

ELITE PHARMACEUTICALS INC /DE/  
Form 10-Q  
August 19, 2009

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

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

For the quarterly period ended June 30, 2009

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  
(State or other jurisdiction of incorporation or organization)

22-3542636  
(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  No

Edgar Filing: ELITE PHARMACEUTICALS INC /DE/ - Form 10-Q

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

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

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

Yes  No

Indicate the number of shares outstanding of the common stock, \$.01 par value, as of June 30, 2009: [70,048,723] (exclusive of 100,000 shares held in treasury).

---

ELITE PHARMACEUTICALS, INC. AND SUBSIDIARIES

INDEX

	Page No.
<b>PART I - FINANCIAL INFORMATION</b>	
Item 1. Financial Statements	
<u>Condensed Consolidated Balance Sheets as of June 30, 2009 (unaudited) and March 31, 2009 (audited)</u>	F-1
<u>Condensed Consolidated Statements of Operations for the three months ended June 30, 2009 (unaudited) and June 30, 2008 (unaudited)</u>	F-3
<u>Condensed Consolidated Statement of Changes in Stockholders' Equity for the three months ended June 30, 2009 (unaudited)</u>	F-4
<u>Condensed Consolidated Statements of Cash Flows for the three months ended June 30, 2009 (unaudited) and June 30, 2008 (unaudited)</u>	F-5
<u>Notes to Condensed Consolidated Financial Statements</u>	F-6
Item 2. <u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	1
Item 3. <u>Quantitative and Qualitative Disclosures About Market Risk</u>	10
Item 4. <u>Controls and Procedures</u>	10
<b>PART II - OTHER INFORMATION</b>	
Item 1. <u>Legal Proceedings</u>	10
Item 1A. <u>Risk Factors</u>	11
Item 2. <u>Unregistered Sales of Equity Securities and Use of Proceeds</u>	22
Item 3. <u>Defaults upon Senior Securities</u>	22
Item 4. <u>Submission of Matters to a Vote of Security Holders</u>	22
Item 5. <u>Other Information</u>	22
Item 6. <u>Exhibits</u>	23
<u>SIGNATURES</u>	24

## ELITE PHARMACEUTICALS, INC. AND SUBSIDIARIES

## CONDENSED CONSOLIDATED BALANCE SHEETS

## ASSETS

	June 30, 2009 (Unaudited)	March 31, 2009 (Audited)
<b>CURRENT ASSETS</b>		
Cash and cash equivalents	\$ 763,117	\$ 282,578
Accounts receivable		1,177
Inventories (net of reserve of 494,425 and nil, respectively)	1,438,943	1,703,766
Prepaid expenses and other current assets	143,509	331,622
Total current assets	2,345,569	2,319,143
<b>PROPERTY AND EQUIPMENT, net of accumulated depreciation and amortization</b>	<b>4,455,374</b>	<b>4,575,487</b>
<b>INTANGIBLE ASSETS net of accumulated amortization</b>	<b>25,860</b>	<b>27,743</b>
<b>OTHER ASSETS</b>		
Accrued interest receivable	9,916	8,539
Deposit on equipment		14,073
Investment in Novel Laboratories, Inc.	3,329,322	3,329,322
Security deposits	13,488	13,488
Restricted cash debt service for EDA bonds	364,351	327,435
EDA Bond offering costs, net of accumulated amortization of \$53,080 and \$49,534, for June and March, respectively	301,372	304,918
Total other assets	4,018,448	3,997,775
<b>TOTAL ASSETS</b>	<b>\$ 10,845,252</b>	<b>\$ 10,920,148</b>

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

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

**LIABILITIES AND STOCKHOLDERS (DEFICIT) EQUITY**

	June 30, 2009 (Unaudited)	March 31, 2009 (Audited)
<b>CURRENT LIABILITIES</b>		
Current portion of EDA Bonds	\$ 210,000	\$ 210,000
Short term loans and current portion of long-term debt	78,124	10,788
Accounts payable and accrued expenses	1,055,521	981,058
Preferred share derivative interest payable	335,460	
Dividends payable		358,621
		<hr/>
Total Current Liabilities	1,679,105	1,560,467
		<hr/>
<b>LONG TERM LIABILITIES</b>		
EDA bonds net of current portion	3,385,000	3,385,000
Long-term debt, less current portion	28,672	31,600
Derivative Liability Preferred Shares	4,841,305	
Derivative Liability Warrants	4,502,436	
		<hr/>
Total Long-Term Liabilities	12,757,413	3,416,600
		<hr/>
Total Liabilities	14,436,518	4,977,067
		<hr/>
<b>COMMITMENTS AND CONTINGENCIES:</b>		
<b>STOCKHOLDERS (DEFICIT) EQUITY</b>		
Preferred Stock - \$0.01 par value;		
Authorized 4,483,442 shares (originally 5,000,000 shares of which 516,558 shares of Series A Convertible Preferred Stock were retired) and 0 shares outstanding as of March 31, 2009 and June 30, 2009, respectively		
Authorized 10,000 Series B convertible Preferred Stock issued and outstanding 896 and 1,046 shares, respectively Reclassified as a liability as of 4/1/09		11
Authorized 20,000 Series C convertible Preferred Stock issued and outstanding 5,418 and 1,3705 shares, respectively Reclassified as a liability as of 4/1/09		137
Authorized 30,000 Series D convertible Preferred Stock issued and outstanding 5,418 and 1,3705 shares, respectively Reclassified as a liability as of 4/1/09		91
Common Stock - \$0.01 par value;		
Authorized 210,000,000 shares as of June 30, 2009 and March 31, 2009 Issued and outstanding 70,048,723 shares and 60,839,374 shares, respectively	700,487	608,394
Subscription receivable	(75,000)	(75,000)
Additional paid-in capital	88,855,849	95,718,082
Accumulated deficit	(92,765,761)	(90,001,793)
Treasury stock, at cost (100,000 shares)	(306,841)	(306,841)

Edgar Filing: ELITE PHARMACEUTICALS INC /DE/ - Form 10-Q

Total Stockholders (Deficit) Equity	(3,591,266)	5,493,081
<b>TOTAL LIABILITIES AND STOCKHOLDERS (DEFICIT) EQUITY</b>	<b>\$ 10,845,252</b>	<b>\$ 10,920,148</b>

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

F-2

---

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

	THREE MONTHS ENDED JUNE 30,	
	2009	2008
	(Unaudited)	(Unaudited)
<b>REVENUES</b>		
Manufacturing Fees	\$ 665,064	\$ 688,287
Royalties	148,811	88,391
<b>Total Revenues</b>	<b>813,875</b>	<b>776,678</b>
Costs of Revenues	550,014	601,925
Inventory Adjustment	311,986	
<b>Gross (loss) Profit</b>	<b>(48,125)</b>	<b>174,753</b>
<b>COST OF OPERATIONS:</b>		
Research and development	251,092	1,346,979
General and administrative	396,537	629,167
Depreciation and amortization	125,542	130,257
<b>Total Cost of Operations</b>	<b>773,171</b>	<b>2,106,403</b>
<b>LOSS FROM OPERATIONS</b>	<b>(821,296)</b>	<b>(1,931,650)</b>
<b>OTHER INCOME (EXPENSES):</b>		
Interest income	2,008	21,783
Interest expense	(71,987)	(65,200)
Non-cash compensation through issuance of stock options and warrants	(55,363)	(306,549)
Change in fair value of outstanding warrant derivatives	154,326	
Change in fair value of preferred share derivatives	2,561,527	
Interest expense attributable to dividends accrued to preferred share derivative liabilities	(359,021)	
Discount in Series E issuance attributable to beneficial conversion features	(258,700)	
<b>Total Other Income / (Expense)</b>	<b>1,972,790</b>	<b>(349,966)</b>
<b>INCOME (LOSS) BEFORE PROVISION FOR INCOME TAXES</b>	<b>1,151,494</b>	<b>(2,281,616)</b>
Provision for Income Taxes		3,120
<b>NET INCOME (LOSS)</b>	<b>1,151,494</b>	<b>\$ (2,284,736)</b>
Preferred Stock Dividends		(553,907)
<b>NET INCOME (LOSS) ATTRIBUTABLE TO COMMON SHAREHOLDERS</b>	<b>\$ 1,151,494</b>	<b>\$ (2,838,643)</b>

NET INCOME (LOSS) PER SHARE

BASIC	\$	0.02	\$	(.12)
DILUTED	\$	0.01	\$	(.12)
WEIGHTED AVERAGE NUMBER OF COMMON SHARES OUTSTANDING	BASIC	66,240,476	23,307,241	
DILUTED		128,304,240	23,307,241	

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



**ELITE PHARMACEUTICALS, INC. AND SUBSIDIARIES**  
**CONDENSED CONSOLIDATED STATEMENT OF CHANGES IN STOCKHOLDER S EQUITY**

	Series B Preferred Stock		Series C Preferred Stock		Series D Preferred Stock		Common Stock		Additional Subscription Received		Paid in Capital		Treasury Stock		Accumulated Deficit	Stockholders Equity
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount		
Balance at March 31, 2009	1,046	\$ 11	13,705	\$ 137	9,154	\$ 91	60,839,374	\$ 608,394	\$ (75,000)	\$ 95,718,082	(100,000)	\$ (306,841)	\$ (90,001,793)	\$ 5,943,081		
Cumulative effect of reclassification of preferred stock and warrants under EITF 07-5		(11)		(137)		(91)						(7,143,892)			(3,915,462)	(11,059,593)
Proceeds received in exchange for beneficial conversion features embedded in Series E preferred shares												258,700				258,700
Conversion of Series B, Series C and Series D preferred shares into common	(150)		(8,287)		(110)		5,203,009	52,030								52,030
Costs associated with raising capital												(351,362)				(351,362)
Non-cash compensation through Issuance of stock options and warrants												55,363				55,363
Net Income for the three months ended June 30, 2009															1,151,494	1,151,494
Dividends							4,006,339	40,063				318,958				359,021
Balance at June 30, 2009	896		5,418		9,044		70,048,722	\$ 700,487	\$ (75,000)	\$ 88,855,849	(100,000)	\$ (306,841)	\$ (92,765,761)	\$ (3,591,266)		

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

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

	<b>THREE MONTHS ENDED</b>	
	<b>JUNE 30,</b>	
	<b>2009</b>	<b>2008</b>
	<b>(Unaudited)</b>	<b>(Unaudited)</b>
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>		
Net Income (Loss)	\$ 1,151,494	\$ (2,284,736)
Adjustments to reconcile income (loss) to cash used in operating activities:		
Depreciation and amortization	125,542	130,257
Inventory Adjustment	311,986	
Change in fair value of warrant derivative liability	(154,326)	
Change in fair value of preferred shares derivative liability	(2,561,527)	
Discount in Series E issuance attributable to embedded beneficial conversion feature	258,700	
Preferred shares derivative interest accrued	359,021	
Non-cash compensation satisfied by issuance of common stock, options and warrants	55,363	306,549
Changes in assets and liabilities:		
Accounts and interest receivable	1,177	(154,382)
Inventories	(47,163)	221,480
Prepaid expenses and other current assets	(9,378)	(5,301)
Accrued Interest Receivable	(1,377)	(948)
Deposit on Equipment	14,073	
Accounts payable, accrued expenses and other current liabilities	16,798	(100,620)
	<b>(479,617)</b>	<b>(1,887,701)</b>
<b>NET CASH USED IN OPERATING ACTIVITIES</b>		
<b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>		
Purchases of property and equipment		(61,071)
Deposits to restricted cash	(36,916)	(1,613)
	<b>(36,916)</b>	<b>(62,684)</b>
<b>NET CASH USED IN INVESTING ACTIVITIES</b>		
<b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>		
Dividends paid		(63,255)
Proceeds from issuance of Series E Preferred Stock and Warrants	1,000,000	
Payment of long-term debt	(2,928)	(2,384)
	<b>997,072</b>	<b>(65,639)</b>
<b>NET CASH PROVIDED BY (USED IN) FINANCING ACTIVITIES</b>		
	<b>\$ 480,539</b>	<b>\$ (2,016,024)</b>
<b>NET CHANGE IN CASH AND CASH EQUIVALENTS</b>		
<b>CASH AND CASH EQUIVALENTS</b> beginning of period	282,578	3,702,615
<b>CASH AND CASH EQUIVALENTS</b> end of period	<b>\$ 763,117</b>	<b>\$ 1,686,591</b>
<b>SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION:</b>		
Cash paid for interest	\$ 11,597	\$ 1,156
Cash paid for income taxes		3,120
<b>SCHEDULE OF NON-CASH FINANCING ACTIVITIES:</b>		

Edgar Filing: ELITE PHARMACEUTICALS INC /DE/ - Form 10-Q

Preferred stock dividends of \$359,021 and \$490,652 paid by issuance of 4,006,339 and 998,639 shares of common stock in 2009 and 2008, respectively.

Accrued dividends		63,255
Accrued dividends on preferred share derivatives recorded as accrued interest	335,460	
Consulting services paid by issuance of 125,000 shares of common stock in 2008		101,250

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

F-5

---

ELITE PHARMACEUTICALS, INC. AND SUBSIDIARIES  
**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**  
THREE MONTHS ENDED JUNE 30, 2009 AND 2008  
(UNAUDITED)

**NOTE 1 - BASIS OF PRESENTATION**

The information in this Form 10-Q Report includes the results of operations of Elite Pharmaceuticals, Inc. and its consolidated subsidiaries (collectively the Registrant) including its wholly-owned subsidiaries, Elite Laboratories, Inc. ( Elite Labs ) and Elite Research, Inc. ( ERI ) for the three months ended June 30, 2009 and 2008. 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 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 Registrant 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 Registrant's Annual Report on Form 10-K for the year ended March 31, 2009. With the exception of the Registrant adopting the requirements of EITF 07-5 with regards to the accounting for warrants and convertible instruments with anti-dilutive properties, there have been no changes in significant accounting policies since March 31, 2009. Please refer to Note 2 of the financial statements in this report for a description of the change in accounting policy related to the adoption of the requirements of EITF 07-5.

The Registrant does not anticipate being profitable for fiscal year ending March 31, 2010; therefore a current provision for income tax was not established for the three months ended June 30, 2009. Only the minimum liability required for state corporation taxes is reflected.

The accompanying unaudited condensed consolidated financial statements were prepared on the assumption that the Registrant will continue as a going concern. The Registrant continues to generate losses and negative cash flow from operations and does not anticipate being profitable for fiscal year 2010. Therefore Elite continues to require additional financing to ensure that we will be able to meet our expenditures to develop and commercialize our products. As of June 30, 2009, we had cash and cash equivalents of \$763,117. We believe that our existing cash and cash equivalents plus revenues from sale of our Lodrane 24® and Lodrane 24D® products will be sufficient to fund our anticipated operating expenses and capital requirements through October 2009. We will require additional funding in order to continue to operate thereafter. If the second and third closings of the transactions contemplated by the Epic Strategic Alliance Agreement are not closed on a timely basis, or if another financing or strategic alternative providing sufficient resources to allow us to continue operations is not consummated upon exhaustion of our current capital, we will be required to cease operations and liquidate our assets. No assurance can be given that we will be able to consummate the second and third closings under the Epic Strategic Alliance Agreement on a timely basis, or consummate such other financing or strategic alternative in the time necessary to avoid the cessation of our operations and liquidation of our assets. Moreover, even if we consummate the second and third closings under the Epic Strategic Alliance Agreement, or such other financing or strategic alternative, we may be required to seek additional capital in the future and there can be no assurances that the Registrant will be able to obtain such additional capital on favorable terms, if at all.

ELITE PHARMACEUTICALS, INC. AND SUBSIDIARIES  
**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**  
THREE MONTHS ENDED JUNE 30, 2009 AND 2008  
(UNAUDITED)

**NOTE 2 - CHANGE IN ACCOUNTING PRINCIPAL AND DERIVATIVE LIABILITIES**

The following discussion of derivative liabilities consists of the following sections:

Overview of Derivative Liability accounting

Preferred Stock Derivative Liabilities

Warrant Derivative Liabilities

Beneficial Conversion Feature of Series E Preferred Stock

Summary of effects of derivatives on the financial statements

In June 2008, the FASB finalized Emerging Issues Task Force ( EITF ) 07-5, Determining Whether an Instrument (or Embedded Feature) is indexed to an Entity's Own Stock, effective for fiscal years beginning after December 15, 2008. Under EITF 07-5, instruments which do not have fixed settlement provisions are deemed to be derivative instruments. The conversion features within, and the detachable warrants issued with the Registrant'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 Registrant issues securities at lower prices in the future. The Registrant was required to include the reset provisions in order to protect the preferred share and warrant holders from potential dilution associated with future financings. In accordance with EITF 07-5, the preferred shares and warrants were recognized as a derivative instrument and have been re-characterized as derivative liabilities at their fair value. SFAS No. 133, Accounting for Derivative Instruments and Hedging Activities ( FAS 133 ) requires that the fair value of these liabilities be re-measured at the end of every reporting period, with the change in value reported in the statement of operations. EITF 07-5 requires that the cumulative effect of this change in accounting principal, for all periods prior the period of implementation, be recognized as an adjustment in the opening balance of retained earnings/(accumulated deficit)

In addition, the Series E Preferred shares included an option, exercisable from the issuance date, to convert to common shares at a price which was below the share price on the date of issuance. The excess of value based on the share price over the cost of shares, based on the option price represents a beneficial conversion feature existing on the issue date. In accordance with EITF 98-5, the beneficial conversion feature was valued separately at issuance and allocated to additional paid in capital. As the options which comprise the beneficial conversion feature were exercisable when issued, a discount resulting from and in the full amount of the beneficial conversion feature was recorded at the time of issuance.

F-7

---

Preferred Stock Derivative Liabilities

The portion of derivative liabilities related to the Series B, Series C, Series D and Series E preferred shares was valued at the market value of the underlying common shares, into which the preferred shares may be converted. Such valuation as of the beginning and end of the period is summarized as follows:

**PREFERRED STOCK DERIVATIVE LIABILITY AS OF APRIL 1, 2009**

	Series B	Series C	Series D	Series E	Total
Preferred shares Outstanding	1,046	13,705	9,154		23,905
Underlying common shares into which Preferred may convert	670,230	8,512,422	45,772,205		54,954,857
Closing price on valuation date	\$ 0.13	\$ 0.13	\$ 0.13	\$ 0.13	\$ 0.13
<b>Preferred stock derivative liability at April 1, 2009</b>	<b>\$ 87,130</b>	<b>\$ 1,106,615</b>	<b>\$ 5,950,386</b>	<b>\$</b>	<b>\$ 7,144,131</b>

As of April 1, 2009, the total preferred stock derivative liability was \$7,144,131. This amount represents the cumulative effect of the change in accounting principal for all periods prior to April 1, 2009 and as per the requirements of EITF 07-5, is recognized as an adjustment in the opening accumulated deficit balance.

**PREFERRED STOCK DERIVATIVE LIABILITY AS OF JUNE 30, 2009**

	Series B	Series C	Series D	Series E	Total
Preferred shares Outstanding	896	5,418	9,044	1,000	16,358
Underlying common shares into which Preferred may convert	574,076	3,365,217	45,222,205	20,000,000	69,161,498
Closing price on valuation date	\$ 0.07	\$ 0.07	\$ 0.07	\$ 0.07	\$ 0.07
<b>Preferred stock derivative liability at June 30, 2009</b>	<b>\$ 40,185</b>	<b>\$ 235,565</b>	<b>\$ 3,165,555</b>	<b>\$ 1,400,000</b>	<b>\$ 4,841,305</b>
<b>Series E liability at issue date (related to beneficial conversion option)</b>				<b>258,700</b>	<b>258,700</b>
<b>Change in preferred stock derivative liability for the three months ended June 30, 2009</b>	<b>\$ (46,945)</b>	<b>\$ (871,050)</b>	<b>\$ (2,784,832)</b>	<b>\$ 1,141,300</b>	<b>\$ (2,561,527)</b>

The decrease of \$2,561,527 in value of the preferred stock derivative liability occurring during the three months ended June 30, 2009 is included in the amount reported in the Other Income / (Expense) section of the statement of operations, in accordance with FAS 133.

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:

	<u>April 1, 2009</u>	<u>June 30, 2009</u>
Risk-Free interest rate	2%	2%
Expected volatility	118% - 137%	116% - 153%
Expected life (in years)	3.2 5.2	3.0 7.0
Expected dividend yield		
Number of warrants	45,469,740	85,469,740
<b>Fair value Warrant Derivative Liability</b>	<b>\$ 3,915,462</b>	<b>\$ 4,502,436</b>
<b>Derivative warrant liability recorded at issue date of Series E Preferred Shares</b>		<b>741,300</b>
<b>Change in Warrant Derivative Liability for the three months ended June 30, 2009</b>		<b>\$ (154,326)</b>

The risk free interest rate was based on rates established by the Federal Reserve. The expected volatility was based on the historical volatility of the Registrant'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 Registrant has not historically paid dividends on common stock and does not expect to pay dividends on common stock in the future.

The warrant derivative liability as of April 1, 2009 was \$3,915,462. This amount represents the cumulative effect of the change in accounting principal for all periods prior to April 1, 2009 and as per the requirements of EITF 07-5, is recognized as an adjustment in the opening accumulated deficit balance.

The decrease of \$154,326 in value of the warrant derivative liability occurring during the three months ended June 30, 2009 is reported in the Other Income (Expenses) section of the statement of operations, in accordance with FAS 133.

Beneficial Conversion Features of Series E Preferred Shares

The Series E Preferred shares included an option, exercisable from the issuance date, to convert to common shares at a price of \$0.05 per share. The share price on the date of issuance was \$0.09. The difference of \$0.04 between the share price and option price represents a beneficial conversion feature existing on the issue date.

In accordance with EITF 98-5, the beneficial conversion feature was valued separately and allocated to additional paid in capital. The valuation of the beneficial conversion feature was valued at \$258,700, calculated using the relative fair value method, as required by FAS 14, allocating the proceeds of \$1 million from issuance of the Series E Preferred shares to the conversion option and detachable warrants included with such issuance as follows:

Allocation % attributable to the Preferred shares conversion option

Proceeds from issuance of Series E preferred shares	\$ 1,000,000
Value of warrants issued with Series E preferred shares (see below for a description of the method of valuation)	2,865,486
Total of proceeds plus warrants	3,865,486
Allocation % attributable to Preferred Shares conversion option (quotient of the proceeds divided by the proceeds plus warrants)	25.9%
Amount of proceeds attributed to conversion option	\$ 258,700

Gross value of beneficial conversion feature

Share price as of issue date	\$ 0.09
Conversion option price	\$ 0.05
Beneficial conversion feature per share	\$ 0.04
Number of common shares	20,000,000
Gross value of beneficial conversion feature	\$ 800,000

**Beneficial conversion option recorded  
(lesser of the gross value or the amount of proceeds attributed to the conversion option)** **\$ 258,700**

The warrants issued with the Series E Preferred shares were valued using the Black Scholes option valuation model, with the following assumptions:

Risk-free interest rate	2%
Expected volatility	115.2%
Expected life (in years)	7
Number of warrants	40 million
Fair value	\$2,865,486

EITF 98-5 requires that a beneficial conversion option be recognized as a discount and amortized from the date of issuance to the earliest conversion date. As the conversion options were exercisable on their issue date, the full value assigned to the conversion option was charged to interest expense.



Summary of effects of derivatives on the financial statements

	<b>Derivative Liabilities</b>	<b>Accumulated Deficit and Paid-in Capital</b>	<b>Other Income/ (Expense)</b>
Cumulative effect of change in accounting principle			
-Preferred Stock Derivative Liability	\$ 7,144,131	\$ (7,144,131)	\$
Cumulative effect of change in accounting principle			
- Warrant Derivative Liability	3,915,462	(3,915,462)	
Beneficial conversion feature of Series E		258,700	
Warrants issued with Series E	741,300		
Amortization of beneficial conversion of Series E as interest expense	258,700		(258,700)
Change in value of preferred stock derivative liability	(2,561,527)		2,561,527
Change in value of warrants derivative liability	(154,326)		154,326
<b>Net Effect of Derivatives</b>	<b>\$ 9,343,740</b>	<b>\$ (10,800,893)</b>	<b>\$ 2,457,153</b>

**NOTE 3 - INVENTORIES**

Inventories are recorded at the lower of cost or market. As of June 30, 2009 the Company established an inventory valuation reserve totaling \$494,425 resulting in a charge to Operations of \$311,986

**NOTE 4 - DIVIDENDS PAYABLE**

Dividends payable as of June 30, 2009 consisted of \$299,460 in dividends earned and accrued during the quarter ended June 30, 2009 plus \$18,000 in dividends earned during the quarter ended December 31, 2008, but not previously paid, plus \$18,000 in dividends earned during the quarter ended March 31, 2009, but not previously paid. The dividends relating to the quarter ended June 30, 2009 were paid via the issuance of 4,236,856 shares of common stock in July 2009. The Registrant expects to also pay the dividends relating to the quarters ended December 31, 2008 and March 31, 2009 via the issuance of common shares and is in the process of executing the necessary waivers to do so. The Registrant expects to have such required waivers executed subsequent to the filing of this Report.

**NOTE 5 - NJEDA BONDS**

On September 2, 1999, the Company completed the issuance of tax exempt bonds by the New Jersey Economic Development Authority ( NJEDA or the Authority ). The aggregate proceeds from the issuance of the fifteen year term bonds was \$3,000,000. Interest on the bonds accrues at 7.75% per annum. A portion of the proceeds were used by the Company to refinance its land and building, and the remaining proceeds were intended to be used for the purchase of manufacturing equipment and building improvements. On August 31, 2005, the Company successfully completed a refinancing of the 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. 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. As of June 30, 2009, all of these proceeds were utilized to upgrade the Company s manufacturing facilities and for the purchase of manufacturing and laboratory equipment. 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 financing costs amounted to \$3,546 and \$3,546 for the years three months ended June 30, 2009 and 2008, respectively.

**NOTE 6 - STOCKHOLDERS EQUITY**

The adoption of EITF 07-5 resulted in a cumulative effect adjustment of \$11,059,593 to the opening balance in the accumulated deficit account. This amount represents the cumulative effect on equity of the reclassification of the Series B, Series C, and Series D preferred shares and the outstanding warrants as derivative liabilities, pursuant to the requirements of EITF 07-5.

Please refer to Note 2 for a discussion of the change in accounting principle and derivative liabilities.

**Options**

At June 30, 2009, the Registrant had 2,879,900 options outstanding with exercise prices ranging from \$1.08 to \$3.00 per share; each option representing the right to purchase one share of Common Stock.

**NOTE 7 - PER SHARE INFORMATION**

In accordance with SFAS No. 128, Earnings per Share, 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. SFAS No. 128 requires the presentation of both Basic and Diluted EPS, if such Diluted EPS is not anti-dilutive, on the face of Company's Consolidated Condensed Statements of Operations. Common stock equivalents totaling 48,141,640 and 26,818,934 shares were excluded from the computation of Diluted EPS for the three months ended June 30, 2009 and 2008, respectively, as their effect on the computation of Diluted EPS would have been anti-dilutive.

The following table sets forth the computation of basic and diluted per share information:

	For the Three Months Ended June 30, 2009	For the Three Months Ended June 30, 2008
<b>Numerator</b>		
Net Income (loss) attributable to common shareholders	\$ 1,151,494	\$ (2,838,643)
<b>Denominator</b>		
Weighted-average shares of common stock outstanding	66,240,476	23,307,241
Dilutive effect of stock options, warrants and convertible securities	62,063,764	
Weighted-average shares of common stock outstanding, assuming dilution	128,304,240	23,307,241
<b>Net (loss) income per share</b>		
Basic	\$ 0.02	\$ (0.12)
Diluted	\$ 0.01	\$ (0.12)

**NOTE 8 - COMMITMENTS AND CONTINGENCIES****Consulting Agreement**

As a result of the Registrant's continuing efforts to reorganize its workforce and decrease its operating expenses the Registrant requested that Dr. Stuart Apfel, the Registrant's Chief Scientific Officer and Chief Medical Officer, change the status of his relationship with the Registrant from employee to consultant. Dr. Apfel agreed to such change in status and will continue to provide his services as the Registrant's Chief Scientific Officer and Chief Medical Officer on an hourly basis, thereby reducing the Registrant's expenses as they relate to Dr. Apfel. In his continuing service as the Registrant's Chief Scientific Officer and Chief Medical Officer, Dr. Apfel will be compensated pursuant to a consulting agreement, dated as of October 20, 2008, between the Registrant and Paralex Clinical Research ( Paralex ). Dr. Apfel is the founder and current president of Paralex. Pursuant to the consulting agreement, Paralex is to provide the Registrant consulting services for its opioid abuse-resistant product, control release opioid product and other such products that the Registrant may request assistance with. Dr. Apfel will be the primary person providing such consulting services for which he will be paid on an hourly basis. The Registrant may terminate the consulting agreement at any time upon written notice to Paralex. Paralex and Dr. Apfel are subject to covenants not to disclose confidential information and assignment of intellectual property and a one year from termination non-competition covenant and non-solicitation covenant.

The Registrant also requested that Dr. Charan Behl, the Registrant's Head of Technical Affairs, change the status of his relationship with the Registrant from employee to consultant. Dr. Behl agreed to such change in status and will continue to provide his services as a consultant to the Registrant on an hourly basis, thereby reducing the Registrant's expenses as they relate to Dr. Behl. In his continuing service to the Registrant as a consultant, Dr. Behl will be compensated pursuant to a consulting agreement, dated as of November 3, 2008, between the Registrant and Dr. Behl. Pursuant to the consulting agreement, Dr. Behl is to provide the Registrant consulting services for its opioid abuse-resistant product, control release opioid product and other such products that the Registrant may request assistance with. Dr. Behl will be paid for such consulting services on an hourly basis. The Registrant may terminate the consulting agreement at any time upon written notice to Dr. Behl. Dr. Behl is subject to covenants not to disclose confidential information and assignment of intellectual property and a one year from termination non-competition covenant and non-solicitation covenant.

**NOTE 10 - SUBSEQUENT EVENTS**

The Registrant has evaluated subsequent events from the balance sheet date through August 19, 2009, the date the accompanying financial statements were issued. The following is a material subsequent event:

Dividends accrued during the quarter ended June 30, 2009 were paid during July 2009 through the issuance of 4,236,856 shares of common stock.

F-14

---

**ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS**  
**THREE MONTH PERIOD ENDED JUNE 30, 2009 COMPARED TO THE**  
**THREE MONTH PERIOD ENDED JUNE 30, 2008**  
**(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 within the meaning of the Private Securities Litigation Reform Act of 1995. Such forward-looking statements involve known and unknown risks, uncertainties and other factors which may cause the actual results, performance or achievements of the Company, or industry results, to be materially different from any future results, performance or achievements expressed or implied by such forward-looking statements. When used in this Form 10-Q, statements that are not statements of current or historical fact may be deemed to be forward-looking statements. Without limiting the foregoing, the words plan, intend, may, will, expect, believe, could, anticipate, estimate, or continue or similar expressions or other variations or comparable terminology are intended to identify such forward-looking statements. Readers are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof. Except as required by law, the Company undertakes no obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise.*

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

**Overview**

Elite is a specialty pharmaceutical company principally engaged in the development and manufacture of oral, controlled-release products, using proprietary technology. Elite's 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. Elite's technology is applicable to develop delayed, sustained or targeted release pellets, capsules, tablets, granules and powders.

Elite has two products, Lodrane 24® and Lodrane 24D®, currently being sold commercially, and a pipeline of five additional drug candidates under active development in the therapeutic areas that include pain management, gastro-intestinal and infection. Of the products under development, ELI-216, a once-a-day, abuse deterrent oxycodone product, and ELI-154, a once-a-day oxycodone product, are in clinical trials and Elite has completed pilot studies on two of Elite's other generic product candidates. Elite has also submitted an ANDA with Elite's co-development partner, The PharmaNetwork, for a pain management generic product. The addressable market for the pipeline of products is approximately \$6 billion. Elite's facility in Northvale, New Jersey is a Good Manufacturing Practice (GMP) and DEA registered facility for research, development and manufacturing.

In January 2006, the FDA accepted Elite's Investigational New Drug Application (an IND) for ELI-154, Elite's once-a-day oxycodone painkiller. Elite has completed two pharmacokinetic studies to evaluate ELI-154's controlled-release formulation, of which the most recent study was completed in 2006. Elite is currently scaling up the product and it will begin its Phase III studies for this product upon the completion of a joint development and distribution agreement. Currently there is no once-daily oxycodone available commercially.

In May 2005, the FDA accepted Elite's IND for ELI-216, Elite's once-a-day, abuse resistant oxycodone painkiller. After the acceptance of the IND, Elite completed two pharmacokinetic studies and a euphoria study in recreational drug users to assess the abuse deterrent properties of ELI-216. Elite met with the FDA in October 2006 and received guidance for the ELI-216 development program and in November 2007, Elite reached agreement with the FDA on a Special Protocol Assessment for the Phase III protocol for ELI-216. Elite is currently scaling up the product and it will begin its Phase III studies for this product upon the completion of a joint development and distribution agreement. Currently there is no abuse deterrent oxycodone product available commercially. Elite estimates that the U.S. market for controlled-release, twice-daily oxycodone was about \$2.8 billion in 2008.

### Strategy

Elite is focusing its efforts on the following areas: (i) development of Elite's pain management products, (ii) manufacturing of Lodrane 24(R) and Lodrane 24D(R) products; (iii) the development of the other products in Elite's pipeline; (iv) development of the eight products with pursuant to the Epic Strategic Alliance Agreement and (v) commercial exploitation of Elite's products either by license and the collection of royalties, or through the manufacture of Elite's formulations, and (vi) development of new products and the expansion of Elite's 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 ( *NDA* ) under Section 505(b)(1) or 505(b)(2) of the Drug Price Competition and Patent Term Restoration Act of 1984 as well as generic drug products (which require abbreviated new drug applications ( *ANDA* )).

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

### Epic Strategic Alliance Agreement

On March 18, 2009, Elite entered into the Epic Strategic Alliance Agreement (amended on April 30, 2009, June 1, 2009 and July 28, 2009), pursuant to which Elite commenced a strategic relationship with Epic, a pharmaceutical company that operates a business synergistic to that of Elite in the research and development, manufacturing, sales and marketing of oral immediate and controlled-release drug products.

### *Use of Facility and Joint Development of Drug Products*

Pursuant to the Epic Strategic Alliance Agreement, on June 3, 2009 (the *Initial Closing Date* ), Elite and Epic conducted the initial closing (the *Initial Closing* ) of the transactions contemplated by the Epic Strategic Alliance Agreement, and Epic and its employees and consultants commenced use of a portion of Elite's facility located at 165 Ludlow Avenue, Northvale, New Jersey (the *Facility* ), for the purpose of developing new generic drug products, all at Epic's sole cost and expense for a period of at least three years (the *Initial Term* ), unless sooner terminated or extended pursuant to the Epic Strategic Alliance Agreement or by mutual agreement of Elite and Epic (the Initial Term, as shortened or extended, the *Term* ). In addition to the use of the Facility, Epic will use Elite's machinery, equipment, systems, instruments and tools residing at the Facility (collectively the *Personal Property* ) in connection with its joint drug development project at the Facility. Under the Epic Strategic Alliance Agreement, Epic has the right, exercisable in its sole discretion, to extend the Initial Term for two periods of one year each by giving written notice to Elite of such extension within ninety days of the end of the Initial Term or any extension thereof. Any such extension will be on the same terms and conditions contained in the Epic Strategic Alliance Agreement. Elite will be responsible for (and Epic will have no responsibility for) any maintenance, services, repairs and replacements in, to or of the Facility and the Personal Property, unless any such maintenance, service, repair or replacement is required as a result of the negligence or misconduct of Epic's employees or representatives, in which case Epic will be responsible for the costs and expenses associated therewith.

## Edgar Filing: ELITE PHARMACEUTICALS INC /DE/ - Form 10-Q

During the Term, Epic will use and occupy a portion of the Facility and use the Personal Property for the purpose of developing (i) at least four controlled-release products (the *Identified CR Products*) and (ii) at least four immediate-release products (the *Identified IR Products*), the identity of each have been agreed upon by Epic and Elite. If, during the Term, Epic determines, in its reasonable business judgment, that the further or continuing development of any Identified CR Product and/or Identified IR Product is no longer commercially feasible, Epic may, upon written notice to Elite, eliminate from development under the Epic Strategic Alliance Agreement such Identified CR Product and/or Identified IR Product, and replace such eliminated product with another controlled-release or immediate-release product, as applicable.

Pursuant to the Epic Strategic Alliance Agreement, Epic will also use a portion of the Facility and use the Personal Property for the purpose of developing (x) additional controlled-release products of Epic (the *Additional CR Products*), subject to the mutual agreement of Epic and Elite, and/or (y) additional immediate-release products of Epic (the *Additional IR Products*), subject to the mutual agreement of Elite and Epic (each Identified CR Product, Identified IR Product, Additional CR Product and Additional IR Product, individually, a *Product*, and collectively, the *Products*). Under the Epic Strategic Alliance Agreement, Epic may not eliminate an Identified CR Product or an Identified IR Product unless it replaces such Product with an Additional CR product or Additional IR Product, as the case may be. Subject to the mutual agreement of Elite and Epic as to additional consideration and other terms, Epic may use and occupy the Facility for the development of other products of Epic (in addition to the Products).

As additional consideration for Epic's use and occupancy of a portion of the Facility and its use of the Personal Property during the Term and the issuance and delivery by Elite to Epic of the Milestone Shares (as defined below) and Milestone Warrants (as defined below), for the period beginning on the First Commercial Sale (as defined in the Epic Strategic Alliance Agreement) of each Product and continuing for a period of ten years thereafter (measured independently for each Product), Epic will pay Elite a cash fee (the *Product Fee*) equal to fifteen percent of the Profit (as defined in the Epic Strategic Alliance Agreement), if any, on each of the Products.

With respect to each Identified CR Product and Additional CR Product developed by Epic at the Facility: (i) Elite will issue and deliver to Epic a seven-year warrant to purchase up to 10,000,000 shares of Common Stock, at an exercise price of \$0.0625, following the receipt by Elite from Epic of each written notice of Epic's receipt of an acknowledgment from the FDA that the FDA accepted for filing an ANDA for such Identified CR Products and/or Additional CR Products, up to a maximum of four such warrants for the right to purchase up to an aggregate of 40,000,000 shares of Common Stock (such warrants, the *CR Related Warrants*), and (ii) Elite will issue and deliver to Epic 7,000,000 shares of Common Stock following the receipt by Elite from Epic of each written notice of Epic's receipt from the FDA of approval for such Identified CR Products and/or Additional CR Products, up to a maximum of an aggregate of 28,000,000 shares of Common Stock (such shares, the *CR Related Shares*).

With respect to each Identified IR Product and Additional IR Product developed by Epic at the Facility, (i) Elite will issue and deliver to Epic a seven year warrant to purchase up to 4,000,000 shares of Common Stock, at an exercise price of \$0.0625, following the receipt by Elite from Epic of each written notice of Epic's receipt of an acknowledgment from the FDA that the FDA accepted for filing an ANDA for such Identified IR Products and/or Additional IR Products, up to a maximum of four such warrants for the right to purchase up to an aggregate of 16,000,000 shares of Common Stock (such warrants, together with the CR Related Warrants, the *Milestone Warrants*), and (ii) Elite will issue and deliver to Epic 3,000,000 shares of Common Stock following the receipt by Elite from Epic of each written notice of Epic's receipt from the FDA of approval for such Identified IR Products and/or Additional IR Products, up to a maximum of an aggregate of 12,000,000 shares of Common Stock (such shares, together with the CR Related Shares, the *Milestone Shares*). The Milestone Warrants may only be exercised by payment of the applicable cash exercise price. Elite will have no obligation to register with the United States Securities and Exchange Commission (the *SEC*) or any state securities commission the resale of the Milestone Shares, Milestone Warrants or the shares of Common Stock issuable upon exercise of the Milestone Warrants.

## Edgar Filing: ELITE PHARMACEUTICALS INC /DE/ - Form 10-Q

Subject to the mutual agreement of Epic and Elite with respect to the selection of Additional CR Products and/or Additional IR Products pursuant to the Epic Strategic Alliance Agreement, Epic will have the sole right to make all decisions regarding all aspects of the Products, including, but not be limited to, (i) research and development, formulation, studies and validation of each Product, (ii) identifying, evaluating and obtaining ingredients for each Product, (iii) preparing and filing the ANDA for each Product with the FDA and addressing and handling all regulatory inquiries, audits and investigations pertaining to the ANDA, and (iv) the manufacture, marketing, supply and commercialization of each Product. In addition, Epic will be the sole and exclusive owner of all right, title and interest in and to each of the Products.

Pursuant to the Epic Strategic Alliance Agreement, the use by each of Elite and Epic of the other party's confidential and proprietary information is restricted by customary confidentiality provisions. Elite and Epic also agreed in the Epic Strategic Alliance Agreement to indemnify and hold each other harmless from certain losses under the Epic Strategic Alliance Agreement.

Under certain circumstances Epic will be entitled to terminate the Term early in the event that the Facility is totally damaged or destroyed such that the Facility is rendered wholly untenable. In addition, subject to certain exceptions, either Elite or Epic may terminate the Term at any time if the other party is in breach of any material obligations under Article V of the Epic Strategic Alliance Agreement and has not cured such breach within sixty days after receipt of written notice requesting cure of such breach.

Elite may also terminate the Term by written notice to Epic if (i) all conditions precedent that Elite is obligated to satisfy pursuant to Article II of the Epic Strategic Alliance Agreement on or prior to a Closing (as defined in the Epic Strategic Alliance Agreement) have been, or will have been, satisfied by Elite in accordance with the terms thereof and (ii) Epic does not consummate such Closing in accordance with Article II. Notwithstanding the foregoing, if Elite terminates the Epic Strategic Alliance Agreement as described in this paragraph, then any and all product fees to which it would otherwise be entitled will remain the obligation of Epic and must be paid to Elite in accordance with the terms of Epic Strategic Alliance Agreement.

### ***Infusion of Additional Capital Necessary for Product Development***

At the Initial Closing, which occurred on June 3, 2009, in order to fund the continued development of Elite's drug products, Elite issued and sold to the Purchaser, in a private placement, pursuant to an exemption from registration under Section 4(2) of the Securities Act, 1,000 shares of its Series E Convertible Preferred Stock, par value \$0.01 per share (the *Series E Preferred Stock*), at a price of \$1,000 per share, each share convertible, at \$0.05 per share (the *Conversion Price*), into 20,000 shares of Common Stock, par value \$0.01 per share (the *Common Stock*). The Conversion Price is subject to adjustment for certain events, including, without limitation, dividends, stock splits, combinations and the like. The Conversion Price is also subject to adjustment for (a) the sale of Common Stock or securities convertible into or exercisable for Common Stock, for which the Purchaser's consent was not required under the Certificate of Designation of Preferences, Rights and Limitations of the Series E Convertible Preferred Stock, at a price less than the then applicable Conversion Price, (b) the issuance of Common Stock in lieu of cash in satisfaction of Elite's dividend obligations on outstanding shares of its Series B 8% Convertible Preferred Stock, par value \$0.01 per share, Series C 8% Convertible Preferred Stock, par value \$0.01 per share, and/or Series D 8% Convertible Preferred Stock, par value \$0.01 per share (the *Series D Preferred Stock*), and (c) the issuance of Common Stock as a result of any holder of Series D Preferred Stock exercising its right to require Elite to redeem all of such holder's shares of Series D Preferred Stock pursuant to the terms thereof. The Purchaser also acquired a warrant to purchase 20,000,000 shares of Common Stock (the *Initial Warrant*), exercisable on or prior to June 3, 2016, at a per share exercise price of \$0.0625 (the *Exercise Price*), subject to adjustments for certain events, including, but not limited to, dividends, stock splits, combinations and the like. The Exercise Price of the Initial Warrant will also be subject to adjustment for the sale of Common Stock or securities convertible into Common Stock, for which the Purchaser's consent was not required under the Alliance Agreement, at a price less than the then applicable Exercise Price of the Initial Warrant. The Purchaser paid an aggregate purchase price of \$1,000,000 for the shares of Series E Preferred Stock and the Initial Warrant issued and sold by Elite to the Purchaser at the Initial Closing, of which \$250,000 was received by Elite, in the form of a cash deposit, on April 30, 2009, pursuant to the First Amendment. The remaining \$750,000 of such aggregate purchase price was paid to Elite by the Purchaser at the Initial Closing.



## Edgar Filing: ELITE PHARMACEUTICALS INC /DE/ - Form 10-Q

On the fifth trading day following the Special Meeting of Stockholders (as defined in the Epic Strategic Alliance Agreement) at which the Shareholder Approval (as defined in the Epic Strategic Alliance Agreement) is obtained, Elite and Epic will conduct a second closing (the *Second Closing* and the date of such Second Closing, the *Second Closing Date* ), provided that all conditions precedent to such Second Closing contained in the Epic Strategic Alliance Agreement have been satisfied or waived by the appropriate party on or before the Second Closing Date. The Second Closing must occur within 180 days of the Initial Closing Date. At the Second Closing, Epic will pay to Elite a sum of \$1,000,000 in exchange for an additional 1,000 shares of Series E Preferred Stock, which such shares of Series E Preferred Stock will be convertible, at the Conversion Price, subject to adjustment, into 20,000,000 shares of Common Stock, and a warrant (the *Second Warrant* ) to purchase an additional 40,000,000 shares of Common Stock. The Second Warrant will be exercisable until the date that is the seventh anniversary of the Second Closing Date and will have a per share exercise price equal to \$0.0625, subject to adjustments for certain events, including, but not limited to, dividends, stock splits, combinations and the like. The per share exercise price of the Second Warrant will also be subject to adjustment for the sale of Common Stock or securities convertible into Common Stock at a price less than the then applicable per share exercise price of the Second Warrant, for which Epic's consent was not required under the Epic Strategic Alliance Agreement.

On the first trading day following the first anniversary of the Initial Closing Date, Elite and Epic will conduct a third closing (the *Third Closing* and the date of such Third Closing, the *Third Closing Date* ), provided that all conditions precedent to such Third Closing contained in the Epic Strategic Alliance Agreement have been satisfied or waived by the appropriate party on or before such Third Closing Date. The Third Closing must occur within thirty days following the first anniversary of the Initial Closing Date. At the Third Closing, Epic will pay to Elite a sum of \$1,000,000 in exchange for an additional 1,000 shares of Series E Preferred Stock, which such shares of Series E Preferred Stock will be convertible, at the Conversion Price, subject to adjustment, into 20,000,000 shares of Common Stock, and a warrant (the *Third Warrant* and collectively with the Initial Warrant and the Second Warrant, the *Warrants* ) to purchase an additional 40,000,000 shares of Common Stock. The Third Warrant will be exercisable until the date that is the seventh anniversary of the Third Closing Date and will have a per share exercise price equal to \$0.0625, subject to adjustments for certain events, including, but not limited to, dividends, stock splits, combinations and the like. The per share exercise price of the Third Warrant will also be subject to adjustment for the sale of Common Stock or securities convertible into Common Stock at a price less than the then applicable per share exercise price of the Third Warrant, for which the Purchaser's consent was not required under the Epic Strategic Alliance Agreement.

In addition, within ten business days following the last day of each calendar quarter, beginning with the first calendar quarter following the Initial Closing Date and continuing for each of the eleven calendar quarters thereafter, Epic will pay to Elite a sum of \$62,500, for an aggregate purchase price over such period of \$750,000, in exchange for an additional 62.5 shares of Series E Preferred Stock per quarter and 750 shares of Series E Preferred Stock, in the aggregate, over such period, which such shares will be convertible into 1,250,000 shares of Common Stock per quarter and 15,000,000 shares of Common Stock, in the aggregate, over such period, subject to adjustment.

If Elite determines, in its reasonable judgment, that additional funding is required for the development of its pharmaceutical products, then, either (i) Elite will issue, and Epic will purchase, such additional number of shares of Series E Preferred Stock or Common Stock from Elite, upon such terms and conditions as may be agreed upon by Elite and Epic at the time of such determination; or (ii) on or after September 15, 2011, Epic will provide a loan to Elite, in an aggregate principal amount not to exceed \$1,000,000, which such loan will (A) have an interest rate equal to the then prime interest rate as published in the Wall Street Journal on the date of such loan, (B) mature on the second anniversary of date of such loan, and (C) be on such other terms and conditions which are customary and reasonable to loans of a similar nature and which are mutually agreed upon between Epic and Elite.

Elite believes, which as to such belief there can be no assurances, the completion of the transactions contemplated by the Epic Strategic Alliance Agreement creates value for our stockholders by adding a new revenue source for Elite upon the commercialization of the Epic products developed at our facility, providing an experienced partner to assist in the development, manufacture and licensing of our pharmaceutical products, and contributing funding for the products. Importantly, Elite will continue the development of its pain products and, with the help of our new partner, work towards securing licensing arrangements for such pain products.

***Board of Directors Composition and Voting Rights***

As of the Initial Closing Date and at all times thereafter, except as otherwise set forth in the Epic Strategic Alliance Agreement, Elite and its Board of Directors will take any and all action necessary so that (i) the size of the Board of Directors will be set and remain at seven directors, (ii) three individuals designated by Epic (the *Epic Directors*) will be appointed to the Board of Directors and (iii) the Epic Directors will be nominated at each annual or special meeting of stockholders at which an election of directors is held or pursuant to any written consent of the stockholders; provided, however, that if at any time following the Lock-Up Period (as defined above) the Purchaser owns less than (i) a number of shares of Series E Preferred Stock equal to ninety percent of the aggregate number of shares of Series E Preferred Stock purchased by the Purchaser at all of the then applicable Closings or (ii) following the conversion by the Purchaser of the Series E Preferred Stock, a number of shares of Common Stock equal to ninety percent of the number of shares of Common Stock so converted, neither Elite nor its Board of Directors will be obligated to nominate Epic Directors or take any other action with respect to those actions described in (i), (ii) and/or (iii) above. No Epic Director may be removed from office for cause unless such removal is directed or approved by (x) a majority of the independent members of the Board of Directors and (y) all of the non-affected Epic Director (s). Any vacancies created by the resignation, removal or death of an Epic Director will be filled by the appointment of an additional Epic Director. Any Epic Director may be removed from office upon the request of the Purchaser, with or without cause. At such time as the Purchaser owns more than 50% of the issued and outstanding Common Stock or other voting securities of Elite, the number of Epic Directors that the Purchaser will be entitled to designate under the Epic Strategic Alliance Agreement will be equal to a majority of the Board of Directors.

In addition, pursuant to the Epic Strategic Alliance Agreement and the Series E Certificate, Elite has agreed that, between the date of the initial closing under the Epic Strategic Alliance Agreement and the date which is the earlier of (x) the date the Epic Directors constitute a majority of the Board of Directors and (y) ninety days following the fifth anniversary of the Initial Closing Date, except as Epic otherwise agrees in writing, Elite may conduct its operations only in the ordinary and usual course of business consistent with past practice. Further, pursuant to the Epic Strategic Alliance Agreement and the Series E Certificate, Elite must obtain the prior written consent of Epic in order to take the actions specifically enumerated therein.

For information regarding composition of the Board and voting rights in connection with Epic Strategic Alliance Agreement, refer to the *Risk Factors* under Item 1A, above, which are incorporated herein by reference.

**Appointment of Chief Financial Officer, Secretary and Treasurer**

On July 1, 2009, Elite appointed Carter J. Ward as its Chief Financial Officer, replacing Mark I. Gittelman, who served as the Elite's Chief Financial Officer through the same date.

In connection with the appointment of Mr. Ward as Chief Financial Officer of the Registrant, Mr. Ward and the Registrant entered into a letter agreement (the *Employment Letter*). As previously disclosed in the Form 8-K filed by Elite on July 8, 2009, Mr. Ward became an at-will employee of the Registrant as its Chief Financial Officer. Mr. Ward will dedicate at least two business days per week toward fulfilling his responsibilities as Chief Financial Officer and he will receive an annual base salary of \$60,000, payable in accordance with the Registrant's payroll practices. In recognition of Mr. Ward's part-time commitment to the Registrant, the Registrant has acknowledged that Mr. Ward will dedicate the remaining three business days per week to the performance of his services to Epic Pharma, LLC ( *Epic* ), the Registrant's strategic partner, and its affiliates. Pursuant to the *Employment Letter*, Mr. Ward agrees to not knowingly undertake or engage in any employment, occupation or business enterprise that is, directly or indirectly, adverse to the interest of the Registrant.

In addition, pursuant to the *Employment Letter*, Mr. Ward may become eligible for cash and/or equity based awards that may be granted by the Registrant in the future, with any such awards to be granted in the discretion of the Registrant and its Chief Executive Officer. Mr. Ward will be entitled to the same benefits generally offered to other employees of Elite, subject to applicable eligibility requirements.

## Edgar Filing: ELITE PHARMACEUTICALS INC /DE/ - Form 10-Q

The Registrant and Mr. Ward also entered into the Registrant's standard Employee Proprietary Information and Non-Solicitation Agreement that the Registrant requires its employees to execute in connection with their employment with the Registrant.

Since June 2009, Mr. Ward has been engaged by Epic as a consultant and the services provided by Mr. Ward to Epic pursuant to such engagement include, but are not limited to, consulting on matters relating to the finances, business development and operations of Epic. Prior to joining the Registrant, from July 2005 to April 2009, Mr. Ward filled multiple finance and supply chain leadership roles with Actavis Group and its U.S. subsidiary Amide Pharmaceuticals. From September 2004 to June 2005, Mr. Ward was a consultant, mainly engaged in improving internal controls and supporting Sarbanes-Oxley compliance of Centennial Communications Inc., a NASDAQ-listed wireless communications provider. From 1999 to September 2004, Mr. Ward was the Chief Financial Officer for Positive Healthcare/Ceejay Healthcare, a U.S.-Indian joint venture engaged in the manufacture and distribution of generic pharmaceuticals and nutraceuticals in India. Mr. Ward began his career as a certified public accountant in the audit department of KPMG and is a certified public accountant. Mr. Ward holds a B.S. in Accounting from Long Island University, Brooklyn, NY, from where he graduated *summa cum laude*.

Effective as of July 1, 2009, Mr. Ward replaced Mr. Gittelman as the Registrant's Chief Financial Officer. Effective as of August 13, 2009, Mr. Ward was appointed as the Registrant's Secretary and Treasurer. Mr. Gittelman ceased providing services to the Registrant in such capacities as of July 1, 2009.

### **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, 2009 Compared to Three Months Ended June 30, 2008

The Registrant's revenues for the three months ended June 30, 2009 were \$813,875 an increase of \$37,197 or approximately 5% over revenues for the comparable period of the prior year, and consisted of \$665,064 in manufacturing fees and \$148,811 in royalty fees. Revenues for the three months ended June 30, 2008, consisted of \$688,287 in manufacturing fees and \$88,391 in royalty fees. Manufacturing fees decreased by approximately 3% due to fluctuations in the number and timing of batches shipped each quarter because of seasonality of sales, and management of higher inventory levels in the market resulting from increased production in the quarters preceding this quarter. Royalties increased by approximately 68% due to growth of product sales.

Research and development costs for the three months ended June 30, 2009, were \$251,092, a decrease of \$1,095,887 or approximately 81% from \$1,346,979 of such costs for the comparable period of the prior year. Decreases were attributed to decreases in salaries and wages, consulting fees associated with the development of products and lower active pharmaceutical ingredient (API) costs for product development. To conserve cash, the Registrant has reduced its number of employees from 43 employees in June 2008, to 12 employees as of June 30, 2009. The reduction in force was implemented during the last two quarters, with cost savings beginning in this quarter. Research and development costs are expected to increase, however, in future periods, once Phase III and other clinical trials for ELI-216 are initiated. Additional funding is required for such research and development costs. Elite is currently scaling up the product and it will begin its Phase III studies for this product upon the completion of a joint development and distribution agreement.

General and administrative expenses for the three months ended June 30, 2009, were \$396,537, a decrease of \$232,630, or approximately 37% from \$629,167 of general and administrative expenses for the comparable period of the prior year. The decrease was primarily attributable to decreases in salaries and fringe benefits offset by increases in legal and accounting fees.

Depreciation and amortization for the three months ended June 30, 2009 were 125,542, a decreased of \$4,715, or approximately 4%, from \$130,257 for the comparable period of the prior year. The decrease was due to the cessation of acquisition of new machinery in the current period.

Other income/(expenses) (net) for the three months ended June 30, 2009 were \$1,972,790, an increase in other income of \$2,322,756 from the net expense of \$349,966 for the comparable period of the prior year. The increase in other income was due to derivative income related to changes in the fair value of Registrant's preferred shares and outstanding warrants of \$2,715,853. The derivative income is resulting from a change in accounting principle required by the adoption of EITF 07-5 as of the beginning of the period. Please refer to Note 2 of the financial statements in this Report for a discussion of the effects of this change in accounting principle.

As a result of the foregoing, the Registrant's net income for the three months ended June 30, 2009 was \$1,151,494 compared to a loss of \$2,281,616 for the three months ended June 30, 2008.

### Material Changes in Financial Condition

The Registrant's working capital (total current assets less total current liabilities), decreased to \$666,464 as of June 30, 2009 from \$758,676 as of March 31, 2008, primarily due to the Registrant's net loss from operations, exclusive of non-cash charges.

The Registrant experienced negative cash flows from operations of \$479,618 for the three months ended June 30, 2009, primarily due to the Registrant's net income from continuing operations of \$1,151,494, increased by non cash charges totaling \$1,110,612, which included depreciation and amortization of \$125,542, inventory adjustments of \$311,986, non cash interest expense related to the series E issuance of \$258,700, dividends accruing to preferred share derivative liabilities of \$359,021, and reduced by non cash income related to the change in fair value of preferred share derivative liabilities of \$2,561,527, and the change in fair value of warrant derivative liabilities of \$154,326. Please refer to Note 2 of the financial statements in this report for discussions on the fair value of preferred share and warrant derivatives, and interest expense recorded as a discount in Series E issuance.

## Edgar Filing: ELITE PHARMACEUTICALS INC /DE/ - Form 10-Q

On November 15, 2004 and on December 18, 2006, the Registrant's partner, ECR, launched Lodrane 24(R) and Lodrane 24D(R), respectively. Under its agreement with ECR, the Registrant is currently manufacturing commercial batches of Lodrane 24(R) and Lodrane 24D(R) in exchange for manufacturing margins and royalties on product revenues. Manufacturing revenues and royalty income earned for the three months ended June 30, 2009 and June 30, 2008 were \$813,875 and \$776,678, respectively. The Registrant expects future cash flows from manufacturing fees and royalties to provide additional cash to help fund its operations. However, no assurance can be given that the Registrant will generate any material revenues from the manufacturing fees and royalties of the Lodrane products.

### LIQUIDITY AND CAPITAL RESOURCES

As of June 30, 2009, the Registrant had approximately four months of cash available based on the Registrant's current operations. As of the date of this Quarterly Report on Form 10-Q, the Registrant is negotiating a strategic transaction with an unaffiliated third party, which such strategic transaction, if consummated in accordance with the current terms under negotiation, should allow the Registrant to maintain its current level of operations. If such strategic transaction is not closed in a timely basis, or if another financing or strategic alternative providing sufficient resources to the Registrant to continue its operations is not consummated in the near future, the Registrant will be required to cease operations and liquidate its assets. No assurance can be given that the Registrant will be able to close such strategic transaction on a timely basis, or consummate such other financing or strategic alternative in the time necessary to avoid the cessation of the Registrant's operations and liquidation of its assets, on favorable terms, if at all. Moreover, even if the Registrant consummates such strategic transaction, or such other financing or strategic alternative, it may be required to seek additional capital in the future and there can be no assurances that the Registrant will be able to obtain such additional capital on favorable terms, if at all.

Based upon the Registrant's current cash position, management has undertaken a review of the Registrant's operations and implemented cost-cutting measures in an effort to eliminate any expenses which are not deemed critical to the Registrant's current strategic objectives. The Registrant will continue this process without impeding its ability to proceed with its critical strategic goals.

For the three months ended June 30, 2009, the Registrant expended \$479,618 in operating activities which the Registrant funded through the \$1,000,000 in gross proceeds raised through the Registrant's private placement of its Series E Preferred Stock and manufacturing and royalty revenues resulting from the manufacture and sale of Lodrane 24® and Lodrane 24D ®. The Registrant's working capital at June 30, 2009 was approximately \$666,000 compared with working capital of approximately \$759,000 at June 30, 2008. Cash and cash equivalents at June 30, 2009, were approximately \$763,000, an increase of approximately \$481,000 from the \$283,000 at June 30, 2008.

As of June 30, 2009, the Registrant's principal source of liquidity was approximately \$763,000 of cash and cash equivalents. Additionally, the Registrant 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.

The Registrant had outstanding, as of June 30, 2009, bonds in the aggregate principal amount of \$3,595,000 consisting of \$3,280,000 of 6.5% tax exempt bonds with an outside maturity of September 1, 2030 and \$315,000 of 9.0% bonds with an outside maturity of September 1, 2012. The bonds are secured by a first lien on the Registrant's facility in Northvale, New Jersey. Pursuant to the terms of the bonds, several restricted cash accounts have been established for the payment of bond principal and interest. Bond proceeds were utilized for the redemption of previously issued tax exempt bonds issued by the Authority in September 1999 and to refinance equipment financing, as well as provide approximately \$1,000,000 of capital for the purchase of additional equipment for the manufacture and development at the Registrant's facility of pharmaceutical products and the maintenance of a \$415,500 debt service reserve. All of the restricted cash, other than the debt service was expended within the year ended March 31, 2008. Pursuant to the terms of the related bond indenture agreement, the Registrant is required to observe certain covenants, including covenants relating to the incurrence of additional indebtedness, the granting of liens and the maintenance of certain financial covenants. As of June 30, 2009, the Registrant was in compliance with the bond covenants.

### **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**

### **Derivative Financial Instruments and Foreign Exchange**

The Registrant had no investments in marketable securities as of June 30, 2009 or assets and liabilities, which are denominated in a currency other than U.S. dollars or involve commodity price risks.

### **Interest Rates**

Our exposure to market risk for changes in interest rates relates primarily to short-term instruments and short-term obligations; thus, fluctuations in interest rates do not have a material impact on the fair value of these securities. At June 30, 2009, we had approximately \$763 thousand in cash and cash equivalents. A hypothetical 5% increase or decrease in either short-term or long-term interest rates would not have a material impact on our earnings or loss, or the fair market value or cash flows of these instruments.

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

As of the end of the period covered by this report, based on an evaluation of the Company's disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934), the acting Chief Executive and Chief Financial Officer of the Company concluded that the Company's disclosure controls and procedures are effective to ensure that information required to be disclosed by the Company in its Exchange Act reports is recorded, processed, summarized and reported within the applicable time periods specified by the SEC's rules and forms.

There have been no changes in the Company's internal control over financial reporting during the quarter ended June 30, 2009 that have materially affected, or are reasonably likely to materially affect, the Company's 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**

In addition to the other information contained in this report, the following risk factors should be considered carefully in evaluating an investment in us and in analyzing our forward-looking statements.

**Risks Related to Our Business**

**We have a relatively limited operating history, which makes it difficult to evaluate our future prospects.**

Although we have been in operation since 1990, we have a relatively short operating history and limited financial data upon which you may evaluate our business and prospects. In addition, our business model is likely to continue to evolve as we attempt to expand our product offerings and our presence in the generic pharmaceutical market. As a result, our potential for future profitability must be considered in light of the risks, uncertainties, expenses and difficulties frequently encountered by companies that are attempting to move into new markets and continuing to innovate with new and unproven technologies. Some of these risks relate to our potential inability to:

develop new products;

obtain regulatory approval of our products;

manage our growth, control expenditures and align costs with revenues;

attract, retain and motivate qualified personnel; and

respond to competitive developments.

If we do not effectively address the risks we face, our business model may become unworkable and we may not achieve or sustain profitability or successfully develop any products.

**We have not been profitable and expect future losses.**

To date, we have not been profitable and we may never be profitable or, if we become profitable, we may be unable to sustain profitability. We have sustained losses in each year since our incorporation in 1990. We incurred net losses of \$6,604,708, \$13,893,060, \$11,803,512, \$6,883,914, and \$5,906,890 for the years ended March 31, 2009, 2008, 2007, 2006 and 2005, respectively. We expect to incur losses for the current year of operation and to continue to incur losses until we are able to generate sufficient revenues to support our operations and offset operating costs.

**There is doubt as to our ability to continue as a going concern.**

On June 3, 2009, after giving effect to the initial closing of the Epic Strategic Alliance Agreement, we had cash reserves of \$737,000 which permits us to continue at our anticipated level of operations, including, but not limited to, the continued development of our pipeline products, through October 2009. The completion of all transactions contemplated by the Epic Strategic Alliance Agreement, including the consummation of the second and third closings thereof, will provide additional funds to permit us to continue development of our product pipeline for more than two years. Beyond two years, we anticipate that, with growth of Lodrane and the launch of the ANDA for a pain management generic product that we submitted last year with our co-development partner, The Pharma Network, Elite could be profitable. In addition, the commercialization of the Epic products developed at the Facility under the Epic Strategic Alliance Agreement will add a new revenue source for Elite. However, there can be no assurances as to the growth, success of the development or the commercialization of these products.

Despite the successful completion of the initial closing of the Epic Strategic Alliance Agreement, there can be no assurances that we will be able to consummate the second and third closings pursuant to the terms and conditions of the Epic Strategic Alliance Agreement. If such transactions are consummated, we will receive additional cash proceeds of \$2.75 million. Even if we were able to successfully complete the second and third closings of 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 this report, 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 and June 5, 2009, which such disclosures are incorporated herein by reference.

**If we are unable to obtain additional financing needed for the expenditures for the development and commercialization of our drug products, it would impair our ability to continue to meet our business objectives.**

We continue to require additional financing to ensure that we will be able to meet our expenditures to develop and commercialize our products. As of June 3, 2009, after giving effect to the initial closing of the Epic Strategic Alliance Agreement, we had cash and cash equivalents of \$737,000. We believe that our existing cash and cash equivalents plus revenues from sale of our Lodrane 24® and Lodrane 24D® products will be sufficient to fund our anticipated operating expenses and capital requirements through September 2009. We will require additional funding in order to continue to operate thereafter. If the second and third closings of the transactions contemplated by the Epic Strategic Alliance Agreement are not closed on a timely basis, or if another financing or strategic alternative providing sufficient resources to allow us to continue operations is not consummated upon exhaustion of our current capital, we will be required to cease operations and liquidate our assets. No assurance can be given that we will be able to consummate the second and third closings under the Epic Strategic Alliance Agreement on a timely basis, or consummate such other financing or strategic alternative in the time necessary to avoid the cessation of our operations and liquidation of our assets. Moreover, even if we consummate the second and third closings under the Epic Strategic Alliance Agreement, or such other financing or strategic alternative, we may be required to seek additional capital in the future and there can be no assurances that the Registrant will be able to obtain such additional capital on favorable terms, if at all.

**If Novel Laboratories issues additional equity in the future our equity interest in Novel may be diluted, resulting in a decrease in our share of any dividends or other distributions which Novel may issue in the future.**

As a result of our determination not to fund our remaining contributions to Novel at the valuation set forth in the Novel Alliance Agreement and the resulting purchase from us of a portion of our shares of Class A Voting Common Stock of Novel by VGS Pharma, LLC, our remaining ownership interest in equity of Novel was reduced to approximately 10% of the outstanding shares of Novel. Novel may seek to raise additional operating capital in the future and may do so by the issuance of equity. If Novel issues additional equity, our future equity interest in Novel will decrease and we will be entitled to a decreased portion of any dividends or other distributions which Novel may issue in the future. Novel also has a company sponsored stock option plan and any equity issued from this stock plan will also reduce Elite's equity interest in Novel.

**Substantially all of our product candidates are at an early stage of development and only a portion of these are in clinical development.**

ELI-154 and ELI-216 are pre-Phase III and two of our generic products are still at an early stage of development. Other than Lodrane 24® and Lodrane 24D®, which are commercial drug products, and a generic drug product for which an ANDA was filed in 2008, we will need to perform additional development work for the additional product candidates in our pipeline before we can seek the regulatory approvals necessary to begin commercial sales.

**If we are unable to satisfy regulatory requirements, we may not be able to commercialize our product candidates.**

We need FDA approval prior to marketing our product candidates in the United States of America. If we fail to obtain FDA approval to market our product candidates, we will be unable to sell our product candidates in the United States of America and we will not generate any revenue from the sale of such products.



This regulatory review and approval process, which includes evaluation of preclinical studies and clinical trials of our product candidates is lengthy, expensive and uncertain. To receive approval, we must, among other things, demonstrate with substantial evidence from well-controlled clinical trials that our product candidates are both safe and effective for each indication where approval is sought. Satisfaction of these requirements typically takes several years and the time needed to satisfy them may vary substantially, based on the type, complexity and novelty of the pharmaceutical product. We cannot predict if or when we might submit for regulatory approval any of our product candidates currently under development. Any approvals we may obtain may not cover all of the clinical indications for which we are seeking approval. Also, an approval might contain significant limitations in the form of narrow indications, warnings, precautions, or contra-indications with respect to conditions of use.

The FDA has substantial discretion in the approval process and may either refuse to accept an application for substantive review or may form the opinion after review of an application that the application is insufficient to allow approval of a product candidate. If the FDA does not accept our application for review or approve our application, it may require that we conduct additional clinical, preclinical or manufacturing validation studies and submit the data before it will reconsider our application. Depending on the extent of these or any other studies that might be required, approval of any applications that we submit may be delayed by several years, or we may be required to expend more resources than we have available. It is also possible that any such additional studies, if performed and completed, may not be considered sufficient by the FDA to make our applications approvable. If any of these outcomes occur, we may be forced to abandon our applications for approval.

We will also be subject to a wide variety of foreign regulations governing the development, manufacture and marketing of our products. Whether or not an FDA approval has been obtained, approval of a product by the comparable regulatory authorities of foreign countries must still be obtained prior to manufacturing or marketing the product in those countries. The approval process varies from country to country and the time needed to secure approval may be longer or shorter than that required for FDA approval. We cannot assure you that clinical trials conducted in one country will be accepted by other countries or that approval of our product in one country will result in approval in any other country.

**Before we can obtain regulatory approval, we need to successfully complete clinical trials, outcomes of which are uncertain.**

In order to obtain FDA approval to market a new drug product, we must demonstrate proof of safety and effectiveness in humans. To meet these requirements, we must conduct extensive preclinical testing and adequate and well-controlled clinical trials. Conducting clinical trials is a lengthy, time-consuming, and expensive process. Completion of necessary clinical trials may take several years or more. Delays associated with products for which we are directly conducting preclinical or clinical trials may cause us to incur additional operating expenses. The commencement and rate of completion of clinical trials may be delayed by many factors, including, for example:

ineffectiveness of our product candidate or perceptions by physicians that the product candidate is not safe or effective for a particular indication;

inability to manufacture sufficient quantities of the product candidate for use in clinical trials;

delay or failure in obtaining approval of our clinical trial protocols from the FDA or institutional review boards;

slower than expected rate of patient recruitment and enrollment;

inability to adequately follow and monitor patients after treatment;

difficulty in managing multiple clinical sites;

unforeseen safety issues;

government or regulatory delays; and

clinical trial costs that are greater than we currently anticipate.

Even if we achieve positive interim results in clinical trials, these results do not necessarily predict final results, and positive results in early trials may not be indicative of success in later trials. A number of companies in the pharmaceutical industry have suffered significant setbacks in advanced clinical trials, even after achieving promising results in earlier trials. Negative or inconclusive results or adverse medical events during a clinical trial could cause us to repeat or terminate a clinical trial or require us to conduct additional trials. We do not know whether our existing or any future clinical trials will demonstrate safety and efficacy sufficiently to result in marketable products. Our clinical trials may be suspended at any time for a variety of reasons, including if the FDA or we believe the patients participating in our trials are exposed to unacceptable health risks or if the FDA finds deficiencies in the conduct of these trials.

Failures or perceived failures in our clinical trials will directly delay our product development and regulatory approval process, damage our business prospects, make it difficult for us to establish collaboration and partnership relationships, and negatively affect our reputation and competitive position in the pharmaceutical community.

Because of these risks, our research and development efforts may not result in any commercially viable products. Any delay in, or termination of, our preclinical or clinical trials will delay the filing of our drug applications with the FDA and, ultimately, our ability to commercialize our product candidates and generate product revenues. If a significant portion of these development efforts are not successfully completed, required regulatory approvals are not obtained, or any approved products are not commercially successful, our business, financial condition, and results of operations may be materially harmed.

**If our collaboration or licensing arrangements are unsuccessful, our revenues and product development may be limited.**

We have entered into several collaborations and licensing arrangements for the development of generic products. However, there can be no assurance that any of these agreements will result in FDA approvals, or that we will be able to market any such finished products at a profit. Collaboration and licensing arrangements pose the following risks:

collaborations and licensing arrangements may be terminated, in which case we will experience increased operating expenses and capital requirements if we elect to pursue further development of the related product candidate;

collaborators and licensees may delay clinical trials and prolong clinical development, under-fund a clinical trial program, stop a clinical trial or abandon a product candidate;

expected revenue might not be generated because milestones may not be achieved and product candidates may not be developed;

collaborators and licensees could independently develop, or develop with third parties, products that could compete with our future products;

the terms of our contracts with current or future collaborators and licensees may not be favorable to us in the future;

a collaborator or licensee with marketing and distribution rights to one or more of our products may not commit enough resources to the marketing and distribution of our products, limiting our potential revenues from the commercialization of a product;

disputes may arise delaying or terminating the research, development or commercialization of our product candidates, or result in significant and costly litigation or arbitration;

one or more third-party developers could obtain approval for a similar product prior to the collaborator or licensee resulting in unforeseen price competition in connection with the development product; and

Epic may decide that the further or continuing development of one or more of the eight designated drug products being developed by Epic at our Facility is no longer commercially feasible, delaying a potential source of revenue to us pursuant to the Epic Strategic Alliance Agreement; in addition, there can be no assurance that any drug product designated by the parties as a replacement would be as strong a candidate for commercial viability as the drug product that it replaced.

**If we are unable to protect our intellectual property rights or avoid claims that we infringed on the intellectual property rights of others, our ability to conduct business may be impaired.**

Our success depends on our ability to protect our current and future products and to defend our intellectual property rights. If we fail to protect our intellectual property adequately, competitors may manufacture and market products similar to ours.

We currently hold five patents and we have three patents pending. We intend to file further patent applications in the future. We cannot be certain that our pending patent applications will result in the issuance of patents. If patents are issued, third parties may sue us to challenge our patent protection, and although we know of no reason why they should prevail, it is possible that they could. It is likewise possible that our patent rights may not prevent or limit our present and future competitors from developing, using or commercializing products that are similar or functionally equivalent to our products.

In addition, we may be required to obtain licenses to patents, or other proprietary rights of third parties, in connection with the development and use of our products and technologies as they relate to other persons' technologies. At such time as we discover a need to obtain any such license, we will need to establish whether we will be able to obtain such a license on favorable terms, if at all. The failure to obtain the necessary licenses or other rights could preclude the sale, manufacture or distribution of our products.

We rely particularly on trade secrets, unpatented proprietary expertise and continuing innovation that we seek to protect, in part, by entering into confidentiality agreements with licensees, suppliers, employees and consultants. We cannot provide assurance that these agreements will not be breached or circumvented. We also cannot be certain that there will be adequate remedies in the event of a breach. Disputes may arise concerning the ownership of intellectual property or the applicability of confidentiality agreements. We cannot be sure that our trade secrets and proprietary technology will not otherwise become known or be independently developed by our competitors or, if patents are not issued with respect to products arising from research, that we will be able to maintain the confidentiality of information relating to these products. In addition, efforts to ensure our intellectual property rights can be costly, time-consuming and/or ultimately unsuccessful.

**Litigation is common in our industry, particularly the generic pharmaceutical industry, and can be protracted and expensive and could delay and/or prevent entry of our products into the market, which, in turn, could have a material adverse effect on our business.**

Litigation concerning patents and proprietary rights can be protracted and expensive. Companies that produce brand pharmaceutical products routinely bring litigation against applicants that seek FDA approval to manufacture and market generic forms of their branded products. These companies allege patent infringement or other violations of intellectual property rights as the basis for filing suit against an applicant. Because the eight drug products being developed by Epic at our Facility are generics, such drug products may be subject to such litigation brought by companies that produce brand pharmaceutical products. If Epic were to become subject to litigation in connection with any drug products it is developing at our Facility under the Epic Strategic Alliance Agreement, Epic may choose to, or be required to, decrease or cease its development and commercialization of such product for an indefinite period of time, which may prevent or delay the first commercial sale of such product and cause us to receive reduced or no product fees payable to us by Epic based on the commercial sales of such product in accordance with the Epic Strategic Alliance Agreement.

Likewise, other patent holders may bring patent infringement suits against us alleging that our products, product candidates and technologies infringe upon intellectual property rights. Litigation often involves significant expense and can delay or prevent introduction or sale of our products.

There may also be situations where we use our business judgment and decide to market and sell products, notwithstanding the fact that allegations of patent infringement(s) have not been finally resolved by the courts. The risk involved in doing so can be substantial because the remedies available to the owner of a patent for infringement include, among other things, damages measured by the profits lost by the patent owner and not by the profits earned by the infringer. In the case of a willful infringement, the definition of which is subjective, such damages may be trebled. Moreover, because of the discount pricing typically involved with bioequivalent products, patented brand products generally realize a substantially higher profit margin than bioequivalent products. An adverse decision in a case such as this or in other similar litigation could have a material adverse effect on our business, financial position and results of operations and could cause the market value of our Common Stock to decline.

**The pharmaceutical industry is highly competitive and subject to rapid and significant technological change, which could impair our ability to implement our business model.**

The pharmaceutical industry is highly competitive, and we may be unable to compete effectively. In addition, the pharmaceutical industry is undergoing rapid and significant technological change, and we expect competition to intensify as technical advances in each field are made and become more widely known. An increasing number of pharmaceutical companies have been or are becoming interested in the development and commercialization of products incorporating advanced or novel drug delivery systems. We expect that competition in the field of drug delivery will increase in the future as other specialized research and development companies begin to concentrate on this aspect of the business. Some of the major pharmaceutical companies have invested and are continuing to invest significant resources in the development of their own drug delivery systems and technologies and some have invested funds in specialized drug delivery companies. Many of our competitors have longer operating histories and greater financial, research and development, marketing and other resources than we do. Such companies may develop new formulations and products, or may improve existing ones, more efficiently than we can. Our success, if any, will depend in part on our ability to keep pace with the changing technology in the fields in which we operate.

As we expand our presence in the generic pharmaceuticals market our product candidates may face intense competition from brand-name companies that have taken aggressive steps to thwart competition from generic companies. In particular, brand-name companies continue to sell or license their products directly or through licensing arrangements or strategic alliances with generic pharmaceutical companies (so-called authorized generics). No significant regulatory approvals are required for a brand-name company to sell directly or through a third party to the generic market, and brand-name companies do not face any other significant barriers to entry into such market. In addition, such companies continually seek to delay generic introductions and to decrease the impact of generic competition, using tactics which include:

- obtaining new patents on drugs whose original patent protection is about to expire;

- filing patent applications that are more complex and costly to challenge;

- filing suits for patent infringement that automatically delay approval of the FDA;

- filing citizens petitions with the FDA contesting approval of the generic versions of products due to alleged health and safety issues;

- developing controlled-release or other next-generation products, which often reduce demand for the generic version of the existing product for which we may be seeking approval;

- changing product claims and product labeling;

- developing and marketing as over-the-counter products those branded products which are about to face generic competition; and

- making arrangements with managed care companies and insurers to reduce the economic incentives to purchase generic pharmaceuticals.

These strategies may increase the costs and risks associated with our efforts to introduce our generic products under development and may delay or prevent such introduction altogether.

**If our product candidates do not achieve market acceptance among physicians, patients, health care payors and the medical community, they will not be commercially successful and our business will be adversely affected.**

The degree of market acceptance of any of our approved product candidates among physicians, patients, health care payors and the medical community will depend on a number of factors, including:

- acceptable evidence of safety and efficacy;

- relative convenience and ease of administration;

- the prevalence and severity of any adverse side effects;

- availability of alternative treatments;

- pricing and cost effectiveness;

- effectiveness of sales and marketing strategies; and

ability to obtain sufficient third-party coverage or reimbursement.

If we are unable to achieve market acceptance for our product candidates, then such product candidates will not be commercially successful and our business will be adversely affected.

**We are dependent on a small number of suppliers for our raw materials and any delay or unavailability of raw materials can materially adversely affect our ability to produce products.**

The FDA requires identification of raw material suppliers in applications for approval of drug products. If raw materials were unavailable from a specified supplier, FDA approval of a new supplier could delay the manufacture of the drug involved. In addition, some materials used in our products are currently available from only one supplier or a limited number of suppliers.

Further, a significant portion of our raw materials may be available only from foreign sources. Foreign sources can be subject to the special risks of doing business abroad, including:

greater possibility for disruption due to transportation or communication problems;

the relative instability of some foreign governments and economies;

interim price volatility based on labor unrest, materials or equipment shortages, export duties, restrictions on the transfer of funds, or fluctuations in currency exchange rates; and

uncertainty regarding recourse to a dependable legal system for the enforcement of contracts and other rights.

In addition, recent changes in patent laws in certain foreign jurisdictions (primarily in Europe) may make it increasingly difficult to obtain raw materials for research and development prior to expiration of applicable United States or foreign patents. Any delay or inability to obtain raw materials on a timely basis, or any significant price increases that cannot be passed on to customers, can materially adversely affect our ability to produce products. This can materially adversely affect our business and operations.

**Even after regulatory approval, we will be subject to ongoing significant regulatory obligations and oversight.**

Even if regulatory approval is obtained for a particular product candidate, the FDA and foreign regulatory authorities may, nevertheless, impose significant restrictions on the indicated uses or marketing of such products, or impose ongoing requirements for post-approval studies. Following any regulatory approval of our product candidates, we will be subject to continuing regulatory obligations, such as safety reporting requirements, and additional post-marketing obligations, including regulatory oversight of the promotion and marketing of our products. If we become aware of previously unknown problems with any of our product candidates here or overseas or our contract manufacturers' facilities, a regulatory agency may impose restrictions on our products, our contract manufacturers or on us, including requiring us to reformulate our products, conduct additional clinical trials, make changes in the labeling of our products, implement changes to or obtain re-approvals of our contract manufacturers' facilities or withdraw the product from the market. In addition, we may experience a significant drop in the sales of the affected products, our reputation in the marketplace may suffer and we may become the target of lawsuits, including class action suits. Moreover, if we fail to comply with applicable regulatory requirements, we may be subject to fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution. Any of these events could harm or prevent sales of the affected products or could substantially increase the costs and expenses of commercializing and marketing these products.

**If key personnel were to leave us or if we are unsuccessful in attracting qualified personnel, our ability to develop products could be materially harmed.**

Our success depends in large part on our ability to attract and retain highly qualified scientific, technical and business personnel experienced in the development, manufacture and marketing of oral, controlled-release drug delivery systems and generic products. Our business and financial results could be materially harmed by the inability to attract or retain qualified personnel.

**If we were sued on a product liability claim, an award could exceed our insurance coverage and cost us significantly.**

The design, development and manufacture of our products involve an inherent risk of product liability claims. We have procured product liability insurance; however, a successful claim against us in excess of the policy limits could be very expensive to us, damaging our financial position. The amount of our insurance coverage, which has been limited due to our limited financial resources, may be materially below the coverage maintained by many of the other companies engaged in similar activities. To the best of our knowledge, no product liability claim has been made against us as of June 30, 2009.

**Risks Related to Our Common Stock**

**Future sales of our Common Stock could lower the market price of our Common Stock.**

Sales of substantial amounts of our shares in the public market could harm the market price of our Common Stock, even if our business is doing well. A significant number of shares of our Common Stock are eligible for sale in the public market under Rule 144, promulgated under the Securities Act of 1933, as amended (the *Securities Act*), subject in some cases to volume and other limitations. These sales, or the perception in the market that the holders of a large number of shares intend to sell shares, could reduce the market price of our Common Stock.

**Our stock price has been volatile and may fluctuate in the future.**

The market price for the publicly traded stock of pharmaceutical companies is generally characterized by high volatility. There has been significant volatility in the market prices for our Common Stock. For the twelve months ended March 31, 2009, the closing sale price on the American Stock Exchange ( *AMEX* ) of our Common Stock fluctuated from a high of \$0.83 per share to a low of \$0.03 per share. The price per share of our Common Stock may not exceed or even remain at current levels in the future. The market price of our Common Stock may be affected by a number of factors, including:

Results of our clinical trials;

Approval or disapproval of our ANDAs or NDAs;

Announcements of innovations, new products or new patents by us or by our competitors;

Governmental regulation;

Patent or proprietary rights developments;

Proxy contests or litigation;

News regarding the efficacy of, safety of or demand for drugs or drug technologies;

Economic and market conditions, generally and related to the pharmaceutical industry;

Healthcare legislation;

Changes in third-party reimbursement policies for drugs;

Fluctuations in our operating results;

Commercial success of the eight drug products of Epic identified under the Epic Strategic Alliance Agreement; and

Our ability to consummate the second and third closings of the transactions contemplated by the Epic Strategic Alliance Agreement

**The voluntary delisting from the American Stock Exchange listing of our Common Stock in order to commence quotation of our Common Stock on the OTC Bulletin Board could have a material adverse affect on the market for our Common Stock and our market price.**

On May 21, 2009, we announced that our Common Stock would begin trading on the over-the-counter markets, on the OTC Bulletin Board, under the symbol ELTP:US. We believe that our commencement of the quotation of our Common Stock on the OTC Bulletin Board, in accordance with the terms of the Epic Strategic Alliance Agreement, is an important step in our continuing efforts to reduce costs. However, our voluntary delisting from the American Stock Exchange listing of the Common Stock in order to commence quotation the Common Stock on the OTC Bulletin Board could have a material adverse affect on the market for our Common Stock and our market price.





The OTC Bulletin Board market is a regulated quotation service that displays real-time quotes, last-sale prices and volume information for over 3,000 companies. Our move to the OTC Bulletin Board market does not affect our business operations and will not change our SEC reporting requirements.

**Raising of additional funding through sales of our securities could cause existing holders of our Common Stock to experience substantial dilution.**

Any financing that involves the further sale of our securities could cause existing holders of our Common Stock to experience substantial dilution. On the other hand, if we incurred debt, we would be subject to risks associated with indebtedness, including the risk that interest rates might fluctuate and cash flow would be insufficient to pay principal and interest on such indebtedness.

**The issuance of additional warrants and shares to Epic under the Epic Strategic Alliance Agreement will cause existing holders of our Common Stock to experience substantial dilution.**

If Elite and Epic consummate the second and third closings under the Epic Strategic Alliance Agreement, Elite will issue to Epic an aggregate of 2,000 shares of Series E Preferred Stock, convertible into an aggregate of 40,000,000 shares of Common Stock, and warrants to purchase an additional 80,000,000 shares of Common Stock. If Epic converts such shares of Series E Preferred Stock into shares of Common Stock and exercises such warrants shares of Common Stock, the existing holders of our Common Stock will experience substantial dilution.

In addition, with respect to the products developed by Epic at the Facility under the Epic Strategic Alliance Agreement, Elite may issue to Epic (a) warrants to purchase up to an aggregate of 56,000,000 shares of its Common Stock upon the receipt by Elite from Epic of written notices of Epic's receipt of an acknowledgment from the FDA that the FDA accepted for filing an ANDA for certain controlled-release and immediate-release products developed by Epic at Elite's facility and (b) up to an aggregate of 40,000,000 additional shares of its Common Stock following the receipt by Elite from Epic of written notices of Epic's receipt from the FDA of approval for certain controlled-release and immediate-release products developed by Epic at the Facility. The existing holders of our Common Stock will also experience substantial dilution upon the issuance of such warrants and such additional shares of its Common Stock to Epic in accordance with the Epic Strategic Alliance Agreement.

**The issuance of additional shares of our Common Stock or our preferred stock could make a change of control more difficult to achieve.**

The issuance of additional shares of our Common Stock or the issuance of shares of an additional series of preferred stock could be used to make a change of control of us more difficult and expensive. Under certain circumstances, such shares could be used to create impediments to, or frustrate persons seeking to cause, a takeover or to gain control of us. Such shares could be sold to purchasers who might side with our Board of Directors (the *Board* or *Board of Directors*) in opposing a takeover bid that the Board of Directors determines not to be in the best interests of our stockholders. It might also have the effect of discouraging an attempt by another person or entity through the acquisition of a substantial number of shares of our Common Stock to acquire control of us with a view to consummating a merger, sale of all or part of our assets, or a similar transaction, since the issuance of new shares could be used to dilute the stock ownership of such person or entity.

**If penny stock regulations become applicable to our Common Stock they will impose restrictions on the marketability of our Common Stock and the ability of our stockholders to sell shares of our stock could be impaired.**

The SEC has adopted regulations that generally define a penny stock to be an equity security that has a market price of less than \$5.00 per share or an exercise price of less than \$5.00 per share subject to certain exceptions. Exceptions include equity securities issued by an issuer that has (i) net tangible assets of at least \$2,000,000, if such issuer has been in continuous operation for more than three years, (ii) net tangible assets of at least \$5,000,000, if such issuer has been in continuous operation for less than three years, or (iii) average revenue of at least \$6,000,000 for the preceding three years. Unless an exception is available, the regulations require that prior to any transaction involving a penny stock, a risk of disclosure schedule must be delivered to the buyer explaining the penny stock market and its risks. Our Common Stock is currently trading at under \$5.00 per share. Although we currently fall under one of the exceptions, if at a later time we fail to meet one of the exceptions, our Common Stock will be considered a penny stock. As such, the market liquidity for our Common Stock will be limited to the ability of broker-dealers to sell it in compliance with the above-mentioned disclosure requirements.

You should be aware that, according to the SEC, the market for penny stocks has suffered in recent years from patterns of fraud and abuse. Such patterns include:

Control of the market for the security by one or a few broker-dealers;

Boiler room practices involving high-pressure sales tactics;

Manipulation of prices through prearranged matching of purchases and sales;

The release of misleading information;

Excessive and undisclosed bid-ask differentials and markups by selling broker-dealers; and

Dumping of securities by broker-dealers after prices have been manipulated to a desired level, which hurts the price of the stock and causes investors to suffer loss.

We are aware of the abuses that have occurred in the penny stock market. Although we do not expect to be in a position to dictate the behavior of the market or of broker-dealers who participate in the market, we will strive within the confines of practical limitations to prevent such abuses with respect to our Common Stock.

**Epic will have the ability to exert substantial influence over Elite.**

Under the Epic Strategic Alliance Agreement, Elite agreed that it and its Board of Directors will take any and all action necessary so that (i) the size of the Board of Directors will be set and remain at seven directors, (ii) three individuals designated by Epic (the *Epic Directors*) will be appointed to the Board of Directors and (iii) the Epic Directors will be nominated at each annual or special meeting of stockholders at which an election of directors is held or pursuant to any written consent of the stockholders; provided, however, that if at any time following the initial closing of the Epic Strategic Alliance Agreement and ending on the later of (a) the date immediately following the first anniversary of the Initial Closing Date and (b) the Third Closing Date, the Purchaser owns less than (1) a number of shares of Series E Preferred Stock equal to ninety percent of the aggregate number of shares of Series E Preferred Stock purchased by the Purchaser at all of the then applicable Closings or (2) following the conversion by the Purchaser of the Series E Preferred Stock, a number of shares of Common Stock equal to ninety percent of the number of shares of Common Stock so converted, neither Elite nor its Board of Directors will be obligated to nominate Epic Directors or take any other action with respect to those actions described in (i), (ii) and/or (iii) above. No Epic Director may be removed from office for cause unless such removal is directed or approved by (A) a majority of the independent members of the Board of Directors and (B) all of the non-affected Epic Director(s). Any vacancies created by the resignation, removal or death of an Epic Director will be filled by the appointment of an additional Epic Director. Any Epic Director may be removed from office upon the request of the Purchaser, with or without cause. Epic, by virtue of having the right to designate the three Epic Directors, will have the ability to exert substantial influence over the election of the other members of Elite's Board of Directors, the outcome of issues submitted to our stockholders for approval and the management and affairs of Elite.

In addition, the Series E Certificate provides that on any matter presented to the holders of our Common Stock for their action or consideration at any meeting of our stockholders (or by written consent of stockholders in lieu of meeting), Epic, as a holder of Series E Preferred Stock, will be entitled to cast the number of votes equal to the number of shares of Common Stock into which the shares of Series E Preferred Stock held by Epic are convertible as of the record date for determining the stockholders entitled to vote on such matter. Except as provided by law or by the other provisions of the Series E Certificate, Epic will vote together with the holders of Common Stock, as a single class. In addition, pursuant to the Epic Strategic Alliance Agreement and the Series E Certificate, Elite has agreed that, between the date of the initial closing under the Epic Strategic Alliance Agreement and the date which is the earlier of (x) the date the Epic Directors constitute a majority of the Board of Directors and (y) ninety days following the fifth anniversary of the Initial Closing Date, except as Epic otherwise agrees in writing, Elite may conduct its operations only in the ordinary and usual course of business consistent with past practice. Further, pursuant to the Epic Strategic Alliance Agreement and the Series E Certificate, Elite must obtain the prior written consent of Epic in order to take the actions specifically enumerated therein. Accordingly, such concentration of ownership Epic will have the ability to exert further influence over Elite and may have the effect of preventing a change of control of Elite.

In addition, with respect to the products developed by Epic at our Facility under the Epic Strategic Alliance Agreement, Elite may issue to Epic (a) warrants to purchase up to an aggregate of 56,000,000 shares of its Common Stock upon the receipt by Elite from Epic of written notices of Epic's receipt of an acknowledgment from the FDA that the FDA accepted for filing an ANDA for certain controlled-release and immediate-release products developed by Epic at the Facility and (b) up to an aggregate of 40,000,000 additional shares of its Common Stock following the receipt by Elite from Epic of written notices of Epic's receipt from the FDA of approval for certain controlled-release and immediate-release products developed by Epic at the Facility. If Elite is required to issue such warrants and such additional shares of its Common Stock to Epic in accordance with the Epic Strategic Alliance Agreement, Epic may beneficially own in excess of 50% of the issued and outstanding Common Stock or other voting securities of Elite. Under the Epic Strategic Alliance Agreement, at such time as Epic owns more than 50% of the issued and outstanding Common Stock or other voting securities of Elite, the number of Epic Directors that the Purchaser will be entitled to designate under the Alliance Agreement will be equal to a majority of the Board of Directors.

**Holders of our preferred stock may exercise their veto rights to make it more difficult for us to take an action or consummate a transaction that may be deemed by the Board to be in our best interest or the best interest of the other stockholders.**

The holders of Series B Preferred Stock, Series C Preferred Stock and Series D Preferred Stock have certain veto rights that may be exercised to prevent us from taking an action or consummating a transaction that may be deemed by the Board to be in our best interest and the best interest of the holders of our Common Stock if the holders of our preferred stock believe such action or transaction would be adverse to their own interests. If the holders of our preferred stock exercise their veto rights to prevent us from taking any such action or consummating any such transaction, our ability to achieve our strategic objectives may be hindered. The ability of holders of our preferred stock to affect our actions through use of their veto rights might limit the price that certain investors would be willing to pay in the future for shares of our Common Stock.

In addition, pursuant to the Epic Strategic Alliance Agreement and the Series E Certificate, Elite has agreed that, between the date of the initial closing under the Epic Strategic Alliance Agreement and the date which is the earlier of (x) the date the Epic Directors constitute a majority of the Board of Directors and (y) ninety days following the fifth anniversary of the Initial Closing Date, except as Epic otherwise agrees in writing, Elite may conduct its operations only in the ordinary and usual course of business consistent with past practice. Further, pursuant to the Epic Strategic Alliance Agreement and the Series E Certificate, Elite must obtain the prior written consent of Epic in order to take the certain actions specifically enumerated therein. Notwithstanding the foregoing, if at any time after Epic has acquired 25% or more of the shares of the capital stock of Elite, on an as-converted basis, pursuant to the terms of Alliance Agreement or the Warrants, the Epic's ownership percentage of the shares of capital stock of Elite falls below 20% of the shares of the capital stock of Elite, on an as-converted basis, as a result of transfers made by Epic, then the prior written consent of Epic will not be required prior to the consummation of such actions under the Epic Strategic Alliance Agreement.

Pursuant to the Alliance Agreement, subject to the satisfaction of certain conditions precedent contained therein, the Purchaser will not, without the prior written consent of Elite, transfer any Common Stock acquired by it upon conversion of the Series E Preferred Stock or otherwise acquired or purchased under the Alliance Agreement or the other transaction documents for a period commencing on the Initial Closing Date and ending on the later of (a) the date immediately following the first anniversary of the Initial Closing Date and (b) the Third Closing Date (such period, the *Lock-Up Period* ).

**Section 203 of the Delaware General Corporation Law may deter a third party from acquiring us.**

Section 203 of the Delaware General Corporation Law prohibits a merger with a 15% shareholder within three years of the date such shareholder acquired 15%, unless the merger meets one of several exceptions. The exceptions include, for example, approval by the holders of two-thirds of the outstanding shares (not counting the 15% shareholder), or approval by the Board of Directors prior to the 15% shareholder acquiring its 15% ownership. This provision makes it difficult for a potential acquirer to force a merger with or takeover of us, and could thus limit the price that certain investors might be willing to pay in the future for shares of our Common Stock.

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

On June 3, 2009, Elite issued and sold to one accredited investor, in a private placement pursuant to an exemption from registration under Section 4(2) of the Securities Act, 1,000 shares of its Series E Convertible Preferred Stock, par value \$0.01 per share (the *Series E Preferred Stock* ), at a price of \$1,000 per share, each share convertible, at \$0.05 per share (the *Conversion Price* ), into 20,000 shares of Common Stock, par value \$0.01 per share. In addition, on June 3, 2009 Elite issued a warrant to the same investor for the purchase 20,000,000 shares of Common Stock (the *Initial Warrant* ), exercisable on or prior to June 3, 2016, at a per share exercise price of \$0.0625 (the *Exercise Price* ), subject to adjustments for certain events, including, but not limited to, dividends, stock splits, combinations and the like. For additional details concerning these securities, please refer the paragraph entitled *Infusion of Additional Capital Necessary for Product Development* in Part I, Item 2 above.

In July 2009, we issued 4,236,856 shares of our common stock to the holders of our Series B, C and D Preferred Stock. These shares were issued pursuant to an exemption from registration under Regulation D. The shares were issued in satisfaction of the Company's obligation to pay \$299,460 in dividends earned and accrued during the quarter ended June 30, 2009. The Company did not receive any proceeds in exchange for the issuance of these securities.

The Registrant expects to also pay the dividends to the holders of the Company's Series C Preferred Stock relating to the quarters ended December 31, 2008 and March 31, 2009 by means of the issuance of common shares and is in the process of executing the necessary waivers to do so. The Registrant expects to have such required waivers executed subsequent to the filing of this Report.

**ITEM 3. DEFAULTS UPON SENIOR SECURITIES**

None.

**ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS**

None.

**ITEM 5. OTHER INFORMATION**

None.

**ITEM 6. EXHIBITS**

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

<b>Exhibit Number</b>	<b>Description</b>
10.1	Amendment to Strategic Alliance Agreement, dated as of April 20, 2009, by and among the Registrant, Epic Pharma, LLC and Epic Investments, LLC, incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K, dated April 30, 2009 and filed with the SEC on May 6, 2009
10.2	Second Amendment to Strategic Alliance Agreement, dated as of June 1, 2009, by and among the Registrant, Epic Pharma LLC and Epic Investments, LLC, incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K, dated June 1, 2009 and filed with the SEC on June 5, 2009.
10.3	Third Amendment to Strategic Alliance Agreement, dated as of Aug 18, 2009, by and among the Registrant, Epic Pharma LLC and Epic Investments, LLC.
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 by Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

**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.

Date: August 19, 2009

\_\_\_\_\_

ELITE PHARMACEUTICALS, INC.

/s/ Chris Dick

\_\_\_\_\_

Chris Dick  
Chief Operating Officer and Acting Chief Executive Officer  
(Principal Executive Officer)

Date: August 19, 2009

\_\_\_\_\_

/s/ Carter J. Ward

\_\_\_\_\_

Carter J. Ward  
Chief Financial Officer  
(Principal Financial and Accounting Officer)

24