ELITE PHARMACEUTICALS INC /DE/ Form 10-Q August 15, 2011

#### U.S. SECURITIES AND EXCHANGE COMMISSION Washington, D.C. 20549 FORM 10-Q

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

For the quarterly period ended June 30, 2011

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: 333-45241

#### ELITE PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware 22-3542636

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

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 x No "

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

Yes o No x

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 x

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

Indicate the number of shares outstanding of each of the issuer's classes of common stock, as of the latest practicable date. As of August 10, 2011 the issuer had outstanding 247,112,408 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, 2011	March 31, 2011
	(Unaudited)	(Audited)
ASSETS	(Ollaudited)	(Audited)
CURRENT ASSETS		
Cash and cash equivalents	\$1,759,451	\$1,825,858
Accounts receivable (net of allowance for doubtful accounts of -0-)	513,532	571,667
Inventories (net of reserve of \$942,337 and \$494,425, respectively)	312,025	616,362
Prepaid expenses and other current assets	87,694	133,472
Trepara expenses and other current assets	07,027	133,472
Total Current Assets	2,672,702	3,147,359
PROPERTY AND EQUIPMENT, net of accumulated depreciation of \$4,311,020 and		
\$3,838,297, respectively	4,231,512	4,118,274
INTANGIBLE ASSETS – net of accumulated amortization of \$-0- and \$-0-, respectively	607,928	597,556
OTHER ASSETS		
Investment in Novel Laboratories, Inc.	3,329,322	3,329,322
Security deposits	28,377	28,377
Restricted cash – debt service for EDA bonds	348,367	291,420
EDA bond offering costs, net of accumulated amortization of \$82,431 and \$68,300,		
respectively	272,021	275,554
Total Other Assets	3,978,087	3,924,673
TOTAL ASSETS	\$11,490,229	\$11,787,862

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

# ELITE PHARMACEUTICALS, INC. AND SUBSIDIARIES

# CONDENSED CONSOLIDATED BALANCE SHEETS

	June 30, 2011 (Unaudited)	March 31, 2011 (Audited)
LIABILITIES AND STOCKHOLDERS' DEFICIT		
CURRENT LIABILITIES		
EDA bonds payable	\$3,385,000	\$3,385,000
Short term loans and current portion of long-term debt	13,528	13,105
Accounts payable and accrued expenses	1,071,097	935,797
Customer Deposits	_	39,400
Deferred revenues – current	13,333	13,333
Preferred share derivative interest payable	142,805	282,680
Total Current Liabilities	4,625,763	4,669,315
LONG TERM LIABILITIES		
Deferred revenues	175,557	178,890
Other long term liabilities	75,129	75,463
Derivative liability – preferred shares	21,329,402	14,192,329
Derivative liability – warrants	24,126,576	10,543,145
Total Long Term Liabilities	45,706,664	24,989,827
· ·		
TOTAL LIABILITIES	50,332,427	29,659,142
STOCKHOLDERS' DEFICIT		
Common stock – par value \$0.001, Authorized 355,516,558 shares Issued an	d	
outstanding – 243,363,531 shares and 180,545,657 shares, respectively	243,364	180,546
	,	200,210
Additional paid-in-capital	106,815,734	97,116,044
1. Table 1.	100,010,70	>,,110,011
Accumulated deficit	(145,594,455)	(114,861,029)
	(110,0)	(111,001,02))
Treasury stock at cost (100,000 common shares)	(306,841)	(306,841)
reason stock at cost (100,000 common shares)	(500,011)	(200,011)
TOTAL STOCKHOLDERS' DEFICIT	(38,842,198)	(17,871,280)
TOTAL OTOCIMIOLDERIO DEI ICIT	(50,012,170)	(17,071,200 )
TOTAL LIABILITIES AND STOCKHOLDERS' DEFICIT	\$11,490,229	\$11,787,862
TOTAL DI INDICITION DEI IOI	ΨII, 170,227	Ψ11,707,002

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

# ELITE PHARMACEUTICALS, INC. AND SUBSIDIARIES

# CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS (Unaudited)

	THREE MON' JUNE	
	2011	2010
REVENUES		
Manufacturing Fees	\$599,439	\$567,069
Royalties and License Fees	310,031	181,034
Lab and Product Development Fee Revenues	80,506	83,817
Total Revenues	989,976	831,920
COSTS OF REVENUES	425,368	411,671
	7.5.4.500	
Gross Profit	564,608	420,249
ODED A TIMO EVIDENCES		
OPERATING EXPENSES	445 407	165,000
Research and Development	445,497	165,008
General and Administrative	324,596	258,321 15,358
Non-cash compensation through issuance of stock options	6,113	
Depreciation and Amortization	124,934	78,331
Total Operating Expenses	901,140	517,018
Total Operating Expenses	901,140	317,010
LOSS FROM OPERATIONS	(336,532)	(96,769 )
OTHER INCOME / (EXPENSES)		
Interest expense, net	(57,370)	(58,069)
Change in fair value of warrant derivatives	(13,583,430)	
Change in fair value of preferred share derivatives	(16,610,788)	
Interest expense attributable to preferred share derivatives	(142,806)	
•		
Total Other Expenses	(30,394,394)	(4,672,625)
LOSS BEFORE PROVISION FOR INCOME TAXES	(30,730,926)	(4,769,394)
PROVISION FOR INCOME TAXES	2,500	
NET LOSS ATTRIBUTABLE TO COMMON SHAREHOLDERS	\$(30,733,426)	\$(4.760.204)
NET LOSS ATTRIBUTABLE TO COMMON SHAREHOLDERS	\$(30,733,420)	\$(4,709,394)
NET LOSS PER SHARE		
Basic	\$(0.13)	\$(0.05)
Diluted	. ,	\$(0.05)
	<b>4(0.12</b> )	<b>4 (0.02</b> )
WEIGHTED AVERAGE NUMBER OF COMMON SHARES OUTSTANDING		
Basic and Diluted	232,003,497	87,094,071

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

# ELITE PHARMACEUTICALS, INC. AND SUBSIDIARIES

# CONDENSED CONSOLIDATED STATEMENT OF CHANGES IN STOCKHOLDERS' DEFICIT (Unaudited)

	Common	Stock	Additional	Treasu	ry Stock		
	Shares	Amount	Paid-In Capital	Shares	Amount	Accumulated Deficit	Stockholders' Deficit
Balance at Mar 31, 2011	180,545,657	\$ 180,546	\$ 97,116,044	100,000	\$ (306,841)	\$ (114,861,029)	\$ (17,871,280)
Net Loss						(30,733,426)	(30,733,426)
Common shares issued in lieu of cash in payment of preferred share derivative interest expense	4,775,017	4,775	277,905				282,680
Conversion of Series D Preferred Shares into Common Shares	58,042,857	58,043	9,415,672				9,473,715
Non-cash compensation through the issuance of stock options			6,113				6,113
Balance at June 30, 2011	243,363,531	\$ 243,364	\$ 106,815,734	100,000	\$ (306,841)	\$ (145,594,455)	\$ (38,842,198)

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)

(Unaudited)						
	TH	IREE MONT	HS E	ND		30,
CACHELOWICEDOM ODED ATING A CTIVITIES		2011			2010	
CASH FLOWS FROM OPERATING ACTIVITIES	ф	(20.722.426	\	ф	(4.760.204	\
Net Loss	\$	(30,733,426	)	Э	(4,769,394	)
Adjustments to reconcile net loss to cash used in operating activities:		104.024			101 044	
Depreciation and amortization		124,934			121,344	\
Change in fair value of warrant derivative liability		13,583,430			(1,823,701	)
Change in fair value of preferred share derivative liability		16,610,788			6,074,338	
Preferred share derivative interest satisfied by the issuance of common stock		282,680			306,440	
Non-cash compensation satisfied by the issuance of common stock and options	S	6,113			15,358	
Other					208	
Non-cash rent expense		2,895			_	
Non-cash lease accretion		312			_	
Changes in Assets and Liabilities						
Accounts receivable		58,135			140,111	
Inventories		304,337			74,849	
Prepaid and other current assets		45,778			44,168	
Security deposits		43,776			(13,126	\
• •		125 722			•	)
Accounts payable, accrued expenses and other current liabilities		135,722	\		(120,444	)
Deferred revenues and Customer deposits		(42,733	)		_	
Derivative interest payable		(139,875	)		<u>—</u>	
NET CACH PROVIDED BY OPENATING A CENTURE		220,000			50.151	
NET CASH PROVIDED BY OPERATING ACTIVITIES		239,089			50,151	
CASH FLOWS FROM INVESTING ACTIVITIES						
Purchases of property and equipment		(29,844	)		(12,082	)
Cost of leasehold improvements		(204,794	)		_	
Costs incurred for intellectual property assets		(10,372	)		(166,714	)
Deposits to restricted cash, net		(56,947	)		(56,541	)
NET CASH USED IN INVESTING ACTIVITIES		(301,956	)		(235,337	)
THE CHAIR COLD IN THE PROPERTY FILES		(301,520	,		(200,007	,
CASH FLOWS FROM FINANCING ACTIVITIES						
Other loan payments		(3,540	)		(3,117	)
NET CARL HAFE BY EDVANCING A CITY WITNES		(2.5.40			(2.117	
NET CASH USED IN FINANCING ACTIVITIES		(3,540	)		(3,117	)
NET CHANGE IN CASH AND CASH EQUIVALENTS		(66,407	)		(188,303	)
		()			( )	
CASH AND CASH EQUIVALENTS – beginning of period		1,825,858			578,187	
CASH AND CASH EQUIVALENTS – end of period	\$	1,759,451		\$	389,884	
CLIDDLE MENTEAL DIGGLOCLIDES OF CASH ELOW DECDA (ATTOM						
SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION		400			600	
Cash paid for interest		423			690	
Cash paid for taxes		2,500				

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, 2011 AND 2010 (UNAUDITED)

#### NOTE 1 - 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") for the three months ended June 30, 2011 and 2010. 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, 2011. There have been no changes in significant accounting policies since March 31, 2011.

The Company does not anticipate being profitable for the fiscal year ending March 31, 2012; therefore a current provision for income tax was not established for the three months ended June 30, 2011. 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 June 30, 2011, the Company had a working capital deficit of \$2.0 million, losses from operations totaling \$0.3 million for the three months ended June 30, 2011, other expenses totaling \$30.4 million for the three months ended June 30, 2011 and net loss of \$30.7 million for the three months ended June 30, 2011.

Please note that revenues and operating profits for the foreseeable future are expected to be significantly and adversely effected by the U.S. Food and Drug Administration's ("US-FDA") removal of the Lodrane® product line from the market. The Lodrane® products, which constituted approximately 97% of the Company's revenues in the periods immediately preceding the quarter ended June 30, 2011, were included on a list of approximately 500 cough/cold and allergy products which are being removed from the U.S. market pursuant to a directive from the US-FDA. Please refer to the Current Report on Form 8-K filed with the SEC on March 4, 2011 and the Annual Report on Form 10-K filed with the SEC on June 29, 2011 for further details, such filings being herein incorporated by reference.

In addition, the Company has received Notice of Default from the Trustee of the NJED Bonds as a result of the utilization of the debt service reserve being used to pay semi-annual interest payments due on September 1st and March 1st of each year. The debt service reserve was first used to make such semi-annual interest payment on September 1, 2009 and has been utilized for all semi-annual interest payments due since September 1, 2009, 4 separate interest payments, totaling \$460k. The debt service reserve was utilized to make such payments as a result of the Company's not having sufficient funds available to make such payments when due.

The Company did not have sufficient funds available to make the principal payments due on September 1, 2010, totaling \$200k 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 \$200k was not made.

The Company has requested a postponement of principal payments due on September 1, 2010, 2011 and 2012, with an aggregate of all such postponed principal payments being added to the principal payments due on September 1, 2013. 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 5 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 of \$2.0 million as of June 30, 2011, includes the entire principal amount due in relation to the NJEDA Bonds. This amount, totaling \$3.4 million 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.

As of June 30, 2011, we had cash reserves of \$1.8 million. The completion of all transactions contemplated by the Epic Strategic Alliance agreement is expected to provide additional funds to permit us to continue development our product pipeline. Despite the successful completion of the initial, second and third closings of the Epic Strategic Alliance Agreement, and the first three of a total of twelve quarterly payments of \$62,500 each, there can be no assurances that we will be able to consummate the remaining nine quarterly payments due under the Epic Strategic Alliance Agreement. If such transactions are consummated, we will receive additional cash proceeds of \$0.5625 million. Even if we were to receive the remaining nine quarterly payments due pursuant to the Epic Strategic Alliance Agreement, we still may be required to seek additional capital in the future and there can be no assurances that we will be able to obtain such additional capital on favorable terms, if at all. 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, which disclosures are incorporated herein by reference.

Furthermore, with regards to our product pipeline, please note that significant delays in the commercialization of Hydromorphone 8mg and Naltrexone 50mg are expected as a result of the a recent notification received from the U.S. Food and Drug Administration ("US-FDA") reclassifying to a Prior Approval Supplement, the Company's Changes Being Effected in 30 Days Supplement ("CBE-30") related to a change the manufacturing and packaging site of Hydromorphone 8mg. Please refer to the current report on Form 8-K filed with the SEC on June 6, 2011 and Annual Report on Form 10-K filed with the SEC on June 29, 2011 for further details, with such filings being herein incorporated by reference.

Management has evaluated subsequent events or transactions occurring through the date the financial statements were issued (please see note 12).

#### NOTE 2 - 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.

#### NOTE 3 - INVENTORIES

Inventories are stated at the lower of cost (first-in, first-out basis) or market (net realizable value).

#### NOTE 4 -

#### **INTANGIBLE ASSETS**

Costs to acquire intangible assets, such as asset purchases of Abbreviated New Drug Applications ("ANDA's") 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 June 30, 2011, the following costs were recorded as intangible assets on the Company's balance sheet:

Intangible assets at March 31, 2011 (audited)	
Patent application costs	147,556
ANDA acquisitions	450,000
Total Intangible Assets at March 31, 2011 (audited)	597,556
Intangible asset costs capitalized during the three months ended June 30, 2011	
Patent application costs	10,372
ANDA acquisition costs	_
Amortization of intangible assets during the three months ended June 30, 2011	
Patent application costs	_
ANDA acquisition costs	<u> </u>
Intangible assets at June 30, 2011 (unaudited)	
Patent application costs	157,928
ANDA acquisitions costs	450,000
Total Intangible Assets at June 30, 2011 (unaudited)	607,928

The costs incurred in patent applications totaling \$10,372 for the three months ended June 30, 2011, were related to our abuse resistant and extended release opioid product lines. The Company is continuing its efforts to achieve approval of such patents. 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 5 - 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 June 30, 2011, 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 \$3,533 for the three months ended June 30, 2011.

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 September 1, 2009, March 1, 2010, September 1, 2010, and March 1, 2011 totaling \$120,775, \$113,075, \$113,075 and \$113,075, respectively were paid from the debt service reserve held in the restricted cash account, due to the Company not having sufficient funds to make such payments when 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 \$200,000, and requested the Trustee to withdraw the funds from debt service reserve held in the restricted cash account and to utilize such funds to make the principal payment due. The Company's request was denied by the Trustee. Accordingly, the principal payment due on September 1, 2010, totaling \$200,000 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 September 1, 2009, March 1, 2010, September 1, 2010 and March 1, 2011.

The Company does not expect to have sufficient available funds to make the interest payment of \$113,075 due on September 1, 2011. The Company also does not expect to have sufficient available funds as of September 1, 2011, to make principal payments, totaling \$470,000, and consisting of \$245,000 due on September 1, 2011 and \$225,000 which was 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 has requested a postponement of principal payments due on September 1st of 2010, 2011 and 2012, with an aggregate of all such postponed principal payments being added to the principal payments due on September 1, 2013. Resolution of the Company's default under the NJED Bonds and our request for postponement of principal payments 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.

#### NOTE 6 - PREFERRED STOCK 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 D and Series E 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 Liability as of June 30, 2011				
	Series B	Series C	Series D	Series E	Total
Preferred shares Outstanding	896	5,418	_	3,062.5	9,376.5
Underlying common shares into which Preferred may convert	574,076	3,365,217	_	121,527,778	125,467,071
Closing price on valuation date	\$ 0.17	\$ 0.17	n/a	\$ 0.17	\$ 0.17
Preferred stock derivative liability at June 30, 2011	\$ 97,593	\$ 572,087	\$ —	\$ 20,659,722	\$ 21,329,402
Preferred stock derivative liability at March 31, 2011	\$ 56,961	\$ 333,906	\$ 4,527,343	\$ 9,274,119	\$ 14,192,329
Change in preferred stock derivative liability for the three months ended June 30, 2011					\$ (16,610,788)

#### 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:

	June 30	
	201	1
Risk-Free interest rate		0.3% - 2.5 %
Expected volatility		153% - 217 %
Expected life (in years)		0.0 - 6.8
Expected dividend yield		_
Number of warrants		154,334,659
Fair value – Warrant Derivative Liability	\$	24,126,576
Change in warrant derivative liability for the three months ended	\$	(13,583,430)

The risk free interest rate was based on rates established by the US 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 7 - PREFERRED SHARE DERIVATIVE INTEREST PAYABLE

Preferred share derivative interest payable as of June 30, 2011 consisted of \$142,805 in derivative interest accrued and owing as of June 30, 2011. The full amount of derivative interest payable as of June 30, 2011, was paid via the issuance of 952,686 shares of common stock in July 2011.

#### NOTE 8 - 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 we have 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 requires significant leasehold improvements and qualification as a prerequisite to achieving suitability for such intended future use. Approximately 3,500 square feet of this property is being used for the storage of pharmaceutical finished goods, raw materials, equipment and documents. The property is currently not being used for manufacturing, packaging and distribution activities.

Leasehold improvements and qualification as suitable for manufacturing, packaging and distribution operations are expected to be achieved within two years from the beginning of the lease term. These are estimates based on current project plans, which are subject to change. There can be no assurance that the construction and qualification will be accomplished during the estimated time frames, or that the property located at 135 Ludlow Avenue, Northvale, New Jersey will ever achieve qualification for intended future utilization.

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

Fiscal year ended March 31, 2012	79,248
Fiscal year ended March 31, 2013	81,228
Fiscal year ended March 31, 2014	83,259
Fiscal year ended March 31, 2015	85,344
Fiscal year ended March 31, 2016	87,363
Total Minimum 5 year lease payments	\$416,442

<sup>\*</sup> 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:

	Three Months	
	Ended	
	June 30, 2010	
Rent Expense	\$ 22,584	
-		
Change in deferred rent liability	2,895	
Balance of deferred rent liability (long-term liability)	50,960	

#### NOTE 9 - DEFERRED REVENUES

Deferred revenues totaling \$188,890 represents the unamortized amount of a \$200,000 advance payment received 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, totaling \$13,333 represents the revenue that will be recognized over the 12 months immediately subsequent to June 30, 2011. The long term portion of deferred revenues, totaling \$175,557, represents the revenue that will be recognized during the period that begins more than twelve months subsequent to June 30, 2011. 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 10 - STOCKHOLDERS' EQUITY

#### Common Stock

During the three months ended June 30, 2011, the Company issued a total of 62,817,874 shares of Common Stock, with such issuances of Common Stock being summarized as follows:

	Shares
	Of
Description	Common Stock
Common shares issued in lieu of cash in payment of preferred share derivative interest expenses totaling \$282,680 which were due and owing as of March 31,	
2011 to holders of the Company's Series B, Series C and Series D Preferred Share	
derivative instruments	4,775,017
Common shares issued pursuant to the conversion of Series D Preferred Share	
derivatives, with such derivative liabilities being valued at an aggregate of	
\$9,473,715 at the time of their conversion	58,042,857
Total Common Shares issued during the three months ended June 30, 2011	62,817,874

#### Options

At June 30, 2011, the Company had 1,960,604 options fully vested and outstanding with exercise prices ranging from \$0.06 to \$3.00 per share; each option representing the right to purchase one share of common stock. In addition, there are 1,096,396 options issued pursuant to the Company's 2004 Stock Option Plan which are outstanding and not vested, with exercise prices ranging from \$0.06 to \$2.50 per share. These options are scheduled to vest in equal annual increments on January 18, 2012 and 2013 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 11 - 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") is 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.

	For the Three Months Ended June 30, 2011		
Numerator			
Net Loss attributable to common shareholders	\$	(30,733,4	426)
Denominator			
Weighted-average shares of common stock outstanding - basic		232,003,	497
Dilutive effect of stock options, warrants and convertible securities			
•			
Weighted-average shares of common stock outstanding - diluted		232,003,	497
Net loss per share			
Basic	\$	(0.13	)
Diluted	\$	(0.13	)

#### NOTE 12 -

# SUBSEQUENT EVENTS

Common shares issued in lieu of cash in payment of derivative interest expense
Derivative interest expense related to the Preferred Share derivatives due and payable as of June 30, 2011 were paid during July 2011 through the issuance of 952,686 shares of common stock.

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

### THREE MONTH PERIOD ENDED JUNE 30, 2011 COMPARED TO THE THREE MONTH PERIOD ENDED JUNE 30, 2010 (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. 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 terminologare intended to identify such forward-looking statements. 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. ar subsidiaries.

#### Overview

We are a specialty pharmaceutical company principally engaged in the development and manufacture of oral, controlled-release products, using proprietary technology and generic pharmaceuticals. 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. Our technology is applicable to the development of delayed-, sustained- or targeted-release pellets, capsules, tablets, granules and powders.

We have one product, Phentermine 37.5mg tablets, currently being sold commercially.

We have also purchased two approved generic products: a generic hydromorphone product and a generic naltrexone product. The manufacturing process for both such generic products from the previous ANDA holders to our facilities in Northvale, New Jersey (the "Northvale Facility"), is currently on-going. The transfer to the Northvale Facility of the manufacturing process for generic hydromorphone was, however, significantly delayed, as a result of the Company being notified by the US-FDA of its reclassification of our CBE-30 supplement to a prior approval supplement. A similar significant delay in the transfer of the manufacturing process of generic Naltrexone to the Northvale Facility is expected, as such transfer includes factors similar to those cited by the US-FDA as the reason for its reclassification of our CBE-30 supplement to a prior approval supplement. The transfer of the manufacturing processes of generic hydromorphone and naltrexone are prerequisites to the commercial launch of each generic product. The commercial launch of these generic products are material events to the Company and any delays in the launch of either or both of these generic products has a significant and adverse effect on the Company's operation and results. A current report on Form 8-K was filed with the SEC on June 6, 2011 related to the reclassification of the Company's CBE-30 supplement

filed with FDA for the transfer of the manufacturing process of generic hydromorphone, with such filing being herein incorporated by reference.

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Elite also executed a license agreement with Precision Dose, Inc. (the "Precision Dose Agreement") and a manufacturing agreement with The PharmaNetwork LLC (the "TPN Agreement"). The Precision Dose Agreement provides for the marketing and distribution, in the United States, Puerto Rico and Canada, of Phentermine 37.5mg tablets, generic hydromorphone, generic naltrexone and certain additional products and dosage strengths that have or will be filed for approval with the US-FDA. Phentermine 37.5mg tablets were launched in April 2011 and are currently the only products included in the Precision Dose Agreement which are approved by the US-FDA. The TPN Agreement, executed on June 23, 2011, provides for the manufacture and packaging by the Company of The PharmaNetwork's Methadone Hydrochloride, 10mg tablets ("Methadone 10mg"), with the Methadone 10mg to be marketed by TPN's wholly owned subsidiary, Ascend Laboratories, LLC. The US-FDA has approved the manufacturing of Methadone 10mg at the Northvale Facility and commercial launch of this product is expected during this fiscal year.

Elite has an undisclosed generic product filed with the US-FDA that we are awaiting review. This product is licensed to TAGI. One of the undisclosed generic products worked on under the Epic Strategic Alliance Agreement has also been filed with the US-FDA.

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

Additionally, the Company is developing ELI-216, an abuse resistant oxycodone product, and ELI-154, a once-daily oxycodone product.

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) set up and launch of approved generic products; (iii) the development of the other products in our pipeline including the eight products pursuant to the Epic Strategic Alliance Agreement; (iv) commercial exploitation of our products either by license and the collection of royalties, or through the manufacture of our formulations, and (v) 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 abbreviated new drug applications ("ANDAs").

Elite believes that its business strategy enables it to reduce 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**

On April 7, 2011, Elite Pharmaceuticals, Inc. announced that the company made the initial shipment of phentermine HC1 37.5 mg tablets to TAGI. This triggered a milestone payment under the Precision Dose Agreement. Phentermine 37.5mg tablets is now a commercial product being distributed by our partner, TAGI and it is currently the Company's only commercial product.

A Current Report on form 8-K was filed on April 7, 2011 in relation to this announcement, such filing being incorporated herein by this reference. Please also refer to the Current Report on Form 8-K filed with SEC on September 10, 2010 and Quarterly Report on Form 10-Q, filed with SEC on November 15, 2010 for further details on the Precision Dose Agreement, such filings being herein incorporated by reference.

Elite's revenue derived from phentermine 37.5mg tablets during the three months ended June 30, 2011 was approximately \$254k, with such amount including a \$145k milestone payment triggered by the first shipment of the product, \$97k in manufacturing revenues and \$12k in royalties paid pursuant to the Precision Dose Agreement.

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#### **Approved Products**

Elite is the owner of the following approved Abbreviated New Drug Applications ("ANDA"):

- Phentermine HCl 37.5mg tablets ("Phentermine 37.5mg")
- Hydromorphone HCl 8mg tablets ("Hydromorphone 8mg")
  - Naltrexone HCl 50mg tablets ("Naltrexone 50mg")

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"). Current reports on form 8-K were filed on September 10, 2010 and February 4, 2011 in relation to the Phentermine Purchase Agreement and the Phentermine ANDA, with such filings being incorporated herein by this reference. Please also refer to exhibit 10.7 of the Quarterly Report on Form 10-Q filed with SEC on November 15, 2010, such filing being incorporated herein by this reference.

Phentermine 37.5mg was commercially launched during April 2011 and is currently being manufactured on a contract basis at Epic until the production process of such product is transferred to the Northvale Facility. Phentermine 37.5mg is marketed pursuant to the Precision Dose License. Please refer to the section titled "Commercial Products" above for further details.

The ANDA for Hydromorphone 8mg was acquired pursuant to an asset purchase agreement with Mikah Pharma LLC (the "Hydromorphone Purchase Agreement"). A current report on Form 8-K was filed with the SEC on May 24, 2010 in relation to the Hydromorphone Purchase Agreement, with such filing being herein incorporated by reference. For further details on the Hydromorphone Agreement, please refer to Exhibit 10.4 to the Quarterly Report on Form 10-Q, filed with the SEC on November 15, 2010, and incorporated herein by reference.

Transfer of the manufacturing process of Hydromorphone 8mg to the Northvale Facility is a prerequisite of the Company's commercial launch of the product and is currently in process. However, please note that the completion of such transfer has been significantly delayed as a result of the US-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 has recorded an impairment of the Hydromorphone 8mg ANDA in an amount equal to the entire purchase price of the acquisition. A current report on Form 8-K was filed with the SEC on June 6, 2011 in relation to this issue, with such filing being herein incorporated by reference. This impairment was recorded and is included in the Company's audited financial statements as of March 31, 2011 and presented in the Annual Report on Form 10-K filed with the SEC on June 29, 2011.

The ANDA for Naltrexone 50mg was acquired pursuant to an asset purchase agreement with Mikah Pharma LLC (the "Naltrexone Purchase Agreement"). A current report on form 8-K was filed on August 27, 2010 in relation to this announcement, such filing being incorporated herein by this reference. Please also refer to exhibit 10.5 of the Quarterly Report on Form 10-Q filed with SEC on November 15, 2010, such filing being incorporated herein by this reference.

Transfer of the manufacturing process of Naltrexone 50mg to the Northvale Facility is a prerequisite of the Company's commercial launch of the product and is currently in process. However, please note that the completion of such transfer could be significantly delayed as it included factors similar to those cited by the US-FDA as the reason for its reclassification of the Company's filings for the transfer of Hydromorphone 8mg. As a result of these probable delays in the transfer of the manufacturing process of Naltrexone 50mg, 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 and presented in the Annual Report on Form 10-K filed with the SEC on June 29, 2011.

Discontinued Products - Lodrane 24® and Lodrane 24D®

On March 3, 2011, the U.S. Food and Drug Administration ("US-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® and Lodrane 24D® (the "Lodrane® Products"), were included in the FDA list of 500 products. After this announcement by the US-FDA, the Company's customer for the Lodrane® Products cancelled all outstanding orders and manufacturing of the Lodrane® 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.

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A Current Report on Form 8-K was filed with the SEC on March 4, 2011 in relation to this announcement by the US-FDA, such filing being herein incorporated by reference.

ECR (the owner and marketer of the Lodrane® Products) has initiated a formal approval process with the FDA in 2010 regarding the Lodrane® Products and issued a press release on March 3, 2011 stating that they will continue to actively pursue approval for the Lodrane® 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 US-FDA with relation to the Lodrane® Products.

The Lodrane® Products were co-developed with our partner, ECR Pharmaceuticals ("ECR") and the Company was receiving revenues from the manufacture of the Lodrane® Products and laboratory stability study services, as well as royalties on in-market sales.

During the three months ended June 30, 2011, Elite made its final shipments of the Lodrane® Products. Elite's revenues for the manufacturing these products for the quarters ended June 30, 2011 and 2010 were \$252k and \$567k, respectively. In addition, the Company sold to ECR, at cost without markup, all raw materials related to the manufacture of the Lodrane® Products which remained in stock subsequent to the final shipment of the Lodrane® Products. Revenues from the sale of these raw materials totaled approximately \$221k. As manufacturing of the Lodrane® Products has ceased, there will be no further manufacturing revenues derived from the Lodrane® Products until such products receive the necessary approvals from the US-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® Products, should such approvals be granted by the US-FDA.

Royalties on in-market sales of the Lodrane® Products earned during the three months ended June 30, 2011 and 2010 were \$150k and \$181k, respectively. While manufacturing of the Lodrane® Products has ceased, the sale of such products in the US market are still permitted by the US-FDA until August 30, 2011. The Company will accordingly continue to earn royalties on any in-market sales that occur up to that date. Such royalties are expected to be significantly less than royalty amounts earned in prior periods.

Revenues from contract laboratory services for the three months ended June 30, 2011 and 2010 were \$51k and \$84k, respectively. Contract laboratory services for the Lodrane® Products will continue, on a residual basis, through the fiscal year ended March 31, 2012, 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 prior periods.

#### Contract Manufacturing of Isradipine and Phendimetrazine

On June 1, 2011, Elite Pharmaceuticals Inc. ("Elite") executed a Manufacturing and Supply Agreement (the "Isradipine/ 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"), including (a) developing and preparing the documentation required for the transfer of the manufacturing process to Elite's facility and the appropriate regulatory filing for the ANDA, and (b) manufacturing finished dosage forms appropriate for commercial sale, marketing and distribution in the United States of America, its territories, possessions, and commonwealths in accordance with the requirements of the Isradipine/ Phendimetrazine Agreement; Elite shall perform, at its sole cost and expense, all Technology Transfer, validation and qualification services (including: equipment, methods and facility qualification), validation and stability services required by Applicable Laws to commence manufacturing Isradipine and Phendimetrazine for commercial sale by Mikah or its designees in accordance with the terms of the Isradipine/ Phendimetrazine Agreement. During the term of the Isradipine/ Phendimetrazine Agreement and subject to the provisions herein, Mikah shall purchase from Elite and Elite agrees to manufacture and supply solely and exclusively to Mikah, such Isradipine and Phendimetrazine as

Mikah may order from time to time pursuant to the Isradipine/ Phendimetrazine Agreement. Mikah will compensate Elite at an agreed upon transfer price for the manufacturing and packaging of Isradipine and Phendimetrazine. For the Isradipine product, Elite will also receive a 10% royalty on net profits of the finished Product. The payment is to be calculated and paid quarterly. Elite will also receive a onetime milestone payment for each Product for the work associated with the Technology transfer. The milestone payment shall be made upon the successful manufacturing and testing of the exhibit batch. The Isradipine/ Phendimetrazine Agreement has a term of five (5) years and shall automatically renew for additional periods of one (1) year unless Mikah provides written notice of termination to Elite at least six (6) months prior to the expiration of the Term or any Renewal Term. Transfer of the manufacturing site to the Northvale Facility, a prerequisite of commercial launch of Isradipine and Phendimetrazine is currently in progress.

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A Current Report on Form 8-K was filed on June 7, 2011 in relation to this announcement, such filing being herein incorporated by this reference.

No revenues were earned by the Company in relation to the Isradipine/Phendimetrazine Agreement during the three months ended June 30, 2011.

#### Contract Manufacturing of Methadone

On June 29, 2011, Elite Pharmaceuticals, Inc. announced that it entered into a commercial manufacturing and supply agreement with ThePharmaNetwork, LLC and its wholly owned subsidiary, Ascend Laboratories LLC (together "TPN"). Under the terms of the agreement, Elite will perform manufacturing and packaging for TPN's Methadone Hydrochloride, 10mg tablets. The US-FDA has approved the manufacturing of Methadone 10mg at the Northvale Facility and commercial launch of this product is expected during this fiscal year.

A Current Report on Form 8-K was filed on June 29, 2011 in relation to this announcement, such filing being herein incorporated by this reference.

No revenues were earned by the Company in relation to this contract manufacturing agreement with TPN during the three months ended June 30, 2011.

#### **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.

#### ELI-154 and ELI-216

For ELI-154, Elite has developed a once-daily oxycodone formulation using its proprietary technology. An investigational new drug application, or IND, has been filed and Elite has completed two pharmacokinetic studies in healthy subjects that compared blood levels of oxycodone from dosing ELI-154 and the twice-a-day product that is on the market currently, OxyContin® marketed in the U.S. by Purdue Pharma LP. These studies confirmed that ELI-154, when compared to twice-daily delivery, demonstrated an equivalent onset, more constant blood levels of the drug over the 24 hour period and equivalent blood levels to the twice-a-day product at the end of 24 hours. Elite has successfully manufactured multiple batches on commercial scale equipment and we have discussions ongoing in Europe for this product. We are looking for a partner who can complete the clinical studies required for Europe and who can sell and distribute the product in key European territories.

ELI-216 utilizes our patent-pending abuse-deterrent technology that is based on a pharmacological approach. ELI-216 is a combination of a narcotic agonist, oxycodone hydrochloride, in a sustained-release formulation intended for use in patients with moderate to severe chronic pain, and an antagonist, naltrexone hydrochloride, formulated to deter abuse of the drug. Both of these compounds, oxycodone hydrochloride and naltrexone hydrochloride, 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. In single-dose studies for ELI-216, it was demonstrated that no quantifiable blood levels of naltrexone hydrochloride were released at a limit of quantification ("LOQ") of 7.5 pg/ml. As described below, when crushed, naltrexone hydrochloride was released at levels that would be expected to eliminate the euphoria from the crushed oxycodone hydrochloride. This data is consistent with the premise of Elite's abuse resistant technology, or ART, that essentially no naltrexone is released and absorbed when administered as intended. Products utilizing the pharmacological approach to deter abuse such as Suboxone®, a product marketed in the United States by Reckitt Benckiser Pharmaceuticals, Inc., and Embeda®, a product marketed in the United States by King Pharmaceuticals, have been approved by the FDA and are being marketed in the United States.

ELI-216 demonstrates a euphoria-blocking effect when the product is crushed. A study completed in 2007 was designed to determine the optimal ratio of oxycodone hydrochloride and the opioid antagonist, naltrexone hydrochloride, to significantly block the euphoric effect of the opioid if the product is abused by physically altering it (i.e., crushing). The study also helped determine the appropriate levels of naltrexone hydrochloride required to reduce or eliminate the euphoria experienced by subjects who might take crushed product to achieve a "high".

Elite met with the FDA for a Type C clinical guidance meeting regarding the NDA development program for ELI-216. Elite has incorporated the FDA's guidance into its developmental plan. Elite has obtained a special protocol assessment, or SPA, with the FDA for the ELI-216 Phase III protocol. Elite will conduct additional Phase I studies including, but not limited to, food effect, ascending dose and multi-dose studies.

Elite has developed ELI-154 and ELI-216 and retains the rights to these products. Elite has currently chosen to develop these products itself but expects to license these products at a later date to a third party who could provide funding for the remaining clinical studies, including a Phase III study, and who could provide sales and distribution for the product. The drug delivery technology underlying ELI-154 was originally developed 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 ELI-154. Upon licensing or commercialization of ELI-154, 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). 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.

Under the Epic Strategic Alliance Agreement (i) at least eight additional generic drug products will be developed by Epic at the Facility with the intent of filing abbreviated new drug applications for obtaining FDA approval of such generic drugs, (ii) Elite will be entitled to 15% of the profits generated from the sales of such additional generic drug products upon approval by the FDA, and (iii) Epic and Elite will share certain resources, technology and know-how in the development of drug products, which Elite believes will benefit the continued development of its current drug products.

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 the 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 and June 5, 2009, which are incorporated herein by reference.

#### **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")

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 the Annual Report on Form 10-K filed with the SEC on June 29, 2011, such filings being herein incorporated by reference.

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No revenues were earned by the Company in relation to the Mikah Development Agreement during the three months ended June 30, 2011.

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 the Annual Report on Form 10-K filed with the SEC on June 29, 2011, such filings being herein incorporated by reference.

Revenues totaling \$28,907 were earned by the Company in relation to the Hi-Tech Development Agreement during the three months ended June 30, 2011.

#### Novel Labs Investment

At the end of 2006, Elite entered into an agreement 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 approximately 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 is more likely than not to be realized. 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, 2011 Compared to Three Months Ended June 30, 2010

Our revenues for the three months ended June 30, 2011 were \$990k an increase of \$158k or approximately 19% over revenues for the comparable period of the prior year, and consisted of \$599k in manufacturing fees, \$81k in lab and product development fees and \$310k in royalties and license fees. Revenues for the three months ended June 30, 2010, consisted of \$567k in manufacturing fees, \$84k in lab and product development fees, and \$181k in royalties and license fees. Manufacturing fees increased by approximately 6% due to the one time sale to ECR, at cost and without markup, of all raw materials related to manufacture of the Lodrane® Products remaining in stock subsequent to the final shipment of these discontinued products. Lab and product development fees decreased by approximately 4% due

to the discontinuance of the Lodrane® Products, offset by product development fees earned from the Hi-Tech Development Agreement. Royalties and license fees increased by 71% due to the milestone payment of \$145k being earned upon the initial shipment of Phentermine 37.5mg, pursuant to the Precision Dose Agreement.

Research and development costs for the three months ended June 30, 2011 were \$445k, an increase of \$280k or approximately 170% from \$165k of such costs for the comparable period of the prior year. The increase was primarily due to the shifting of personnel and operational resources from commercial manufacturing to product development as a result of the discontinuance of the Lodrane® Products.

General and administrative expenses for the three months ended June 30, 2011, were \$325k, an increase of \$66k, or approximately 26% from \$258k of general and administrative expenses for the comparable period of the prior year. The increase was primarily due to overhead costs related to excess capacity at the Northvale Facility which has resulted from the discontinuance of the Lodrane® Products, increased real estate taxes at the Northvale Facility and increased legal fees related to the conversion of Series D Preferred Shares to Common Shares and preparation of the preliminary proxy statement which was filed in July 2011.

Depreciation and amortization for the three months ended June 30, 2011 was \$125k, an increase of \$47k, or approximately 59%, from \$78k for the comparable period of the prior year. The increase was primarily due to depreciation expense related to excess capacity at the Northvale Facility which has resulted from the discontinuance of the Lodrane® Products.

Non-cash compensation through the issuance of stock options and warrants for the three months ended June 30, 2011 was \$6k, a decrease of \$9k, or approximately 60% from \$15k for the comparable period of the prior year. The decrease was due to the timing of the amortization schedule established at the time of issuance of the related stock options and warrants.

As a result of the foregoing, our loss from operations for the three months ended June 30, 2011 was \$336k, compared to a loss from operations of \$97k for the three months ended June 30, 2010.

Other expenses for the three months ended June 30, 2011 were \$30,394k, an increase in other expenses of \$25,722k from the net other expenses of \$4,673k for the comparable period of the prior year. The increase in other expenses 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, 2011 totaling \$30,194k, as compared to a net derivative expense of \$4,251k for the comparable period of the prior year. Please note that derivative income/(expenses) are most significantly determined by the closing price of the Company's Common Stock as of the end of each annual or quarterly reporting period, with incomes being generated by decreases in such closing price and expenses being incurred by increases in such closing price. The closing price of the Company's Common Stock as of June 30, 2011 was \$0.17, as compared to a closing price of \$0.086 as of March 31, 2011. This significant rise in the closing price of the Company's Common Stock was a significant factor in the derivative expenses incurred during the quarter ended June 30, 2011.

As a result of the foregoing, our net loss for the three months ended June 30, 2011 was \$30,733k, compared to a net loss of \$4,769k for the three months ended June 30, 2010.

#### Material Changes in Financial Condition

Our working capital (total current assets less total current liabilities), decreased to a deficit of \$2.0 million as of June 30, 2011 from a working capital deficit of \$1.5 million as of March 31, 2011, 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 5 to our financial statements and Item 3 of this current report on Form 10-Q for further details.

We achieved a positive cash flow from operations of \$239k for the three months ended June 30, 2011, primarily due to our net loss from continuing operations of \$30,733k, offset by non-cash charges totaling \$30,611k, which included, without limitation, depreciation and amortization of \$125k, expense from the change in fair value of derivative liabilities of \$30,194k, derivative interest payments satisfied through the issuance of common shares in lieu of cash of \$283k, non cash compensation satisfied by the issuance of common stock and options of \$6k, decreases in inventories of \$304k, decreases in accounts receivable of \$58k and increases in accounts payable and other current liabilities of \$136k.

## LIQUIDITY AND CAPITAL RESOURCES

### Going concern considerations

As of June 30, 2011, the Company had a working capital deficit of \$2.0 million, losses from operations totaling \$0.3 million for the three months ended June 30, 2011, other expenses totaling \$30.4 million for the three months ended and a net loss of \$30.7 million for the three months ended June 30, 2011. 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, 2012.

Revenues and operating profits for the foreseeable future are expected to be significantly and adversely effected by the U.S. Food and Drug Administration's ("US-FDA") removal of the Lodrane® product line from the market. The Lodrane® products, which constituted approximately 97% of the Company's revenues in the periods immediately preceding the quarter ended June 30, 2011, were included on a list of approximately 500 cough/cold and allergy products which are being removed from the U.S. market pursuant to a directive from the US-FDA. Please refer to the Current Report on Form 8-K filed with the SEC on March 4, 2011 and the Annual Report on Form 10-K filed with the SEC on June 29, 2011 for further details, such filings being herein incorporated by reference.

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 due on September 1, 2009, March 1, 2010, September 1, 2010 and March 1, 2011, totaling \$121k, \$113k, \$113k and \$113k, respectively, and principal payments due on September 1, 2009 totaling \$210k. The debt service reserve was utilized to make such payments as a result of the Company's not having sufficient funds available to make such payments when due.

The Company did not have sufficient funds available to make the principal payments due on September 1, 2010, totaling \$200k 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 \$200k was not made.

The Company has requested a postponement of principal payments due on September 1, 2010, 2011 and 2012, with an aggregate of all such postponed principal payments being added to the principal payments due on September 1, 2013. 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 5 to our financial statements and Item 3 of this current report on Form 10-Q for a more detailed discussion of the NJEDA Bonds and Notice of Default.

As of June 30, 2011, we had cash reserves of \$1.8 million. The completion of all transactions contemplated by the Epic Strategic Alliance agreement is expected to provide additional funds to permit us to continue development our product pipeline. Despite the successful completion of the initial, second and third closings of the Epic Strategic Alliance Agreement, and the first three of a total of twelve quarterly payments of \$62,500 each, there can be no assurances that we will be able to consummate the remaining nine quarterly payments due under the Epic Strategic Alliance Agreement. If such transactions are consummated, we will receive additional cash proceeds of \$0.5625 million. Even if we were to receive the remaining nine quarterly payments due pursuant to the Epic Strategic Alliance Agreement, we still may be required to seek additional capital in the future and there can be no assurances that we will be able to obtain such additional capital on favorable terms, if at all. 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, which disclosures are incorporated herein by reference.

Furthermore, with regards to our product pipeline, please note that significant delays in the commercialization of Hydromorphone 8mg and Naltrexone 50mg are expected as a result of the a recent notification received from the U.S. Food and Drug Administration ("US-FDA") reclassifying to a Prior Approval Supplement, the Company's Changes Being Effected in 30 Days Supplement ("CBE-30") related to a change the manufacturing and packaging site of Hydromorphone 8mg. Please refer to the current report on Form 8-K filed with the SEC on June 6, 2011 and Annual Report on Form 10-K filed with the SEC on June 29, 2011 for further details, with such filings being herein incorporated by reference.

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.

For the three months ended June 30, 2011, we realized approximately \$0.2 million positive cash flow from operating activities. Our working capital deficit at June 30, 2011 was approximately \$2.0 million compared with working capital deficit of approximately \$1.5 million at June 30, 2010. Please note that the working capital deficits include the entire principal amount due in relation to the NJEDA Bonds. This amount, totaling \$3.4 million is classified as a current liability due to the Notice of Default received from the Trustee in relation to the NJEDA Bonds. Please refer to Note 5 to our financial statements and Item 3 of this current report on Form 10-Q for a more detailed discussion of the NJEDA Bonds and Notice of Default.

Cash and cash equivalents at June 30, 2011, were approximately \$1.76 million, a decrease of approximately \$0.07 million from the approximately \$1.83 million at June 30, 2010.

As of June 30, 2011, our principal source of liquidity was approximately \$1.76 million of cash and cash equivalents. Additionally, we may have access to funds through the exercise of outstanding stock options and warrants. There can be no assurance that the exercise of outstanding warrants or options will generate or provide sufficient cash. 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.

Management has determined that, as of June 30, 2011, there were material weaknesses in both the design and effectiveness of our internal control over financial reporting. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis.

The deficiencies in our internal controls over financial reporting and disclosure controls and procedures are related to the lack of segregation of duties due to the size of our accounting department, which replaced an outside accounting firm and non-employee Chief Financial Officer on July 1, 2009, and limited enterprise resource planning systems. When our financial position improves, we intend to hire additional personnel and implement enterprise resource planning systems required to remedy such deficiencies.

## 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 quarter ended June 30, 2011 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, 2011.

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

During the quarter ended June 30, 2011, we issued 62,817,874 shares of Common Stock to the holders of our Series B, C and D Preferred Stock. Of this amount, 4,775,017 shares were issued in satisfaction of our obligation to pay \$282,680 in dividends earned and/or owing during the quarter ended March 31, 2011, and 58,042,857 shares were issued pursuant to the conversion of Series D Preferred Share derivatives, with such derivative liabilities being valued at an aggregate of \$9,473,715 at the time of their conversion. We did not receive any proceeds in exchange for the issuance of these securities. We relied on the exemption provided by Section 4(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. REMOVED AND RESERVED

ITEM 5. OTHER INFORMATION

None.

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

#### Exhibit

## Number Description

- 3.1(a) Certificate of Incorporation of the Company, together with all other amendments thereto, as filed with the Secretary of State of the State of Delaware, incorporated by reference to (a) Exhibit 4.1 to the Registration Statement on Form S-4 (Reg. No. 333-101686), filed with the SEC on December 6, 2002 (the "Form S-4"), (b) Exhibit 3.1 to the Company's Current Report on Form 8-K dated July 28, 2004 and filed with the SEC on July 29, 2004, (c) Exhibit 3.1 to the Company's Current Report on Form 8-K dated June 26, 2008 and filed with the SEC on July 2, 2008, and (d) Exhibit 3.1 to the Company's Current Report on Form 8-K dated December 19, 2008 and filed with the SEC on December 23, 2008.
- 3.1(b) Certificate of Designations, Preferences and Rights of Series A Preferred Stock, as filed with the Secretary of the State of Delaware, incorporated by reference to Exhibit 4.5 to the Current Report on Form 8-K dated October 6, 2004, and filed with the SEC on October 12, 2004.
- 3.1(c) Certificate of Retirement with the Secretary of the State of the Delaware to retire 516,558 shares of the Series A Preferred Stock, as filed with the Secretary of State of Delaware, incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K dated March 10, 2006, and filed with the SEC on March 14, 2006.
- 3.1(d) Certificate of Designations, Preferences and Rights of Series B 8% Convertible Preferred Stock, as filed with the Secretary of the State of Delaware, incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K dated March 15, 2006, and filed with the SEC on March 16, 2006.
- 3.1(e) Amended Certificate of Designations of Preferences, Rights and Limitations of Series B 8% Convertible Preferred Stock, as filed with the Secretary of State of the State of Delaware, incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K dated April 24, 2007, and filed with the SEC on April 25, 2007.
- 3.1(f) Certificate of Designations, Preferences and Rights of Series C 8% Convertible Preferred Stock, as filed with the Secretary of the State of Delaware, incorporated by reference to Exhibit 3.2 to the Current Report on Form 8-K dated April 24, 2007, and filed with the SEC on April 25, 2007.
- 3.1(g) Amended Certificate of Designations, Preferences and Rights of Series C 8% Convertible Preferred Stock, as filed with the Secretary of the State of Delaware, incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K dated April 24, 2007, and filed with the SEC on April 25, 2007
- 3.1(h) Amended Certificate of Designations of Preferences, Rights and Limitations of Series B 8% Convertible Preferred Stock, as filed with the Secretary of State of the State of Delaware, incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K dated September 15, 2008, and filed with the SEC on September 16, 2008.
- 3.1(i) Amended Certificate of Designations, Preferences and Rights of Series C 8% Convertible Preferred Stock, as filed with the Secretary of the State of Delaware, incorporated by reference to Exhibit 3.2 to the Current Report on Form 8-K dated September 15, 2008, and filed with the SEC on September 16, 2008.
- 3.1(j) Amended Certificate of Designations of Preferences, Rights and Limitations of Series D 8% Convertible Preferred Stock, as filed with the Secretary of State of the State of Delaware, incorporated by reference to

Exhibit 3.3 to the Current Report on Form 8-K dated September 15, 2008, and filed with the SEC on September 16, 2008.

- 3.1(k) 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(1) 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(m) 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
- 3.2 By-Laws of the Company, as amended, incorporated by reference to Exhibit 3.2 to the Company's Registration Statement on Form SB-2 (Reg. No. 333-90633) made effective on February 28, 2000 (the "Form SB-2").
- 4.1 Form of specimen certificate for Common Stock of the Company, incorporated by reference to Exhibit 4.1 to the Form SB-2.
- 4.2 Form of specimen certificate for Series A 8% Convertible Preferred Stock of the Company, 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.
- 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 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.
- 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.
- 4.7 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.
- 4.8 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
- 4.9 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.

- 4.10 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.
- 4.11 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.
- 4.12 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.
- 4.13 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.
- 4.14 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.
- 4.15 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.
- 4.16 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.
- 4.17 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.
- 4.18 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.
- 4.19 Form of Warrant to purchase shares of Common Stock issued to purchasers in the private placement which closed on April 24, 2007 (the "Series C Financing"), incorporated by reference to Exhibit 4.2 to the Current Report on Form 8-K, dated April 24, 2007 and filed with the SEC on April 25, 2007.
- 4.20 Form of Warrant to purchase shares of Common Stock issued to the placement agent in the Series C Financing, incorporated by reference to Exhibit 4.3 to the Current Report on Form 8-K, dated April 24, 2007 and filed with the SEC on April 25, 2007.
- 4.21 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.

4.22 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.

4.23	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.
4.24	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.
4.25	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.
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, 2011, 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.
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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 15, 2011 /s/ Jerry Treppel

Jerry Treppel

Chief Executive Officer (Principal Executive Officer)

Date: August 15, 2011 /s/ Carter J. Ward

Carter J. Ward

Chief Financial Officer

(Principal Financial and Accounting Officer)