form 8-K, dated April 24, 2007 and filed with the SEC on April 25, 2007.\*
- 4.12 Form of specimen certificate for Series D 8% Convertible Preferred Stock of the Company, incorporated by reference to Exhibit 4.1 to the Current Report on Form 8-K, dated September 15, 2008 and filed with the SEC on September 16, 2008.\*
- 4.13 Form of Warrant to purchase shares of Common Stock issued to purchasers in the private placement which closed on September 15, 2008 (the "Series D Financing"), incorporated by reference to Exhibit 4.2 to the Current Report on Form 8-K, dated September 15, 2008 and filed with the SEC on September 16, 2008.\*
- 4.14 Form of Warrant to purchase shares of Common Stock issued to the placement agent in the Series D Financing, incorporated by reference to Exhibit 4.3 to the Current Report on Form 8-K, dated September 15, 2008 and filed with the SEC on September 16, 2008.\*
- 4.15 Form of specimen certificate for Series E Convertible Preferred Stock of the Company, incorporated by reference to Exhibit 4.1 to the Current Report on Form 8-K, dated June 1, 2009, and filed with the SEC on June 5, 2009.\*
- 4.16 Warrant to purchase shares of Common Stock issued to Epic Investments, LLC in the initial closing of the Strategic Alliance Agreement, dated as of March 18, 2009, by and among the Company, Epic Pharma, LLC and Epic Investments, LLC, incorporated by reference to Exhibit 4.2 to the Current Report on Form 8-K, dated June 1, 2009, and filed with the SEC on June 5, 2009.\*
- 4.17 Form of specimen certificate for Series G Convertible Preferred Stock of the Company, incorporated by reference to Exhibit 4.2 to the Current Report on Form 8-K, dated April 18, 2013 and filed with the SEC on April 22, 2013.
- 4.18 Form of specimen certificate for Series I Convertible Preferred Stock of the Company, incorporated by reference to Exhibit 4.2 to the Current Report on Form 8-K, dated February 6, 2014 and filed with the SEC on February 7, 2014.
- 4.19 Rights Agreement, dated as of November 15, 2013, between the Company and American Stock Transfer & Trust Company, LLC., incorporated by reference to Exhibit 1 to the Registration Statement on Form 8-A filed with the SEC on November 15, 2013.
- 4.20 Form of Series H Preferred Stock Certificate, incorporated by reference to Exhibit 1 to the Registration Statement on Form 8-A filed with the SEC on November 15, 2013.
- 10.1 Elite Pharmaceuticals, Inc. 2014 Equity Incentive Plan, incorporated by reference to Appendix B to the Company's Definitive Proxy Statement for its Annual Meeting of Shareholders, filed with the SEC on April 3, 2014.
- 10.2 Form of Confidentiality Agreement (corporate), incorporated by reference to Exhibit 10.7 to the Form SB-2.
- 10.3 Form of Confidentiality Agreement (employee), incorporated by reference to Exhibit 10.8 to the Form SB-2.





- 10.4 Product Development and Commercialization Agreement, dated as of June 21, 2005, between the Company and IntelliPharmaceuticals, Corp., incorporated by reference as Exhibit 10.1 to the Current Report on Form 8-K, dated June 21, 2005 and originally filed with the SEC on June 27, 2005, as amended on the Current Report on Form 8-K/A filed September 7, 2005, as further amended by the Current Report on Form 8-K/A filed December 7, 2005 (Confidential Treatment granted with respect to portions of the Agreement).
- 10.5 Agreement, dated December 12, 2005, by and among the Company, Elite Labs, and IntelliPharmaCeutics Corp., incorporated by reference as Exhibit 10.1 to the Current Report on Form 8-K, dated December 12, 2005, and originally filed with the SEC on December 16, 2005, as amended by the Current Report on Form 8-K/A filed March 7, 2006 (Confidential Treatment granted with respect to portions of the Agreement).
- 10.6 Loan Agreement, dated as of August 15, 2005, between New Jersey Economic Development Authority (“NJEDA”) and the Company, incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K, dated August 31, 2005 and filed with the SEC on September 6, 2005.
- 10.7 Series A Note in the aggregate principal amount of \$3,660,000.00 payable to the order of the NJEDA, incorporated by reference to Exhibit 10.2 to the Current Report on Form 8-K, dated August 31, 2005 and filed with the SEC on September 6, 2005.
- 10.8 Series B Note in the aggregate principal amount of \$495,000.00 payable to the order of the NJEDA, incorporated by reference to Exhibit 10.3 to the Current Report on Form 8-K, dated August 31, 2005 and filed with the SEC on September 6, 2005.
- 10.9 Mortgage from the Company to the NJEDA, incorporated by reference to Exhibit 10.4 to the Current Report on Form 8-K, dated August 31, 2005 and filed with the SEC on September 6, 2005.
- 10.10 Indenture between NJEDA and the Bank of New York as Trustee, dated as of August 15, 2005, incorporated by reference to Exhibit 10.5 to the Current Report on Form 8-K, dated August 31, 2005 and filed with the SEC on September 6, 2005.
- 10.11 Form of Securities Purchase Agreement, between the Registrant and the signatories thereto, incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K, dated March 15, 2006 and filed with the SEC on March 16, 2006.
- 10.12 Form of Registration Rights Agreement, between the Registrant and signatories thereto, incorporated by reference to Exhibit 10.2 to the Current Report on Form 8-K, dated March 15, 2006 and filed with the SEC on March 16, 2006.
- 10.13 Form of Placement Agent Agreement, between the Registrant and Indigo Securities, LLC, incorporated by reference as Exhibit 10.3 to the Current Report on Form 8-K, dated March 15, 2006, and filed with the SEC on March 16, 2006.
- 10.14 Financial Advisory Agreement between the Registrant and Indigo Ventures LLC, incorporated by reference as Exhibit 10.1 to the Current Report on Form 8-K dated July 12, 2006 and filed with the SEC on July 18, 2006.

10.15

Product Collaboration Agreement between the Registrant and ThePharmaNetwork LLC, incorporated by reference as Exhibit 10.1 to the Current Report on Form 8-K, dated November 10, 2006 and filed with the SEC on November 15, 2006. (Confidential Treatment granted with respect to portions of the Agreement).

Strategic Alliance Agreement among the Registrant, VGS Pharma (“VGS”) and Veerappan S.

10.16 Subramanian (“VS”), incorporated by reference as Exhibit 10(a) to the Current Report on Form 8-K, dated December 6, 2006 and filed with the SEC on December 12, 2006.

10.17 Advisory Agreement, between the Registrant and VS, incorporated by reference as Exhibit 10(b) to the Current Report on Form 8-K, dated December 6, 2006 and filed with the SEC on December 12, 2006.

10.18 Registration Rights Agreement between the Registrant, VGS and VS, incorporated by reference as Exhibit 10(c) to the Current Report on Form 8-K, dated December 6, 2006 and filed with the SEC on December 12, 2006.

10.19 Employment Agreement between Novel Laboratories Inc. (“Novel”) and VS, incorporated by reference as Exhibit 10(d) to the Current Report on Form 8-K, dated December 6, 2006 and filed with the SEC on December 12, 2006.

10.20 Stockholders’ Agreement between Registrant, VGS, VS and Novel, incorporated by reference as Exhibit 10(e) to the Current Report on Form 8-K, dated December 6, 2006 and filed with the SEC on December 12, 2006.

10.21 Form of Securities Purchase Agreement, between the Registrant and the signatories thereto, incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K, dated April 24, 2007 and filed with the SEC on April 25, 2007.

10.22 Form of Registration Rights Agreement, between the Registrant and the signatories thereto, incorporated by reference to Exhibit 10.2 to the Current Report on Form 8-K, dated April 24, 2007 and filed with the SEC on April 25, 2007.

10.23 Form of Placement Agent Agreement, between the Company and Oppenheimer & Company, Inc., incorporated by reference as Exhibit 10.3 to the Current Report on Form 8-K, dated April 24, 2007 and filed with the SEC on April 25, 2007.

10.24 Form of Securities Purchase Agreement, between the Registrant and the signatories thereto, incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K, dated July 17, 2007 and filed with the SEC on July 23, 2007.

10.25 Form of Registration Rights Agreement, between the Registrant and the signatories thereto, incorporated by reference as Exhibit 10.2 to the Current Report on Form 8-K, dated July 17, 2007 and filed with the SEC on July 23, 2007.

10.26 Consulting Agreement, dated as of July 27, 2007, between the Registrant and Willstar Consultants, Inc., incorporated by reference as Exhibit 10.1 to the Quarterly Report on Form 10-Q for the period ending September 30, 2007 and filed with the SEC on November 14, 2007.

10.27 Form of Securities Purchase Agreement, between the Company and the signatories thereto, incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K, dated September 15, 2008 and filed with the SEC on September 16, 2008.

10.28 Form of Placement Agent Agreement, between the Company, ROTH Capital Partners, LLC and Boenning & Scattergood, Inc., incorporated by reference to Exhibit 10.3 to the Current Report on Form 8-K, dated September 15, 2008 and filed with the SEC on September 16, 2008.

10.29

Separation Agreement and General Release of Claims, dated as of October 20, 2008, by and between the Company and Stuart Apfel, incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K, dated October 15, 2008 and filed with the SEC on October 21, 2008.

10.30 Consulting Agreement, dated as of October 20, 2008, by and between the Company and Paralex Clinical Research, incorporated by reference to Exhibit 10.2 to the Current Report on Form 8-K, dated October 15, 2008 and filed with the SEC on October 21, 2008.

- 10.31 Separation Agreement and General Release of Claims, dated as of November 3, 2008, by and between the Company and Charan Behl, incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K, dated October 28, 2008 and filed with the SEC on November 3, 2008.
- 10.32 Consulting Agreement, dated as of November 3, 2008, by and between the Company and Charan Behl, incorporated by reference to Exhibit 10.2 to the Current Report on Form 8-K, dated October 28, 2008 and filed with the SEC on November 3, 2008.
- 10.33 Separation Agreement and General Release of Claims, dated as of November 5, 2008, by and between the Company and Bernard J. Berk, incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K, dated November 6, 2008 and filed with the SEC on November 6, 2008.
- 10.34 Compensation Agreement, dated as of December 1, 2008, by and between the Company and Jerry I. Treppel, incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K, dated December 1, 2008 and filed with the SEC on December 4, 2008.
- 10.35 Strategic Alliance Agreement, dated as of March 18, 2009, by and among the Company, Epic Pharma, LLC and Epic Investments, LLC, incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K, dated March 18, 2009 and filed with the SEC on March 23, 2009.
- 10.36 Amendment to Strategic Alliance Agreement, dated as of April 30, 2009, by and among the Company, Epic Pharma, LLC and Epic Investments, LLC, incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K, dated April 30, 2009 and filed with the SEC on May 6, 2009.
- 10.37 Second Amendment to Strategic Alliance Agreement, dated as of June 1, 2009, by and among the Company, Epic Pharma, LLC and Epic Investments, LLC, incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K, dated June 1, 2009, and filed with the SEC on June 5, 2009.
- 10.38 Third Amendment to Strategic Alliance Agreement, dated as of Aug 18, 2009, by and among the Company, Epic Pharma LLC and Epic Investments, LLC, incorporated by reference to Exhibit 10.3 to the Quarterly Report on Form 10-Q, for the period ending June 30, 2009 and filed with the SEC on August 19, 2009.
- 10.39 Employment Agreement, dated as of November 13, 2009, by and between the Company and Chris Dick, , incorporated by reference to Exhibit 10.1 to the Quarterly Report on Form 10-Q, for the period ending September 30, 2009 and filed with the SEC on November 16, 2009.
- 10.40 Employment Agreement, dated as of November 13, 2009, by and between the Company and Carter J. Ward, incorporated by reference to Exhibit 10.2 to the Quarterly Report on Form 10-Q, for the period ending September 30, 2009 and filed with the SEC on November 16, 2009.
- 10.41 Elite Pharmaceuticals Inc. 2009 Equity Incentive Plan, as adopted November 24, 2009, incorporated by reference to Exhibit 10.1 to the Registration Statement Under the Securities Act of 1933 on Form S-8, dated December 18, 2009 and filed with the SEC on December 22, 2009.
- 10.42 Stipulation of Settlement and Release, dated as of June 25, 2010, by and among the Company, Midsummer Investment, Ltd., Bushido Capital Master Fund, LP, BCMF Trustees, LLC, Epic Pharma, LLC and Epic Investments, LLC, incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K, dated June

25, 2010 and filed with the SEC on July 1, 2010

10.43 Amendment Agreement, dated as of June 25, 2010, by and among the Company, and the investors signatory thereto, incorporated by reference to Exhibit 10.2 to the Current Report on Form 8-K, dated June 25, 2010 and filed with the SEC on July 1, 2010

25

- 10.44 Amendment Agreement, dated as of June 2010, by and among the Company, Epic Pharma, LLC and Epic Investments, LLC, incorporated by reference to Exhibit 10.3 to the Current Report on Form 8-K, dated June 25, 2010 and filed with the SEC on July 1, 2010
- 10.45 Asset Purchase Agreement dated as of May 18, 2010, by and among Mikah Pharma LLC and the Company, incorporated by reference to Exhibit 10.4 to the Quarterly Report on Form 10-Q, for the period ended September 30, 2010 and filed with the SEC on November 15, 2010.
- 10.46 Asset Purchase Agreement, dated as of August 27, 2010, by and among Mikah Pharma LLC and the Company, incorporated by reference to Exhibit 10.5 to the Quarterly Report on Form 10-Q, for the period ended September 30, 2010 and filed with the SEC on November 15, 2010 (Confidential Treatment granted with respect to portions of the Agreement).
- 10.47 Master Development and License Agreement, dated as of August 27, 2010, by and among Mikah Pharma LLC and the Company incorporated by reference to Exhibit 10.6 to the Quarterly Report on Form 10-Q, for the period ended September 30, 2010 and filed with the SEC on November 15, 2010 (Confidential Treatment granted with respect to portions of the Agreement).
- 10.48 Purchase Agreement, dated as of September 10, 2010, by and among Epic Pharma LLC and the Company, incorporated by reference to Exhibit 10.7 to the Quarterly Report on Form 10-Q, for the period ended September 30, 2010 and filed with the SEC on November 15, 2010 (Confidential Treatment granted with respect to portions of the Agreement).
- 10.49 License Agreement, dated as of September 10, 2010, by and among Precision Dose Inc. and the Company, incorporated by reference to Exhibit 10.8 to the Quarterly Report on Form 10-Q, for the period ended September 30, 2010 and filed with the SEC on November 15, 2010 (Confidential Treatment granted with respect to portions of the Agreement).
- 10.50 Manufacturing and Supply Agreement, dated as of September 10, 2010, by and among Precision Dose Inc. and the Company, incorporated by reference to Exhibit 10.9 to the Quarterly Report on Form 10-Q, for the period ended September 30, 2010 and filed with the SEC on November 15, 2010 (Confidential Treatment granted with respect to portions of the Agreement).
- 10.51 Product Development Agreement between the Company and Hi-Tech Pharmacal Co., Inc. dated as of January 4, 2011, incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K, dated January 4, 2011 and filed with the SEC on January 10, 2011 (Confidential Treatment granted with respect to portions of the Agreement).
- 10.52 Settlement Agreement between the Company and ThePharmaNetwork, LLC, dated as of March 11, 2011, incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K, dated March 11, 2011 and filed with the SEC on March 17, 2011.
- 10.53 Manufacturing & Supply Agreement between the Company and Mikah Pharma LLC, dated as of June 1, 2011, incorporated by reference to Exhibit 10.70 to the Annual Report on Form 10-K, for the period ended March 31, 2011 and filed with the SEC on June 29, 2011 (Confidential Treatment granted with respect to portions of the Agreement).

10.54 Manufacturing & Supply Agreement between the Company and ThePharmaNetwork, LLC, dated as of June 23, 2011, incorporated by reference to Exhibit 10.71 to the Annual Report on Form 10-K, for the period ended March, 31, 2011 and filed with the SEC on June 29, 2011 (Confidential Treatment granted with respect to portions of the Agreement).

26



- 10.55 Amendment, dated as of November 1, 2011, to the Master Development and License Agreement, dated as of August 27, 2010, by and amount Mikah Pharma LLC and the Company (Confidential Treatment granted with respect to portions of the Agreement), incorporated by reference to Exhibit 10.1 to Quarterly Report on Form 10-Q for three and nine months ended December 31, 2011.
- 10.56 Settlement Agreement between the Company and ThePharmaNetwork, LLC, dated as of March 11, 2011, incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K, dated March 11, 2011 and filed with the SEC on March 17, 2011.
- 10.57 Securities Purchase Agreement with Socius dated December 30, 2011, incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed with the SEC on January 5, 2012.
- 10.58 Amendment to Agreement with Socius dated February 28, 2012, incorporated by reference to Exhibit 10.3 to the Current Report on Form 8-K/A filed with the SEC February 29, 2012.
- 10.59 Manufacturing & Supply Agreement between the Company and Mikah Pharma LLC, dated as of June 1, 2011, incorporated by reference to Exhibit 10.70 to the Annual Report on Form 10-K, for the period ended March, 31, 2011 and filed with the SEC on June 29, 2011 (Confidential Treatment granted with respect to portions of the Agreement).
- 10.60 Amendment, dated as of November 1, 2011, to the Master Development and License Agreement, dated as of August 27, 2010, by and amount Mikah Pharma LLC and the Company (Confidential Treatment granted with respect to portions of the Agreement), incorporated by reference to Exhibit 10.1 to Quarterly Report on Form 10-Q for three and nine months ended December 31, 2011.
- 10.61 Treppel \$500,000 Bridge Loan Agreement dated June 12, 2012, incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed with the SEC on June 13, 2012.
- 10.62 December 5, 2012 amendment to the Treppel Bridge Loan Agreement incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed with the SEC on December 10, 2012.
- 10.63 Development And License Agreement between the Company and a Hong Kong-based client dated March 16, 2012 incorporated by reference to Exhibit 10.77 to the Annual Report on Form 10-K filed with the SEC on June 29,2012 (Confidential Treatment granted with respect to portions of the Agreement).
- 10.64 Letter Agreement between the Company and ThePharmaNetwork LLC, dated September 21, 2012 incorporated by reference to Exhibit 10.6 to the Quarterly Report on Form 10-Q filed with the SEC on November 14,2012 (Confidential Treatment granted with respect to portions of the Agreement).
- 10.65 Purchase Agreement between the Company and Lincoln Park Capital LLC dated April 19, 2013 , incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K, dated April 18, 2013 and filed with the SEC on April 22, 2013.
- 10.66 Registration Rights Agreement between the Company and Lincoln Park Capital LLC dated April 19, 2013 , incorporated by reference to Exhibit 10.2 to the Current Report on Form 8-K, dated April 18, 2013 and filed with the SEC on April 22, 2013.

10.67 August 1, 2013 Employment Agreement with Nasrat Hakim, incorporated by reference to Exhibit 10.4 to the Current Report on Form 8-K, dated August 1, 2013 and filed with the SEC on August 5, 2013.

27

- 10.68 August 1, 2013 Mikah LLC Asset Purchase Agreement, incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K, dated August 1, 2013 and filed with the SEC on August 5, 2013. (Confidential Treatment granted with respect to portions of the Agreement).
- 10.69 Revised Schedule 1 to the August 1, 2013 Mikah LLC Asset Purchase Agreement (revised to remove confidential treatment with regard to one item set forth thereon) incorporated by reference to Exhibit 10.12 to the Quarterly Report on Form 10-Q for the period ending December 31, 2013, filed with the SEC on February 14, 2014.
- 10.70 August 1, 2013 Secured Convertible Note from the Company to Mikah Pharma LLC., incorporated by reference to Exhibit 10.2 to the Current Report on Form 8-K, dated August 1, 2013 and filed with the SEC on August 5, 2013.
- 10.71 August 1, 2013 Security Agreement from the Company to Mikah Pharma LLC., incorporated by reference to Exhibit 10.3 to the Current Report on Form 8-K, dated August 1, 2013 and filed with the SEC on August 5, 2013.
- 10.72 Termination of June 2011, Manufacturing and Supply Agreement between Mikah Pharma LLC and the Company, incorporated by reference to Exhibit 10.15 of the Quarterly Report on Form 10-Q for the period ending December 31, 2014 and filed with the SEC on February 14, 2014.
- 10.73 October 15, 2013 Hakim Credit Line Agreement, incorporated by reference to Exhibit 10.16 to the Quarterly Report on Form 10-Q for the period ended September 30, 2013.
- 10.74 October 2, 2013 Manufacturing and Licensing Agreement with Epic Pharma LLC, incorporated by reference to Exhibit 10.17 to the Amended Quarterly Report on Form 10-Q/A for the period ended September 30, 2013 and filed with the SEC on April 25, 2014. Confidential Treatment granted with respect to portions of the Agreement.
- 10.75 August 19, 2013, Master Services Agreement with Camargo Pharmaceutical Services, LLC, incorporated by reference to Exhibit 10.18 to the Quarterly Report on Form 10-Q for the period ended September 30, 2013 and filed with the SEC on November 14, 2013
- 10.76 November 21, 2013 Unsecured Convertible Note from the Company to Jerry Treppel, incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K, dated November 26, 2013 and filed with the SEC on November 26, 2013.
- 10.77 February 7, 2014 Amendment to Secured Convertible Note from the Company to Mikah, incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K, dated February 7, 2014 and filed with the SEC on February 7, 2014.
- 10.78 February 7, 2014 Amendment to Secured Convertible Note from the Company to Jerry Treppel, incorporated by reference to Exhibit 10.2 to the Current Report on Form 8-K, dated February 7, 2014 and filed with the SEC on February 7, 2014.
- 10.79 Purchase Agreement between the Company and Lincoln Park Capital LLC dated April 10, 2014, incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K, dated April 10,

2014 and filed with the SEC on April 14, 2014.

10.80 Registration Rights Agreement between the Company and Lincoln Park Capital LLC dated April 10, 2014 , incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K, dated April 10, 2014 and filed with the SEC on April 14, 2014.

28

10.81 Employment Agreement with Dr. G. Kenneth Smith, dated October 20, 2014, incorporated by reference to Exhibit 10.82 to the Quarterly Report on Form 10-Q for the period ended September 30, 2014 and filed with the SEC on November 14, 2014.

10.82 January 19, 2015 Second Amendment to TPN-Elite Manufacturing and Supply Agreement dated June 23, 2011 and First Amendment to the TPN-Elite Manufacturing and Supply Agreement dated September 21, 2012, incorporated by reference to Exhibit 10.82 to the Quarterly Report on Form 10-Q for the period ended December 31, 2014, and filed with the SEC on February 17, 2015. Confidential Treatment granted with respect to portions of the Agreement.

10.83 January 28, 2015 First Amendment to the Loan Agreement between Nasrat Hakim and Elite Pharmaceuticals dated October 15, 2013, incorporated by reference to Exhibit 10.83 to the Quarterly Report on Form 10-Q for the period ended December 31, 2014 and filed with the SEC on February 17, 2015.

10.84 January 28, 2015 Termination of Development and License Agreement for Mikah-001 between Elite Pharmaceuticals, Inc. and Mikah Pharma LLC and Transfer of Payment, incorporated by reference to Exhibit 10.84 to the Quarterly Report on Form 10-Q for the period ended December 31, 2014 and filed with the SEC on February 17, 2015 .

10.85 June 4, 2015 License Agreement with Epic Pharma LLC, incorporated by reference to Exhibit 10.85 to the Annual Report on Form 10-K for the fiscal year ended March 31, 2015 and filed with the SEC on June 15, 2015. Confidential portions of this exhibit have been redacted and filed separately with the Commission pursuant to a confidential treatment request in accordance with Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

101 The following materials from Elite Pharmaceuticals' Quarterly Report on Form 10-Q, related to the unaudited financial statements as and for the three months ended September 30, 2015 and 2014, formatted in eXtensible Business Reporting Language ("XBRL"): (i) the Consolidated Statements of Income; (ii) the Consolidated Balance Sheets; (iii) the Consolidated Statements of Cash Flows; and (iv) Notes to Consolidated Financial Statements.\*\*

31.1 Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002\*\*

31.2 Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002\*\*

32.1 Certification of Chief Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002\*\*

32.2 Certification of Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002\*\*

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

\*\* Filed herewith.



SIGNATURES

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

ELITE PHARMACEUTICALS, INC.

Date: December 30, 2015 /s/ Nasrat Hakim  
Nasrat Hakim  
Chief Executive Officer  
(Principal Executive Officer)

Date: December 30, 2015 /s/ Carter J. Ward  
Carter J. Ward  
Chief Financial Officer  
(Principal Financial and Accounting Officer)