ELITE PHARMACEUTICALS INC /NV/
Form 10-Q
November 09, 2015

U.S. SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

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

For the quarterly period ended September 30, 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)

(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 x No ¨

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

Yes x No ¨

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, 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 x Non-Accelerated Filer ¨ Smaller Reporting Company ¨

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

Yes ¨ No x

Indicate the number of shares outstanding of each of the issuer’s classes of common stock, as of the latest practicable date. 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).

ELITE PHARMACEUTICALS, INC. AND SUBSIDIARY

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ELITE PHARMACEUTICALS, INC. AND SUBSIDIARY

CONDENSED CONSOLIDATED BALANCE SHEETS

	September 30, 2015 (Unaudited)	**March 31, 2015 (Audited)**
ASSETS		
CURRENT ASSETS		
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, net of accumulated depreciation of $6,392,827 and $6,074,117, respectively	7,554,519	6,401,802
INTANGIBLE ASSETS – net of accumulated amortization of $-0-	6,399,667	6,381,774
OTHER ASSETS		
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
TOTAL ASSETS	$28,698,744	$25,920,279

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

ELITE PHARMACEUTICALS, INC. AND SUBSIDIARY

CONDENSED CONSOLIDATED BALANCE SHEETS

	September 30, 2015 (Unaudited)	**March 31, 2015 (Audited)**
LIABILITIES AND STOCKHOLDERS' DEFICIT		
CURRENT LIABILITIES		
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	13,333	13,333
Total Current Liabilities	4,507,950	5,069,097
LONG TERM LIABILITIES		
EDA bonds payable – non current	1,845,000	2,065,000
Deferred revenues	118,890	125,557
Other long term liabilities	549,486	629,138
Derivative liabilities	9,184,216	17,762,573
Total Long Term Liabilities	11,697,592	20,582,268
TOTAL LIABILITIES	16,205,542	25,651,365
MEZZANINE EQUITY		
Convertible preferred shares	32,857,143	35,000,000
STOCKHOLDERS' DEFICIT		
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	116,204,254	108,819,628
Accumulated deficit	(136,943,114)	(143,875,035)

Treasury stock at cost (100,000 common shares)	(306,841)	(306,841)
TOTAL STOCKHOLDERS' DEFICIT	(20,363,941)	(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

ELITE PHARMACEUTI CALS, INC. AND SUBSIDIARY

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(Unaudited)

	THREE MONTHS ENDED September 30,		**SIX MONTHS ENDED September 30,**	
	2015	2014	2015	2014
REVENUES				
Manufacturing Fees	$2,553,195	$850,934	$4,228,968	$1,799,971
Licensing Fees	143,312	405,483	547,311	613,128
Product Development Licensing	---	---	5,000,000	---
Lab Fee Revenues	---	---	---	5,000
Total Revenues	2,696,507	1,256,417	9,776,279	2,418,099
COSTS OF REVENUES	1,414,529	681,669	2,611,497	1,410,199
Gross Profit	1,281,978	574,748	7,164,782	1,007,900
OPERATING EXPENSES				
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	9,500,511
(LOSS) FROM OPERATIONS	(4,017,339)	(4,061,337)	(1,507,181)	(8,492,611)
OTHER INCOME / (EXPENSES)				
Interest expense	(63,824)	(70,075)	(136,507)	(148,281)
Change in fair value of derivative liabilities	2,149,787	10,379,665	8,578,358	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	8,439,101	12,647,269
NET INCOME (LOSS)	$(1,931,376)	$6,248,253	$6,931,920	$4,154,659
Change in value of convertible preferred share mezzanine equity	(5,071,406)	15,131,571	2,142,857	12,823,356
	$(7,002,782)	$21,379,824	$9,074,777	$16,978,014

NET INCOME (LOSS) ATTRIBUTABLE TO COMMON SHAREHOLDERS				
NET INCOME (LOSS) PER SHARE				
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

ELITE PHARMACEUTICALS, INC. AND SUBSIDIARY

CONDENSED CONSOLIDATED STATEMENT OF CHANGES IN STOCKHOLDERS' DEFICIT

(Unaudited)

	COMMON STOCK			TREASURY STOCK			
	Shares	Amount	**Additional Paid-In Capital**	Shares	Amount	**Accumulated Deficit**	**Stockholders' Deficit**
Balance at March 31, 2015	631,160,701	$631,162	$108,819,628	100,000	$(306,841)	$(143,875,035)	$(34,731,086)
Net Income						6,931,921	6,931,921
Change in value of convertible preferred mezzanine equity			2,142,857				2,142,857
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)				---

Common shares issued pursuant to the exercise of cash warrants	37,252,079	37,252	2,291,003				2,328,255
Common Shares Issued Pursuant to Director Salaries	54,169	54	12,446				12,500
Balance at September 30, 2015	681,756,279	$681,759	$116,204,255	100,000	$(306,841)	$(136,943,114)	$(20,363,941)

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

ELITE PHARMACEUTICALS, INC. AND SUBSIDIARY

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(Unaudited)

	SIX MONTHS ENDED SEPTEMBER 30	
	2014	**2015**
CASH FLOWS FROM OPERATING ACTIVITIES		
Net Income (Loss)	$6,931,921	$4,154,659
Adjustments to reconcile net loss to cash used in operating activities:		
Depreciation and amortization	325,799	435,537
Change in fair value of derivative liabilities	(8,578,358)	(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	242,720	(60,861)
Accounts payable, accrued expenses and other current liabilities	(960,122)	(183,608)
Deferred revenues and Customer deposits	(6,667)	(6,667)
NET CASH USED IN OPERATING ACTIVITIES	(1,588,019)	(8,641,036)
CASH FLOWS FROM INVESTING ACTIVITIES		
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
NET CASH USED IN INVESTING ACTIVITIES	(1,423,526)	3,862,455
CASH FLOWS FROM FINANCING ACTIVITIES		
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)
NET CASH PROVIDED BY FINANCING ACTIVITIES	4,578,453	5,463,882

NET CHANGE IN CASH AND CASH EQUIVALENTS	1,566,908	685,301
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

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**)

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

"**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 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 condensed consolidated financial statements have been prepared pursuant to rules and regulations of the Securities and Exchange Commission 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 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.

There have been no changes in significant accounting policies since March 31, 2015, other than the accounting for convertible preferred share mezzanine as discussed in Note 12 to these financial statements, with such changes to be considered when reviewing the Annual Report on Form 10-K filed with the SEC on June 15, 2015.

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 9, 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.

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 ANDA’s for generic products or 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. During the three and six months ended September 30, 2015 and 2014, the Company recognized $5,000k and none, respectively for branded products, including payments received for the research and development of products for which NDA’s are expected to be filed.

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.

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 - 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.

NOTE 5 - 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 6 - NJEDA BONDS

Bond financing consisting of the following, as of:

	September 30 2015	March 31 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 7 - 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.

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 8 - 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
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	76,654
Vehicles	66,855	66,855
Total	$13,947,346	$12,475,938
Less: Accumulated depreciation and amortization	6,392,827	6,074,116
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 9 - 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:

	September 30 2015	**March 31 2015**
Total loans	$ 742,716	$ 825,503
Current Portion	251,836	265,165
Long-term portion, net of current maturities	$ 490,880	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 10 - 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

	March 31	**September 30**
	2015	**2015**
Risk-Free interest rate	0.05% - 0.89%	0.1% - 0.9%
Expected volatility	93% - 113%	68% - 95%
Expected life (in years)	1.2 – 3.1	0.0 – 2.6
Expected dividend yield	---	---
Number of warrants	89,870,034	52,617,955
Fair Value of Warrant Derivative Liability	$17,762,573	$9.184,206

CHANGE IN VALUE OF WARRANT DERIVATIVE LIABILITY

	Three months ended		Six months ended	
	September 30		September 30	
	2015	2014	2015	2014
Change in Warrant Derivative Liability	($2,149,787)	$10,379,665	($8,578,358)	$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 11 - CONVERTIBLE PREFERRED SHARES MEZZANINE EQUITY

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, there are 100 shares issued and outstanding. The certificate of designations ("COD") for the Series I Preferred contain the following financial instruments:

- Conversion Feature
- Subsequent Dilutive Issuances
- Subsequent Dividend Issuances

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.

Management has determined that the Series I Preferred be classified as temporary equity, due to the floorless down round provisions included in the Series I Preferred COD creating the possibility of a redemption event being not within the control of the Company. The Series I Preferred is valued in temporary equity at its fair value, based upon the underlying value of common shares on an "as converted" basis.

Since the Series I Preferred is to be classified as temporary equity, changes in value are adjusted through additional paid-in capital, with such changes in value being 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 in the calculation of earnings per share.

	Series I Convertible Preferred Mezzanine Equity		
	March 31	**June 30**	**Sept 30**
	2015	**2015**	**2015**
Shares Authorized	500	500	500
Shares Outstanding	100	100	100
Common shares to be issued upon redemption	142,857,143	142,857,143	142,857,143
Closing price on valuation date	$0.2450	$0.2000	$0.2300
Fair value of temporary equity	$35,000,000	$28,571,429	$32,857,143

	(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	(5,071,406)	15,131,571	2,142,857	12,823,356

Please see Note 12 below.

NOTE 12 - RECLASSIFICATION OF CONVERTIBLE PREFERRED SHARES

The Company has determined and reclassified its convertible preferred shares from debt to a quasi equity instrument, which are recorded as mezzanine equity for financial reporting purposes.

Amounts recorded as convertible preferred share derivative liabilities are reclassified as convertible preferred share mezzanine equity of equal value. In addition, changes in fair value of the convertible preferred shares are not included in the other income (expense) section of the statement of operations, but are charged directly to additional paid in capital and included in the calculation of net income available to common shareholders.

The effects of the reclassification on the Company's balance sheet are summarized as follows:

	(amounts in 000's) As of March 31, 2015		
	As Reported	Reclassification	Difference
Convertible Preferred Share Derivative Liability	35,000	-0-	(35,000)
Convertible Preferred Share Mezzanine Equity	-0-	35,000	35,000
Accumulated Deficit	(196,077)	(143,875)	52,202
Additional Paid-In Capital	161,022	108,820	(52,202)

The effects of the reclassification on the Company's statement of operations for the three months ended September 30, 2014 are summarized as follows:

(amounts in 000's)

	Three Months Ended September 30, 2014		
	As Reported	Reclassification	Difference
Change in fair value of convertible preferred share derivatives	15,132	-0-	(15,132)
Net Income	21,380	6,248	(15,132)
Change in fair value convertible preferred share mezzanine equity	-0-	15,132	15,132
Net Income Attributable to Common Shareholders	21,380	21,380	-0-

The effects of the reclassification on the Company's statement of operations for the six months ended September 30, 2014 are summarized as follows:

	(amounts in 000's) Six Months Ended September 30, 2014		
	As Reported	Reclassification	Difference
Change in fair value of convertible preferred share derivatives	12,823	-0-	(12,823)
Net Income	16,978	4,155	(12,823)
Change in fair value convertible preferred share mezzanine equity	-0-	12,823	12,823
Net Income Attributable to Common Shareholders	16,978	16,978	-0-

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		**Six months ended**	
	September 30,		**September 30,**	
	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)	
	June 30 2015	September 30 2015
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.

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

	For the Three Months Ended September 30		**For the Six Months Ended September 30**	
	2015	2014	2015	2014
Numerator				
Net Income (loss) attributable to common shareholders – Basic	$(7,002,780)	$21,379,824	$9,074,778	$16,978,014
Effect of dilutive instruments on Net Income	2,921,619	(25,511,236)	(10,721,215)	(23,944,980)
Net Income attributable to common shareholders – Diluted	$(4,081,161)	$(4,131,412)	$(1,646,437)	$(6,966,966)

Denominator				
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	162,178,204
Weighted average shares of common stock outstanding - diluted	823,495,279	739,869,496	814,306,324	733,633,231
Net (loss) income per share				
Basic	$(0.01)	$0.04	$0.01	$0.03
Diluted	$(0.00)	$(0.01)	$(0.00)	$(0.01)

NOTE 16 - RELATED PARTY TRANSACTION AGREEMENTS

The Company has entered into two agreements with Epic Pharma LLC (“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, Elite executed an exclusive license agreement with Epic to market and sell, in the United States, ELI-200, an undisclosed opioid with sequestered naltrexone capsules, owned by Elite (the "ELI-200 Agreement"). As of the date of filing of this Quarterly Report on Form 10-Q, this product had not yet received marketing authorization from the FDA. Epic will have an exclusive right to market ELI-200 and its various dosage forms, subsequent to marketing authorization being granted by the FDA. ELI-200 will be manufactured by Elite. Epic is responsible for all regulatory and pharmacovigilance matters related to the ELI-200.

Pursuant to the ELI-200 Agreement, Elite received $5 million for research and development activities completed prior to the agreement. Elite will also receive 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 ELI-200 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 ELI-200 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 ELI-200 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 17 - 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.

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.

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 18 - 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 19 - 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 20 - 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 21 - 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 Securities and Exchange Commission (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.

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 22 - 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

COMPARED TO THE

THREE AND SIX MONTHS ENDED SEPTEMBER 30, 2014

(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:

Product	Branded Product Equivalent	Therapeutic Category	Launch Date
Phentermine HCl 37.5mg tablets (“Phentermine 37.5mg”)	Adipex-P®	Bariatric	April 2011
Lodrane D ® Immediate Release capsules (“Lodrane D”)	n/a	OTC Allergy	September 2011
Methadone HCl 10mg tablets (“Methadone 10mg”)	Dolophine®	Pain	January 2012
Hydromorphone HCl 8mg tablets (“Hydromorphone 8mg”)	Dilaudid®	Pain	March 2012
Phendimetrazine Tartrate 35mg tablets (“Phendimetrazine 35mg”)	Bontril®	Bariatric	November 2012
Phentermine HCl 15mg and 30mg capsules (“Phentermine 15mg” and “Phentermine 30mg”)	Adipex-P®	Bariatric	April 2013
Naltrexone HCl 50mg tablets (“Naltrexone 50mg”)	Revia®	Pain	September 2013
Isradipine 2.5mg and 5mg capsules (“Isradipine 2.5mg” and “Isradipine 5mg”)	n/a	Cardiovascular	January 2015
Hydroxyzine HCl 10mg, 25mg and 50mg tablets		Antihistamine	April 2015

(“Hydroxyzine 10mg” and “Hydroxyzine 25mg” and “Hydroxyzine 50mg”)	Atarax®, Vistaril®

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.