

ELITE PHARMACEUTICALS INC /NV/  
Form 10-Q  
August 14, 2013

U.S. SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

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

For the quarterly period ended June 30, 2013

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  
(State or other jurisdiction of incorporation or organization)

22-3542636  
(I.R.S. Employer Identification No.)

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

07647  
(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  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 August 9, 2013, the issuer had outstanding 403,454,380 shares of common stock, \$0.001 par value (exclusive of 100,000 shares held in treasury).



**ELITE PHARMACEUTICALS, INC. AND SUBSIDIARIES**

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

	June 30, 2013 (Unaudited)	March 31, 2013 (Audited)
<b>ASSETS</b>		
<b>CURRENT ASSETS</b>		
Cash and cash equivalents	\$231,102	\$369,023
Accounts receivable (net of allowance for doubtful accounts of -0-)	499,083	665,154
Inventories (net of reserve of -0- and \$93,338, respectively)	938,624	1,358,146
Prepaid expenses and other current assets	116,218	151,051
<b>Total Current Assets</b>	<b>1,785,027</b>	<b>2,543,374</b>
<b>PROPERTY AND EQUIPMENT</b> , net of accumulated depreciation of \$5,174,531 and \$5,068,522, respectively	3,958,495	4,028,943
<b>INTANGIBLE ASSETS</b> – net of accumulated amortization of \$-0-	712,922	694,426
<b>OTHER ASSETS</b>		
Investment in Novel Laboratories, Inc.	3,329,322	3,329,322
Security deposits	14,314	14,314
Restricted cash – debt service for EDA bonds	348,650	267,820
EDA bond offering costs, net of accumulated amortization of \$111,064 and \$107,519, respectively	243,389	246,934
<b>Total Other Assets</b>	<b>3,935,675</b>	<b>3,858,390</b>
<b>TOTAL ASSETS</b>	<b>\$10,392,119</b>	<b>\$11,125,133</b>

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

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

	June 30, 2013 (Unaudited)	March 31, 2013 (Audited)
<b>LIABILITIES AND STOCKHOLDERS' DEFICIT</b>		
<b>CURRENT LIABILITIES</b>		
EDA bonds payable	\$3,385,000	\$3,385,000
Short term loans and current portion of long-term debt	604,621	606,296
Accounts payable and accrued expenses	1,283,739	1,325,126
Deferred revenues – current	13,333	13,333
Preferred share derivative interest payable	23,584	27,500
<b>Total Current Liabilities</b>	<b>5,310,277</b>	<b>5,357,255</b>
<b>LONG TERM LIABILITIES</b>		
Deferred revenues	148,890	152,223
Other long term liabilities	93,822	91,571
Derivative liability – preferred shares	6,273,022	6,334,621
Derivative liability – warrants	4,966,391	7,862,848
<b>Total Long Term Liabilities</b>	<b>11,482,125</b>	<b>14,441,263</b>
<b>TOTAL LIABILITIES</b>	<b>16,792,402</b>	<b>19,798,518</b>
<b>STOCKHOLDERS' DEFICIT</b>		
Common stock – par value \$0.001, Authorized 690,000,000 shares. Issued 395,785,872 shares and 374,493,959 shares, respectively. Outstanding 395,685,872 shares and 374,393,959 shares, respectively	395,787	374,495
Additional paid-in-capital	121,020,480	119,690,336
Accumulated deficit	(127,509,709)	(128,431,375)
Treasury stock at cost (100,000 common shares)	(306,841 )	(306,841 )
<b>TOTAL STOCKHOLDERS' DEFICIT</b>	<b>(6,400,283 )</b>	<b>(8,673,385 )</b>
<b>TOTAL LIABILITIES AND STOCKHOLDERS' DEFICIT</b>	<b>\$10,392,119</b>	<b>\$11,125,133</b>

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

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**ELITE PHARMACEUTICALS, INC. AND SUBSIDIARIES****CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS***(Unaudited)*

	THREE MONTHS ENDED	
	June 30,	
	2013	2012
REVENUES		
Manufacturing Fees	\$543,434	\$379,697
Royalties & Profit Splits	173,255	128,495
Lab Fee Revenues	5,000	70,364
Total Revenues	721,689	578,556
COSTS OF REVENUES	579,012	454,364
Gross Profit	142,677	124,192
OPERATING EXPENSES		
Research and Development	569,492	196,882
General and Administrative	376,456	364,961
Non-cash compensation through issuance of stock options	9,487	6,113
Depreciation and Amortization	162,833	41,998
Total Operating Expenses	1,118,268	609,954
(LOSS) FROM OPERATIONS	(975,592 )	(485,762 )
OTHER INCOME / (EXPENSES)		
Interest expense, net	(74,778 )	(58,539 )
Change in fair value of warrant derivatives	2,896,457	(5,088,733 )
Change in fair value of preferred share derivatives	(900,838 )	(4,643,484 )
Interest expense attributable to preferred share derivatives	(23,584 )	(55,077 )
Discount in Series E issuance attributable to beneficial conversion features	—	(187,500 )
Total Other Income / (Expense)	1,897,258	(10,033,332 )
INCOME (LOSS) BEFORE PROVISION FOR INCOME TAXES	921,666	(10,519,095 )
PROVISION FOR INCOME TAXES	—	3,000
NET INCOME (LOSS) ATTRIBUTABLE TO COMMON SHAREHOLDERS	\$921,666	\$(10,522,095 )

NET (LOSS) PER SHARE

Basic	\$0.00	\$ (0.03	)
Diluted	\$ (0.00	) \$ (0.03	)

WEIGHTED AVERAGE NUMBER OF COMMON SHARES OUTSTANDING

Basic	387,969,981	337,272,222
Diluted	580,388,867	337,272,222

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

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

	Common Stock			Treasury Stock		Accumulated Deficit	Stockholders' Deficit
	Shares	Amount	Additional Paid-In Capital	Shares	Amount		
Balance at March 31, 2013	374,493,959	\$374,495	\$119,690,336	100,000	\$(306,841)	\$(128,431,375)	\$(8,673,385)
Net Income						921,666	921,666
Common shares sold pursuant to the Lincoln Park Capital purchase agreement	5,873,618	5,874	394,126				400,000
Common shares issued in lieu of cash in payment of preferred share derivative interest expense	341,562	342	27,158				27,500
Conversion of Series C, Series E and Series G Preferred Shares into Common Shares	12,030,453	12,030	950,406				962,436
Non-cash compensation through the issuance of stock options			9,487				9,487
Costs associated with raising capital			(47,987)				(47,987)

Common shares issued as commitment shares pursuant to the Lincoln Park Capital purchase agreement	3,046,280	3,046	(3,046	)				—
Balance at June 30, 2013	395,785,872	\$395,787	\$121,020,480	100,000	\$(306,841)	\$(127,509,709)	\$(6,400,283)	)

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

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

	THREE MONTHS ENDED JUNE	
	30	
	2013	2012
<b>CASH FLOWS FROM OPERATING ACTIVITIES</b>		
Net Income / (Loss)	\$ 921,666	\$ (10,522,095 )
Adjustments to reconcile net loss to cash used in operating activities:		
Depreciation and amortization	109,553	118,442
Change in fair value of warrant derivative liability	(2,896,457 )	5,088,733
Change in fair value of preferred share derivative liability	900,838	4,643,484
Discount in Series E issuance attributable to embedded beneficial conversion feature	—	187,500
Preferred share derivative interest satisfied by the issuance of common stock	27,500	82,489
Non-cash compensation satisfied by the issuance of common stock and options	9,487	6,113
Non-cash rent expense	1,899	2,403
Non-cash lease accretion	351	331
Changes in Assets and Liabilities		
Accounts receivable	166,071	(101,056 )
Inventories	419,522	(58,083 )
Prepaid and other current assets	34,833	43,893
Accounts payable, accrued expenses and other current liabilities	(43,061 )	241,210
Deferred revenues and Customer deposits	(3,333 )	(3,336 )
Derivative interest payable	(3,916 )	(27,411 )
<b>NET CASH USED IN OPERATING ACTIVITIES</b>	<b>(355,047 )</b>	<b>(297,383 )</b>
<b>CASH FLOWS FROM INVESTING ACTIVITIES</b>		
Purchases of property and equipment	(35,561 )	(8,067 )
Cost of leasehold improvements	—	(7,206 )
Costs incurred for intellectual property assets	(18,496 )	(15,947 )
Deposits to restricted cash, net	(80,830 )	(40,718 )
<b>NET CASH USED IN INVESTING ACTIVITIES</b>	<b>(134,887 )</b>	<b>(71,939 )</b>
<b>CASH FLOWS FROM FINANCING ACTIVITIES</b>		
Proceeds from issuance of Series E Convertible Preferred Stock	—	187,500
Proceeds from sale of common shares to Lincoln Park Capital	400,000	
Other loan payments	—	(1,674 )
Costs associated with raising capital	(47,987 )	(9,856 )
<b>NET CASH PROVIDED BY FINANCING ACTIVITIES</b>	<b>352,013</b>	<b>175,970</b>

NET CHANGE IN CASH AND CASH EQUIVALENTS	(137,921	)	(193,352	)
CASH AND CASH EQUIVALENTS – beginning of period	369,023		668,407	
CASH AND CASH EQUIVALENTS – end of period	\$ 231,102		\$ 475,055	
SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION				
Cash paid for interest	\$ 13,962		\$ 1,669	
Cash paid for taxes	—		3,000	
Non-Cash Financing Transactions				
Commitment shares issued to Lincoln Park Capital	219,296			
Conversion of Preferred Shares to Common Shares	962,436			

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

**ELITE PHARMACEUTICALS, INC. AND SUBSIDIARIES**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

**THREE MONTHS ENDED JUNE 30, 2013 AND 2012**

**(UNAUDITED)**

**NOTE 1 - DEFINITIONS**

“**Cash Reserves**” are equal to the amount listed in Note 2

“**Current Balance Sheet Date**” means June 30, 2013

“**Current Bond Liability**” is equal to the amount listed in Note 2

“**Current Fiscal Year**” means the twelve months ended March 31, 2014

“**Current Quarter**” means the three months ended June 30, 2013

“**Current YTD**” means the three months ended June 30, 2013

“**Derivative Interest Liability Common Shares**” means the following Common Shares issued in lieu of cash in payment of Derivative Interest due and owing as of the Current Balance Sheet Date:

**Common Shares Issued**

371,457

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

**“Outstanding Bond Principal Payments”** means principal payments which were due and owing on the NJEDA Bonds on or before the Current Balance Sheet Date and not made, consisting of the following:

Payment Date	Amount
September 1, 2010	225,000
September 1, 2011	470,000
September 1, 2012	730,000

**“Prior Year Balance Sheet Date”** means June 30, 2012

**“Prior Fiscal Year”** means the twelve months ended March 31, 2013

**“Prior Year Quarter”** means the three months ended June 30, 2012

**“Restricted Cash Interest Payments”** means the following withdrawal of funds from the debt service reserve, with such funds being used to make interest payments due to holders of the NJEDA Bonds:

Payment Date	Amount
March 1, 2009	\$120,775
September 1, 2009	120,775
March 1, 2010	113,075
September 1, 2010	113,075
March 1, 2011	113,075
September 1, 2011	113,075
March 1, 2012	113,075
September 1, 2012	113,075
March 1, 2013	113,075



“**Restricted Cash Principal Payments**” means the following withdrawal of funds from the debt service reserve, with such funds being used to make principal payments due to holders of the NJEDA Bonds:

Payment Date	Amount
September 1, 2009	210,000

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

“**Treppel Credit Line Balance**” equals \$600,000

“**Treppel Credit Line Interest Due**” equals \$15,123

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

“**Working Capital Deficit**” is equal to the amount listed in Note 2

## **NOTE 2 - BASIS OF PRESENTATION AND LIQUIDITY**

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, 2013 and filed with the SEC on June 21, 2012. There have been no changes in significant accounting policies since March 31, 2013.

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.

The accompanying unaudited condensed consolidated financial statements were prepared on the assumption that the Company will continue as a going concern. As of the Current Balance Sheet Date, the Company had the following:

Cash reserves ("Cash Reserves")	\$ 0.2 million
Working capital deficit ("Working Capital Deficit")	\$ 3.5 million
Losses from operations for the Current Quarter	\$ 1.0 million
Other income for the Current Quarter	\$ 2.1 million
Net income for the Current Quarter	\$ 0.9 million
NJEDA Bonds Payable ("Current Bond Liability")	\$ 3.4 million

The financial statements do not include adjustments relating to the recoverability and realization of assets and classification of liabilities that might be necessary should the Company be unable to continue in operation.

In addition, the Company has received Notice of Default from the Trustee of the NJEDA Bonds as a result of the utilization of the debt service reserve being used to pay semi-annual interest payments due on September 1<sup>st</sup> and March 1<sup>st</sup> of each year. The debt service reserve was first used to make such semi-annual interest payments on March 1, 2009 and has been utilized for all semi-annual interest payments due since then, with the Restricted Cash Interest Payments constituting such payments.

The Company has replenished all amounts withdrawn from the debt service reserve for the payment of semi-annual interest payments, as required, and in accordance with the applicable terms and conditions of such replenishments.

The Company did not have sufficient funds available to make the Restricted Cash Principal Payments and the Outstanding Principal Payments.

The debt service reserve was utilized to make the Restricted Cash Principal Payments, with the Company replenishing such amounts withdrawn from the debt service reserve, as required and in accordance with the applicable terms and conditions of such replenishments.

The Company requested that the Trustee utilize the debt service reserve to pay the principal payment due on September 1, 2010. This request was denied and accordingly the principal payment due on September 1, 2010 was not made.

The Company did not have sufficient funds available to make the principal payments due on September 1, 2011 and 2012, with such amount due including principal payments due in the prior year but not paid. There were not sufficient funds available in the debt service reserve and the payment was not made.

Please refer to the definition of Outstanding Bond Principal Payments for details on the amounts of the principal payments which were due and not made.

Resolution of the Company's default on the NJEDA Bonds and our request for postponement of principal payments will have a significant effect on our ability to operate in the future.

Please refer to Note 6 to our financial statements for a more detailed discussion of the NJEDA Bonds and Notice of Default.

Please also note that the Working Capital Deficit includes the Current Bond Liability. This amount was first classified as a current liability as of March 31, 2010, due to the Notice of Default received from the Trustee in relation to the NJEDA Bonds. Please refer to the balance sheet and note 6 to our financial statements for details on the Current Bond Liability.

As of the Current Balance Sheet Date, we had Cash Reserves.

On June 12, 2012, Elite entered into a bridge loan agreement, as amended on December 5, 2012, and August 2, 2013, (the "Treppel Credit Line Agreement") with Jerry Treppel, the Company's Chairman and CEO. Under the terms of the Treppel Credit Line Agreement, Elite has the right, in its sole discretion to a line of credit (the "Treppel Credit Line") in the maximum principal amount of up to the Treppel Credit Line Limit, at any one time. Mr. Treppel provided the Treppel Credit Line for the purpose of supporting the acceleration of Elite's product development activities. The outstanding amount is evidenced by a promissory note which shall mature on July 31, 2014, at which time the entire unpaid principal balance, plus accrued interest thereon shall be due and payable in full. Elite may prepay any amounts owed without penalty. Any such prepayments shall first be due and owing and then to principal. Interest only shall be payable quarterly on July 1, October 1, January 1 and April 1 of each year. Prior to maturity or the occurrence of an Event of Default as defined in the Treppel Credit Line Agreement, the Company may borrow, repay and reborrow under the Treppel Credit Line through maturity. Amounts borrowed under the Treppel Credit Line bear interest at the rate of ten percent (10%) per annum. For more detailed information, please refer to the Current Reports on Form 8-K filed with the SEC on June 13, 2012 December 10, 2012 and August 6, 2013, with such filings being herein incorporated by reference.

As of the Current Balance Sheet, the principal balance of the Treppel Credit Line was equal to the Treppel Credit Line Balance and the interest due was equal to the Treppel Credit Line Interest Due.

On April 19, 2013, the Company entered into a purchase agreement (the "LPC Purchase Agreement"), together with a registration rights agreement (the "LPC Registration Rights Agreement"), with Lincoln Park Capital Fund, LLC ("LPC").

Under the terms and subject to the conditions of the LPC Agreement, the Company has the right to sell to and LPC is obligated to purchase up to \$10 million in shares of the Company's Common Stock, subject to certain limitations, from time to time, over the 36 month period commencing on May 9, 2013, the date that the registration statement, which the Company agreed to file with the Securities and Exchange Commission (the "SEC") pursuant to the LPC Registration Rights Agreement, was declared effective by the SEC. The Company may direct LPC, at its sole discretion and subject to certain conditions, to purchase stock in amounts of up to \$80,000 on any single business day, so long as at least two business days have passed since the most recent purchase, increasing to up to \$500,000 per purchase, depending upon the closing sale price of the Common Stock. The purchase price of the 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 (or over a period of up to 12 business days leading up to such time), but in no event will shares be sold to LPC on a day the Common Stock closing price is less than the floor price of \$0.07 per share, subject to adjustment. The Company's sales of shares of Common Stock to LPC under the LPC Purchase Agreement are limited to no more than the number of shares that would result in the beneficial ownership by LPC and its affiliates, at any single point in time, of more than 9.99% of the then outstanding shares of Common Stock.

A Current Report on Form 8-K was filed with the SEC on April 22, 2013 with regards to the LPC Purchase Agreement and LPC Registration Rights Agreement with such filing being herein incorporated by reference. A Securities Registration Statement on Form S-1 was filed with the SEC on April 25, 2013 and declared effective by the SEC on May 9, 2013. A post-effective amendment to the Registration Statement was filed with the SEC and declared effective on June 26, 2013.

Despite having entered into the Treppel Credit Line Agreement, and entered into the LPC Purchase Agreement we still may be required to seek additional capital in the future and there can be no assurances that Elite will be able to obtain such additional capital on favorable terms, if at all.

Management has evaluated subsequent events or transactions occurring through the date the financial statements were issued (please see note 14).

## **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 operates in one segment for the three months ended June 30, 2013.

**NOTE 3 - CASH AND CASH EQUIVALENTS**

The Company considers all highly liquid investments with an original maturity of three months or less to be cash equivalents. Cash and cash equivalents consist of cash on deposit with banks and money market instruments. The Company places its cash and cash equivalents with high-quality, U.S. financial institutions and, to date, has not experienced losses on any of its balances.

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**NOTE 4 - 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:

	June 30, 2013	March 31, 2013
Raw Materials	696,668	774,758
Work-in-Process	241,956	676,726
Finished Goods	—	—
Less: Inventory Reserve	—	(93,338 )
Total Inventory	938,624	1,358,146

**NOTE 5 - INTANGIBLE ASSETS**

Costs to acquire intangible assets, such as asset purchases of Abbreviated New Drug Applications (“ANDAs”) which are approved by the FDA or costs incurred in the application of patents are capitalized and amortized on the straight-line method, based on their estimated useful lives ranging from five to fifteen years, commencing upon approval of the patent or site transfers required for commercialization of an acquired ANDA. Such costs are charged to expense if the patent application or ANDA site transfer is unsuccessful.

As of the Current Balance Sheet Date, the following costs were recorded as intangible assets on the Company’s balance sheet:

	Patent Application Costs	ANDA Acquisitions	Total Intangible Assets
Intangible Assets as of March 31, 2013	244,424	450,000	694,424
<u>Costs Capitalized During Current Fiscal Year</u>			
Three months ended June 30, 2013	18,496	—	18,496
Total Costs Capitalized-three months ended June 30, 2013	18,496	—	18,496
<u>Amortization of Intangible Assets During Current Fiscal Year</u>			
Three months ended June 30, 2013	—	—	—
Total Amortization – three month ended June 30, 2013	—	—	—
Intangible Assets as of June 30, 2013	262,922	450,000	712,922

The costs incurred in patent applications for the Current YTD and Current Quarter, were related to our abuse resistant opioid product lines. Additional costs incurred in relation to such patent applications will be capitalized as intangible assets, with amortization of such costs to commence upon approval of the patents.

**NOTE 6 - 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”) via the issuance of the following:

Description	Principal Amount On Issue Date	Interest Rate	Maturity
Series A Note	3,660,000	6.50 %	September 1, 2030
Series B Note	495,000	9.0 %	September 1, 2012

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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 the Current Balance Sheet Date, 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 Debt Service Reserve Fund as follows:

Description	Amount
Series A Note Proceeds	366,000
Series B Note Proceeds	49,500
Total	415,500

The Debt Service Reserve is maintained in restricted cash accounts that are classified in Other Assets.

Bond issue costs were paid from the bond proceeds and are being amortized over the life of the bonds. These costs and amortization activity are summarized as follows:

Description	Balances As of March 31, 2013	Amortization Expense Current YTD	Balances As of Current Balance Sheet Date
Bond Issue Costs	354,453		354,453
Accumulated Amortization	(107,519	) (3,545	) (111,064
Unamortized Balance	246,934		243,389

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

Due to the Company not having sufficient funds, the following withdrawals were made from the debt service reserve, with the funds being used to make interest payments due to the holders of the NJEDA Bonds:

Payment Date	Amount
March 1, 2009	\$120,775
September 1, 2009	120,775
March 1, 2010	113,075
September 1, 2010	113,075
March 1, 2011	113,075
September 1, 2011	113,075
March 1, 2012	113,075
September 1, 2012	113,075
March 1, 2013	113,075

Due to the Company not having sufficient funds, the following withdrawal was made from the debt service reserve, with the funds being used to make a principal payment due to the holders of the NJEDA Bonds:

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Payment Date	Amount
September 1, 2009	\$210,000

Pursuant to the terms of the NJEDA Bonds, the Company is required to replenish any amounts withdrawn from the debt service reserve and used to make principal or interest payments in six monthly installments, each being equal to one-sixth of the amount withdrawn and with the first installment due on the 15<sup>th</sup> of the month in which the withdrawal from debt service reserve occurred and the remaining five monthly payments being due on the 15<sup>th</sup> of the five immediately subsequent months. The Company has, to date, made all payments required in relation to the withdrawals made from the debt service reserve in relation to the Restricted Cash Interest Payments and the Restricted Cash Principal Payment.

In addition, the Company did not have sufficient funds available to make the principal payments due on September 1, 2010, September 1, 2011 and September 1, 2012. These principal payments are summarized as follows:

Payment Date	Amount
September 1, 2010	\$225,000 <sup>(1)</sup>
September 1, 2011	470,000 <sup>(2)</sup>
September 1, 2012	730,000 <sup>(3)</sup>

(1) The Company request to withdraw funds from the debt service reserve to pay the amount due on September 1, 2010 was denied by the Trustee and accordingly, the principal payment due on such date was not made.

(2) The principal payment due on September 1, 2011, included the amount due and September 1, 2010 and not paid. There were not sufficient funds available in the debt service reserve and the principal payment due on September 1, 2011 was not made.

(3) The principal payment due on September 1, 2012, included the amount due and September 1, 2011 and not paid. There were not sufficient funds available in the debt service reserve and the principal payment due on September 1, 2012 was not made.

The Company does not expect to have sufficient available funds as of September 1, 2013, to make principal payments, totaling \$915,000, and consisting of \$185,000 due on September 1, 2013, plus scheduled principal payments totaling \$730,000, consisting of \$260,000 due on September 1, 2012, and not paid, plus \$245,000 due on September 1, 2011 and not paid plus \$225,000 due on September 1, 2010 and not paid.

The Company has received Notice of Default from the Trustee of the NJEDA Bonds in relation to the withdrawals from the debt service reserve, and no payment of scheduled principal amounts. Resolution of the Company's default under the NJED Bonds will have a significant effect on our ability to operate in the future.

Due to issuance of a Notice of Default being received from the Trustee of the NJEDA Bonds, and until the event of default is waived or rescinded, the Company has classified the Current Bond Liability, as a current liability.

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**NOTE 7 - 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 and convertible preferred instruments issued by the Company. As the conversion features within, and the detachable warrants issued with the Company’s Series B, Series C, Series E and Series G Preferred Stock, do not have fixed settlement provisions because their conversion and 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.

**Preferred Stock Derivative Liabilities**

Preferred Stock Derivative Liability as of Current Balance Sheet Date

	<b>Series C</b>	<b>Series E</b>	<b>Series G</b>	<b>Total</b>
Preferred shares Outstanding	24	1,800	1,085	2,909
Underlying common shares into which Preferred may convert	160,000	73,954,598	15,500,002	89,614,600
Closing price on valuation date	\$0.07	\$0.07	\$0.07	\$0.07
Preferred stock derivative liability at Current Balance Sheet Date	\$11,200	\$5,176,822	\$1,085,000	\$6,273,022
Preferred stock derivative liability at March 31, 2013	\$697,584	\$5,637,037	—	\$6,334,621

**CHANGE IN VALUE OF PREFERRED STOCK DERIVATIVE LIABILITY**

	Three months ended	
	June 30,	
	2013	2012
Change in Preferred Stock Derivative Liability	\$(900,838)	\$(4,643,484)

**Warrant 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 2013	June 30 2013
Risk-Free interest rate	0.04% - 0.77%	0.02% - 1.41%
Expected volatility	106% - 168%	35% - 97%
Expected life (in years)	0.5 – 5.1	0.2 – 4.8
Expected dividend yield	—	—
Number of warrants	139,344,939	139,344,939
Fair Value of Warrant Derivative Liability	\$7,862,848	\$4,966,391

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CHANGE IN VALUE OF WARRANT DERIVATIVE LIABILITY

	Three months ended June 30	
	2013	2012
Change in Warrant Derivative Liability	\$ 2,896,457	\$ (5,088,733 )

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 8 - PREFERRED SHARE DERIVATIVE INTEREST PAYABLE**

Preferred share derivative interest payable as of the Current Balance Sheet Date consisted of the amount reported on the liability section of the balance sheet and titled "Preferred Share Derivative Interest Payable". This amount was paid via the issuance of the Derivative Interest Liability Common Shares in July 2013.

**NOTE 9 - OPERATING LEASES**

The Company entered into a lease for a portion of a one-story warehouse, located at 135 Ludlow Avenue, Northvale, New Jersey, consisting of approximately 15,000 square feet of floor space. The lease term began on July 1, 2010 and is classified as an operating lease. The lease includes an initial term of 5 years and 6 months and the Company has the option to renew the lease for two additional terms, each of 5 years. The property related to this lease will be used for the storage of pharmaceutical finished goods, raw materials, equipment and documents as well as engaging in manufacturing, packaging and distribution activities.

This property required significant leasehold improvements and qualification as a prerequisite to achieving suitability for such intended future use and in January 2013, the Company began using the facility at 135 Ludlow Avenue for commercial production and commenced shipping packaged products from the facility.

Minimum 5 year payments\* for the leasing of 15,000 square feet at 135 Ludlow are as follows:

Fiscal year ended March 31, 2014	83,259
Fiscal year ended March 31, 2015	85,344
Fiscal year ended March 31, 2016	87,363
Fiscal year ended March 31, 2017	89,112
Fiscal year ended March 31, 2018	90,894
Total Minimum 5 year lease payments	\$435,972

\* 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 June 30,	
	2013	2012
Rent Expense	\$ 22,584	\$ 22,584
Change in deferred rent liability	\$ 1,899	\$ 2,403



DEFERRED  
RENT  
LIABILITY  
(LONG-TERM  
LIABILITY)

	March 31	June 30
	2013	2013
Balance of Deferred Rent Liability	\$ 68,260	\$ 70,160

**NOTE 10 - DEFERRED REVENUES**

Deferred revenues are summarized as follows:

Advance payment received	\$200,000
Total revenue recognized as of March 31, 2013	(34,444 )
Revenue recognized three months ended June 30, 2013	(3,333 )
Total Deferred Revenues as of Current Balance Sheet Date	162,223
Current Portion of Deferred Revenues as of Current Balance Sheet Date	13,333
Non-Current Portion of Deferred Revenues as of Current Balance Sheet Date	148,890

Deferred revenues represents the unamortized amount of an advance payment received from Precision Dose Inc. for a licensing agreement with a fifteen year term beginning in September 2010 and ending in August 2025. The advance payment was recorded as deferred revenue when received and is earned, on a straight line basis over the fifteen year life of the license. The current portion of deferred revenues, represents the revenue that will be recognized over the 12 months immediately subsequent to Current Balance Sheet Date. The long term portion of deferred revenues, represents the revenue that will be recognized during the period that begins more than twelve months subsequent to the Current Balance Sheet Date. Please refer to exhibit 10.9 of the quarterly report on form 10-Q filed on November 15, 2010 for further details on the Precision Dose Manufacturing Agreement, with such exhibit being herein incorporated by this reference.

**NOTE 11 - STOCKHOLDERS'  
EQUITY**

**Common Stock**

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

Description	Shares Of Common Stock
Common Shares issued in lieu of cash in payment of Preferred Share Derivative Interest	341,562
Common Shares issued pursuant to the conversion of Series C, Series E and Series G Preferred Share derivatives	12,030,453
Common shares sold pursuant to the LPC Purchase Agreement	5,873,618
Common shares issued as commitment shares pursuant to the LPC Purchase Agreement	3,046,280
Total Common Shares issued during the Current YTD	21,291,913

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**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	2,752,332	\$0.06 to \$2.80
Non-Vested Options	1,156,668	\$0.12 to \$2.25

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 January 18, 2013 and through June 19, 2015, 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 12 - 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 June 30,	
	2013	2012
Numerator		
Net Income (loss) attributable to common shareholders - Basic	\$921,666	\$(10,522,095 )
Net Income attributable to common shareholders - Diluted	(1,223,977 )	n/a
Denominator		
Weighted-average shares of common stock outstanding	387,969,981	337,272,222
Dilutive effect of stock options, warrants and convertible securities	192,418,886	n/a
Net (loss) income per share		
Basic	\$0.00	\$(0.03 )
Diluted	\$(0.00 )	\$(0.03 )

**NOTE 13 - RELATED PARTY TRANSACTION - BORROWING AGAINST TREPPEL CREDIT LINE**

As of the Current Balance Sheet Date, Elite owed the Treppel Credit Line Balance and the Treppel Credit Line Interest Due in relation to the Treppel Credit Line. Both amounts were recorded as current liabilities on Elite's balance and included in the line item titled "Short term loans and current portion of long-term debt".

For further details on the Treppel Credit Line, please refer to Note 2 of these financial statements and the Current Reports on Form 8-K filed with the SEC on June 13, 2012 and December 10, 2012, with such filings being herein incorporated by reference.

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## **NOTE 14 - SUBSEQUENT EVENTS**

### **Common shares issued in lieu of cash in payment of derivative interest expense**

The Derivative Interest Liability Common Shares were issued during July 2013 in payment of those amounts listed as a current liability as of June 30, 2013 under the line item “Preferred Share Derivative Interest Payable”.

### **Appointment of New Chief Executive Officer**

On August 1, 2013, the Company hired Nasrat Hakim as its President and Chief Executive Officer, effective August 2, 2013, pursuant to an executive employment agreement (the “Hakim Employment Agreement”). Mr. Hakim, age 52, has more than 30 years of pharmaceutical and medical industry experience in Quality Assurance, Analytical Research and Development, Technical Services and Regulatory Compliance. He brings with him proven management experience, in-depth knowledge of manufacturing systems, development knowledge in immediate and extended release formulations and extensive regulatory experience of GMP and FDA regulations. From 2004 through June 2013, Mr. Hakim was employed by Actavis, Watson and Alparma in various senior management positions. Most recently, Mr. Hakim served as International Vice President of Quality Assurance at Actavis, overseeing 25 sites with more than 3,000 employees under his leadership. Mr. Hakim also served as Corporate Vice President of Technical Services, Quality and Regulatory Compliance for Actavis U.S., Global Vice President, Quality and Regulatory Compliance for Alparma, as well as Executive Director of Quality Unit at TheraTech, overseeing manufacturing and research and development. In 2009, Mr. Hakim founded Mikah Pharma LLC, a virtual, fully functional pharmaceutical company.

In conjunction with the retention of Mr. Hakim, Mr. Jerry Treppel resigned as the Company’s CEO. Mr. Treppel remains Chairman of the Board of Directors.

Mr. Hakim’s career started in Medical Laboratory Technology from the Academy of Health and Science in the U.S. Army based in San Antonio, TX, followed by Graduate Certification in Regulatory Affairs (RAC) from California State University at Sacramento, Sacramento, CA; Bachelor in Chemistry/Bio-Chemistry and Masters of Science in Chemistry from California State University at Sacramento, Sacramento, CA; and a Masters in Law with Graduate Certification in U.S. Taxation from St. Thomas University, School of Law, Miami, FL.

Pursuant to the Hakim Employment Agreement, Mr. Hakim will receive an annual salary of \$350,000 per year (the “Hakim Salary”). The Hakim Salary will be paid in shares of the Common Stock pursuant to the Company’s current procedures for paying Company executives in Common Stock. He also will be entitled to an annual bonus equal to up to 100% of his annual salary (also payable in Common Stock) based upon his ability to meet certain Company milestones to be determined by the Company’s Board of Directors (the “Board”). The Board may also award discretionary bonuses in its sole discretion. Mr. Hakim is entitled to employee benefits (e.g. health insurance, vacation, employee benefit plans and programs) consistent with other Company employees of his seniority and a car allowance.

The Hakim Employment Agreement contains confidentiality, non-competition and other standard restrictive covenants.

Mr. Hakim's employment is terminable by the Company for cause (as defined in the Hakim Employment Agreement). The Hakim Employment Agreement also may be terminated by the Company upon at least 30 days written notice due to disability (as defined in the Hakim Employment Agreement) or without cause. Mr. Hakim can terminate the Hakim Employment Agreement by resigning, provided he give notice of at least 60 days prior to the effective resignation date. If Mr. Hakim is terminated for cause or he resigns, he only is entitled to accrued and unpaid salary, accrued vacation time and any reasonable and necessary business expenses, all through the date of termination and payable in Common Stock ("Basic Termination Benefits"). If Mr. Hakim is terminated because of disability or death, in addition to Basic Termination Benefits, he is entitled to his pro rata annual bonus through the date of termination (payable in Common Stock). If the Company terminates Mr. Hakim without cause, in addition to Basic Termination Benefits, Mr. Hakim is entitled to his pro rata annual bonus through the date of termination and an amount equal to two years' annual salary (all payable in Common Stock).

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Upon a Change of Control (as defined in the Hakim Employment Agreement), Mr. Hakim is entitled to a payment in an amount equal to two years base annual salary in effect upon the Date of Termination, less applicable deductions and withholdings, payable in Common Stock computed in the same manner as set forth as the Hakim Salary.

The foregoing description of the Hakim Employment Agreement is qualified in its entirety by reference to the full text of the Hakim Employment Agreement, a copy of which is attached as Exhibit 10.4 to the Current Report on Form 8-K filed with the SEC on August 5, 2013, with such filing being herein incorporated by reference.

### **Completion of Acquisition of Assets**

On August 1, 2013, Elite Laboratories Inc. (“Elite Labs”), a wholly owned subsidiary of the Company, executed an asset purchase agreement (the “Mikah Purchase Agreement” with Mikah Pharma LLC (“Mikah”) and acquired from Mikah a total of 13 Abbreviated New Drug Applications (“ANDAs”) consisting of 12 ANDAs approved by the U.S. Food and Drug Administration (the “FDA”) and one ANDA under active review with the FDA, and all amendments thereto (the “Acquisition”) for aggregate consideration of \$10,000,000, payable pursuant to a secured convertible note due in August 2016 (the “Note”).

Elite previously purchased two ANDA products and has a development agreement with Mikah (please see the relevant disclosure in the Company’s Annual Report on Form 10-K for the fiscal year ended March 31, 2013 and filed with the SEC on June 21, 2013).

The products referenced in the approved ANDAs require site transfer approval with the FDA. Elite will submit filings to the FDA for each of the products for the manufacturing site transfer. The Company believes that the site transfers qualify for a CBE 30 review with one exception, which would allow for the product manufacturing transfer on an expedited basis. However, the Company can give no assurances that the site transfers will qualify for a CBE 30 review, or on the timing of these transfers and the timing is dependent on the FDA reviews. The approved ANDAs include pain, antipsychotic, hypertension, antihistamine, bariatric and muscle relaxant products. Of the thirteen products, two products are in markets where there is only one other generic competitor.

The Note is interest free and due and payable on the third anniversary of its issuance. Subject to certain limitations, the principal amount of the Note is convertible at the option of Mikah on and after the first anniversary of the date of the Note into shares of Common Stock at a rate of \$0.07 (approximately 14,286 shares per \$1,000 in principal amount), the closing market price of the Company’s Common Stock on the date that the asset purchase agreement and Note were executed. The conversion rate is adjustable for customary corporate actions such as stock splits and, subject to certain exclusions, includes weighted average anti-dilution for common stock transactions at prices below the then applicable conversion rate. Pursuant to a security agreement (the “Security Agreement”), repayment of the Note is secured by the ANDAs acquired in the Acquisition.

As noted above, in conjunction with the Acquisition, Nasrat Hakim, the President, CEO and principal of Mikah, was appointed President, CEO and a Director of the Company.

The foregoing descriptions of the Purchase Agreement, Note and Security Agreement are qualified in their entirety by reference to the full text of the Purchase Agreement, Note and Security Agreement, copies of which are attached as Exhibit 10.1 10.2 and 10.3, respectively to the Current Report on Form 8-K filed with the SEC on August 5, 2013, with the exhibits and current report being herein incorporated 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.

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**Common Stock sold pursuant to the LPC Purchase Agreement**

Subsequent to the Current Balance Sheet Date and up to August 9, 2013 (the latest practicable date), a total of 5,868,479 shares of Common Stock were sold pursuant to the LPC Purchase Agreement.

For further details on the LPC Agreement and LPC Registration Rights Agreement, please refer to the Current Report on Form 8-K filed with the SEC on April 22, 2013, with such filing being herein incorporated by reference. A Registration Statement on Form S-1 was filed with the SEC on April 25, 2013 and declared effective by the SEC on May 9, 2013. A post-effective amendment to the Registration Statement was filed with the SEC and declared effective on June 26, 2013.

**Amendment to Treppel Credit Line**

On August 2, 2013, the Treppel Credit Line Agreement was amended to extend the date on which the unpaid principal amount then outstanding plus accrued interest thereon be paid in full from July 31, 2013 to July 31, 2014. In addition, the requirement that the unpaid principal amount then outstanding plus accrued interest thereon be paid on such date that the Company raises at least \$2,000,000 in gross proceeds from the sale of any of its equity securities was removed. All other terms remain the same.

**Appointment of New Executive Vice President of Operations**

On August 12, 2013, the Company hired industry veteran Doug Plassche as Executive Vice President of Operations to run manufacturing and to lead the operational initiatives of the Company as it expands its product pipeline. Mr. Plassche has a proven track record in all critical areas including quality, compliance, process, operations, planning and personnel development.

Doug Plassche has more than 23 years of pharmaceutical industry experience. From 2009 to 2013, Mr. Plassche was employed by Actavis as Managing Director of the New Jersey Solid Oral Dose Operations, overseeing 450 employees and the production of more than 100 products. From 2007 to 2009, Mr. Plassche was Senior Director of Manufacturing for PAR Pharmaceuticals overseeing 200 employees and the production of more than 70 products. From 1990 - 2007, he was employed by Schering-Plough progressing steadily through multiple disciplines, locations and technical operations sectors with increasing levels of responsibility.

**ITEM 2.**

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

**THREE MONTH PERIOD ENDED JUNE 30, 2013**

**COMPARED TO THE**

**THREE MONTH PERIOD ENDED JUNE 30, 2012**

**(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, 2013. 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, license or contract manufacture seven products currently being sold commercially, as follows:

- Phentermine 37.5mg tablets (“Phentermine 37.5mg”)
- Lodrane D<sup>®</sup> Immediate Release capsules (“Lodrane D”)
- Methadone 10mg tablets (“Methadone 10mg”)
- Hydromorphone Hydrochloride 8mg tablets (“Hydromorphone 8mg”)

- Phendimetrazine tartrate 35mg tablets (“Phendimetrazine 35mg”)
- Phentermine 15mg capsules (“Phentermine 15mg”)
- Phentermine 30mg capsules (“Phentermine 30mg”)

We own the following product which has been approved for manufacture by the United States Food and Drug Administration (“US-FDA”), but for which commercial production has not yet begun:

- Naltrexone HCl (“Naltrexone Generic”)

We also recently acquired approved Abbreviated New Drug Applications (“ANDAs”) for 12 products (the “Mikah Approved ANDAs”) and one ANDA that is under active review with the FDA (the “Mikah ANDA Application Product”) that were acquired pursuant to the asset purchase agreement with Mikah Pharma dated August 1, 2013 (the “Mikah Asset Purchase Agreement”). For further details on the Mikah Asset Purchase Agreement, Mikah Approved ANDAs and Mikah ANDA Application Product, please refer to the Current Report on Form 8-K filed with the SEC on August 5, 2013 and herein incorporated by reference.

Elite has executed a license agreement with Precision Dose, Inc. (the “Precision Dose License Agreement”) and a manufacturing agreement with The PharmaNetwork LLC (the “TPN Agreement”). The PharmaNetwork LLC was recently purchased by Alkem Laboratories Ltd (“Alkem”). The PharmaNetwork now goes by the name Ascend Laboratories LLC (“Ascend”) and is a wholly owned subsidiary of Alkem.

The Precision Dose License Agreement provides for the marketing and distribution, in the United States, Puerto Rico and Canada, of Phentermine 37.5mg, Phentermine Capsules, Hydromorphone 8mg, Naltrexone Generic, and certain additional products that require approval from the FDA. Phentermine 37.5mg tablets were launched in April 2011. Hydromorphone 8mg was launched in March 2012. Phentermine 15mg and Phentermine 30mg were launched in April 2013. Naltrexone Generic was approved by the US-FDA in January 2013, but not yet launched.

The TPN Agreement, executed on June 23, 2011, and amended on September 24, 2012, provides for the manufacture and packaging by the Company of Ascend’s methadone hydrochloride, 10mg tablets (“Methadone 10mg”), with the Methadone 10mg to be marketed by Ascend. The FDA has approved the manufacturing of Methadone 10mg at the Northvale Facility and the initial shipment of Methadone 10mg occurred during January 2012.

In addition, Elite also has an undisclosed generic product filed with the FDA that is awaiting review and for which Elite retains all rights.

The Company also has a pipeline of additional generic drug candidates under active development.

Additionally, the Company is developing abuse resistant opioid products, and once-daily opioid products.

On May 22, 2012, the United States Patent and Trademark Office (“USPTO”) issued U.S. Patent No. 8,182,836, entitled “Abuse-Resistant Oral Dosage Forms and Method of Use Thereof, with such patent providing further protection for the Company’s Abuse Resistant Technology.

On April 23, 2013, the USPTO issued U.S. Patent No. 8,425,933, entitled “Abuse-Resistant Oral Dosage Forms and Method of User Thereof”, with such patent providing further protection for the Company’s Abuse Resistant Technology.

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**

### **Phentermine**

On April 7, 2011, Elite made the initial shipment of phentermine HCl 37.5 mg tablets to TAGI. This triggered a milestone payment under the Precision Dose License Agreement. Phentermine 15mg and Phentermine 30mg were launched in April 2013. Phentermine 37.5mg tablets and Phentermine 15mg and 30mg capsules are now a commercial product being distributed by our partner, TAGI.

### **Lodrane D<sup>®</sup> Immediate Release capsules**

On September 27, 2011, the Company, along with ECR Pharmaceuticals ("ECR"), a wholly owned subsidiary of Hi-Tech Pharmacal ("Hi-Tech") launched Lodrane<sup>®</sup> D, an immediate release formulation of brompheniramine maleate and pseudoephedrine HCl, an effective, low-sedating antihistamine combined with a decongestant.

Lodrane D<sup>®</sup> is promoted and distributed in the U.S. by ECR, Hi-Tech's branded division. Lodrane<sup>®</sup> D is available over-the-counter but also has physician promotion. Lodrane D<sup>®</sup> is the one of the only adult brompheniramine

containing products available to the consumer at this time.

Lodrane D<sup>®</sup> 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.

Elite is manufacturing the product for ECR and will receive revenues for the manufacturing, packaging and laboratory stability study services for the product, as well as royalties on sales. The current U.S. allergy market exceeds \$3.5 billion.

#### **Methadone 10mg tablets**

On January 17, 2012, Elite commenced shipping Methadone 10mg tablets to Ascend Laboratories, LLC. (“Ascend”) pursuant to a commercial manufacturing and supply agreement dated June 23, 2011 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**

On March 13, 2012, Elite commenced shipping Hydromorphone 8mg to TAGI Pharma. This triggered a milestone payment under the License, Manufacturing and Supply Agreement with Precision Dose. Hydromorphone 8mg is now a commercial product being distributed by our partner, TAGI Pharma.

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

On November 13, 2012, the Company made the initial shipment of Phendimetrazine Tartrate 35mg tablets, the generic equivalent of Bontril PDM<sup>®</sup> 35mg tablets under a previously announced manufacturing and supply agreement with Mikah Pharma (“Mikah”).

As part of the Mikah Asset Purchase Agreement, the ANDA for Phendimetrazine Tartrate 35mg tablets was acquired by the Company.

The Company is currently assessing various options with regards to the commercial marketing and distribution of this product.

Bontril PDM<sup>®</sup> and its generic equivalents had total U.S. sales of approximately \$3.5 million for the twelve months ended September 2012, based on IMS Health Data. The Company will be compensated at an agreed upon price for the manufacturing and packaging of this product.

### **Approved Products**

Elite is the owner of the following approved Abbreviated New Drug Applications:

- Phentermine HCl 37.5mg tablets (“Phentermine 37.5mg”)
- Hydromorphone HCl 8mg tablets (“Hydromorphone 8mg”)
- Naltrexone HCl 50mg tablets (“Naltrexone 50mg”)
- Phentermine HCl 15mg capsules (“Phentermine 15mg”)
- Phentermine HCl 30mg capsules (“Phentermine 30mg”)
- Phendimetrazine Tartrate 35mg tablets (“Phendimetrazine 35mg”)

### **Phentermine HCl 37.5mg tablets**

The 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”).



**Hydromorphone HCl 8mg tablets**

The ANDA for Hydromorphone 8mg was acquired pursuant to an asset purchase agreement with Mikah Pharma LLC (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. However, please note that the completion of such transfer had been significantly delayed as a result of the FDA’s reclassification of the Company’s CBE-30 supplement filing to a prior approval supplement filing. As a result of the delays caused by this reclassification, the Company recorded an impairment of the Hydromorphone 8mg ANDA in an amount equal to the entire purchase price of the acquisition. This impairment was recorded and is included in the Company’s audited financial statements as of March 31, 2011.

**Naltrexone HCl 50mg tablets**

The ANDA for Naltrexone 50mg was acquired pursuant to an asset purchase agreement with Mikah Pharma LLC (the “Naltrexone Purchase Agreement”).

Transfer of the manufacturing process of Naltrexone 50mg to the Northvale Facility is a prerequisite of the Company's commercial launch of the product. The completion of such transfer had been significantly delayed as a result of the FDA's reclassification of the Company's CBE-30 supplement filing to a prior approval supplement filing. However, on January 31, 2013, the FDA approved the Company's supplemental application for the manufacturing and packaging of naltrexone hydrochloride 50mg tablets. This approval will allow the Company to commence the commercial manufacturing and packaging of this product for its sales and marketing partner, which will distribute the product as part of a multi-product distribution agreement. As a result of the prior delays caused by this reclassification, the Company has recorded an impairment of the Naltrexone 50mg ANDA in an amount equal to the entire purchase price of the acquisition. This impairment was recorded and is included in the Company's audited financial statements as of March 31, 2011.

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

Elite received approval as of September 28, 2012 from the US-FDA for Phentermine 15mg and Phentermine 30mg. These products were developed by Elite. The commercial launch of Phentermine 15mg and Phentermine 30mg had been delayed due to the sole supplier of the API approved for these products restricting the amount of such API available to Elite. We resolved this issue and the Phentermine 15mg and Phentermine 30mg products were launched in April 2013. The resolution of this issue related to the supply of API, however, required us to pay substantially higher prices than previously paid for the Phentermine API. Elite anticipates that some of the increase in API pricing could be offset with increase manufacturing efficiencies, but also that volumes and profits from these products will be impaired.

### **Phendimetrazine 35mg**

The ANDA for Phendimetrazine 35mg was included as one of the 13 products acquired pursuant to the Mikah Asset Purchase Agreement.

The Northvale Facility had previously been approved as a manufacturing site for this product, with commercial production commencing in 2012 and initial shipment of this product being made in November 2012, pursuant to a manufacturing and supply agreement between the Company and Mikah dated June 1, 2011.

The Company is now the owner of this ANDA and is assessing various marketing and distribution options.

### **Contract Manufacturing of Isradipine and Phendimetrazine**

On June 1, 2011, Elite executed a Manufacturing and Supply Agreement (the "Phendimetrazine Agreement") with Mikah Pharma, LLC ("Mikah") to undertake and perform certain services relating to two generic products: Isradipine Capsules USP, 2.5 mg and 5 mg ("Isradipine") and Phendimetrazine Tartrate Tablets USP, 35 mg ("Phendimetrazine").

On September 21, 2012, the Phendimetrazine Agreement was amended to remove Isradipine from the agreement, due to the discontinuance of development activities related to Isradipine.

On August 9, 2013, the Isradipine/Phendimetrazine Agreement was terminated by the written agreement of both parties, as a result of the Mikah Asset Purchase Agreement making the Phendimetrazine Agreement not relevant.

#### **Development and License Agreement with Hong Kong based company**

On March 16, 2012, Elite executed a Development and License Agreement (“D&L Agreement”) with a private Hong Kong-based company (the “Hong Kong-based Customer”) for Elite to develop for the Hong Kong-based Customer a branded prescription pharmaceutical product in the United States. The Hong Kong-based Customer has informed us that it has been in business for more than five years and it has multiple FDA approved manufacturing sites outside of the United States.

Pursuant to the D&L Agreement, the Hong Kong-based Customer has engaged Elite to develop and manufacture a prescription pharmaceutical product (the "Prescription Product"). Elite agrees to be the Preferred Manufacturer and supplier of the Prescription Product pursuant to the D&L Agreement and perform maintenance activities such as stability or annual report filings for the Prescription Product. The Hong Kong-based Customer, or its designees, shall prepare all applications necessary to obtain any Prescription Product registration and permits required to file the Prescription Product in the Territories required to market the Prescription Product. All Registrations shall be solely owned by the Hong Kong-based Customer including any NDA filed with the FDA for the Prescription Product. Elite shall provide the Hong Kong-based Customer with all pharmaceutical, technical, and clinical data and information in support of the NDA application by the Hong Kong-based Customer for the approval of the Prescription Product. In consideration of Elite's performance in accordance with the terms and conditions of the D&L Agreement, the Hong Kong-based Customer shall pay Elite milestone for the Development Program and shall pay Elite for the manufacturing of the Prescription Product. Maintenance activities will be paid separately on a quarterly basis.

The Hong Kong-based Customer shall own and market the Prescription Product under its own Trademark. The term of this D&L Agreement shall be effective from the date consummated and shall continue for a five (5) year term after the commercial launch of the Prescription Product. Upon the expiration of the initial term or any renewal term, this D&L Agreement will automatically renew for an additional one (1) year term, unless one Party gives at least six (6) months notice in writing in advance of its intent not to renew.

#### **Discontinued Products - Lodrane 24<sup>®</sup> and Lodrane 24D<sup>®</sup>**

On March 3, 2011, the FDA announced its intention to remove approximately 500 cough/cold and allergy related products from the U.S. market. The once daily allergy products manufactured by Elite, Lodrane 24<sup>®</sup> and Lodrane 24D<sup>®</sup> (the "Lodran<sup>®</sup> Extended Release Products"), were included in the FDA list of 500 products. After this announcement by the FDA, the Company's customer for the Lodran<sup>®</sup> Extended Release Products cancelled all outstanding orders and manufacturing of the Lodrane<sup>®</sup> Extended Release Products has ceased. The shipments made during the quarter ended June 30, 2011 consisted solely of quantities that were in production at the time ECR cancelled all outstanding orders. There were no shipments of the Lodrane Extended Release Products subsequent to those that were made during the quarter ended June 30, 2011.

ECR (the owner and marketer of the Lodrane<sup>®</sup> Extended Release Products) initiated a formal approval process with the FDA in 2010 regarding the Lodrane<sup>®</sup> Extended Release Products and issued a press release on March 3, 2011 stating that they will continue to actively pursue approval for the Lodrane<sup>®</sup> Extended Release Products. In addition, on April 29, 2011, ECR filed a Petition for Review with the United States Court of Appeals for the District of Columbia, petitioning such court to review and set aside the final order of the FDA with relation to the Lodrane<sup>®</sup> Extended Release Products. The Company has received no further information from ECR with regards to the status of the Petition filed.

The Lodrane<sup>®</sup> Extended Release Products were co-developed with our partner, ECR, and the Company was receiving revenues from the manufacture of the Lodrane<sup>®</sup> Products and laboratory stability study services, as well as royalties on

in-market sales. Contracts relating to the manufacture and sale of the Lodrane<sup>®</sup> Extended Release Products were formally terminated on April 26, 2013.

During the three months ended June 30, 2011, Elite made its final shipments of the Lodrane<sup>®</sup> Extended Release Products. In addition, the Company sold to ECR, at cost without markup, all raw materials related to the manufacture of the Lodrane<sup>®</sup> Extended Release Products which remained in stock subsequent to the final shipment of the Lodrane<sup>®</sup> Extended Release Products. As manufacturing of the Lodrane<sup>®</sup> Extended Release Products has ceased, there will be no further manufacturing revenues derived from the Lodrane<sup>®</sup> Extended Release Products unless and until such products receive the necessary approvals from the FDA.

Please note that there can be no assurances that such approvals will be granted or that future manufacturing revenues will be earned by the Company from the manufacture of the Lodrane<sup>®</sup> Extended Release Products, should such approvals be granted by the FDA. Furthermore, the Company has been advised that ECR has decided not to proceed with the development of the extended release formulations marketed under the Lodrane<sup>®</sup> brand. The company has received FDA feedback on clinical protocols for the extended release brompheniramine product. It also has filed a Citizen Petition with the FDA related to the extended release brompheniramine/pseudoephedrine product. The Company believes a successful resolution of the Citizen Petition would put this product in a position to move forward with clinical trials and eventually secure the requisite approvals for introduction of the product to the market. The Company may proceed with the development of these formulations and may seek partners in conjunction with such activities, but there can be no assurances that the Company will pursue the development of these formulations, or that such development activities, if pursued, will result in approvals from the FDA. Please also note that the Company does not have ownership of the Lodrane<sup>®</sup> brand name, and that if any products containing the formulations associated with the Lodrane<sup>®</sup> brand name are approved and marketed, such would be done under a different brand name.

While Elite's manufacturing of the Lodrane<sup>®</sup> Extended Release Products has ceased, the sale of such products in the US market was still permitted by the FDA until August 30, 2011. The Company earned royalties on any in-market sales that occurred up to that date.

Contract laboratory services for the Lodrane<sup>®</sup> Extended Products will continue, on a residual basis, as such services consist of stability studies that must be performed over certain defined time periods. These revenues are expected to be significantly less than laboratory service revenues earned in periods prior to the removal of the Extended Release Lodrane products from the market.

### **Products Under Development**

It is our general policy not to disclose products in our development pipeline or the status of such products until a product reaches a stage that we determine, for competitive reasons, in our discretion, to be appropriate for disclosure and because the disclosure of such information might suggest the occurrence of future matters or events that may not occur.

### **Abuse Resistant and Sustained Release Opioids**

A once-daily oxycodone formulation was developed by Elite, using its proprietary technology. An investigational new drug application, or IND, has been filed. Elite has completed two pharmacokinetic studies in healthy subjects and has scaled up the product. We are looking for a partner for this product.

The abuse resistant opioid products utilize our patented abuse-deterrent technology that is based on a pharmacological approach. These products are combinations of a narcotic agonist, in a sustained-release formulation intended for use in

patients with moderate to severe chronic 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 an IND for the product and has tested the product in a series of pharmacokinetic studies. The Company expects their first commercially scaled-up, abuse-resistant opioid product to enter human pilot studies later this year. Work has also been conducted on another abuse-resistant opioid product. Products utilizing the pharmacological approach to deter abuse such as Suboxone<sup>®</sup>, a product marketed in the United States by Reckitt Benckiser Pharmaceuticals, Inc., and Embeda<sup>®</sup>, a product marketed in the United States by Pfizer, Inc., has been approved by the FDA and is 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. The drug delivery technology development underlying the sustained release products was initiated 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 a once daily oxycodone product, 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.

### **Epic Strategic Alliance Agreement**

On March 18, 2009, Elite and Epic Pharma, LLC and Epic Investments, LLC, a subsidiary of Epic Pharma LLC (collectively, "Epic") entered into the Epic Strategic Alliance Agreement (amended on April 30, 2009, June 1, 2009 and July 28, 2009). The Epic Strategic Alliance Agreement expired on June 4, 2012. Epic is a pharmaceutical company that operates a business synergistic to that of Elite in the research and development, manufacturing and sales and marketing of oral immediate release and controlled-release drug products.

### **Product Development Agreements**

Elite is currently performing services pursuant to product development agreements with the following:

- Mikah Pharma LLC (the "Mikah Development Agreement")
- Hi-Tech Pharmacal Co. (the "Hi-Tech Development Agreement")
- A Private Hong Kong based company (the "Hong Kong D&L Agreement")

For further details on the Mikah Development Agreement, please refer to the current report on Form 8-K filed with the SEC on September 1, 2010 and exhibit 10.63 of our Annual Report on Form 10-K for the fiscal year ended March 31, 2011, such filings being herein incorporated by reference.

For further details on the Hi-Tech Development Agreement, please refer to the current report on Form 8-K filed with the SEC on January 4, 2011 and exhibit 10.68 of our Annual Report on Form 10-K for the fiscal year ended March 31, 2011, such filings being herein incorporated by reference.

For further details on the Hong Kong D&L Agreement, please refer to the current report on Form 8-K filed with the SEC on March 22, 2012, our amended Annual Report on Form 10-K/A for the fiscal year ended March 31, 2012 (filed with the SEC on September 14, 2012), and exhibit 10.77 of our Annual Report on Form 10-K for the fiscal year ended March 31, 2012, such filings being herein incorporated by reference.

### **Novel Labs Investment**

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. Novel's business strategy is to focus on its core strength in identifying and timely executing niche business opportunities in the generic pharmaceutical area. Elite owns less than 10% of the outstanding shares of Class A Voting Common Stock of Novel. To date, Elite has received no distributions or dividends from this investment.



### **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 are more likely than not to be realized. We assess a need for allowances relating to the valuation of inventories. We assess the recoverability of 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 June 30, 2013 Compared to Three Months Ended June 30, 2012**

Our revenues for the three months ended June 30, 2013 were \$722k an increase of \$143k or approximately 25% over revenues for the comparable period of the prior year, and consisted of \$543k in manufacturing fees, \$5k in lab and product development fees and \$173k in royalties and license fees. Revenues for the three months ended June 30, 2012, consisted of \$380k in manufacturing fees, \$70k in lab and product development fees, and \$128k in royalties and license fees. Manufacturing fees increased by approximately 43% as a result of the launch in April 2013 of two new products, Phentermine 15mg and 30mg capsules and the strong year-on-year growth of Elite's Phentermine 37.5mg tablets, Hydromorphone 8mg tablets and contract manufactured Methadone 10mg product lines. Please note that the profit margins earned on the Phentermine 37.5mg tablets, and the Phentermine 15mg and 30mg capsules have been adversely effected by significant increases in the price of raw materials required for the manufacture of these products. Lab and product development fees decreased by approximately 93% due to the decreased lab stability study revenues relating to the discontinuance of the Lodrane<sup>®</sup> Extended Release Products and also development fees being earned in the prior year in relation to the Hi-Tech Development Agreement. Royalties and license fees increased by approximately 35% due to the strong growth in sales from the Phentermine and Hydromorphone product lines. Please see the discussion above in "Overview; Approved Products concerning certain delays related to Phentermine due to issues with the sole supplier that have been resolved.

Research and development costs for the three months ended June 30, 2012 were \$569k, an increase of \$373k or approximately 189% from \$197k of such costs for the comparable period of the prior year. The increase was primarily due to increased activities related to the development of Elite's abuse resistant opioid products, for which a second patent was granted in May 2013.

General and administrative expenses for the three months ended June 30, 2013, were \$376k, an increase of \$11k, or approximately 3% from \$365k of general and administrative expenses for the comparable period of the prior year. The increase was primarily due to increases in regulatory costs, including, without limitation, increased fees paid to the US-FDA and the hiring of additional staff to support regulatory compliance activities, and increases in legal fees, insurance, employee benefits, offset by cost reductions achieved in operating overheads.

Depreciation and amortization for the three months ended June 30, 2013 was \$162k, an increase of \$121k, or approximately 288%, from \$42k for the comparable period of the prior year. The increase was primarily due to the commissioning, for commercial operations, of the new facility at 135 Ludlow in January of 2013, with the cost related assets and capital investments being placed in service and absorbed into manufacturing operations through depreciation expenses.

Non-cash compensation through the issuance of stock options and warrants for the three months ended June 30, 2013 was \$9k, an increase of \$3k, or approximately 50% from \$6k for the comparable period of the prior year. The increase is due to the issuance of employee stock options in June of 2012. For further details on such employee stock options, please see Note 11 of the financial statements filed with this Current Report on Form 10-Q.

As a result of the foregoing, our loss from operations for the three months ended June 30, 2013 was \$976k, compared to a loss from operations of \$486k for the three months ended June 30, 2012.

Other income for the three months ended June 30, 2013 were a net of \$1.9 million, an increase in other income of \$11.9 million from the net other expense of \$10.0 million for the comparable period of the prior year. The increase in other income was due to derivative income relating to changes in the fair value of our preferred shares and outstanding warrants during the quarter ended June 30, 2013 totaling \$2.0 million, as compared to a net derivative expense of \$9.7 million for the comparable period of the prior year. Please note that derivative income/(expenses) are most significantly determined by the number of preferred shares outstanding and the closing price of the Company's Common Stock as of the end of each annual or quarterly reporting period. As of June 30, 2013, there were an aggregate of 2,909 shares of Preferred Series C, Preferred Series E and Preferred Series G outstanding, as compared to an aggregate of 3,387.50 shares of Preferred Series B, Preferred Series C and Preferred Series E outstanding as of June 30, 2012.

As a result of the foregoing, our net income for the three months ended June 30, 2013 was \$0.9 million, compared to a net loss of \$10.5 million for the three months ended June 30, 2012.

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

Our working capital (total current assets less total current liabilities), decreased to a deficit of \$3.5 million as of June 30, 2013 from a working capital deficit of \$2.8 million as of March 31, 2013, primarily due to our net loss from operations, exclusive of non-cash charges. In addition, it should be noted that current liabilities includes the entire principal amount due on the Company's NJEDA Bonds Payable. This amount, totaling \$3.4 million has been classified as a current liability as a result of the Company receiving a notice of default from the Trustee of the NJ-EDA Bonds. Please refer to Note 6 to our financial statements and Item 3 of this quarterly report on Form 10-Q for further details.

Net cash used by operations was \$0.4 million for the three months ended June 30, 2013, primarily due to our net income from continuing operations of \$1.1 million, offset by non-cash charges totaling \$1.9 million, which included, without limitation, depreciation and amortization of \$0.1 million and net income from the change in fair value of derivative liabilities of \$2.0 million. In addition, net cash used by operations was effected by changes in the balances of assets and liabilities, including, without limitation, decreases in accounts receivable and inventories of \$0.2 million and \$0.4 million, respectively (resulting in a net inflow of cash).

### **LIQUIDITY AND CAPITAL RESOURCES**

#### **Going concern considerations**

As of June 30, 2013, the Company had a working capital deficit of \$3.5 million, losses from operations totaling \$1.0 million for the three months ended June 30, 2013, net other income totaling \$1.9 million for the three months then ended and a net income of \$0.9 million for the three months ended June 30, 2013. Please note that the Company's other income/(expenses) are significantly influenced by the fluctuations in the fair value of outstanding preferred share and warrant derivatives, and that such fair values strongly correlate to and vary inversely with the market share price of the Company's Common Stock.

The Company does not anticipate being profitable for the fiscal year ending March 31, 2014. In addition, the Company has received Notice of Default from the Trustee of the NJEDA Bonds as a result of the utilization of the debt service reserve being used to pay interest payments as well as the company's failure to make scheduled principal payments. See "NJEDA Bonds" below.

### **Lincoln Park Capital Purchase Agreement**

On April 19, 2013, the Company entered into a purchase agreement (the "LPC Purchase Agreement"), together with a registration rights agreement (the "LPC Registration Rights Agreement"), with Lincoln Park Capital Fund, LLC ("LPC").

Under the terms and subject to the conditions of the LPC Agreement, the Company has the right to sell to and LPC is obligated to purchase up to \$10 million in shares of the Company's Common Stock, subject to certain limitations, from time to time, over the 36 month period commencing on May 9, 2013, the date that the registration statement, which the Company agreed to file with the Securities and Exchange Commission (the "SEC") pursuant to the LPC Registration Rights Agreement, was declared effective by the SEC. The Company may direct LPC, at its sole discretion and subject to certain conditions, to purchase stock in amounts of up to \$80,000 on any single business day, so long as at least two business days have passed since the most recent purchase, increasing to up to \$500,000 per purchase, depending upon the closing sale price of the Common Stock. The purchase price of the 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 (or over a period of up to 12 business days leading up to such time), but in no event will shares be sold to LPC on a day the Common Stock closing price is less than the floor price of \$0.07 per share, subject to adjustment. The Company's sales of shares of Common Stock to LPC under the LPC Purchase Agreement are limited to no more than the number of shares that would result in the beneficial ownership by LPC and its affiliates, at any single point in time, of more than 9.99% of the then outstanding shares of Common Stock. As of August 9, 2013 (the latest practicable date), a total of 14,788,377 shares have been sold pursuant to the LPC Purchase Agreement, inclusive of purchase and commitment shares, with total proceeds totaling \$800,000.

A Current Report on Form 8-K was filed with the SEC on April 22, 2013 with regards to the LPC Purchase Agreement and LPC Registration Rights Agreement with such filing being herein incorporated by reference. A Securities Registration Statement on Form S-1 was filed with the SEC on April 25, 2013 and declared effective by the SEC on May 9, 2013. A post-effective amendment to the Registration Statement was filed with the SEC and declared effective on June 26, 2013.

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

On June 12, 2012 (the "Effective Date"), we entered into a bridge loan agreement (the "Loan Agreement") with Jerry Treppel, our Chairman and CEO. Under the terms of the Loan Agreement, we have the right, in our sole discretion, to a line of credit (the "Credit Line") in the maximum principal amount of up to \$500,000 at any one time. By amendments, the maximum principal amount was increased to \$1,000,000 and the maturity date was amended and extended. Mr. Treppel provided the Credit Line for the purpose of supporting the acceleration of our product development activities. The current term of the Loan Agreement ends on July 31, 2014, 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 July 1, October 1, January 1 and April 1 of each year. Prior to maturity or the occurrence of an Event of Default as defined in the Loan Agreement, we may borrow, repay, and reborrow under the Credit Line through maturity. Amounts borrowed under the Credit Line will bear interest at the rate of ten percent (10%) per annum. As of June 30, 2013, the principal balance owed under the Credit Line was \$600,000 with an additional \$15,123 in accrued interest being also owed, in accordance with the terms and conditions of the Credit Line. For more detailed information, please see the Loan Agreement filed as an exhibit to our Current Report on Form 8-K filed with the SEC on June 13, 2012, and the amendments thereto filed as an exhibit to our Current Reports on Form 8-K filed with the SEC on December 10, 2012 and August 6, 2013 which forms 8-K and exhibits are incorporated by reference herein.

### **Completion of Epic Strategic Alliance Payments**

We have successfully completed the initial, second and third closings of the Epic Strategic Alliance Agreement and the twelve quarterly payments, with each such quarterly payment being equal to the Epic Quarterly Payment Amount and have accordingly received the full investment from Epic, exclusive of warrant exercise, as provided for in the Epic Strategic Alliance Agreement. For additional information regarding the Epic Strategic Alliance Agreement, please see our disclosures under “Epic Strategic Alliance Agreement” in Item 7 of Part II of our Annual Report on Form 10-K, and in our Current Reports on Form 8-K, filed with the SEC on March 23, 2009, May 6, 2009, June 5, 2009, July 1, 2010 and June 29, 2011, such disclosures being herein incorporated by reference.

Despite having received the full investment from Epic Investments LLC, exclusive of warrant exercise, as provided for in the Epic Strategic Alliance Agreement, entered into the Treppel Credit Line Agreement, and entered into the LPC Purchase Agreement we still may be required to seek additional capital in the future and there can be no assurances that Elite will be able to obtain such additional capital on favorable terms, if at all.

Based upon our current cash position, management has undertaken a review of our operations and implemented cost-cutting measures in an effort to eliminate any expenses which are not deemed critical to our current strategic objectives. We will continue this process without impeding our ability to proceed with our critical strategic goals, which, as noted above, include developing our pain management and other products and manufacturing our current products.

Cash and cash equivalents at June 30, 2013, were approximately \$0.2 million, a decrease of approximately \$0.3 million from the approximately \$0.5 million balance of cash and cash equivalents at June 30, 2012.

As of June 30, 2013, our principal source of liquidity was approximately \$0.2 million of cash and cash equivalents. Additionally, we may have access to funds through the exercise of outstanding stock options and warrants and, as mentioned above, from the LPC Purchase Agreement and Treppel Credit Line. There can be no assurance that any of these sources will generate or provide sufficient cash.

### **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 March 31, 2013, 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. \$1,274,311 of the proceeds had been deposited in a short-term restricted cash account to fund the purchase of manufacturing equipment and development of the Company's facility.

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 \$3,545 for the three months ended June 30, 2013.

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.

The interest payments due on March 1st and September 1st of 2009, 2010, 2011 and 2012, as well as the interest payment due on March 1st 2013, totaling \$1,033,075 for all nine payments, were paid from the debt service reserved



held in the restricted cash account, due to the Company not having sufficient funds to make such payments when they were due.

The principal payment due on September 1, 2009, totaling \$210,000 was paid from the debt service reserve held in the restricted cash account, due to the Company not having sufficient funds to make the payment when due.

The Company did not have sufficient funds available to make the principal payments due on September 1, 2010, totaling \$225,000 and requested that the Trustee withdraw such funds from the debt service reserve. The Company's request was denied and accordingly the principal payment due on September 1, 2010, totaling \$225,000 was not made.

The Company did not have sufficient funds available to make the principal payments due on September 1, 2011, totaling \$470,000, with such amount including the principal payments due on September 1, 2010 and not paid. There were not sufficient funds available in the debt service reserve and accordingly, the principal payment totaling \$470,000 was not made.

The Company did not have sufficient funds available to make the principal payments due on September 1, 2012, totaling \$730,000, with such amount including the principal payments due on September 1, 2011 and not paid. There were not sufficient funds available in the debt service reserve and accordingly, the principal payment totaling \$730,000 was not made.

Pursuant to the terms of the NJEDA Bonds, the Company is required to replenish any amounts withdrawn from the debt service reserve and used to make principal or interest payments in six monthly installments, each being equal to one-sixth of the amount withdrawn and with the first installment due on the 15th of the month in which the withdrawal from debt service reserve occurred and the remaining five monthly payments being due on the 15th of the five immediately subsequent months. The Company has, to date, made all payments required in relation to the withdrawals made from the debt service reserve on March 1, 2009, September 1, 2009, March 1, 2010, September 1, 2010, March 1, 2011, September 1, 2011, March 1, 2012, September 1, 2012 and March 1, 2013.

The Company does not expect to have sufficient available funds as of September 1, 2013, to make principal payments, totaling \$915,000, and consisting of \$185,000 due on September 1, 2013, plus scheduled principal payments totaling \$730,000, consisting of \$260,000 due on September 1, 2012, and not paid, plus \$245,000 due on September 1, 2011 and not paid plus \$225,000 due on September 1, 2010 and not paid.

The Company has received Notice of Default from the Trustee of the NJEDA Bonds in relation to the withdrawals from the debt service reserve, and no payment of scheduled principal amounts. Resolution of the Company's default under the NJED Bonds will have a significant effect on our ability to operate in the future.

Due to issuance of a Notice of Default being received from the Trustee of the NJEDA Bonds, and until the event of default is waived or rescinded, the Company has classified the entire principal due, an amount aggregating \$3.385 million, as a current liability.

### **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**

Not applicable.

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

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

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 Securities Exchange Act of 1934 (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 and Chief Financial Officers concluded that our disclosure controls and procedures as of the end of the period covered by this report were not effective so that 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. 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.

## **Changes in Internal Controls**

There have been no changes in our internal control over financial reporting (as such term is defined in Rules 13a-15(f) and 15d-15 (f) under the Exchange Act) during the three months ended June 30, 2013, 2012 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. There is no past, 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.

### **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, 2013.

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

During the three months ended June 30, 2013, we issued 12,372,015 shares of Common Stock to the holders of our Series C, Series E and Series G Preferred Stock. Of this amount, 341,562 shares were issued in satisfaction of our obligation to pay \$27,500 in dividends earned and/or owing during the three months ended March 31, 2013, 2012, and 12,030,453 shares were issued pursuant to the conversion of Series E, and Series G Preferred Share derivatives, with such derivative liabilities being valued at an aggregate of \$962,436 at the time of their conversion. We relied on the exemption provided by Section 4(a)(2) of the Securities Act of 1933 to issue the common stock. The securities were offered and sold without any form of general solicitation or general advertising and the offerees made representations that they were accredited investors.

### **ITEM 3. DEFAULTS UPON SENIOR SECURITIES**

Please see the discussion in Note 5 to our financial statements titled “NJEDA Bonds” which is incorporated herein by this reference.

### **ITEM 4. Mine Safety Disclosures.**

Not applicable.

### **ITEM 5. Other Information**

#### **Appointment of New Chief Executive Officer**

On August 1, 2013, the Company hired Nasrat Hakim as its President and Chief Executive Officer, effective August 2, 2013, pursuant to an executive employment agreement (the “Hakim Employment Agreement”). Mr. Hakim, age 52, has more than 30 years of pharmaceutical and medical industry experience in Quality Assurance, Analytical Research and Development, Technical Services and Regulatory Compliance. He brings with him proven management experience, in-depth knowledge of manufacturing systems, development knowledge in immediate and extended release formulations and extensive regulatory experience of GMP and FDA regulations. From 2004 through June 2013, Mr. Hakim was employed by Actavis, Watson and Alpharma in various senior management positions. Most recently, Mr. Hakim served as International Vice President of Quality Assurance at Actavis, overseeing 25 sites with more than 3,000 employees under his leadership. Mr. Hakim also served as Corporate Vice President of Technical Services, Quality and Regulatory Compliance for Actavis U.S., Global Vice President, Quality and Regulatory Compliance for Alpharma, as well as Executive Director of Quality Unit at TheraTech, overseeing manufacturing and research and development. In 2009, Mr. Hakim founded Mikah Pharma LLC, a virtual, fully functional pharmaceutical company.

In conjunction with the retention of Mr. Hakim, Mr. Jerry Treppel resigned as the Company's CEO. Mr. Treppel remains Chairman of the Board of Directors.

Mr. Hakim's career started in Medical Laboratory Technology from the Academy of Health and Science in the U.S. Army based in San Antonio, TX, followed by Graduate Certification in Regulatory Affairs (RAC) from California State University at Sacramento, Sacramento, CA; Bachelor in Chemistry/Bio-Chemistry and Masters of Science in Chemistry from California State University at Sacramento, Sacramento, CA; and a Masters in Law with Graduate Certification in U.S. Taxation from St. Thomas University, School of Law, Miami, FL.

Pursuant to the Hakim Employment Agreement, Mr. Hakim will receive an annual salary of \$350,000 per year (the "Hakim Salary"). The Hakim Salary will be paid in shares of the Common Stock pursuant to the Company's current procedures for paying Company executives in Common Stock. He also will be entitled to an annual bonus equal to up to 100% of his annual salary (also payable in Common Stock) based upon his ability to meet certain Company milestones to be determined by the Company's Board of Directors (the "Board"). The Board may also award discretionary bonuses in its sole discretion. Mr. Hakim is entitled to employee benefits (e.g. health insurance, vacation, employee benefit plans and programs) consistent with other Company employees of his seniority and a car allowance. The Hakim Employment Agreement contains confidentiality, non-competition and other standard restrictive covenants.

Mr. Hakim's employment is terminable by the Company for cause (as defined in the Hakim Employment Agreement). The Hakim Employment Agreement also may be terminated by the Company upon at least 30 days written notice due to disability (as defined in the Hakim Employment Agreement) or without cause. Mr. Hakim can terminate the Hakim Employment Agreement by resigning, provided he give notice of at least 60 days prior to the effective resignation date. If Mr. Hakim is terminated for cause or he resigns, he only is entitled to accrued and unpaid salary, accrued vacation time and any reasonable and necessary business expenses, all through the date of termination and payable in Common Stock ("Basic Termination Benefits"). If Mr. Hakim is terminated because of disability or death, in addition to Basic Termination Benefits, he is entitled to his pro rata annual bonus through the date of termination (payable in Common Stock). If the Company terminates Mr. Hakim without cause, in addition to Basic Termination Benefits, Mr. Hakim is entitled to his pro rata annual bonus through the date of termination and an amount equal to two years' annual salary (all payable in Common Stock).

Upon a Change of Control (as defined in the Hakim Employment Agreement), Mr. Hakim is entitled to a payment in an amount equal to two years base annual salary in effect upon the Date of Termination, less applicable deductions and withholdings, payable in Common Stock computed in the same manner as set forth as the Hakim Salary.

The foregoing description of the Hakim Employment Agreement is qualified in its entirety by reference to the full text of the Hakim Employment Agreement, a copy of which is attached as Exhibit 10.4 to the Current Report on Form 8-K filed with the SEC on August 5, 2013, with such filing being herein incorporated by reference.



### **Completion of Acquisition of Assets**

On August 1, 2013, Elite Laboratories Inc. (“Elite Labs”), a wholly owned subsidiary of the Company, executed an asset purchase agreement (the “Mikah Purchase Agreement” with Mikah Pharma LLC (“Mikah”) and acquired from Mikah a total of 13 Abbreviated New Drug Applications (“ANDAs”) consisting of 12 ANDAs approved by the U.S. Food and Drug Administration (the “FDA”) and one ANDA under active review with the FDA, and all amendments thereto (the “Acquisition”) for aggregate consideration of \$10,000,000, payable pursuant to a secured convertible note due in August 2016 (the “Note”).

Elite previously purchased two ANDA products and has a development agreement with Mikah (please see the relevant disclosure in the Company’s Annual Report on Form 10-K for the fiscal year ended March 31, 2013 and filed with the SEC on June 21, 2013).

The products referenced in the approved ANDAs require site transfer approval with the FDA. Elite will submit filings to the FDA for each of the products for the manufacturing site transfer. The Company believes that the site transfers qualify for a CBE 30 review with one exception, which would allow for the product manufacturing transfer on an expedited basis. However, the Company can give no assurances that the site transfers will qualify for a CBE 30 review, or on the timing of these transfers and the timing is dependent on the FDA reviews. The approved ANDAs include pain, antipsychotic, hypertension, antihistamine, bariatric and muscle relaxant products. Of the thirteen products, two products are in markets where there is only one other generic competitor.

The Note is interest free and due and payable on the third anniversary of its issuance. Subject to certain limitations, the principal amount of the Note is convertible at the option of Mikah on and after the first anniversary of the date of the Note into shares of Common Stock at a rate of \$0.07 (approximately 14,286 shares per \$1,000 in principal amount), the closing market price of the Company’s Common Stock on the date that the asset purchase agreement and Note were executed. The conversion rate is adjustable for customary corporate actions such as stock splits and, subject to certain exclusions, includes weighted average anti-dilution for common stock transactions at prices below the then applicable conversion rate. Pursuant to a security agreement (the “Security Agreement”), repayment of the Note is secured by the ANDAs acquired in the Acquisition.

As noted above, in conjunction with the Acquisition, Nasrat Hakim, the President, CEO and principal of Mikah, was appointed President, CEO and a Director of the Company.

The foregoing descriptions of the Purchase Agreement, Note and Security Agreement are qualified in their entirety by reference to the full text of the Purchase Agreement, Note and Security Agreement, copies of which are attached as Exhibit 10.1 10.2 and 10.3, respectively to the Current Report on Form 8-K filed with the SEC on August 5, 2013, with the exhibits and current report being herein incorporated 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.

#### Appointment of New Executive Vice President of Operations

On August 12, 2013, the Company hired industry veteran Doug Plassche as Executive Vice President of Operations to run manufacturing and to lead the operational initiatives of the Company as it expands its product pipeline. Mr. Plassche has a proven track record in all critical areas including quality, compliance, process, operations, planning and personnel development.

Doug Plassche has more than 23 years of pharmaceutical industry experience. From 2009 to 2013, Mr. Plassche was employed by Actavis as Managing Director of the New Jersey Solid Oral Dose Operations, overseeing 450 employees and the production of more than 100 products. From 2007 to 2009, Mr. Plassche was Senior Director of Manufacturing for PAR Pharmaceuticals overseeing 200 employees and the production of more than 70 products. From 1990 - 2007, he was employed by Schering-Plough progressing steadily through multiple disciplines, locations and technical operations sectors with increasing levels of responsibility.

#### Item 6. Exhibits

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

#### Exhibit

##### Number Description

- |        |   |
|--------|---|
| 2.1    | Agreement and Plan of Merger between Elite Pharmaceuticals, Inc., a Delaware corporation (“Elite-Delaware”) and Elite Pharmaceuticals, Inc., a Nevada corporation (“Elite-Nevada”), incorporated by reference to Exhibit 2.1 to the Current Report on Form 8-K filed with the SEC on January 9, 2012. |
| 3.1(a) | Articles of Incorporation of Elite-Nevada, incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K filed with the SEC on January 9, 2012.  |

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) 3.1(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.\*

Certificate of Designations, Preferences and Rights of Series A Preferred Stock, as filed with the Secretary of 3.1(c) 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.\*

Certificate of Retirement with the Secretary of the State of the Delaware to retire 516,558 shares of the Series 3.1(d) 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.\*

Certificate of Designations, Preferences and Rights of Series B 8% Convertible Preferred Stock, as filed with 3.1(e) 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.\*

Amended Certificate of Designations of Preferences, Rights and Limitations of Series B 8% Convertible 3.1(f) 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.\*

Certificate of Designations, Preferences and Rights of Series C 8% Convertible Preferred Stock, as filed with 3.1(g) 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.\*

Amended Certificate of Designations, Preferences and Rights of Series C 8% Convertible Preferred Stock, as 3.1(h) 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.\*

Amended Certificate of Designations of Preferences, Rights and Limitations of Series B 8% Convertible 3.1(i) 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.\*

Amended Certificate of Designations, Preferences and Rights of Series C 8% Convertible Preferred Stock, as 3.1(j) 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.\*

Amended Certificate of Designations of Preferences, Rights and Limitations of Series D 8% Convertible 3.1(k) 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 July 1, 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 July 1, 2010 and filed with the SEC on July 1, 2010.\*
- 3.1 (o) Certificate of Designations of the Series G Convertible Preferred Stock as filed with the Secretary of State of the State of Nevada on April 18, 2013, incorporated by reference to Exhibit 4.1 to the Current Report on Form 8-K, dated April 18, 2013 and filed with the SEC on April 22, 2013.\*
- 3.2(a) By-Laws of Elite-Nevada, incorporated by reference to Exhibit 3.2 to the Current Report on Form 8-K filed with the SEC on January 9, 2012.
- 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 Socius Warrant to Purchase Common Stock, incorporated by reference to Exhibit 4.1 to the Current Report on Form 8-K filed with the SEC on January 5, 2012.
- 4.2 Form of specimen certificate for Common Stock of the Company, incorporated by reference to Exhibit 4.1 to the Form SB-2.
- 4.3 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.\*
- 4.4 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.\*
- 4.5 Form of specimen certificate for Series G 8% 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.
- 4.4 Warrant to purchase 100,000 shares of Common Stock issued to DH Blair Investment Banking Corp., incorporated by reference to Exhibit 10.2 to the Quarterly Report on Form 10-Q for the period ended September 30, 2004.\*
- 4.7 Warrant to purchase 50,000 shares of Common Stock issued to Jason Lyons incorporated by reference to Exhibit 10.3 to the Quarterly Report on Form 10-Q for the period ended June 30, 2004.\*
- 4.8 Form of Warrant to purchase shares of Common Stock issued to designees of lender with respect to financing of an equipment loan incorporated by reference to Exhibit 10.2 to the Quarterly Report on Form 10-Q for the period ended June 30, 2004.\*



4.9 Form of Short Term Warrant to purchase shares of Common Stock issued to purchasers in the private placement which initially closed on October 6, 2004 (the "Series A Financing"), incorporated by reference to Exhibit 4.6 to the Current Report on Form 8-K, dated October 6, 2004, and filed with the SEC on October 12, 2004.\*

4.10 Form of Long Term Warrant to purchase shares of Common Stock issued to purchasers in the Series A Financing, incorporated by reference to Exhibit 4.7 to the Current Report on Form 8-K, dated October 6, 2004, and filed with the SEC on October 12, 2004.\*

4.11 Form of Warrant to purchase shares of Common Stock issued to the Placement Agent, in connection with the Series A Financing, incorporated by reference to Exhibit 4.8 to the Current Report on Form 8-K, dated October 6, 2004, and filed with the SEC on October 12, 2004.\*

4.12 Form of Replacement Warrant to purchase shares of Common Stock in connection with the offer to holders of Warrants in the Series A Financing (the "Warrant Exchange"), incorporated by reference to Exhibit 4.1 to the Current Report on Form 8-K, dated December 14, 2005, and filed with the SEC on December 20, 2005.\*

4.13 Form of Warrant to purchase shares of Common Stock to the Placement Agent, in connection with the Warrant Exchange, incorporated by reference to Exhibit 4.2 to the Current Report on Form 8-K, dated December 14, 2005, and filed with the SEC on December 20, 2005.\*

4.14 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.\*

4.15 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.\*

4.16 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.\*

4.17 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.\*

4.18 Form of Warrant to purchase up to 478,698 shares of Common Stock issued to VGS PHARMA, LLC, incorporated by reference to Exhibit 3(a) to the Current Report on Form 8-K, dated December 6, 2006 and filed with the SEC on December 12, 2006.\*

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

4.20 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.\*

Form of Warrant to purchase shares of Common Stock issued to the placement agent in the Series C Financing, 4.21 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.\*

4.22 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.\*

4.23 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.\*

4.24 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.\*

4.25 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.\*

4.26 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.\*

10.1 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 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.

10.2 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.

10.3 Form of Lock-Up Agreement (included as Exhibit D to the Securities Purchase Agreement with Socius mentioned in 10.2 above), incorporated by reference to Exhibit 10.2 to the Current Report on Form 8-K filed with the SEC on January 5, 2012.

10.4 Treppel 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.

10.5 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.

10.6 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).

10.7 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)





10.8 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.

10.9 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.

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

10.11 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 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.

10.12 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)

10.13 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.

10.14 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.

10.15 Termination of June 2011, Manufacturing and Supply Agreement between Mikah Pharma LLC and the Company.

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

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

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

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

101 The following materials from Elite Pharmaceuticals' Quarterly Report on Form 10-Q for the period ended June 30, 2013, formatted in eXtensible Business Reporting Language ("XBRL"): (i) the Condensed Consolidated Statements of Income; (ii) the Condensed Consolidated Balance Sheets; (iii) the Condensed Consolidated Statements of Cash Flows; and (iv) Notes to Condensed Consolidated Financial Statements.

\* 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.

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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: August 14, 2013 /s/ Nasrat Hakim  
Nasrat Hakim  
Chief Executive Officer  
(Principal Executive Officer)

Date: August 14, 2013 /s/ Carter J. Ward  
Carter J. Ward  
Chief Financial Officer  
(Principal Financial and Accounting Officer)