

ELITE PHARMACEUTICALS INC /DE/  
Form 10-Q  
February 17, 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 December 31, 2008

or

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

For the transition period ended

to

Commission File Number: 001-15697

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

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

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

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

APPLICABLE ONLY TO ISSUERS INVOLVED IN BANKRUPTCY  
PROCEEDINGS DURING THE PRECEDING FIVE YEARS:

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Indicate by check mark whether the registrant has filed all documents and reports required to be filed by Sections 12, 13 or 15 (d) of the Securities Exchange Act of 1934 subsequent to the distribution of securities under a plan confirmed by a court.

Yes [ ] No [ ]

APPLICABLE ONLY TO CORPORATE ISSUERS:

Indicate the number of shares outstanding of the common stock, \$.01 par value, as of February 13, 2009:  
[ \_\_\_\_\_ ] (exclusive of 100,000 shares held in treasury).

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**ELITE PHARMACEUTICALS, INC. AND SUBSIDIARIES**

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

	<b>December 31, 2008</b>	<b>March 31, 2008</b>
	(Unaudited)	(Audited)
<b>CURRENT ASSETS:</b>		
Cash and cash equivalents	\$ 336,273	\$ 3,702,615
Accounts receivable	162,558	148,484
Inventories	1,742,055	2,124,420
Prepaid expenses and other current assets	152,906	177,972
<b>Total current assets</b>	<b>2,393,792</b>	<b>6,153,491</b>
<b>PROPERTY AND EQUIPMENT, net of accumulated depreciation and amortization</b>	<b>4,681,622</b>	<b>5,008,701</b>
<b>INTANGIBLE ASSETS - net of accumulated amortization</b>	<b>29,633</b>	<b>35,276</b>
<b>OTHER ASSETS:</b>		
Accrued interest receivable	7,590	4,744
Deposit on equipment	14,073	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	435,831	432,079
EDA Bond offering costs, net of accumulated amortization of \$45,994 and \$35,356, respectively	308,458	319,096
<b>Total other assets</b>	<b>4,108,762</b>	<b>4,112,802</b>
<b>Total assets</b>	<b>\$ 11,213,809</b>	<b>\$ 15,310,270</b>

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

**ELITE PHARMACEUTICALS, INC. AND SUBSIDIARIES**  
**CONDENSED CONSOLIDATED BALANCE SHEETS**  
**LIABILITIES AND STOCKHOLDERS' EQUITY**

	<b>December 31, 2008</b>	<b>March 31, 2008</b>
	(Unaudited)	(Audited)
<b>CURRENT LIABILITIES:</b>		
Current portion of EDA Bonds	\$ 210,000	\$ 200,000
Current portion of long-term debt	10,346	9,864
Accounts payable and accrued expenses	682,542	850,442
Dividends payable	199,681	63,255
Total current liabilities	1,102,569	1,123,561
<b>LONG TERM LIABILITIES:</b>		
EDA bonds – net of current portion	3,385,000	3,595,000
Long-term debt, less current portion	34,592	42,338
Total long-term liabilities	3,419,592	3,637,388
Total liabilities	4,522,161	4,760,949
<b>COMMITMENTS AND CONTINGENCIES</b>		
<b>STOCKHOLDERS' EQUITY:</b>		
Preferred Stock -- \$.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 December 31, 2008 and March 31, 2008	---	---
Authorized 10,000 Series B Convertible Preferred Stock - issued and outstanding – 1,046 and 8,410 shares, respectively	11	84
Authorized 20,000 Series C Convertible Preferred Stock issued and outstanding– 13,705 and 19,155 shares, respectively	137	192
Authorized 30,000 Series D Convertible Preferred Stock – Issued and outstanding – 13,814 shares at December 31, 2008	138	---
Common Stock - \$.01 par value;		
Authorized – 210,000,000 shares as of December 31, 2008 and 150,000,000 shares at March 31, 2008		
Issued and outstanding – 35,059,616 shares and 23,131,035 shares respectively	350,596	231,310
Subscription receivable	(75,000)	(75,000)
Additional paid-in capital	95,628,417	91,889,978
Accumulated deficit	(88,905,810)	(81,190,402)
	6,998,489	10,856,162
Treasury stock, at cost (100,000 shares)	(306,841)	(306,841)
Total stockholders' equity	6,691,648	10,549,321
Total liabilities and stockholders' equity	\$ 11,213,809	\$ 15,310,270

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

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

	<b>THREE MONTHS ENDED</b>		<b>NINE MONTHS ENDED</b>	
	<b>DECEMBER 31,</b>		<b>DECEMBER 31,</b>	
	<b>2008</b>	<b>2007</b>	<b>2008</b>	<b>2007</b>
	(Unaudited)	(Unaudited)	(Unaudited)	(Unaudited)
<b>REVENUES</b>				
Manufacturing Fees	\$ 162,558	\$ 116,366	\$ 1,255,850	\$ 671,239
Royalties	74,222	59,805	232,800	167,728
<b>Total Revenues</b>	<b>236,780</b>	<b>176,171</b>	<b>1,488,650</b>	<b>838,967</b>
Costs of Revenues	159,651	140,937	1,161,147	671,174
Gross Profit	77,129	35,234	327,503	167,793
<b>COST OF OPERATIONS:</b>				
Research and development	600,680	1,560,253	3,144,370	5,394,043
General and administrative	467,487	632,133	1,741,760	1,814,958
Depreciation and amortization	130,257	170,266	390,771	459,304
	1,198,424	2,362,652	5,276,901	7,668,304
<b>LOSS FROM OPERATIONS</b>	<b>(1,121,295)</b>	<b>(2,327,418)</b>	<b>(4,949,398)</b>	<b>(7,500,512)</b>
<b>OTHER INCOME (EXPENSES):</b>				
Interest income	8,482	83,201	38,583	310,031
Interest expense	(61,437)	(64,753)	(190,691)	(226,907)
Non-cash compensation through issuance of stock options and warrants	(246,858)	(549,133)	(839,031)	(2,125,626)
	(299,813)	(530,685)	(991,139)	(2,042,502)
<b>LOSS BEFORE PROVISION FOR INCOME TAXES</b>	<b>(1,421,108)</b>	<b>(2,858,103)</b>	<b>(5,940,537)</b>	<b>(9,543,014)</b>
Provision for Income Taxes	---	---	(3,120)	(3,120)
Loss from continuing operations	(1,421,108)	(2,858,103)	(5,943,657)	(9,546,134)
Loss from discontinued operations	---	---	---	(2,979,600)
<b>NET LOSS</b>	<b>\$ (1,421,108)</b>	<b>\$ (2,858,103)</b>	<b>\$ (5,943,657)</b>	<b>\$ (12,576,740)</b>
Preferred Stock Dividends	(659,562)	(563,552)	(1,771,751)	(1,543,991)
<b>NET LOSS ATTRIBUTABLE TO COMMON SHAREHOLDERS</b>	<b>\$ (2,080,670)</b>	<b>\$ (3,421,655)</b>	<b>\$ (7,715,408)</b>	<b>\$ (14,069,725)</b>
<b>BASIC AND DILUTED LOSS PER COMMON SHARE</b>	<b>\$ (.07)</b>	<b>\$ (.15)</b>	<b>\$ (0.30)</b>	<b>\$ (.65)</b>
<b>WEIGHTED AVERAGE NUMBER OF COMMON SHARES OUTSTANDING</b>	<b>29,799,888</b>	<b>22,262,379</b>	<b>25,886,117</b>	<b>21,536,585</b>

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



**ELITE PHARMACEUTICALS, INC. AND SUBSIDIARIES**  
**CONDENSED CONSOLIDATED STATEMENT OF CHANGES IN STOCKHOLDERS' EQUITY**

	Series B Preferred Stock		Series C Preferred Stock		Series D Preferred Stock		Common Stock		Sub Re
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	
<b>BALANCE AT MARCH 31, 2008</b>	<b>8,410</b>	<b>\$ 84</b>	<b>19,155</b>	<b>\$ 192</b>	<b>-</b>	<b>\$ -</b>	<b>23,131,035</b>	<b>\$ 231,310</b>	<b>\$</b>
Equity Investment in Company	-	-	-	-	1,777	18	-	-	
Conversion of Series B Preferred and Series C Preferred into Series D Preferred	(7,139)	(71)	(4,898)	(49)	12,037	120	-	-	
Conversion of Preferred to Common	(225)	(2)	(552)	(6)	-	-	432,973	4,330	
Issuance of stock for consulting services	-	-	-	-	-	-	125,000	1,250	
Costs associated with Raising Capital	-	-	-	-	-	-	-	-	
Non-cash compensation through issuance of stock options and warrants	-	-	-	-	-	-	-	-	
Net loss for the nine months ended December 31, 2008	-	-	-	-	-	-	-	-	
Dividends	-	-	-	-	-	-	11,370,608	113,706	
<b>BALANCE AT DECEMBER 31, 2008</b>	<b>1,046</b>	<b>\$ 11</b>	<b>13,705</b>	<b>\$ 137</b>	<b>13,814</b>	<b>\$ 138</b>	<b>35,059,616</b>	<b>\$ 350,596</b>	<b>\$</b>

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

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

	<b>NINE MONTHS ENDED</b>	
	<b>DECEMBER 31, 2008</b>	
	<b>2008</b>	<b>2007</b>
	<b>(Unaudited)</b>	<b>(Unaudited)</b>
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>		
Net loss	\$ (5,943,657)	\$ (12,500,000)
Adjustments to reconcile loss from continuing operations to cash used in operating activities:		
Depreciation and amortization	390,771	400,000
Non-cash compensation satisfied by issuance of common stock, options and warrants	839,031	2,100,000
Changes in assets and liabilities:		
Accounts and interest receivable	(16,920)	200,000
Inventories	382,365	(100,000)
Prepaid expenses and other current assets	126,315	(100,000)
Security deposit	---	---
Accounts payable, accrued expenses and other current liabilities	(167,900)	(900,000)
<b>NET CASH USED IN OPERATING ACTIVITIES</b>	<b>(4,389,995)</b>	<b>(7,700,000)</b>
<b>DISCONTINUED OPERATIONS:</b>		
Loss from discontinued operations	---	3,000,000
Equity in loss of discontinued operations	---	(3,000,000)
<b>NET CASH PROVIDED BY DISCONTINUED OPERATIONS</b>	<b>---</b>	<b>---</b>
<b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>		
Purchases of property and equipment	(47,411)	(500,000)
Deposit for manufacturing equipment	---	---
Deposits to restricted cash	(3,752)	---
Investment in Novel Laboratories, Inc.	---	(5,000,000)
<b>NET CASH USED IN INVESTING ACTIVITIES</b>	<b>(51,163)</b>	<b>(5,500,000)</b>
<b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>		
Dividends paid	(163,403)	(300,000)
Proceeds from issuance of Series C 8% Convertible Stock and Warrants	---	20,000,000
Proceeds from issuance of Series D 8% Preferred Stock and Warrants	1,777,000	---
Principal repayments NJEDA bonds	(200,000)	(100,000)
Proceeds - equipment note	---	---
Principal equipment note payments	(7,314)	---
Proceeds from exercise of stock options	---	---
Proceeds from exercise of stock warrants	---	300,000
Costs associated with raising capital	(331,467)	(1,500,000)
<b>NET CASH PROVIDED BY FINANCING ACTIVITIES</b>	<b>1,074,816</b>	<b>18,300,000</b>
<b>NET CHANGE IN CASH AND CASH EQUIVALENTS</b>	<b>(3,366,342)</b>	<b>5,100,000</b>
CASH AND CASH EQUIVALENTS – beginning of period	3,702,615	8,800,000
CASH AND CASH EQUIVALENTS – end of period	\$ 336,273	\$ 5,900,000

SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION:

Cash paid for interest	\$	131,518	\$	1
Cash paid for income taxes			3,120	

SCHEDULE OF NON-CASH FINANCING ACTIVITIES:

Beneficial Conversion Dividend	\$		---	\$	2,3
Preferred stock dividends of \$1,596,036 and \$1,133,158 paid by issuance of 10,985,465 and 576,812 shares of common stock in 2008 and 2007, respectively.				---	
Accrued dividends			199,681		
Consulting services paid by issuance of 125,000 shares of common stock			101,250		

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

ELITE PHARMACEUTICALS, INC. AND SUBSIDIARIES  
**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**  
NINE MONTHS ENDED DECEMBER 31, 2008 AND 2007  
(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 nine months ended December 31, 2008 and 2007 and its variable interest entity, Novel Laboratories Inc. ("Novel"), for the six months ended September 30, 2008. In the quarter ended December 31, 2007, Novel ceased to be a variable interest entity of the Registrant. Accordingly, the information in this Form 10-Q has been prepared as if the Registrant divested of Novel as a wholly-owned subsidiary on April 1, 2007 and the operations are being reflected as a discontinued operation. As of December 31, 2008, the financial statements of all wholly owned entities are consolidated and all significant intercompany accounts are eliminated upon consolidation. 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, 2008, as amended. There have been no changes in significant accounting policies since March 31, 2008.

The Registrant does not anticipate being profitable for fiscal year ending March 31, 2009; therefore a current provision for income tax was not established for the nine months ended December 31, 2008. 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 2009. Therefore the Registrant's ability to continue is dependent upon its ability to obtain additional financing to allow it to continue to develop its products or enter into a collaboration licensing or partnership agreement with expenses either shared or borne by the other parties. As of the date hereof, 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.

ELITE PHARMACEUTICALS, INC. AND SUBSIDIARIES  
**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**  
NINE MONTHS ENDED DECEMBER 31, 2008 AND 2007  
(UNAUDITED)

**NOTE 2 - BANK LOANS PAYABLE**

On October 1, 2007, the Registrant borrowed \$58,004 at a 9% interest rate from a commercial bank to be used to pay for transportation equipment, which was collateral for the loan. The loan is to be repaid in 60 installments of \$1,180 per month through September 1, 2012. Interest expense through December 31, 2008 was \$3,431

**NOTE 3 - STOCKHOLDERS' EQUITY**

**Series D 8% Convertible Preferred Stock**

On September 15, 2008, the Registrant completed a private placement of 1,777 shares of its Series D Preferred Stock, par value \$0.01 per share (the "Series D Preferred Stock"), for gross proceeds of \$1,777,000. The shares were issued at a price of \$1,000 per share with each share initially convertible at \$0.20 into 5,000 shares of the Registrant's Common Stock, par value \$0.01 per share (the "Common Stock"), or an aggregate of 8,885,000 shares of Common Stock. Each purchaser of Series D Preferred Stock also received a warrant to purchase shares of the Registrant's Common Stock. The warrants are exercisable on or before September 15, 2013 and represent the right to purchase an aggregate of 17,770,000 shares of Common Stock at an exercise price of \$0.25 per share. The newly-created Series D Preferred Stock is senior as to dividends, liquidation and redemption to the Registrant's Series B Preferred Stock and Series C Preferred Stock (collectively, the "Existing Preferred Stock"). The Registrant has authorized, in total, 30,000 shares of Series D Preferred Stock.

The gross proceeds of the private placement for shares of the Registrant's Series D Preferred Stock were \$1,777,000 before payment of \$263,743 in expenses. Pursuant to the placement agent agreement, the Registrant issued to the placement agent warrants to purchase 355,400 shares of Common Stock exercisable at \$0.25 per share. The Registrant will account for these warrants as a cost of raising capital and will include the instrument as equity in our financial statements. Accordingly, there will be no net impact on the Registrant's financial position or results of operations.

As part of the private placement for shares of the Registrant's Series D Preferred Stock, holders of existing preferred stock who met a pre-defined level of participation in this placement ("Qualifying Holders") received the right to exchange (the "Exchange"): (i) shares of their existing preferred stock for shares of Series D Preferred Stock at a rate equal to one share of Series D Preferred Stock for each share of existing preferred stock held by the Qualifying Holder and (ii) warrants to purchase Common Stock which were originally issued to each Qualified Holder in connection with the purchase of such exchanged existing preferred stock (such originally issued warrants, the "Original Warrants") for warrants exercisable for the same number of shares of Common Stock with terms identical to the warrants issued to the purchasers of Series D Preferred Stock (such warrants, the "Exchange Warrants"). The Exchange Warrants have an exercise price of \$0.25 per share. To be a Qualifying Holder, a holder of existing preferred stock was required to purchase shares of Series D Preferred Stock with a stated value of at least the lesser of (x) US\$400,000 and (y) 20% of the aggregate stated value of the shares of Existing Preferred Stock then held by such holder. In connection with the private placement for shares of the Registrant's Series D Preferred Stock, Qualifying Holders exchanged (a) shares of their existing preferred stock for an aggregate of approximately 12,037 additional shares of Series D Preferred Stock,

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which such shares of Series D Preferred Stock are convertible into an aggregate of approximately 60,185,000 shares of Common Stock, and (b) their Original Warrants for Exchange Warrants to purchase an aggregate of approximately 2,336,000 shares of Common Stock.

**Common Stock**

On December 19, 2008, the Registrant filed a Certificate of Amendment of its Certificate of Incorporation in order to increase the authorized number of shares of the Registrant's Common Stock from 150,000,000 shares of Common Stock to 210,000,000 shares of Common Stock.

During the nine month period ended December 31, 2008, the Registrant issued 125,000 shares of Common Stock to New Castle Consulting, LLC for services. See Note 4.

During the nine month period ended December 31, 2008, a holder of 225 shares of Series B Preferred Stock converted such shares into 191,168 shares of Common Stock. In connection with such conversion, the Registrant issued 46,498 shares of Common Stock in satisfaction of dividend obligations of the Registrant on such shares of Series B Preferred Stock, which such dividend obligations accrued through the date of such conversion.

During the nine month period ended December 31, 2008, holders of 552 shares of Series C Preferred Stock converted such shares into 241,775 shares of Common Stock. In connection with such conversions, the Registrant issued 46,498 shares of Common Stock and \$93 in cash in satisfaction of dividend obligations of the Registrant on such shares of Series C Preferred Stock, which such dividend obligations accrued through the date of such conversions.

Dividend obligations on outstanding shares Series B Preferred Stock through December 31, 2008, totaling \$217,421, were satisfied by the issuance of 872,993 shares of Common Stock.

Dividend obligations on outstanding shares Series C Preferred Stock through December 31, 2008, totaling \$944,220, were satisfied by the issuance of 4,017,801 shares of Common Stock and payment of \$100,055 in cash. There are 2,619,922 of unissued shares as of December 31, 2008.

Dividends obligations on outstanding shares Series D Preferred Stock through December 31, 2008, totaling \$504,451, were satisfied by the issuance of 6,095,571 shares of Common Stock.

A holder of Series C Preferred Stock elected to defer its July 1, 2008 dividend until September 15, 2008, resulting in a dividend payment equal to \$72,517. In order to satisfy such dividend obligation, the Registrant will issue to such holder 385,143 shares of Common Stock.

**Options and Warrants**

At December 31, 2008, the Registrant had 4,477,800 options outstanding with exercise prices ranging from \$1.08 to \$3.00 per share and 38,538,644 warrants with exercise prices ranging from \$0.25 to \$3.74 per share; each option and warrant representing the right to purchase one share of Common Stock.

**NOTE 4 - COMMITMENTS AND CONTINGENCIES**

**Consulting Agreement**

On April 14, 2008, the Registrant entered into a consulting agreement with New Castle Consulting, LLC ("New Castle") whereby New Castle provided consulting services to the Registrant for a six month term. The consulting agreement with New Castle terminated on October 14, 2008. For its services New Castle



ELITE PHARMACEUTICALS, INC. AND SUBSIDIARIES  
**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**  
NINE MONTHS ENDED DECEMBER 31, 2008 AND 2007  
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received 125,000 shares of the Registrant's common stock valued at \$101,250 which was written off over the life of the consulting agreement. Additionally New Castle received \$8,000 per month. For the nine months ended December 31, 2008, New Castle was paid \$48,000.

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 5 - SUBSEQUENT EVENTS**

On January 27, 2009, a holder of 4,400 shares of Series D Preferred Stock converted their shares into 22,000,000 shares of Common Stock.

Unissued shares, totaling 241,418 shares as a result of the December 31, 2008 accrual of Series C Preferred, were issued on January 26, 2009.



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

**NINE MONTH PERIOD ENDED DECEMBER 31, 2008 COMPARED TO  
THE NINE MONTH PERIOD ENDED DECEMBER 31, 2007  
(UNAUDITED)**

The following discussion and analysis should be read in conjunction with the Consolidated Financial Statements, the related Notes to Consolidated Financial Statements and Management's Discussion and Analysis of Financial Condition and Results of Operations included in the Registrant's Annual Report on Form 10-K for the fiscal year ended March 31, 2008, as amended (the "Form 10-K") and the accompanying Unaudited Condensed Consolidated Financial Statements and related Notes to Condensed Consolidated Financial Statements included in Item 1 of Part I of this Quarterly Report on Form 10-Q.

The Registrant has included in this Quarterly Report certain "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995 concerning the Registrant's business, operations and financial condition. "Forward-looking statements" consist of all non-historical information, and the analysis of historical information, including the references in this Quarterly Report to future revenue growth, future expense growth, future credit exposure, earnings before interest, taxes, depreciation and amortization, future profitability, anticipated cash resources, anticipated capital expenditures, capital requirements, and the Registrant's plans for future periods. In addition, the words "could", "expects", "anticipates", "objective", "plan", "may affect", "may depend", "believes", "estimates", "projects" and similar words and phrases are also intended to identify such forward-looking statements.

Actual results could differ materially from those projected in the Registrant's forward-looking statements due to numerous known and unknown risks and uncertainties, including, among other things, unanticipated technological difficulties, the volatile and competitive environment for drug delivery products, changes in domestic and foreign economic, market and regulatory conditions, the results of development agreements with pharmaceutical companies, the inherent uncertainty of financial estimates and projections, the uncertainties involved in certain legal proceedings, instabilities arising from terrorist actions and responses thereto, and other considerations described as "Risk Factors" in other filings by the Registrant with the SEC including, but not limited to, the Form 10-K. Such factors may also cause substantial volatility in the market price of the Registrant's Common Stock. All such forward-looking statements are current only as of the date on which such statements were made. The Registrant does not undertake any obligation to publicly update any forward-looking statement to reflect events or circumstances after the date on which any such statement is made or to reflect the occurrence of unanticipated events.

**Overview**

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

The Registrant has two products, Lodrane 24(R) and Lodrane 24D(R), currently being sold commercially, and a pipeline of five additional drug candidates under active development in the therapeutic areas that include pain management, allergy 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 the Registrant has completed pilot studies on two of the Registrant's other generic product candidates. The Registrant has also submitted an ANDA with the Registrant's co-development partner, The PharmaNetwork, for a pain management generic product. The addressable market for the pipeline of products is approximately \$6 billion. The Registrant'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 the Registrant's Investigational New Drug Application (an "IND") for ELI-154, the Registrant's once-a-day oxycodone painkiller. The Registrant has completed two pharmacokinetic studies to evaluate ELI-154's control release formation of which the most recent study was completed in 2006. The Registrant submitted a proposed clinical plan and received guidance from the FDA for this product. The Registrant 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 the Registrant's IND for ELI-216, the Registrant's once-a-day, abuse resistant oxycodone painkiller. After the acceptance of the IND, the Registrant completed two pharmacokinetic studies and a euphoria study in recreational drug users to assess the abuse deterrent properties of ELI-216. The Registrant met with the FDA in October 2006 and received guidance for the ELI-216 development program and in November 2007, the Registrant reached agreement with the FDA on a Special Protocol Assessment for the Phase III protocol for ELI-216. The Registrant is currently scaling up the product and preparing for additional studies including a multi-dose study in opioid dependent patients, a food effect study and the Phase III study for ELI-216. Currently there is no abuse deterrent oxycodone product available commercially. The Registrant estimate that the U.S. market for control release, twice-daily oxycodone was about \$2.4 billion in 2007.

At the end of 2006, the Registrant entered into a joint venture with VGS Pharma, LLC ("VGS") and created Novel Laboratories, Inc. ("Novel"), a privately-held company specializing in pharmaceutical research, development, manufacturing, licensing, acquisition and marketing of specialty generic pharmaceuticals. Novel's business strategy is to focus on its core strength in identifying and timely executing niche business opportunities in the generic pharmaceutical area. At the end of 2007, the Registrant elected not to fund the Registrant's remaining contributions to Novel upon the terms set forth in the Alliance Agreement because the Registrant recently reached agreement with the Food and Drug Administration under a Special Protocol Assessment on the Phase III clinical trial of ELI-216, the Registrant's Abuse Deterrent Oxycodone product and determined that the Registrant's funds would be better used to support the clinical trials for ELI-216. The Registrant and VGS negotiated alternative structures that would permit investments by the Registrant at valuations which differed from those set forth in the Alliance Agreement, however VGS and the Registrant were unable to agree upon an alternative acceptable to both parties. Accordingly, upon the Registrant's determination not to fund the Registrant's remaining contributions to Novel at the valuation set forth in the Alliance Agreement, VGS exercised its rights to purchase from the Registrant the Registrant's shares of Class A Voting Common Stock of Novel proportionate to the amount of remaining contributions which were not funded by the Registrant. As a result, the Registrant's remaining ownership interest in Class A Voting Common Stock of Novel is approximately 10% of the outstanding shares of Class A Voting Common Stock of Novel. Until VGS purchased the Registrant's shares of Class A Voting Common Stock of Novel, Novel was consolidated into the Registrant's financial statements as a "variable interest entity" because of the extent of its dependence on the Registrant. Since then, Novel is no longer considered a "variable interest entity" of the Registrant and therefore is not consolidated into the Registrant's financial statements. As of October 1, 2007, the Registrant deconsolidated its financial statements and as a result, for the nine months ended December 31, 2007, the Registrant reported a \$3,030,606 loss from discontinued operations. The Registrant's investment in Novel at December 31, 2008 was decreased from \$7,009,800 to \$3,329,322 to recognize the cumulative losses of \$3,672,638 from Novel from inception through September 30, 2007 and the return of 80% of the Registrant's initial investment of \$9,800. In preparation of the filing of this Quarterly Report on Form 10-Q, the Registrant has made several requests to Novel for information relative to the Registrant's ability to evaluate the current value to the Registrant of its remaining ownership interest in Class A Voting Common Stock of Novel. As of the date hereof, the Registrant is yet to receive any responses from Novel to such requests.

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, and Dr. Charan Behl, the Registrant's Head of Technical Affairs, change the status of their respective relationships with the Registrant from employees to consultants.

As previously disclosed on the Form 8-K filed by the Registrant with the with the United States Securities and Exchange Commission (the "SEC") on October 21, 2008, 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. As previously disclosed on the Form 8-K filed by the Registrant with the with the SEC on November 3, 2008, 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 Dr. Behl.



## Strategy

The Registrant is focusing its efforts on the following areas: (i) development of the Registrant's pain management products, (ii) manufacturing of Lodrane 24(R) and Lodrane 24D(R) products; (iii) the development of the other products in the Registrant's pipeline; and (iv) commercial exploitation of the Registrant's products either by license and the collection of royalties, or through the manufacture of the Registrant's formulations, and (v) development of new products and the expansion of the Registrant's licensing agreements with other pharmaceutical companies, including co-development projects, joint ventures and other collaborations.

The Registrant 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")).

The Registrant believes that its business strategy enables the Registrant to reduce the Registrant'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 the Registrant to share costs of development and to improve cash-flow.

## CRITICAL ACCOUNTING POLICIES AND ESTIMATES

Management's discussion addresses the Registrant's condensed 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 condensed consolidated financial statements. The Registrant's most critical accounting policies include the recognition of revenue upon completion of certain phases of projects under research and development contracts. The Registrant also assesses a need for an allowance to reduce the Registrant's deferred tax assets to the amount that the Registrant believes are more likely than not to be realized. The Registrant assesses 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. The Registrant assesses its exposure to current commitments and contingencies. It should be noted that actual results might differ from these estimates under different assumptions or conditions.

## Results of Consolidated Operations

### Three Months Ended December 31, 2008 Compared to Three Months Ended December 31, 2007

The Registrant's revenues for the three months ended December 31, 2008 were \$236,780, an increase of \$60,609 or approximately 34% over revenues for the comparable period of the prior year, and consisted of \$162,558 in manufacturing fees and \$74,222 in royalty fees. Revenues for the three months ended December 31, 2007, consisted of \$116,366 in manufacturing fees and \$59,805 in royalty fees. Manufacturing fees increased by approximately 40% due to fluctuations in the number of batches shipped each quarter because of seasonality of sales and inventory adjustments and due to growth of product sales. Royalties increased by approximately 24% due to growth of product sales.

Research and development costs for the three months ended December 31, 2008, were \$600,680, a decrease of \$959,573 or approximately 62% from \$1,560,253 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 December 2007, to 16 employees in December 2008. The reduction in

force was implemented last quarter 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.

General and administrative expenses for the three months ended December 31, 2008, were \$467,487 and decrease of \$164,646, or approximately 26% from \$632,133 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 decreased by \$40,009, or approximately 31%, from \$170,266 for the comparable period of the prior year to \$130,257. The decrease was due to the cessation of acquisition of new machinery in the current period.

Other expenses for the three months ended December 31, 2008 were \$299,813, a decrease of \$230,872 or approximately 44% from \$530,685 for the comparable period of the prior year due to a decrease of \$302,275 in charges related to the issuances of stock options and warrants and a decrease in interest expense due to lower outstanding balances. These decreases were somewhat offset by decreases in interest income due to lower compensating balances as a result of the use of cash to sustain the Registrant's operating activities.

As a result of the foregoing, the Registrant's net loss for the three months ended December 31, 2008 was \$1,421,108 compared to \$2,858,103 for the three months ended December 31, 2007.

#### **Nine Months Ended December 31, 2008 Compared to Nine Months Ended December 31, 2007**

The Registrant's revenues for the nine months ended December 31, 2008 were \$1,488,650, an increase of \$649,683 or approximately 77% over revenues for the comparable period of the prior year, and consisted of \$1,255,850 in manufacturing fees and \$232,800 in royalty fees. Revenues for the nine months ended December 31, 2007, consisted of \$671,239 in manufacturing fees and \$167,728 in royalty fees. Manufacturing fees increased by approximately 87% and royalties increased by approximately 39% due to growth of product sales.

Research and development costs for the nine months ended December 31, 2008, were \$3,144,370, a decrease of \$2,249,673 or approximately 42% from \$5,394,043 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 December 2007, to 16 employees in December 2008. The reduction in force was implemented last quarter 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.

General and administrative expenses for the nine months ended December 31, 2008, were \$1,741,760, a decrease of \$73,198, or approximately 4% from \$1,814,958 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 decreased by \$68,533, or approximately 15%, from \$459,304 for the comparable period of the prior year to \$390,771. The decrease was due to the cessation of acquisition of new machinery and equipment in the current period.

Other expenses for the nine months ended December 31, 2008 were \$991,139, a decrease of \$1,051,363 or approximately 52% from \$2,042,502 for the comparable period of the prior year due to a decrease of \$1,286,595 in charges related to the issuances of stock options and warrants and decreases in interest expense of \$36,216 due to lower outstanding balances. These decreases were somewhat offset by decreases in interest income due to lower compensating balances as a result of the use of cash to sustain the Registrant's operating activities.

The Registrant's prior period comparable financial statements were restated as a result of the Registrant's decision not to continue to fund Novel and therefore not include Novel's expenses as part of the Registrant's operating activities for three and nine months ending December 31, 2008 and 2007. Consequently, losses from

discontinued operations of \$-0- and \$3,030,606, respectively, are reflected in the 2008 and 2007 financial statements.

As a result of the foregoing, the Registrant's net loss for the nine months ended December 31, 2008 was \$5,943,657 compared to \$12,525,734 for the nine months ended December 31, 2007.

## Material Changes in Financial Condition

The Registrant's working capital (total current assets less total current liabilities), decreased to \$1,191,223 as of December 31, 2008 from \$5,029,930 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 \$4,389,995 for the nine months ended December 31, 2008, primarily due to the Registrant's net loss from operations of \$5,943,657, offset by decreases in prepaid expenses of \$126,315, net reductions in inventories of \$382,365 and by non-cash charges of \$1,229,802, which included \$839,031 in connection with the issuance of stock options and warrants and \$390,771 in depreciation and amortization expenses.

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 nine months ended December 31, 2008 and December 31, 2007 were \$1,488,650 and \$838,967, 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 December 31, 2008, the Registrant had approximately two 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 nine months ended December 31, 2008, the Registrant expended \$4,398,995 in operating activities which the Registrant funded through the \$20,000,000 in gross proceeds raised through the Registrant's private placement of its Series C Preferred Stock and \$1,777,000 in gross proceeds of its Series D Preferred Stock. The Registrant's working capital at December 31, 2008 was approximately \$1.2 million compared with working capital of approximately \$6.0 million at December 31, 2007. Cash and cash equivalents at December 31, 2008 were approximately \$336,000, a decrease of approximately \$5.6 million from the \$5.9 million at December 31, 2007.

The Registrant spent approximately \$48,000 on improvements and machinery and equipment during the nine months ended December 31, 2008.

As of December 31, 2008, the Registrant's principal source of liquidity was approximately \$336,000 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 December 31, 2008, 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 December 31, 2008, the Registrant was in compliance with the bond covenants.

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

The Registrant had no investments in marketable securities as of December 31, 2008 or assets and liabilities, which are denominated in a currency other than U.S. dollars or involve commodity price risks.

### ITEM 4. CONTROLS AND PROCEDURES

As previously disclosed on the Forms 8-K filed by the Registrant with the SEC on October 21, 2008 and November 6, 2008, and the Form 10-K/A filed by the Registrant with the SEC on January 16, 2009, the Audit committee of the Registrant's Board of Directors (the "Audit Committee") became aware of certain reimbursements of expenses that were made by the Registrant to Bernard J. Berk, the then-President, Chief Executive Officer and Chairman of the Registrant's Board of Directors, without the prior receipt by the Registrant from Mr. Berk of adequate substantiation of such expenses. The Audit Committee took action to investigate such reimbursement and review the Registrant's internal controls to determine how such reimbursements occurred. On November 6, 2008, Mr. Berk resigned as the Registrant's President and Chief Executive Officer and also voluntarily resigned as the Chairman of the Board and as a member thereof, and the Registrant appointed Chris Dick as its Acting Chief Executive Officer and Jerry I. Treppel, a member of the Registrant's Board of Directors, as the Chairman thereof.

As a result of the matters involving Mr. Berk described above, the Registrant disclosed on the Form 10-Q for the quarterly period ending September 30, 2008 filed with the SEC on November 14, 2008 (the "Form 10-Q"), that its disclosure controls and procedures as of September 30, 2008 had deficiencies with respect to its expense reimbursement procedures that caused the Registrant's controls and procedures to be ineffective.

The Registrant has taken various remedial measures to correct deficiencies in its internal controls and prevent the Registrant's reimbursement of unsubstantiated expenses in the future, including the following:

- The Audit Committee directed Mr. Berk to promptly deliver to the Registrant expense reports that substantiate the basis for each expense that was reimbursed to Mr. Berk, including the valid business purpose therefor. The Audit Committee received expense reports for the reimbursed expenses and reviewed such reports to determine which of the expenses had a valid business purpose.
- At the direction of the Audit Committee, the Registrant's Chief Financial Officer implemented check writing restrictions to the Registrant's bank accounts that require the signatures of each of the Registrant's Acting Chief Executive Officer and its Chief Financial Officer for all payments (including expense reimbursements) over \$5,000.
- The Registrant commenced a review of its internal control and compliance policies and procedures, including (1) reviewing, expanding, and formalizing its policies related to all potential advances and/or extensions of credit to employees, executive officers and directors, including, without limitation, with respect to the use of the Registrant's credit cards, and advances of any other kind; and (2) enhancing its training of employees, executive officers and directors regarding compliance with the letter and the spirit of the Registrant's Code of Ethics.
- The Registrant engaged Rosen Seymour Shapss Martin & Company, LLP ("RSSM"), the Registrant's registered public accounting firm, to evaluate the accounting procedures and related internal controls over expenditures.

RSSM's evaluation of the Registrant's accounting procedures and related internal controls over expenditures was completed on or about January 23, 2009. As a result of such evaluation, RSSM has concluded that the Registrant's revised accounting procedures and related internal controls over expenditures are effective.

The Registrant's management, with the participation of its Acting Chief Executive Officer and Chief Financial Officer, has evaluated the effectiveness of the Registrant's disclosure controls and procedures (as such term is defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the "Exchange Act")) as of the end of the period covered by this Quarterly Report on Form 10-Q. Based on that evaluation, the Registrant's Acting Chief Executive Officer and Chief Financial Officer have concluded that, as of the end of such period, the Registrant's disclosure controls and procedures are effective to ensure that information required to be disclosed by the Registrant in the reports that it files or submits under the Exchange Act is (i) recorded,

processed, summarized and reported, within the

time periods specified in the SEC's rules and forms; and (ii) accumulated and communicated to management, including the Registrant's Acting Chief Executive Officer and Chief Financial Officer, as appropriate to allow timely decisions regarding required disclosure.

During the period covered by this Quarterly Report on Form 10-Q, there has been no change in the Registrant's internal control over financial reporting that has materially affected, or is reasonably likely to materially affect, the Registrant's internal control over financial reporting.

## **PART II. OTHER INFORMATION**

### **ITEM 1A. Risk Factors**

In addition to the Risk Factors set forth in the Registrant's the Form 10-K, stockholder and potential investors should consider the following in evaluating an investment in the Registrant and in analyzing the Registrant's forward-looking statements:

**If the Registrant is unable to obtain additional financing needed for the expenditures for the development and commercialization of the Registrant's drug products, it would impair the Registrant's ability to continue to meet its business objectives.**

As of December 31, 2008, the Registrant had cash and cash equivalents aggregate approximately \$336,000. The Registrant anticipates that such amount is adequate to finance its operations through February 28, 2009 but thereafter, the Registrant will require additional financing to insure that the Registrant will be able to meet the expenditures to develop and commercialize its products for which the Registrant has no current arrangements. The Registrant intends to seek additional funds through the sale of additional equity and/or a licensing transaction with respect to certain of its products. No representation can be made that the Registrant will be able to obtain additional financing or if obtained it will be on favorable terms, or at all. No assurance can be given that any offering if undertaken will be successfully concluded or that if concluded the proceeds will be material. The Registrant's inability to obtain additional financing when needed would impair its ability to continue its business. Other possible sources of the required financing are the cash exercise of warrants and options that are currently outstanding. If any future financing involves the further sale of the Registrant's securities, the Registrant's then-existing stockholders' equity could be substantially diluted.

**AMEX may consider suspending dealing in, or removing from the list, the securities of the Registrant based upon the Registrant's ability to continue operation and/or meet its obligations as they mature.**

Section 1003(a)(iv) of the AMEX Company Guide (Application of Policies) provides that the AMEX will normally consider suspending dealing in, or removing from the list, the securities of an issuer which has sustained losses which are so substantial in relation to its overall operations or its existing financial resources, or its financial condition has become so impaired that it appears questionable, in the opinion of the AMEX, as to whether such issuer will be able to continue operations and/or meet its obligations as they mature. In the event the Registrant is unable to increase its revenue, obtain additional financing or otherwise obtain funding for its ongoing operations, the AMEX may seek to suspend or delist the securities of the Registrant if it determines that the Registrant's financial condition has become so impaired that it appears questionable as to whether the Registrant will be able to continue operations and/or meet its obligations as they mature.

**ITEM 5. OTHER INFORMATION**

None.

**ITEM 6. EXHIBITS**

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

Exhibit

Number Description

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.

ELITE PHARMACEUTICALS, INC.

Date: February 17, 2009 By: /s/ Chris Dick  
Chris Dick  
Chief Operating Officer and Acting Chief Executive Officer  
(Principal Executive Officer)

Date: February 17, 2009 By: /s/ Mark I. Gittelman  
Mark I. Gittelman  
Chief Financial Officer and Treasurer  
(Principal Financial and Accounting Officer)